Chambers AND PARTNERS

CHAMBERS GLOBAL PRACTICE GUIDES

Life Sciences 2024

Definitive global law guides offering comparative analysis from top-ranked lawyers

Contributing Editor
Christian López Silva
Baker McKenzie

Chambers

Global Practice Guides

Life Sciences

Contributing Editor

Christian Lopez-Silva

Baker McKenzie

2024

Chambers Global Practice Guides

For more than 20 years, Chambers Global Guides have ranked lawyers and law firms across the world. Chambers now offer clients a new series of Global Practice Guides, which contain practical guidance on doing legal business in key jurisdictions. We use our knowledge of the world's best lawyers to select leading law firms in each jurisdiction to write the 'Law & Practice' sections. In addition, the 'Trends & Developments' sections analyse trends and developments in local legal markets.

GPG Director Katie Burrington
Content Management Director Claire Oxborrow
Content Manager Jonathan Mendelowitz
Senior Content Reviewer Sally McGonigal, Ethne Withers
Content Reviewers Vivienne Button, Lawrence Garrett, Sean Marshall, Marianne Page, Heather Palomino, Deborah Sinclair, Stephen Dinkeldein and Adrian Ciechacki
Content Coordination Manager Nancy Laidler
Senior Content Coordinator Carla Cagnina
Content Coordinator Hannah McDowell
Head of Production Jasper John
Production Coordinators Genevieve Sibayan, Pete Polanyk and Paul Cummings

Published by
Chambers and Partners
165 Fleet Street
London
EC4A 2AE
Tel +44 20 7606 8844
Fax +44 20 7831 5662
Web www.chambers.com

CONTENTS

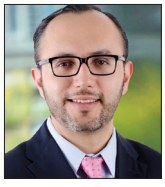
CONTENTS

INTRODUCTION

Contributed by: Christian Lopez-Silva, Vanina Caniza, Jane Hobson and Oren Livne, **Baker McKenzie**

Baker McKenzie has the insider knowledge and global reach to help clients anticipate and manage new risk, being one of the largest dedicated global life sciences and healthcare groups in the legal industry, comprising over 800 lawyers in 45 jurisdictions. The firm's expertise and experience in the global life sciences market stretch over 60 years, further enhanced by lawyers who have higher scientific degrees, hold leadership and advisory positions with industry associations, and bring previous experience working as in-house counsel for big pharma, medtech companies and regulators such as the EMA and other ministries of health. Baker McKenzie provides deep industry expertise in key areas of law, including transactions, tax, compliance, employment, intellectual property investigations, disputes and healthcare regulatory.

Contributing Editor



Christian Lopez-Silva is a partner and head of the healthcare and life sciences group of Baker McKenzie in Mexico. He has more than 20 years' experience in the regulation of life sciences, pharmaceutical law and biotechnology matters, and is a member of the Latin America and North America Healthcare Steering Committees. Christian advises on regulatory, transactional and IP matters in the registration, manufacturing, import, distribution, advertising, labelling, commercialisation and post-market vigilance of medicines, medical devices, food and beverages, cosmetics, seeds, veterinary products, chemicals, alcohol and tobacco. He is a member of the Healthcare and Life Sciences Committee of the IBA and the co-ordinator of the Health Regulation Committee of the Mexican Association of In-House Lawyers (ANADE).

Co-authors

Vanina Caniza is the global chair of the healthcare and life sciences group and is a partner in Baker McKenzie's Buenos Aires office. She advises a range of multinational and domestic clients on corporate and commercial law matters, with extensive experience in corporate compliance, commercial agreements, M&A and regulatory advice. Vanina has extensive knowledge in the pharmaceutical, biotech and medical device sectors. She completed postgraduate courses on biotechnology at Universidad Torcuato Di Tella and on health law at Universidad de Buenos Aires. She previously led the Latin America healthcare and life sciences group.

INTRODUCTION

Contributed by: Christian Lopez-Silva, Vanina Caniza, Jane Hobson and Oren Livne, **Baker McKenzie**

Jane Hobson is a corporate partner in Baker McKenzie's London office. She heads the London private M&A practice and is a member of the global and EMEA healthcare and life sciences steering committees. Her practice focuses on cross-border M&A, licensing transactions and joint ventures in the pharmaceutical and healthcare sector. Jane has substantial expertise in life sciences transactions, having advised on some of the biggest M&A deals in the industry in the last decade.

Oren Livne is a corporate partner in Bake McKenzie's New York/Princeton office. He advises a wide range of healthcare and life sciences clients, from start-ups to multinationals, on a variety of corporate and transactional matters. He focuses on complex collaboration and licensing agreements, joint ventures, spin outs, commercial contracts, M&A and other IP transactions. Prior to joining the firm, Oren co-founded a university technology transfer office and managed its licensing operations. He is a guest lecturer in the law and business classes at New York University, and has authored several licensing and intellectual property articles.

Baker McKenzie

Edificio Virreyes
Pedregal #24, Floor 12th
Col. Lomas Virreyes
CP 11040
Mexico City
Mexico

Tel: +52 55 4335 6419
Fax: +52 52 79 2999
Email: Adrian.Rodriguez-Montfort@bakermckenzie.com
Web: www.bakermckenzie.com

INTRODUCTION

Contributed by: Christian Lopez-Silva, Vanina Caniza, Jane Hobson and Oren Livne, **Baker McKenzie**

Adapting and Innovating: The Dynamic Landscape of the Life Sciences Industry in 2024

The life sciences industry continues to evolve at record speed. This evolution brings with it more government attention and more challenges. Regulations with respect to AI, for example, continue to lag behind innovation so industry players are faced with guessing when regulations will appear and how they will affect research and development as well as commercialisation. Medtech suffers the same regulatory trap in many instances. Government regulations with respect to compliance issues continue to be of increasing concern as well, while competition authorities are heavily involved in monitoring and controlling M&A within and outside their jurisdictions.

Once again intellectual property is a major concern in the industry. The risk of shrinking patent rights is stretching across the globe where the EU Pharma Package is taking a lead. This risk arises out of the growing importance of access to medicines and the focus on reducing healthcare costs, especially those related to medicines. Protection of the many facets of AI has also raised uncertainties around intellectual property rights.

Pharmaceutical pricing continues to dominate conversations, particularly in the United States, where the impact of the Inflation Reduction Act is continuing to be felt.

International trade is an integral part of the life sciences industry. One of the biggest challenges the industry faces is to operate efficiently and legally while its supply chain, research and development and commercial activities literally span the globe.

AI continues to contribute to the healthcare and life sciences industry

AI has tremendous potential to facilitate R&D and improve medical outcomes, but the promising progress implies risks to industry players. Regulations around the use of AI in the industry are inconsistent and, in many cases, non-existent. They sometimes overlap with other regulatory frameworks, which offers unique challenges. The potential of AI to transform drug discovery is unquestionable but it will not necessarily make the process less expensive, primarily because of the substantial expense associated with software development and computational power. AI in the industry also introduces significant risks around confidentiality and cybersecurity, as well as onerous data-handling obligations, especially in view of the highly sensitive nature of healthcare data.

AI has the potential to help in virtually every step of the drug development process, from early-stage computer simulations to late-stage trial design, patient recruitment and data analysis. AI can also reduce the operating costs of clinical trials in a number of ways including by improving trial design, enhancing recruitment effectiveness, and facilitating increased data monitoring. Finally, AI can provide widespread benefits in easing healthcare providers' day-to-day tasks by allowing them to spend more time treating patients.

Research and development is becoming more focused

Oncology remains the largest therapeutic area under study. Cell and gene therapy continue to be major focuses for the industry. CAR-T therapies have revolutionised treatment of blood cancer over the last decade, but early academic data suggest they could now transform the

INTRODUCTION

Contributed by: Christian Lopez-Silva, Vanina Caniza, Jane Hobson and Oren Livne, **Baker McKenzie**

lives of people living with severe autoimmune diseases.

In 2023 we saw the approval of the world's first CRISPR gene editing therapy aimed at treating sickle cell disease. These treatments require complex supply chain arrangements and complex commercial models, and face pricing and reimbursement challenges due to their high specialisation and cost.

Obesity drugs have skyrocketed in popularity since debuting a few years ago. The popularity of obesity drugs has led to shortage challenges and an increase in counterfeit medicines.

Digital transformation at its best

Digital transformation has continued to raise opportunities for pharma, medtech and healthcare providers. AI has been a key trend in this area as mentioned above; however, aside from AI, other trends and developments are worth flagging. The convergence of science and technology is increasing the speed of innovation. Computing power is booming, experiments are moving from labs to computers, and this allows for much faster experimentation and innovation. Regulators have a key role to play in the field of digital health, and we are seeing signs of them trying to catch up. Remote audits, decentralised clinical trials and "collaboration from a distance" have become a common feature since the pandemic, with numerous related legal developments cropping up across jurisdictions. The US FDA recently created a "Digital Health Advisory Committee" to better inform the agency of "the complex, scientific and technical issues" related to digital health technologies. At EU level, the EU Pharmaceutical Package contains measures aimed to adapt the EU's pharmaceutical legislation to current technologies.

Compliance continues to hover over the industry as new types of compliance risks emerge

Increased government control across the globe continues to plague the healthcare and life sciences industry. Due to the inherent importance of the sector, enforcement is aggressive. Key compliance areas for the industry include clinical trial issues; adverse event reporting; GCP, GMP and GDP requirements (which are also binding on third-party intermediaries); interaction with healthcare providers; advertising and promotion; and hospitality and funding of events. Globally speaking, there is a broader trend in the passage of new transparency laws. In the US, there is increased control at both the federal and state levels. In Latin America, post-marketing surveillance has increased. In Brazil and Colombia in particular, there are increased and more stringent inspections regarding GMP compliance, sometimes resulting in the closure of manufacturing plants. In the broad sense of compliance, there is a more aggressive enforcement environment, which is particularly evident in the fields of transactions, trade (sanctions) and data privacy.

Proposed EU Pharma Package creates concern across the industry

In April of 2023, the European Commission published a proposal to amend the EU's general pharmaceutical legislation and the legislation on orphan and paediatric medicines. The proposal contains far-reaching measures that will have a significant and negative impact on innovation in the industry. At the heart of the reform is the aim to provide affordable, timely and equitable access to medicines. Of key concern to the pharmaceutical industry is the proposal to cut down on regulatory incentives to protect innovation. Other measures are aimed at addressing unmet medical needs. In addition, there is a drive to fight shortages and a new set of measures to

Contributed by: Christian Lopez-Silva, Vanina Caniza, Jane Hobson and Oren Livne, **Baker McKenzie**

protect the environment. Although the approval of the legislation is not imminent, pharma companies are already preparing – and bracing – for the change given the extent and impact of the amendments that are being proposed.

Targeted M&A and transactional activity is expected to rebound

M&A levels are expected to rebound in 2024, led by big pharma; however, restructuring is expected to continue in 2024. M&A, carve outs and spin offs remain popular with industry players and generate cross-jurisdiction demands. This is especially seen in the increased separation of consumer businesses from pharma companies. Transactions reveal a focus on expanding capabilities in specific areas such as immunology, oncology, and gene therapy. Pharmaceutical companies are focusing on smaller and more specialist deals.

Licensing and collaboration deals are increasingly important

Licensing and collaboration deals continue to remain critical for pharma in maintaining their drug pipelines. Coupled with biotech's need for financing, this has driven deal flow, although levels remain below their 2021 peak. Oncology and biologics continued to maintain their importance, especially with big pharma, and cell and gene therapies continue to attract large R&D licensing deals. Regulatory clearance is becoming more complex, both from a competition law and foreign direct investment perspective, and generates greater deal uncertainty. Digital transformation influences many of these agreements as life sciences companies are partnering to use AI as well as develop products with a digital component.

Conclusion

The complexities of the life sciences industries continue to grow as do the accompanying legal issues. These complex legal issues must be analysed viewing the whole picture, taking into account the geographic scope and effects as well as the broad legal reach that often goes well beyond one area of law. Most importantly, however, the analysis must be supported by deep knowledge of the life sciences industry. Counsel must not only be legal experts, but trusted partners with industry knowledge and business understanding.

ARMENIA

Law and Practice

Contributed by:
Narine Beglaryan, Ashot Poghosyan, Georgi Aslanyan and Anahit Aloyan
Concern Dialog

Contents

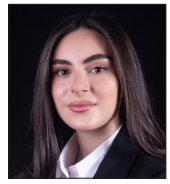
Concern Dialog is a top-tier, full-service law firm, headquartered in Yerevan, Armenia. It has been a trusted partner for businesses and individuals seeking legal counsel and representation since 1998. The firm is renowned for its work in the areas of corporate law, labour law, competition law, tax law, contract law, family law (including child abduction cases), and regulatory issues. Concern Dialog has extensive experience in regulatory matters in TMT, mining, energy, utilities, banking and finance, medical services, real estate, and not-for-profit sectors. In addition to its renowned consulting and transaction practice, the firm's litigation practice is regarded as one of the leaders in Armenia for landmark litigation and arbitration cases. Concern Dialog's membership of TagLaw and Nextlaw networks, as well as its co-operation with individual law firms from various jurisdictions, allow the firm to provide services to its Armenian clients virtually worldwide.

Authors

Narine Beglaryan has been a senior partner at Concern Dialog since July 2023, after joining the firm as a senior associate in 2013 and being promoted to the position of partner in 2016. She leads the corporate law and M&A, banking law and capital markets, and privacy and data protection practices of the firm. Prior to joining Concern Dialog, Narine was a legal adviser at Armentel CJSC (currently Team Telecom Armenia) and held the position of chief lawyer at BTA Bank CJSC.

Ashot Poghosyan is a senior associate at Concern Dialog. In parallel to his main activity, Ashot holds a teaching position at both the French University in Armenia and the Armenian-Russian University.

Georgi Aslanyan is an associate at Concern Dialog. Before that, he worked as an investor support and aftercare service manager (lawyer-analyst).



Anahit Aloyan is a legal assistant at Concern Dialog. Before that, as an intern, she was involved in the work of the Republic of Armenia's Human Rights Defender's Office. Currently, Anahit is pursuing her education.

Concern Dialog

1 Charents Street
Office 207
Yerevan 0025
Armenia

Tel: +374 60 27 88 88
Email: info@dialog.am
Web: www.dialog.am/en

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Within the framework of national legislation, pharmaceuticals are governed by the Law on Medicinal Products of the Republic of Armenia (RA) (the "Law on Medicinal Products"). Medical devices fall under the jurisdiction of the Law on Medical Aid and Service to the Population of the RA and are also regulated by the Agreement on Common Principles and Rules for the Circulation of Medical Devices (Medical Products and Medical Equipment) in the Framework of the Eurasian Economic Union adopted on 23 December 2014 ("the Agreement").

The Law on Medicinal Products oversees the interactions associated with the distribution of drugs, pharmaceuticals, herbal raw materials, and investigational medicinal products.

Furthermore, at subordinate level, various government regulations and decrees of the Minister of Health specify the provisions of the laws.

The Health and Labour Inspection Body of the RA (HLIB) is responsible for implementing and enforcing pharmaceuticals regulations and regulations regarding the marketing of medical devices. The HLIB operates under the authority of the government of the RA.

The Ministry of Health (MoH) oversees the registration, denial, suspension and annulment (declaring void) of medicinal product registrations. Additionally, the MoH handles the registration, denial, suspension and annulment (declaring void) of registration certificates for medical devices.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Enforceable decisions by regulatory bodies qualify as administrative acts, which can be challenged by the addressee (or by a third party having legal standing) by lodging an objection with the regulatory body that has issued the administrative act. One also can directly appeal it to the RA Administrative Court, without applying an objection to the regulatory body.

Objections against administrative acts and lawsuits must be lodged in writing and within two months of notification of the decision to be challenged. The aforementioned procedure applies

to pharmaceuticals and medical devices as well as to other regulated products.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals may qualify as prescription-only and non-prescription, as well as controlled drugs and pharmaceuticals. "Controlled drugs and pharmaceuticals" refer to medications and substances that require numerical registration in the healthcare system of the RA.

The categorisation of a drug into prescription, non-prescription, and/or controlled groups is established during the state registration process of the medication.

The categorisation of medical devices is ruled by Decision No 173 of the Board of the Eurasian Economic Commission dated 22 December 2015.

Medical devices, depending on the degree of possible risk of their use, are divided into four classes:

- Class 1 includes medical devices with a low degree of potential risk of use;
- Class 2a includes medical devices with an average degree of potential risk of use;
- Class 2b includes medical devices with the highest possible risk of use; and
- Class 3 includes medical devices with a high degree of possible risk of use.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials for pharmaceuticals are conducted in compliance with the guidelines of "Good Clinical Practice" as stipulated by the regulatory authority (Order of the Minister of Health of the RA N25-N of 17 May 2017 "On adopting the rules on Good Clinical Practice", which refers to the Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001, Commission Directive 2005/28/EC of 8 April 2005 and the "Rules of Good Clinical Practice of the Eurasian Economic Union" in the Decision No 79 of the Council of the Eurasian Economic Commission dated 3 November 2016).

The MoH is responsible for overseeing and conducting clinical and clinic-laboratory trials (research) of medicinal products. The permission to conduct clinical trials is granted by the MoH after approving the trial plan and attached documents on the basis of a positive expert opinion and a positive opinion from the clinical trial ethics committee.

The expert opinions are given by the Scientific Centre of Drug and Medical Technologies Expertise after Academician Emil Gabrielyan CJSC (hereinafter referred to as "the SCDMTE") and the Ethics Committee for Clinical Trials (the "Ethics Committee").

The conduct of clinical trials for medical devices is regulated by Decision No 29 of the Council of the Eurasian Economic Commission dated 12 February 2016 ("Decision No 29"). While Armenian national law grants authority to the Armenian government to oversee this issue, there are currently no governmental decisions specifically addressing the clinical trials of medical devices.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

To obtain authorisation for conducting a pharmaceutical clinical trial, one must submit an application to the MoH. Then the MoH must confirm the receipt of the application within the same

day by sending a return letter to the applicant's email address and, at the same time, inform the SCDMTE by sharing the documents requesting the clinical trial. If the expert opinion from the SCDMTE is positive, the MoH will share a copy of the expert opinion with the Ethics Committee within two working days. After receiving the Ethics Committee's opinion, the Minister of Health will issue an order either granting or denying permission to conduct the clinical trial.

The steps for securing authorisation to undertake a clinical trial of a medical device are described in the Rules dated 9 December 2011 of Decision No 29.

To obtain authorisation for conducting a clinical trial of medical devices, as a general rule the following must be submitted to the MoH:

- statement asserting that the medical device complies with safety and efficacy requirements;
- the Ethics Committee's decision;
- researcher's brochure;
- technical specification of the medical device;
- clinical trials (research) programme; and
- the list of adverse events (incidents).

2.3 Public Availability of the Conduct of a Clinical Trial

Despite the fact that – according to the Law on Medicinal Products – the MoH is required to compile a register of authorised and rejected clinical trials, only a list of medication approved for clinical trials is published. Neither information about rejections nor information about the results of clinical trials are publicly available. As for medical devices, no information about clinical trials of medical devices is publicly available.

2.4 Restriction on Using Online Tools to Support Clinical Trials

Currently, no regulations restricting the use of online tools to support clinical trials have been adopted in Armenia.

2.5 Use of Data Resulting From Clinical Trials

Data resulting from a clinical trial can be qualified under the Data Protection Law of the RA as "biometric data" and "special category data". Biometric data includes information related to the physical, physiological and biological characteristics of an individual, whereas special category data encompasses data concerning race, national origin, political views, religious or philosophical beliefs, association membership, health status, and sexual life. Therefore, data arising from clinical trials on humans is considered both "biometric" and to fall within the "special category of personal data".

As a matter of general rule, the processing of personal data – including its transfer – is subject to explicit consent of data subject.

2.6 Databases Containing Personal or Sensitive Data

The creation of a database containing personal or sensitive data would be subject to additional requirements. Regarding the processing of personal data, it is mandatory for the processor to employ encryption keys. This measure aims to safeguard information systems containing personal data from inadvertent loss, unauthorised access, unlawful use, recording, destruction, alteration, blocking, copying, dissemination of personal data, and other forms of interference.

Additionally, Decision No 1175-N dated 15 October 2015, issued by the government of the RA, outlines the specifications for biometric personal

data carriers and the technologies used to store such data beyond information systems. Furthermore, clinical trial participants must receive information about how their data will be used and stored within such a database.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The classification of a specific product as either a pharmaceutical or a medical device is determined by the definitions provided by applicable regulation. Article 45(1) of the Law on Medical Aid and Service to the Population of the RA explicitly references the Agreement.

A pharmaceutical product – as defined by Article 3(1), point 1 of the Law on Medicinal Products – includes substances sourced from human, animal, vegetable, chemical, or biotechnological origins. These substances are formulated in appropriate dosages and forms, accompanied by packaging and labelling. These products are presented with attributes intended for the treatment or prevention of diseases in humans or animals. Additionally, they may be:

- employed to restore, correct or modify physiological functions through pharmacological, immunological or metabolic actions; or
- used for medical diagnostic purposes.

According to Article 2 of the Agreement, "medical devices" refer to any instruments, apparatus, devices, equipment, materials and other products used for medical purposes either independently or in conjunction with one another, including necessary accessories for their intended use (eg, special software). These products – as intended by the manufacturer – are designed for:

- the prevention, diagnosis and treatment of diseases;
- medical rehabilitation; and
- monitoring of the human body's condition.

They are also used for medical research, restoration, replacement, and alteration of anatomical and medical conditions of the human body, as well as for the utilisation of devices, equipment, materials, and other products.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

As with other pharmaceuticals, biologic medicinal products must undergo a registration process in order to be introduced to the market. All medicinal products, including biologics, require research for registration. However, biologic medicinal products must align with the criteria outlined in documents accepted by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and/or World Health Organization (WHO) guidelines.

Additionally, in its Decision No 89 dated 3 November 2016, the Council of the Eurasian Economic Commission established rules concerning the approval to conduct research into biological medicines in the Eurasian Economic Union, which – according to the Agreement on the Eurasian Economic Union – is applicable in the RA.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

The state registration of pharmaceuticals is valid for five years (see Article 16(18) of the Law on

Medicinal Products, as well as Regulation No 162-N of the Armenian government dated 28 February 2019 ("Decision No 162-N")). However, according to Article 4(6), paragraph 3 of the Agreement, the registration of medical devices is indefinite.

After the initial registration period concludes, re-registration (renewal) for a duration of five years may be conducted, involving the reassessment of the product's safety, efficacy, and quality. Following the expiration of the re-registration term, the maturity of the registration certificate may be prolonged – with the approval of the registration certificate holder – once every five years, based on the outcomes of professional post-registration safety monitoring by the MoH. The maximum timeframe for the re-registration of medicinal products is set at 31 calendar days, which includes the period for expert examination required for registration (a maximum duration of 21 calendar days). The maximum duration for extending the maturity of the medicinal product's registration certificate is 10 calendar days. The re-registration and extension of the registration certificate term should be applied if a favourable expert examination conclusion is granted.

The registration, re-registration, or certificate maturity extension of a medicinal product may be declared void by the MoH in the following circumstances:

- discovery of non-conformity with established requirements, specifications, and new scientific data, where this poses a threat to human life and cannot be corrected;
- receipt of justified and credible negative data about the medicinal product from foreign or international specialised structures and competent authorities regulating medicinal products in other countries;
- negative results from quality testing of three different series after product registration; and
- documentation of serious adverse reactions during post-registration safety monitoring – for example, death, life-threatening situations, hospitalisation, incapacity, or infliction of physical mutilation or congenital defects.

Upon declaring the voidance of medicinal product registration, it becomes prohibited to manufacture, import, distribute, dispense, sell, or apply such medicinal product.

The registration of a medicinal product will be suspended by the MoH if:

- the registration certificate holder has filed a substantiated application;
- non-conformity of safety, efficacy, and quality with the established requirements, specifications or new scientific data has been discovered, where this can be corrected;
- the registration certificate holder has not communicated new data on product quality, safety or efficacy, or has not made changes in the registration documents in accordance with the new data; or
- the registration certificate holder has made changes in the registered medicinal product documents or product packaging, label or marking or to the use and application instructions, where these changes were not agreed upon with the authorised body.

The withdrawal of medicinal products is ruled by Decision No 164-N dated 28 February 2019 of the government of the RA. The HLIB can withdraw (recall) a marketing authorisation for a pharmaceutical or a medical device in the following circumstances:

- if there is a notification indicating a potential issue with the pharmaceutical or the medical device, such as safety concerns or non-compliance;
- if the product is found to be unregistered, non-compliant with quality requirements, or expired, or if its registration has been invalidated or suspended;
- if the pharmaceutical or the medical device is imported in violation of the legislation of the RA; and
- if the withdrawal may apply to drugs, counterfeit drugs, medicinal materials, herbal raw materials, and researched pharmaceutical products.

For medical devices, the MoH performs the registration, rejection of registration, suspension and invalidation of registration certificates, provides duplicates of registration certificates, and processes changes to the registration certificate in accordance with the law. Nevertheless, as of now, there are no existing national regulations that oversee the relevant legal relationships at the subordinate level – for example, government decisions or orders of the Minister of Health.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

In the RA, only registered pharmaceuticals are permitted for manufacturing, importation, distribution, dispensation, sale and usage.

Medicinal products (drugs) must undergo registration using either the standard process or a simplified process. The simplified process is applicable to medicinal products registered in a member state of the international professional organisation designated by the Armenian government or those pre-qualified by the WHO.

For the state registration of a pharmaceutical product, application must be submitted with the following attachments:

- a set of documents (dossier) aligned with the ICH universal technical document;
- the evaluation report conducted by the competent authority of another country or obtained during WHO pre-qualification, along with the original specifications and application instructions constituting part of the report (additionally, all relevant materials must be translated into Russian or English if originally in a different language (mandatory for the simplified procedure)); and
- original documents confirming the payment of the state tax and examination fee.

The following changes are not subject to registration:

- alteration of the name and/or location of the rights holder of the registration certificate, provided that the legal entity remains unchanged;
- modification solely to the name of the drug, without any accompanying alterations;
- change in the generic name without any modification to the drug substance;
- adjustment of the manufacturer's name without altering the manufacturer or its location; and
- modification in the form of release (specifically associated with variations in the quantity of units included in the packaging).

The change of other information – for example, the name, ingredient, strength, dosage form, presentation, new indication, manufacturer (including every performer of the production process), and registration certificate holder of a medicinal product – is subject to registration.

Changes in the therapeutic indication, formulation, posology, patient population, packaging, or labelling also need to be appropriately registered.

The process of obtaining marketing authorisation for medical devices involves the state registration of these devices. This registration aims to evaluate whether the devices meet the safety, quality, and efficacy standards established for medical devices. The assessment is conducted by examining the technical and biological impact of the device, as well as reviewing the results of clinical and clinical-laboratory tests or research submitted by the manufacturer.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

The registration of a medicinal product is not required when it is imported for the purpose of a curative course or for personal use by individuals. In the RA, the utilisation of novel drugs, methods, forms, and tools – as well as the conduct of biomedical research – is permissible within the framework of delivering medical care and services, following the procedures established by the government.

As of now, however, no corresponding regulation has been issued by the Armenian government. Additionally, explicit guidelines for compassionate use programmes in Armenia are not in place. Nevertheless, when treating patients with new drugs, methods, forms, and tools, or conducting biomedical research, obtaining the explicit written consent of the patient is a necessary requirement. Also, medicinal products or investigational medicinal products undergoing clinical trials in foreign countries can be utilised for treating patients with life-threatening illnesses, provided that approval from the MoH has been obtained following the procedure outlined in this Article.

As regards the use of medical devices on patients, Armenian law refers to the law of the Eurasian Economic Union. Article 4(11) of the Agreement governs exceptions to the registration of medical devices.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

Pharmacovigilance is defined here as the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long-term and short-term side effects of medicines.

Technovigilance is defined here as the science relating to the detection, assessment, understanding and prevention of adverse incidents, particularly long-term and short-term side-effects of medical devices.

The medicinal product registration certificate holder must document the cases of adverse reactions and report them under the procedure established by the MoH.

The holder of the registration certificate is obligated to report instances of serious adverse reactions to the MoH. Such reactions include but are not limited to cases involving death or life-threatening conditions, necessitating inpatient hospitalisation or extension of ongoing hospitalisation, leading to persistent or significant disability or incapacity, or resulting in congenital anomalies or birth defects.

In the context of medical devices, when the SCDMTE uncovers information pertaining to their safety, quality, and efficacy, it promptly

communicates these findings to the manufacturer or its authorised representative. If deemed necessary, the SCDMTE may request supplementary information about the medical devices.

Healthcare professionals have a duty to promptly notify the authorised body in writing regarding any adverse events associated with medical devices.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

If an application for marketing authorisation has been either granted or refused, a third party can access information on the Medicinal Products Register. This information includes details such as the trade name, International Non-proprietary Name (INN), potency, pharmaceutical form, packaging, manufacturer, country of origin, Anatomical Therapeutic Chemical (ATC) code and/or classification, registration certificate number, registration deadline, legal status for supply, manufacturing authorisation holder's name and address, primary and/or secondary packaging, label, mock-ups (including coloured versions), summary of product characteristics (SmPC), and package information leaflet (PIL).

Information on drugs that have been denied registration is also accessible, providing details such as the date, trade name, common name of the active substance, pharmaceutical form, strength and packaging presentation, all manufacturing sites involved in the production process (name and location), country, registration certificate holder's name and location, and legal status for supply.

According to Article 16 (14), the Law on Medicinal Products specifies that the MoH is mandated to safeguard the confidentiality of the data found in the submitted registration documents. This data, protected by the laws of the RA, is not subject to public disclosure. Additionally, the expert responsible for the registration examination is compelled to sign a declaration affirming their commitment to confidentiality and acknowledging any potential conflicts of interest.

It is important to note that confidential information primarily pertains to the documents submitted for the state registration of the drug.

3.8 Rules Against Illegal Medicines and/or Medical Devices

The Armenian Administrative Offences Code provides various measures for offences related to pharmaceuticals. Article 47(3) of the Armenian Administrative Offences Code, for instance, stipulates that importing, manufacturing, storing, distributing, or selling medicines not registered in the RA (except for cases defined by Armenian legislation) – or whose registration has been suspended in accordance with the law – is in violation of the law. For each drug the following fines may be imposed:

- for a package of up to five medicines – AMD1 million (which is approximately equal to EUR2,270); and
- for a package of more than five medicines – AMD2 million (which is approximately equal to EUR4,540).

The Armenian Administrative Offences Code establishes a general provision for offences related to medical devices. By way of example, the violation of the requirements outlined in the field of medical device circulation results in a fine ranging from AMD100,000 to AMD1 million.

The Armenian Criminal Code penalises the unlawful trafficking of pharmaceuticals and

medical devices (refer to Articles 408 to 411 of the Criminal Code of the RA). As an illustrative example, Article 408(1) of the Criminal Code of the RA states, in essence:

"Engaging in the sale, production, manufacturing, storage, transportation, shipment, import, export, supply, marketing, or selling of medicine, drugs, herbal raw materials, auxiliary substances, medicinal products, their components, or investigational medicinal products without the state registration mandated by law, or when the registration has been suspended, terminated, or revoked according to the law, and without the required medicine or special permission (licence), is subject to penalties. The penalties may include imprisonment, public works for a duration of 80 to 150 hours, restriction of freedom for a year, suspended imprisonment lasting two months, or imprisonment for a period of two years."

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

In the efforts to combat counterfeit pharmaceuticals and medical devices through border measures, the Anti-Smuggling Department of the State Revenue Committee of the RA serves as an investigative body, actively engaging in operative-investigative activities. The department is vested with several powers, including but not limited to:

- prevention and detection of smuggling and other customs offences;
- implementation of customs control to ensure the integrity of borders;
- implementation of actions within the scope of powers assigned to the investigation body by the Criminal Procedure Code of the RA;
- initiation of administrative proceedings in the event of a violation of customs rules; and
- authority to appoint customs examination when deemed necessary, among other related responsibilities.

These powers enable the Anti-Smuggling Department to play a crucial role in safeguarding against the influx of fake pharmaceuticals and medical devices through comprehensive border control measures.

4. Manufacturing of Pharmaceuticals and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

The production of pharmaceuticals, substances, and investigational medicinal products, as well as the processing of medicinal herb materials, must be conducted by legal entities or sole entrepreneurs possessing a manufacturing licence specifically for medicinal products. Possession of a medicinal product manufacturing licence is mandatory for engaging in any production processes. The licence specifically for medicinal products grants the MoH.

The MoH issues a licence for the manufacturing of medicinal products based on the findings of the expert examination.

The following activities require licensing:

- production of medicines;
- pharmacy activities;
- implementation of medical care and maintenance;
- wholesale of pharmaceuticals;

• production of medical devices; and
• maintenance of medical devices.

In order to obtain a licence for the production of medical devices, the applicant must submit to the MoH an application to obtain a licence together with the state registration certificate demonstrating the applicant's ownership (use) right to the area intended for the licensed activity (along with the plan of the designated area) issued by the competent authority in the name of the applicant, as well as a favourable expert opinion issued by the organisation conducting the expertise (in Armenia, the SCDMTE).

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

Establishments engaged in wholesale of pharmaceutical devices are required to acquire a licence (see **4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices**). The MoH grants the authorisation.

To obtain the licence, the applicant must submit the same documents as prescribed in **4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices**. Licences for the wholesale sale of pharmaceuticals are issued and granted for an indefinite period.

5.2 Different Classifications Applicable to Pharmaceuticals

Pharmaceuticals are classified into prescription, non-prescription and controlled medicinal products based on varying regulations and requirements (see **1.3 Different Categories of Pharmaceuticals and Medical Devices**).

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

Importation and Exportation of Drugs

Within the framework of Armenian legislation, the importation and exportation of drugs are primarily governed by the Law on Medicinal Products and the decision of the government dated 28 February 2019, No 202.

In Armenia, import (compliance) or export certificates are issued for the actual import or export of each pharmaceutical product (drug) group across the customs border.

Pharmaceutical products (drugs) entering the RA require an import (compliance) certificate issued by the MoH. The export of pharmaceutical products from the RA can be conducted with an export certificate issued by the MoH, if desired by the exporter.

In adherence to the Law on Medicinal Products, import (compliance) and export certificates for pharmaceutical products are issued by the MoH. This issuance is based on the expert opinion of the SCDMTE, the organisation appointed by the government decision of 28 February 2019, No 150.

Importation and Exportation of Medical Devices

Separately, the importation and exportation of medical devices fall under the jurisdiction of the Law on Medical Aid and Service to the Population of the RA and the government decision dated 30 March 2023, No 429.

Medical devices are imported to the RA on the basis of the import (compliance) certificate issued by the MoH. The issuance of this certificate is contingent upon the expert opinion provided by the SCDMTE.

The import (compliance) certificate becomes invalid after customs clearance.

The HLIB is authorised to exercise the state control over the field of drug circulation.

6.2 Importer of Record of Pharmaceuticals and Medical Devices

The following are entitled to import drugs, medicinal substances, herbal raw materials, and researched pharmaceutical products into the territory of the RA:

- suppliers holding a licence for the wholesale sale of drugs; and
- entities without a wholesale licence, falling into the following categories:
  - (a) legal entities or individual entrepreneurs engaged in activities related to researching, conducting tests, quality assurance, efficiency assessment, and safety control of drugs, medicinal substances, and herbal raw materials, within the necessary scope for these activities;
  - (b) legal entities or individual entrepreneurs importing drugs within the context of qualified charitable or humanitarian programes;
  - (c) legal entities and individual entrepreneurs possessing a licence to manufacture drugs in the RA, specifically in the case of importing medicinal substances and herbal raw materials for production purposes;
  - (d) representative offices or representatives of foreign manufacturers, when importing or exporting registration and/or test samples (medicines, pharmaceuticals, herbal raw materials, researched pharmaceutical products) and/or exhibition samples;
  - (e) state bodies; and
  - (f) natural persons in instances where an import or export certificate is not required (see **6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices**).

As regards medical devices, to secure a certificate of import (compliance) for medical devices entering the RA, the legal entities engaged in importing medicinal products – along with individual entrepreneurs or their authorised representatives – are required to submit an electronic application to the MoH.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Both medical devices and pharmaceuticals imported into the RA need to be accompanied by an import (compliance) certificate issued by the MoH.

Import or export certificates are not required:

- for the treatment of an individual travelling to or from a foreign state, or for medicinal products of personal use, in quantities established by the RA government;
- for medicinal products imported for personal needs by foreign and international organisa-

tions' diplomatic and consular representatives, staff, and family members living with them;
- for medicinal products necessary for the treatment and care of drivers, staff, and passengers of transportation means arriving in the RA; and
- for medicinal products necessary for the treatment and care of participants of international cultural and sports events and international research teams.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

When importing drugs and medical devices, non-tariff regulations and restrictions are established for the import from the Eurasian Economic Union member countries and third countries.

An import (compliance) certificate issued by the MoH (which is issued on the basis of the expert opinion provided by the SCDMTE) is regarded as a form of non-tariff regulation and restriction when importing medicinal products or medical devices from member countries of the Eurasian Economic Union and third countries.

In addition to the above-mentioned non-tariff regulations and restrictions concerning medical devices, once the import compliance certificate is obtained, the importer of medical devices is required to adhere to the following procedures before commencing sales.

- Verification of the alignment between the data presented in the documents accompanying the medical devices and the actual information pertaining to the medical devices, ensuring adherence to the stipulated requirements. This encompasses a thorough examination of compliance with any specified conditions for special storage and transportation.
- For registered medical devices, validation of the existence of a designated circulation mark as endorsed by the decision of the Council of the Eurasian Economic Commission No 26 dated 12 February 2016. Additionally, scrutiny of the compliance of the product's marking with the requirements established by the decision of the Council of the Eurasian Economic Commission No 27 dated 12 February 2016.
- Confirmation of the presence of essential details such as the name, trade mark, and contact information of the manufacturer of the imported medical device, along with the official representative in the RA. This verification extends to the packaging or instructions for the use of unregistered medical devices.

Prior to sale, the importer is responsible for verifying the adherence of storage and transportation conditions for the medical devices under their jurisdiction to the general safety and efficiency requirements established by the decision of the Council of the Eurasian Economic Commission on 12 February 2016, No 27, as well as the conditions specified by the manufacturer (if applicable).

In addition to the aforementioned non-tariff regulations and restrictions, it is noteworthy that under Article (21)8 of the Law on Medicinal Products the import and export of drugs, pharmaceuticals, herbal raw materials, and researched pharmaceutical products in the RA may face rejection due to non-compliance with packaging requirements.

For more on the laws or regulations that list the types of products that are subject to regulations upon importation, see **6.1 Governing Law for the Importation and Exportation of Pharma-**

ceuticals and Medical Devices and Relevant Enforcement Bodies.

6.5 Trade Blocs and Free Trade Agreements

Armenia is a member of the Eurasian Economic Union. Armenia is also a party to the Agreement on the Free Trade Zone (signed on 18 November 2011), which entered into force on 17 October 2012.

Meanwhile, the interim agreement on the establishment of a free trade area between the Eurasian Economic Union and Iran was signed on 17 May 2018 and came into effect on 27 October 2019. Subsequently, a comprehensive free trade agreement was signed on 25 December 2023 (which has not entered into legal force as of 23 February 2024), aiming to supersede the temporary agreement that had been in effect since 2019.

As of 1 January 2022, Armenia is no longer a beneficiary of the Generalised Scheme of Preferences Plus (GSP+) preferential trade regime. Nevertheless, specific developed countries – including the USA, Canada, Switzerland, Japan, and Norway – still offer Armenia the opportunity to avail itself of the Generalised Scheme of Preferences (GSP).

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

According to Article 8(1) of the Law on Medicinal Products, the primary principles of state policy regarding the provision of medicinal products and the development of pharmaceuticals include guaranteeing the physical accessibility and affordability of medicinal products. These objectives are implemented, in particular, by the Armenian government defining the lists of social or special groups of the population and the list of illnesses for which medicinal products will be provided to beneficiaries with full or partial reimbursement of their price. Additionally, the government outlines the procedure for reimbursing and supplying such medicinal products.

Armenian law, as well as the law of the Eurasian Economic Union, does not include regulations pertaining to pricing in the production of pharmaceuticals or medical devices. Generally, market control is exercised within the framework of antitrust regulations. However, the State does influence pricing to some extent, as it co-finances the acquisition of specific medications (referred to as “essential medicines” in a list published by the government). This is done to ensure access to medications. Nevertheless, there are no regulations directly addressing specific pricing in the production of pharmaceuticals and medical devices.

7.2 Price Levels of Pharmaceuticals or Medical Devices

Although Armenia is a member of the Eurasian Economic Union, there are currently no regulations for standardising prices of medications or medical devices within the Eurasian single market. Consequently, the prices for the same medications or medical devices may vary across different member countries of the Eurasian Economic Union.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

The Law on Medicinal Products defines reimbursed medicines as medications that receive full or partial reimbursement of their price through a

government-guaranteed process funded by the state budget of the RA. The Armenian government, through Regulation No 642-N dated 30 May 2019, has outlined the social and special groups and diseases for which the state partially or fully covers the costs.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

For the private sector, there are generally no standardised rules mandating the application of cost-benefit analyses or health technology assessments in determining the pricing of pharmaceuticals or medical devices. Pricing decisions in the private sector are often influenced by factors such as market dynamics, competition, production costs, and business considerations.

The state regulation of prices takes into account the INN of the medicinal product, focusing on products registered in Armenia under the stipulated procedure and considering dosage form and strength. The RA government, with recommendations from a commission dedicated to state regulation of medicinal product prices, establishes the reference price and the maximum wholesale and retail price premiums.

The government defines various aspects related to cost-benefit analyses and health technology assessment, including the methodology for calculating reference prices and premiums, the list of countries used for price comparison, and procedures for determining and revising reference prices and premiums. The transparency of this process is emphasised, as the MoH is required to publish the reference price of reimbursed medicinal products and the maximum wholesale and retail premiums on its website.

It is important to note that specific government regulations pertaining to this matter have not been enacted as of now.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Medicinal products are dispensed with a prescription based on the INN of the product. Pharmacies are required to provide comprehensive information to individuals purchasing medicinal products, including details about all available products containing the same active ingredient, having the same strength and dosage form, and being interchangeable. This information, presented without promotional influence, includes pricing details.

Dispensing a prescription with the trade name of the medicinal product is allowed only when accompanied by a reasoned justification from the prescribing doctor. A copy of this justification is submitted to the pharmacy along with the prescription and another copy is attached to the patient's medical documents. The requirements for justifying the dispensing of prescriptions with the trade name are prescribed by the MoH.

8. Digital Healthcare

8.1 Rules for Medical Apps

Currently, there is only one medical app – named "ArMed E-Health" – designed to provide comprehensive information about episodes of medical care and the services rendered. The usage of the system is regulated by the decree of the Minister of Health No 40-N dated 18 May 2021.

8.2 Rules for Telemedicine

The procedure of telemedicine is governed by the Order No 42-N of the Minister of Health of the RA dated 8 July 2022. Telemedical consul-

tation must take place in an online environment utilising a software application (referred to as "the System") with the capability to record and save the consultation.

The telemedical consultation is conducted under the following circumstances:

- when the patient – and, in the case of a patient under the age of 16 or recognised as legally incapacitated, their legal representative – is physically incapable of personally visiting a medical organisation;
- if the location of the patient (or their legal representative) or the consulting doctor prevents the organisation of an in-person visit; and
- with the consent of the consulting doctor, the treating doctor, and the patient (or their legal representative), even if the above-mentioned conditions mentioned are not applicable.

8.3 Promoting and/or Advertising on an Online Platform

There are specific rules governing the promotion and advertising of medicines in electronic and print mass media, as well as through online portals, company websites, and social networks in the RA. According to the regulations, any advertisement of medicinal products in electronic and print mass media must include specific information. This information comprises the number, day, month, year, and validity term of the state registration certificate of the medicinal product in the RA, along with the number and day, month, and year of the permission for advertising granted by the MoH.

Advertising in the mass media is permitted solely for non-prescription medicinal products that do not include narcotics or psychotropic (psychoactive) substances.

Outdoor advertising of medicinal products is prohibited in the RA.

In accordance with the Law on Advertising of the RA, the following are prohibited:

- advertising medications, medical equipment, and methods of medical treatment without the permission of the Ministry of Health of the RA; and
- advertising medications, medical equipment, and methods of medical treatment requiring a special medical prescription for use.

There are no special rules for the promotion and/or advertising of medical devices.

8.4 Electronic Prescriptions

In the RA, electronic prescriptions have become the standard practice, while paper prescriptions are now the exception. A prescription is defined as the written prescription of a medicinal product, which can be in either paper or electronic form. Authorised doctors have the discretion to issue prescriptions, and this authority extends to both traditional and electronic formats.

8.5 Online Sales of Medicines and Medical Devices

Given that there are no prohibitions on the online sale of medications and medical devices, they are allowed to be sold online.

8.6 Electronic Health Records

The e-health system in Armenia is defined as a set of information and infrastructure that facilitates the entry, processing, storage, archiving, and use of health data about each person in an electronic environment (Article 2(1), paragraph 43 of the Law on Medical Aid and Service to the Population of the RA).

The electronic healthcare system operates based on the following principles.

- Information within the electronic healthcare system is personalised unless otherwise defined under the law for specific cases.
- The database is standardised for all participants in the electronic healthcare system.
- Information is accessible at all times to individuals authorised to use the electronic healthcare system as stipulated by law and within the scope of their authority.
- Information is treated as confidential and safeguarded.

Health-related information falls under the category of "biometric" and "special category data" (see **2.5 Use of Data Resulting From Clinical Trials**).

There are no special requirements for cloud platforms. There is no restriction on the storage of sensitive information on cloud platforms either.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices

The Law on Patents of the RA and the Law on Industrial Design of RA apply to patents in Armenia. Additionally, Armenia is also a party to various international patent treaties such as the Eurasian Patent Convention (EPC), Patent Co-operation Treaty (PCT), the 1883 Paris Convention, and the Trade Related Aspects of Intellectual Property Rights (TRIPS).

There are no specific patentability requirements for pharmaceuticals and medical devices as such. In general, patents are issued for inventions, which may also include pharmaceuticals or medical devices if they meet the patentability requirements for an invention – namely, they should be new, involve an inventive step, and be useful for industrial application (Article 12(2) of the Law on Patents). Meanwhile, a patent can also be granted for the protection of an industrial design as specified in **10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices**.

9.2 Second and Subsequent Medical Uses

None of the international patent treaties to which Armenia is a party explicitly prohibit granting legal protection to second and subsequent medical uses of a known product, new dosage regimes and new or selected patient populations, thereby enabling the regulation of these issues by national laws. Meanwhile, the national laws of the RA do not contain specific provisions to regulate the legal protection of the mentioned categories. Thus, under the RA Law on Patents – given that second and subsequent medical uses of a known product, new dosage regimes, and new or selected patient populations may constitute a method of using an already known product – it is possible for them to be granted protection under a short-term patent, provided they are new, do not directly derive from the state of the art and are useful for industrial application (Articles 12(1) and 12(3) of the Law on Patents).

If second and subsequent medical uses of a known product, new dosage regimes and new or selected patient populations are indeed granted protection as short-term patent inventions, the general provisions on patent infringement as described in **9.4 Pharmaceutical or Medical Device Patent Infringement** should apply to them.

9.3 Patent Term Extension for Pharmaceuticals

In general, the validity period of a patent for an invention is 20 years, whereas for short-term patents it is ten years as from the filing day of the application, which may not be extended (Articles 28(1) and 29(1) of the Law on Patents). However, specifically in the case of pharmaceuticals that require permission from a competent authority to be used, the 20-year validity period of the exclusive right may be extended upon the request of the patent holder for no more than five years, in case granting the first usage permission takes more than five years following the date on which the application to receive a patent was filed (Articles 28(3) and 65(1) of the Law on Patents).

During the entire period of its validity, the patent may be declared invalid in full or in part by a judicial act having entered into legal force upon the request of a third party. The request to declare the Eurasian patent invalid in the territory of the RA must be submitted in accordance with the procedures provided for by the Eurasian Convention and the Patent Instruction attached to it, as well as by the national legislation (Article 65(8) of the Law on Patents).

9.4 Pharmaceutical or Medical Device Patent Infringement

Manufacturing, using, offering for sale, selling, or importing or acquiring the patented product for the purpose of one of the previously mentioned actions without the patent holder's permission constitutes a patent infringement (Article 24(1) of the Law on Patents). Applying for marketing authorisation will not infringe a patent if the patented product has already been legally put into civil circulation by means of sale by the patent holder or with their consent or in any other lawful way, such as compulsory licences (Article 27(1) of the Law on Patents). The threat of infringement, as opposed to actual infringement, is actionable so long as it constitutes acquiring a pharmaceutical or medical device for the purpose of conducting any of the above-mentioned actions that amount to an infringement. Thus, there is a requirement of an "imminent" infringement, which can be understood as a well-founded belief that such intent exists or is likely to occur in the foreseeable future.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

General defences to patent infringement, which equally apply to pharmaceuticals and medical devices, include the usage of these products:

- for personal needs without the purpose of earning income;
- as a subject of scientific experiment or scientific research;
- in the case of one-time preparation of medicines in pharmacies with a doctor's prescription;
- for the performance of necessary studies, tests and experiments for the purpose of testing medical (including phytosanitary) products during the two years preceding the expiration of the patent; and
- in emergency situations, as well as for the purpose of ensuring national security, if the patent holder is informed about such use as soon as possible (Article 25(1) of the Law on Patents).

However, this is only permitted under the condition that it does not cause unjustified harm to the normal use of the patented invention and does not unreasonably violate the legitimate interests of the patent holder, and that the legitimate interests of third parties are taken into account (Article 25(2) of the Law on Patents).

Compulsory licences are available for any person or the RA if the person submitting the request proves that they have made efforts to conclude a licence agreement with the patent holder within a reasonable time limit and on reasonable commercial terms but such efforts have failed to succeed. Compulsory licences are granted upon a judicial act having entered into legal force, where:

- it is so required for the public interest – in particular, the areas of national security, nutrition, health (including lack of availability and access to medicinal products) or other areas of vital importance;
- the patent holder or the licensee does not use the patent rights in good faith – in particular, where the manner of use contradicts the customary business practices by restricting competition; or
- the invention has not been used or has been used insufficiently during a period of four years from the date on which the application was filed or three years from the date on which the patent was granted (Articles 72(1) and 72(3) of the Law on Patents).

9.6 Proceedings for Patent Infringement

The patent holder and the licensee who holds an exclusive licence have legal standing to start patent infringement proceedings. The general rule under the Civil Code is that, in cases of actions mentioned in **9.4 Pharmaceutical or Medical Device Patent Infringement** that infringe a patent, the person who has legal standing can seek the termination of violating actions as well as compensation for the damages caused (Article 1155 of the Civil Code). However, in some cases Armenian legislation limits the patent holder's right to seek remedies – for instance, the defences to patent infringement or compulsory licences as mentioned in **9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices**.

Additionally, the defendant can claim that the patent that was allegedly infringed is invalid. However, such a claim can be brought only in separate proceedings by filing a claim with a specialised court – namely, the Administrative Court. In this case, Armenian legislation provides for a legal tool, such as the suspension of judicial proceedings until the final decision regarding the validity of the patent enters into legal force (Article 157(1) of the Civil Procedure Code).

9.7 Procedures Available to a Generic Entrant

Armenian legislation does not require a declaratory action for a generic product to enter the market and clearing the way is not a requirement for generic market entry either. According to the Law on Medicinal Products, the generic entrant can be granted marketing authorisation in Armenia ten years after the registration of the original drug (Article 16(15) of the Law on Medicinal Products). Hence, the marketing authorisation procedure for pharmaceuticals and medical devices does not take patent protection into account and does not infringe a patent.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Illegal use of an object of patent right constitutes an offence under the Armenian Administrative Offences Code if the damages do not exceed AMD500,000 (approximately USD1,237), for which a sanction in the form of a fine is foreseen. However, if damages exceed AMD500,000, then the act will constitute a crime under the Criminal Code of the RA. Moreover, the Criminal Code of

the RA also foresees punishment for illegal circulation of pharmaceuticals and medical devices, making and using fake identification documents and the illegal circulation of genuine documents – for which punishments from a fine to imprisonment are foreseen (Articles 228, 409, 410 and 411 of the Criminal Code).

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

There are no specific restrictions on trade marks that can be used for pharmaceuticals and medical devices; however, the Law on Trade Marks establishes the absolute and relative grounds for refusal of trade mark registration. These include general restrictions – for example, that the trademark should not contradict public order, principles of humanity or morality, consist of or contain information that is false and/or misleading to consumers, reproduce or contain national emblems, flags or symbols, official names of states or their abbreviated forms, be identical or confusingly similar to an earlier registered trade mark, etc (Articles 9 and 10 of the Law on Trade Marks). Hence, a restriction under the Law on Trade Marks that would restrict the importing or distributing of non-counterfeit genuine pharmaceutical or medical device products is that the trade mark should not be identical or confusingly similar to an earlier registered trade mark or meet any of the other absolute or relative grounds for refusal of trade mark registration.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

The trade dress or design of pharmaceuticals and medical devices (such as tablets) or their packaging will fall under IP protection if they meet the criteria to qualify as an industrial design – namely, the design characterising the outward appearance of a product should be new and unique. The industrial design will meet the criteria of being new where no identical industrial design has been made available to the public. However, to satisfy the criteria of uniqueness, the overall impression made by an industrial design on the informed consumer should differ from the overall impression produced by any other industrial design.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Under the Law on Medicinal Products, the documents that were submitted for marketing authorisation are protected under data exclusivity for eight years. After eight years data exclusivity is no longer valid and reproduced drugs can be granted marketing authorisation based on the documents that were submitted to receive the marketing authorisation for the genuine product. However, even if the marketing authorisation is granted after eight years, the reproduced pharmaceutical still cannot be put into circulation unless ten years pass from the registration of the genuine drug (Article 16(15) of the Law on Medicinal Products). Hence, to some extent, the data exclusivity is still under protection during the course of the remaining two years.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

During the COVID-19 pandemic, a series of measures were implemented to prevent the spread of the virus. To prevent shortages of medicinal products such as face masks, ventilators, disposable medical gloves, and clothing, strict restrictions on the export of medicinal products were imposed. By decree of the Chief Co-ordinator (the Deputy Prime Minister) dated 3

April 2020, the export of various medical devices abroad – including to Eurasian countries – was temporarily prohibited.

Restrictions concerning medicinal products, however, were not implemented.

11.2 Special Measures Relating to Clinical Trials

No special measures were issued in relation to ongoing clinical trials during the COVID-19 pandemic. However, following Decree No 65-N of the Minister of Health dated 20 August 2021, employees in government or self-administration authorities were required to present a PCR test every three days (otherwise entry was denied) or provide evidence of full vaccination.

The order of the Minister of Health No 21 dated 17 August 2020 delineates the rules and norms for implementing vaccinations against communicable diseases in the RA. Although these regulations do not explicitly refer to the COVID-19 disease, they were enacted in response to the pandemic. This directive covers the management of medical contraindications and handling cases of adverse post-vaccination reactions. It further addresses planning to meet the demand for medical immunobiological preparations, encompassing receipt, storage, transportation, accounting, and expenditure. The order also establishes stringent requirements for the utilisation of open vials, with the overarching goal of eradicating manageable infectious diseases. Emphasis is placed on reducing morbidity and mortality rates attributed to such diseases, minimising unjustified contraindications, and achieving timely (95% and more) and comprehensive (90% and more) coverage of vaccinations within target populations. Additionally, the order outlines the process of immunosuppression to ensure the safety and efficacy of the overall vaccination initiative.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

There were no specific regulations concerning emergency approvals for the importation of medicines or medical devices. Armenian law permitted the importation of medicines without registration during a state of emergency, such as the COVID-19 pandemic. Additionally, the requirement for a registered medicinal product to obtain an import certificate is waived in cases of emergencies (or the threat thereof).

Meanwhile, the specific procedures and a list governing the sale, acquisition, and circulation of food, medicine, and essential goods during martial law were established through the government's Decision No 1632-N dated 3 October 2020.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

No simplifications or flexibilities (eg, automatic renewal or temporary extensions) were introduced in relation to obtaining required certifications owing to COVID-19, as a state of emergency was declared and registration was not needed for importing medications into Armenia under such circumstances.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

For import/export restrictions or flexibilities introduced in relation to medical devices, please refer to **11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices**.

There were no restrictions on exporting or importing pharmaceuticals into Armenia. A

flexibility for the import of medications can be observed in the fact that drugs were allowed to be imported into Armenia even if they were not registered, following Decision No 1632-N of 3 October 2020 of the Government of the RA (see **11.3 Emergency Approvals of Pharmaceuticals and Medical Devices**).

11.6 Drivers for Digital Health Innovation Due to COVID-19

The regulations for telemedicine were implemented in the Law on Medicinal Products on 6 May 2020 and, as such, during the COVID-19 pandemic. Also, the digital app "ArMed E-Health" launched during the COVID-19 pandemic (see **8.1 Rules for Medical Apps**).

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

The Armenian government has not announced any intention to issue compulsory licences for treatments or vaccines related to COVID-19. However, under Armenian law, compulsory licences may be granted without the consent of the patentee through a judicial act if the interests of society – including national security, food production, public health (including the unavailability of medicinal products), or other vital areas – necessitate such action (see **9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices**).

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

No exemptions from liability have been implemented for treatments or vaccines related to COVID-19. The standard liability regulations for pharmaceuticals remain in effect.

11.9 Requisition or Conversion of Manufacturing Sites

Existing provisions were not used – nor were new ones introduced – to allow the requisition or conversion of manufacturing sites owing to COVID-19.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

There were no changes made to the system of public procurement of medicines and medical devices in response to COVID-19.

AUSTRIA

Law and Practice

Contributed by:
Sonja Hebenstreit, Michael Cepic and Maximilian Kröpfl
Herbst Kinsky Rechtsanwälte GmbH

Contents

Herbst Kinsky Rechtsanwälte GmbH has become one of Austria's leading commercial law firms since its establishment in 2005. Its specialised and highly committed lawyers combine many years of experience gained abroad and in reputable Austrian law firms. The firm's practice covers a full range of services in all areas of commercial, corporate, civil and public law, including banking, insurance and capital markets, corporate and M&A, IP, IT and life sciences, antitrust and competition, data protection, real estate, dispute resolution and arbitration. Herbst Kinsky Rechtsanwälte has established a particularly strong presence in the field of life sciences and healthcare. The firm's clients range from large international privately held and publicly listed companies to SMEs, as well as start-ups.

Authors

Sonja Hebenstreit is a partner at Herbst Kinsky Rechtsanwälte GmbH, which she joined in 2005. She specialises in the fields of intellectual and industrial property law, unfair competition, life sciences and data protection. Sonja represents Austrian and international clients – including (biotech) start-ups and numerous pharmaceutical and medical devices companies – in a variety of regulatory, licensing and contractual issues, as well as in data protection, unfair competition and reimbursement matters.

Michael Cepic joined Herbst Kinsky Rechtsanwälte GmbH as an associate in November 2023 and specialises in the areas of life sciences, IP, data protection law and litigation. Before joining Herbst Kinsky, Michael worked as a research associate at the University of Vienna contributing to biomedical and law enforcement research projects. In addition to his law degree, he holds a BSc in biology.

Maximilian Kröpfl joined Herbst Kinsky Rechtsanwälte GmbH as an associate in October 2023. He specialises and advises clients in the areas of data protection law, IT and technology, intellectual property and unfair competition. Before joining Herbst Kinsky, he worked for an Austrian telecommunications company, served as accredited parliamentary assistant to a member of the European Parliament, and practised as an associate in two renowned Vienna law firms.

Herbst Kinsky Rechtsanwälte GmbH

Dr Karl Lueger Platz 5
Vienna
A-1010
Austria

Tel: +43 1 904 21 80
Fax: +43 1 904 21 80 210
Email: office@herbstkinsky.at
Web: www.herbstkinsky.at

HERBST KINSKY

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Austrian medicinal products law is strongly determined by EU legislation. However, at a national level, the Austrian Medicinal Products Act (*Arzneimittelgesetz*, or AMG) constitutes the primary legal basis with regard to pharmaceuticals ("medicinal products") for human use. It implements the main EU legal acts in this respect – specifically, Directive 2001/83/EC. Since 28 January 2022, medicinal products for veterinary use have been governed by the Regulation on Veterinary Medicinal Products (Regulation (EU) 2019/6) which, since January 2024, has been complemented in Austria by the new Austrian Veterinary Medicinal Products Act (*Tierarzneimittelgesetz*).

Specific provisions in relation to medicinal products can also be found in other Austrian laws, such as the Austrian Pharmaceutical Products Import Act (*Arzneiwareneinfuhrgesetz*, or AWEG) or the Austrian Prescription Act (*Rezeptpflichtgesetz*). Furthermore, the manufacture and distribution of medicinal products is governed by several national ordinances (*Durchführungsverordnungen*), which are based on the AMG, including the Medicinal Products Operations Ordinance (*Arzneimittelbetriebsordnung*, or AMBO).

Medicinal products law is also increasingly regulated by directly applicable EU regulations – for example, Regulation (EC) 726/2004 (see **3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices**), Regulation (EU) 536/2014 ("Clinical Trials Regulation", or CTR), and Regulation (EC) 1394/2007 ("Advanced Therapy Medicinal Products Regulation", or ATMPR).

As of 26 May 2021, medical devices have mainly been governed by the Regulation (EU) 2017/745 ("Medical Devices Regulation", or MDR), which is complemented by the Austrian Medical Devices Act 2021 (*Medizinproduktegesetz*, or MPG) providing for rules regarding the safety, functionality and quality of medical devices with regard to their construction, operation, use and maintenance. Since 26 May 2022, in vitro diagnostic (IVD) devices have been governed by Regulation

(EU) 2017/746 ("In Vitro Diagnostics Regulation", or IVDR), which is likewise complemented by the MPG. The MPG came into force on 1 July 2021 for medical devices and on 26 May 2022 for IVD devices.

The competent national authority for medicinal products, medical devices and IVD devices is the Austrian Federal Office for Safety in Healthcare (*Bundesamt für Sicherheit im Gesundheitswesen*, or BASG). The BASG is responsible for the approval and control of medicinal products in Austria, as well as for the control and approval of clinical trials (see **2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial**). Together with the competent European agencies, the BASG further monitors nationally the medicinal products, medical devices and IVD devices already on the market with regard to their efficacy, safety, production, transport and storage.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Decisions by regulatory bodies qualify as specific administrative acts (*Bescheide*), which can be challenged by the addressee – or by a third party having a legal interest, if applicable – by lodging an appeal with the regulatory body that has issued the administrative act. The decision on the appeal is made by the competent administrative court.

Appeals against administrative acts must be made in writing and – unless regulated otherwise in the respective regulation – filed within four weeks of the date of the decision to be challenged. There is no legal obligation for the appellant to be represented by an attorney.

1.3 Different Categories of Pharmaceuticals and Medical Devices

In Austrian medicinal products law, various criteria exist on the basis of which medicinal products are categorised and regulated differently. By way of an example, the AMG distinguishes between medicinal products that are available for the patient only upon prescription and over-the-counter (OTC) medicinal products available without prescription. Medicinal products requiring prescription may not be advertised to the general public ("lays") but, rather, only to healthcare professionals under the preconditions laid down in the AMG.

The AMG makes another relevant distinction between medicinal products that are, in principle, subject to marketing authorisation – known as "medicinal specialties" (*Arzneispezialitäten*) – and medicinal products not subject to such authorisation. Furthermore, the AMG differentiates on the basis of the material composition of a medicinal product (eg, biological medicinal products, herbal medicinal products, radioactive medicinal products, or homeopathic medicinal products).

Likewise, medical devices may be qualified by the Ministry of Health as requiring a prescription or as only available through certain specialised dealers. Prescription-only medical devices may not be advertised to the general public either. However, in practice, the vast majority of medical devices are freely available and not qualified as prescription-only, or are exclusively available in specialist stores.

There is also an essential distinction between IVD devices – to which the IVDR applies – and other medical devices, which are subject to the MDR. In addition, the MDR and IVDR differentiate on the basis of the purpose or use of a

medical device (eg, active device, implantable device, invasive device, or single-use device) and its inherent risks (Class I, IIa, IIb, III for medical devices/Class A, B, C and D for IVD devices).

2. Clinical Trials

2.1 Regulation of Clinical Trials

The regulatory system for clinical trials of medicinal products underwent a comprehensive restructuring as of 1 February 2022, aimed at further harmonising the rules on the conduct of clinical trials within the EU member states. The legal framework of clinical trials on medicinal products is now essentially defined by the CTR, thereby replacing the former system for clinical trials based on Directive 2001/20/EC. Supplementary provisions for national implementation and within the scope of so-called opening clauses of the CTR have been introduced into the Austrian legal system through the AMG by an amendment in Federal Law Gazette I 2022/8.

If genetically modified organisms (GMOs) are used for therapeutic purposes – as defined in Section 4(24) of the Austrian Gene Technology Act (*Gentechnikgesetz*, or GTG) – in the course of a clinical trial, a prior permit according to Section 74 of the GTG must also be obtained.

Clinical trials of medical devices (known as "clinical investigations") are mainly regulated by the MDR and clinical trials of IVD devices (known as "performance studies") are regulated by the IVDR. Supplementary provisions have been included in the MPG.

For non-interventional studies, the provisions of the CTR and the MDR/IVDR do not apply. Instead, there are specific national provisions in the AMG and the MPG for these studies, including provisions concerning data protection and inspections by the BASG. The following may also apply:

- general provisions of civil, criminal and data protection law; or
- specific rules for clinical research under, for example, the Austrian Hospital and Sanatoria Act (*Krankenanstalten- und Kuranstaltengesetz*, or KAKuG) or the Austrian University Act 2002 (*Universitätsgesetz*, or UG).

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Since 31 January 2023, all new applications for clinical trials of medicinal products must be submitted in accordance with the CTR. The authorisation procedure is initiated by the sponsor sending the application dossier to the EU member states concerned via the EU portal, known as the Clinical Trials Information System (CTIS). The reporting member state must then carry out a validation within ten days and notify the sponsor via the portal of the results. In Austria, the BASG is responsible for the validation procedure, whereby the ethics committee can issue an opinion on certain parts of the application (Section 31, paragraph 4 of the AMG). The validation procedure is followed by the evaluation procedure, which is divided into the following two parts.

- In Part I, a co-ordinated assessment of the application between the reporting and concerned member states takes place, in which aspects of the clinical trial – such as whether it is minimally interventional, the expected therapeutic and public health benefits, and the risk of harm posed to the trial subjects – are evaluated. The assessment report must be prepared and submitted within 45 days of validation; however, this term may be extend-

ed under certain conditions. The responsibilities regarding Part I of the assessment procedure are divided nationally between the BASG and an assessing ethics committee (Section 35 of the AMG).
- Part II of the evaluation procedure includes the aspects that are to be assessed nationally by each member state – for example, requirements for informed consent, patient recruitment, and subject insurance. The evaluation report must also be submitted within 45 days of validation. In Austria, the responsibility for preparing the assessment report in Part II is assigned to the evaluating ethics committee.

The decision to authorise the clinical trial must then be taken by each member state within five days of the conclusion of the evaluation procedure. If a timely notification is not made, the conclusion regarding Part I of the assessment report is automatically deemed to be the decision of the respective member state.

The approval of a clinical investigation into a medical device for the purposes of the conformity assessment referred to in Article 62, paragraph 1 of the MDR essentially follows the MDR. Depending on the type of investigation, different procedures are provided for (eg, authorisation procedure/notification procedure/instruction procedure).

An application for authorisation must be submitted electronically to the BASG. Upon receipt of the application, the BASG must carry out the validation within ten days.

With regard to Class I investigational devices or Class IIa/IIb non-invasive devices, the clinical investigation may be commenced immediately after validation – provided that the BASG has confirmed proper notification and the ethics committee has given a favourable opinion (ie, notification procedure).

In the case of other investigational devices (Class III investigational devices or Class IIa/IIb invasive devices), the clinical investigation may only commence after notification of the authorisation by the BASG – again with the prerequisite that a favourable opinion by the competent ethics committee must be provided. The decision about the authorisation must usually be communicated to the sponsor within 45 days of validation (ie, authorisation procedure).

For clinical investigations of medical devices that already bear a CE marking, thereby confirming *conformité européenne* ("European conformity"), a different procedure applies under certain conditions (Article 74 MDR). The sponsor must notify the BASG of the conduct of such investigation at least 30 days before it begins. In this case, the BASG will confirm the notification without further subsequent assessment (ie, information procedure).

Clinical investigations of medical devices for other purposes than the demonstration of conformity are also subject to prior approval by the BASG if they have an impact on the diagnostics and/or therapy of a trial subject (Article 82 of the MDR, in conjunction with Section 13, paragraph 3 of the MPG); otherwise, it is only necessary to conduct an information procedure.

For performance studies on IVD devices, the provisions of the MPG are largely applicable mutatis mutandis – although there are certain exceptions (see Article 66 et seq of the IVDR and Section 36 of the MPG for comparison).

2.3 Public Availability of the Conduct of a Clinical Trial

For medicinal products, information on clinical trials initiated under the CTR as of 31 January 2022 (including the start and end dates of the trial, details of the sponsor, and trial results) is publicly available on the EU Clinical Trials website. Information on clinical trials initiated under the former system of Directive 2001/20/EC (before 31 January 2022) may still be accessed via the EU Clinical Trials Register.

For clinical investigations and performance studies under the MDR and the IVDR, no publicly accessible register is currently provided at EU or national level. However, information on such trials will be accessible via the EUDAMED database as soon as the entire EUDAMED system has been declared fully functional.

At national level, the option to provide for the maintenance of a (publicly accessible) register for non-interventional studies of medical devices via ordinance was not exercised by the legislator.

2.4 Restriction on Using Online Tools to Support Clinical Trials

In Austria, it is not generally prohibited to conduct the consent procedure remotely or to remotely supervise certain tasks/procedures carried out at home by a physician. Remote access to source data for the purpose of monitoring is also permissible; however, this only applies to original electronic medical records and where a correspondingly validated record system is being used.

In December 2022, a recommendation paper on decentralised (remote) elements in clinical trials was published by the EU Decentralised Clinical Trial (DCT) project team, comprising experts from the Clinical Trial Coordination Group, the Clinical Trial Expert Group, European Medicines Agency (EMA) scientific committees, EMA working parties, and EMA staff. This document also includes guidance concerning national provisions on the use of online tools in clinical studies within the EU.

As regards special measures due to COVID-19, see **11.2 Special Measures Relating to Clinical Trials**.

2.5 Use of Data Resulting From Clinical Trials

Clinical studies involve the processing of patients' contact and health information, which may qualify as personal data as defined by Article 4(1) of the General Data Protection Regulation (EU) 2016/679 (GDPR). To the extent that patients are identified or at least identifiable in data resulting from the clinical trial, these data sets must also be qualified as personal (sensitive) data.

The processing of personal data in the context of a clinical trial is generally based on the patient's consent pursuant to Article 6, paragraph 1(a) in conjunction with Article 9, paragraph 2(a) of the GDPR. Accordingly, any disclosure of personal data to third parties must be covered by this consent.

2.6 Databases Containing Personal or Sensitive Data

The processing of personal data (including sensitive data) within databases is subject to compliance with the GDPR, (potentially) the Austrian Research Organisation Act (*Forschungsorganisationsgesetz*, or FOG) and the Austrian Data Protection Act (*Datenschutzgesetz*, or DSG).

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The distinction between medicinal products and medical devices is made in accordance with the product definitions as set forth in the AMG (Section 1, paragraph 1) and the MDR (Article 2(1)).

"Medicinal products", within the meaning of the AMG, are substances or preparations of substances that either:

- are intended for use in or on the body and as agents with properties to cure or alleviate or prevent diseases or pathological complaints (so-called presentation medicinal products); or
- may be applied in or on the body or administered to a human (so-called functional medicinal products) with a view to either:
  (a) restoring, correcting or modifying physiological functions by a pharmacological, immunological or metabolic action; or
  (b) making a medical diagnosis.

According to the MDR, the term "medical device" means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means:

- the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
- the diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability;
- the investigation, replacement or modification of the anatomy or of a physiological or pathological process or state; and
- for providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations.

Furthermore, devices for the control or support of conception, as well as certain products specifically intended for the cleaning, disinfection or sterilisation of devices will be deemed medical devices.

The distinction between medicinal products and medical devices can be made, in most cases, on the basis of the principal mode of action of the product (see Article 1, paragraph 6(b) of the MDR). A product with an essentially pharmacological, immunological or metabolic action is not to be classified as a medical device. The principal mode of action of medical devices is mostly of a physical or mechanical kind.

In the case of diagnostic devices, distinction must be made on the basis of the nature of the product (substance/instrument, apparatus, etc) and the place of application (in vivo or in vitro).

In Austria, manufacturers of products (or their representatives) may initiate a procedure with the BASG, whereby questions concerning the product classification – including the demarcation between the medicinal product and the medical device status of the product – will be

clarified (Section 10 of the MPG and Section 49a of the AMG).

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Within the meaning of the AMG, the term "biological medicinal products" comprises:

- certain immunological medicinal products;
- certain medicinal products manufactured by using human blood or blood plasma as a starting material; and
- medicinal products listed in Annex I(1) and (1a) Regulation (EC) 726/2004, such as:
  - (a) medicinal products developed by means of recombinant DNA technology, controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes (including transformed mammalian cells), or hybridoma and monoclonal antibody methods; and
  - (b) ATMP.

Austrian law does not provide for a marketing authorisation procedure specific to biological medicinal products. However, for medicinal products listed in Annex 1(1) and (1a) Regulation (EC) 726/2004, a central marketing authorisation according to said regulation is mandatory. In addition, differences with regard to the required application documents may arise for different types of biological medicinal products.

Furthermore, the AMG contains specific provisions for certain immunological medicinal products, as well as medicinal products manufactured by the use of human blood or blood plasma. According to Section 7, paragraph 8 of the AMG, for example, blood and blood components intended for direct transfusion are exempt from the obligation to obtain a marketing authorisation. Also, there may be an additional requirement of a batch release as a prerequisite for supplying certain biological medicinal products in national Austrian law (see Section 26 of the AMG). Lastly, specific provisions for so-called biosimilars can be found in Section 10, paragraph 6 of the AMG.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

A national marketing authorisation of a medicinal product is generally granted by the BASG for a period of five years (Section 20, paragraph 1 of the AMG). An extension of the marketing authorisation (at the request of the marketing authorisation holder) is valid without a time limit, unless the BASG again sets a time limit of five years for reasons of pharmacovigilance.

If an authorised medicinal product has not actually been placed on the domestic market within three years of the marketing authorisation being granted, or has not been on the market for three consecutive years, the marketing authorisation may expire in accordance with Section 22 of the AMG (the so-called sunset clause). In certain cases, the marketing authorisation must also be revoked. Similar rules apply according to Regulation (EC) 726/2004 with regard to the period of validity of marketing authorisations for medicinal products authorised under the centralised procedure.

The placing on the market of medical devices is not subject to a marketing authorisation; however, the manufacturer must perform a conformity assessment procedure (see **3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices**). According to Article 56 of the MDR, certificates of conformity issued by the notified bodies will be valid for the period they indicate, which must not exceed

five years. Upon application by the manufacturer, the validity may be extended for further periods (of no more than five years), based on a re-assessment. The CE marking will be suspended, restricted or withdrawn if a notified body finds that the requirements of the MDR are no longer met by the manufacturer.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

Marketing Authorisation for Medicinal Products

There are, in practice, four different procedures for obtaining a marketing authorisation for medicinal products.

- For medicinal products according to Annex I Regulation (EC) 726/2004 (eg, ATMP), marketing authorisation must be obtained via the centralised procedure. Under certain conditions (see Article 3, paragraph 2), the centralised procedure is also available for other medicinal products. A marketing authorisation obtained under the centralised procedure is issued by the European Commission and is valid in all EU member states. Applications must be submitted to the EMA.
- For other medicinal products, marketing authorisation may be obtained under the national procedure according to Sections 7 et seq of the AMG via application to the BASG. The BASG is also the competent authority for issuing the national marketing authorisation, which is only valid on Austrian territory.
- Where a national authorisation already exists in a member state, it may be extended to the territory of other member states through a mutual recognition procedure (Section 18a of the AMG).
- For medicinal products that cannot be authorised under the centralised procedure, a marketing authorisation in different EU member states may be applied for through a decentralised procedure (Section 18a of the AMG).

Variations to marketing authorisations

Variations to marketing authorisations are governed by Regulation (EC) 1234/2008 for all types of authorisations. Depending on the degree of health risk and the impact on quality, safety and efficacy, either a simple notification procedure, a notification obligation with a prohibition reservation or a prior authorisation procedure is required. In contrast, applications for authorisation extensions (eg, in the case of relevant changes to the active substance) must be evaluated according to the same procedure as the application for the original authorisation.

Transfers of marketing authorisations

Transfers of marketing authorisations obtained under the centralised procedure must be applied for with the EMA according to the procedure set down in Regulation (EC) 2141/96. Otherwise, the procedure is governed by Section 25 of the AMG according to which a declaration of waiver of the authorisation by the previous marketing authorisation holder and a declaration of acceptance by the transferee must be submitted to the BASG.

Medical Device and IVD Device Compliance

Placing medical devices and IVD devices on the market is not subject to obtaining a marketing authorisation. Medical devices or IVD devices, however, may only be placed on the market or put into service if they comply with the MDR/IVDR. Specifically, they must meet the general safety and performance requirements, taking into account their intended purpose. Also, an assessment of the conformity of the device must be conducted and a corresponding declaration of conformity issued. Depending on the

risk classification of a medical device, a notified body must be involved in the process. Conformity with the applicable requirements is indicated by CE marking of the product. Transfers of CE markings are not provided for in the MDR/IVDR.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

Medicinal Products

As far as medicinal products are subject to a marketing authorisation, the marketing authorisation is a prerequisite for lawful placing on the market in Austria. For this reason, opportunities to supply such medicinal products to patients without any marketing authorisation are limited. Nevertheless, there are a number of exceptions to this principle. The following are among the exceptions to the authorisation requirement.

- Named Patient Use (Section 8, paragraph 1(2) of the AMG) – no marketing authorisation is needed if a physician or dentist authorised to practise independently in Austria certifies that:
  - (a) a medicinal product is urgently needed to prevent a threat to life or serious damage to the health of a specific patient; and
  - (b) this threat or damage cannot be prevented with an authorised and available medicinal product according to the state of the art.
- Compassionate Use Programmes (Section 8a of the AMG and Article 83 of Regulation (EC) 726/2004) – marketing authorisation is not needed within Compassionate Use Programmes, which may be established (subject to prior approval by the BASG) for a defined group of patients suffering from a debilitating chronic or severe disease or whose disease is life-threatening and cannot be satisfactorily treated with an authorised and available medicinal product.
- Clinical trials (Section 8, paragraph 1(1) of the AMG) – medicinal products intended for the use in non-clinical or clinical studies or clinical trials do not need a marketing authorisation.
- Hospital exemption (Section 7, paragraph 4 of the AMG and Article 28 of Regulation (EC) 1394/2007) – ATMP that are manufactured on a non-routine basis in Austria on the basis of an individual medical prescription specifically for a particular patient, in order to be used on that patient in an Austrian hospital under the exclusive professional responsibility of a physician, are not subject to a marketing authorisation.
- Officinal and magisterial medicinal preparations (Section 7, paragraphs 2 and 3 of the AMG) – certain medicinal products manufactured in pharmacies are not subject to a marketing authorisation.

Further exemptions are listed in Sections 7 et seq of the AMG.

It should be noted that a marketing authorisation is a prerequisite for placing medicinal products on the market, but not for their use. For this reason, medicinal products can, in principle, be used on patients beyond the scope of their marketing authorisation (off-label use). In this context, however, there are increased obligations on the part of the physician to provide information to the patient.

Medical Devices and IVD Devices

With regard to medical devices and IVD devices, the MDR/IVDR provide for exemptions from the obligation of CE marking for custom-made devices, investigational devices and devices for performance studies (Article 20 of the MDR and

Article 18 of the IVDR). Furthermore, the placing on the market and putting into service of a medical device for which no conformity assessment has been carried out may be authorised by the BASG in specific cases upon request for reasons of public health or patient health and safety (Article 59 of the MDR, Article 54 of the IVDR and Section 12 of the MPG).

As per the above-mentioned definition of Named Patient Use, if a physician or dentist authorised to practise independently in Austria confirms that a medical device is required for a specific patient in order to avert a danger to life or a serious impairment of health – and that the treatment cannot be expected to be successful with a medical device for which conformity assessment procedures have already been carried out – then such authorisation is not necessary. The same applies to medical devices used in connection with certain deployments of the Federal Armed Forces (Section 12, paragraphs 2 and 3 of the MPG).

Finally, under certain conditions there are far-reaching exemptions from the obligations of the MDR/IVDR for in-house products that are manufactured and used only in healthcare facilities (Article 5, paragraph 5 of the MDR/IVDR and Section 9 of the MPG).

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

Medicinal Products

Holders of a marketing authorisation for a medicinal product must operate a pharmacovigilance system (Section 75i et seq of the AMG). Within the framework of this system, the holder must, among other things:

- appoint a pharmacovigilance officer;
- keep a pharmacovigilance master file;
- operate a risk management system;
- monitor the results of risk minimisation measures;
- monitor pharmacovigilance data; and
- subject the pharmacovigilance system to regular audits.

The applicable law also provides for reporting obligations (Section 75j of the AMG, Article 28 of Regulation (EC) 726/2004 and Article 107 of Directive 2001/83/EC) and information obligations of the holder (Section 75m of the AMG). In addition, holders are obliged to regularly prepare periodic safety update reports (PSUR) and transmit them electronically to an archive maintained by the EMA.

Other obligations of the holder include the following:

- The holder must inform the BASG about the date of actual placing on the market of a medicinal product, as well as a temporary or permanent removal from the market (Section 21 of the AMG).
- The holder must ensure that complete documentation of all activities related to the marketing authorisation or the medicinal product is available at all times (Section 24b of the AMG).
- If there are concerns regarding the risks of the medicinal product, the holder may face additional requirements or conditions imposed by the BASG, such as the performance of post-authorisation safety studies. If findings on the disease or clinical methodology indicate that previous assessments of efficacy may need to be significantly corrected, an efficacy study must be imposed (Section 19a of the AMG).

Medical Devices and IVD Devices

For medical devices and IVD devices, the MDR/IVDR require the manufacturer to plan, establish, document, implement, maintain and update a post-market surveillance system as part of the quality management system in a manner appropriate for the risk class and type of the product (Article 83 of the MDR and Article 78 of the IVDR). To this end, a post-market surveillance plan must be established (Article 84 of the MDR and Article 79 of the IVDR) and post-market surveillance reports must be prepared and updated (Article 85 of the MDR and Article 80 of the IVDR). Further obligations concern, for example, the preparation of PSUR (Article 86 of the MDR and Article 81 of the IVDR), the reporting and analysis of serious incidents and safety corrective measures (Articles 87 and 89 of the MDR and Articles 82 and 84 of the IVDR) and trend reports (Article 88 of the MDR and Article 83 of the IVDR).

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

On an EU level, a list of medicinal products under current evaluation under the centralised procedure is published monthly by the EMA. A list of all medicinal products that have received a marketing authorisation under the centralised procedure is provided in the "Union Register" published by the European Commission. This register includes information on the name of a product, the registration number, name and address of the marketing authorisation holder, the active substance, the therapeutic indication, and relevant documents – as well as suspended, withdrawn or refused marketing authorisations.

On a national level, the BASG keeps a public register of all medicinal products for which a national marketing authorisation has been obtained (*Arzneispezialitätenregister*). Any granting, variation, cancellation and transfer of a marketing authorisation must be entered into this register. Entries regarding the granting of a marketing authorisation include information on the authorisation number, the name of the product, the authorisation holder, prescription-only or narcotic status, and the composition of the medicinal product.

Furthermore, the BASG operates an internet portal on medicinal products for public information purposes. In addition to information on the granting of a marketing authorisation and the variation of a medicinal product, the BASG shall (inter alia) publish the technical information and approved directions for use, information on approved variations, and the conditions and constraints of marketing authorisations. Also, every expert opinion provided in the context of an application for marketing authorisation shall be published after all confidential information in the party's commercial interest has been removed.

For products authorised via a mutual recognition procedure, information can be found in the MRI Product Index. Information on medical devices and IVD devices (including summaries of safety and clinical performance) and their manufacturers and importers, as well as certificates, may be publicly accessed via the EUDAMED database.

3.8 Rules Against Illegal Medicines and/or Medical Devices

The core Austrian regulations concerning the protection of the legal supply chain against falsified medicinal products and active substances were implemented in the AMG by Federal Law Gazette I 2013/48 in implementation of Directive 2011/62/EU. These include, inter alia, the following (legislative) measures.

- The outer packaging of specific medicinal specialties intended for human use must bear safety features and a mechanism to detect possible tampering with the outer packaging (Section 17, paragraph 5 of the AMG) (see also the AMBO).
- The counterfeiting of medicinal products, active substances or excipients – as well as the stockpiling, exporting and importing of counterfeit medicinal products, active substances or excipients with the aim of transferring them to another person – and the offering, procuring, transferring of such products are criminal offences punishable by imprisonment, as are the counterfeiting and falsification of commercial packages or other documents relating to medicinal products, active substances or excipients (see Section 82b AMG).
- There are increased obligations for entities involved in the distribution chain – for example, when a medicinal product is authorised, a manufacturer must attach written confirmation to the application that they have verified and established the active substance manufacturer's compliance with Good Manufacturing Practice (GMP) by means of audits.
- Counterfeit medicines, active ingredients, excipients and related documents can be confiscated by the authorities (Section 82c of the AMG).

With regard to medical devices and IVD devices, Section 5 of the MPG prohibits the erection, installation, putting into service, or use of such products if there are reasonable grounds for suspecting or establishing that they are falsified. According to the MDR and the IVDR, importers of medical devices and IVD devices are obliged to inform the competent authority if they suspect such product to be falsified (Articles 13 and 14 of the MDR/IVDR). Authorities may confiscate, destroy or otherwise render inoperable falsified devices or IVD devices if it is necessary to protect public health (Article 93 of the MDR and Article 88 of the IVDR).

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

If certain facts indicate that falsified medicinal products, active substances, excipients or documents are being transported to or from Austria, the customs authorities are authorised to seize them. They shall immediately report the seizure to the competent public prosecutor's office (Section 82d of the AMG).

With regard to medical devices and IVD devices, border controls may suspend the release of falsified products for free circulation on the community market on the basis of Article 27, paragraph 3 of Regulation (EC) 2008/765. In this case, they shall immediately notify the market surveillance authorities of such suspension.

4. Manufacturing of Pharmaceuticals and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

The manufacture of medicinal products (including packaging, labelling and final release of the finished product) may only be carried out based on a manufacturing authorisation (known as an "operating licence") to be applied for in accordance with the AMG.

The authorisation is granted by the BASG upon application, in which the applicant must provide details of:

- the nature, scope and location of the intended manufacturing activity;
- the nature, size, equipment, dedication and location of the premises (as well as their furnishings and equipment);
- the nature of the technical equipment; and
- the appointed Qualified Person (QP) (*sachkundige Person*) who needs to be appropriately qualified, experienced and reliable.

Another prerequisite for the manufacturing licence is a trade permit for the manufacturing of medicinal products. This is issued, in accordance with the Trade Act (*Gewerbeordnung*, or GewO), by the Trade Authority – ie, the competent district administrative authority (*Bezirksverwaltungsbehörde*) at the intended manufacturing site. Such permit requires the nomination of a "managing director under trade law" (*gewerberechtlicher Geschäftsführer*) who is appropriately qualified (as further defined in the GewO).

The manufacturing licence will only be issued after a successful on-site inspection of the manufacturing premises by BASG in which the authority checks compliance with the requirements of the AMBO and that the quality of the medicinal products as required for the health and life of humans (or animals) is ensured on the basis of the provided facts. The statutory timeframe for issuing a manufacturing licence is 90 days from the submission of a complete application. Any additional requests by the authority or missing information identified in the inspection will lead to a clock-stop.

The manufacturing authorisation is granted for a specific site, for specific manufacturing activities and types of medicinal products as specified in the application, and – in principle – for an unlimited period. However, the authorisation remains subject to regular GMP inspections by the BASG, and can be withdrawn in the case of any detected and non-remedied deficiencies.

The manufacture of medical devices and IVD devices is not subject to a specific governmental authorisation. However, requirements as applicable to any manufacturing activity – for example, those under construction law and under trade law regarding operating plants – will apply.

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

In order to be able to carry out wholesale distribution of medicinal products, a wholesale dealer licence (WDL) is required (also called an "operating licence"). Such WDL is required not only if the respective entity actually carries out physical handling and storage of medicinal products, but also for selling and supplying medicinal products – even though the actual logistics are outsourced to a third party (likewise requiring a WDL itself).

The WDL is granted by the BASG upon application, in which the applicant must provide details of:

- the nature, scope and location of the intended distributing activity;
- the nature, size, equipment, dedication and location of the premises as well as their furnishings and equipment;
- the nature of the technical equipment; and
- the appointed responsible person (*fachkundige Person*) for wholesale distribution being appropriately qualified, experienced and reliable.

Furthermore, a trade permit is also required for the wholesale of medicinal products (see **4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices**). Such permit requires the nomination of a managing director under trade law who is appropriately qualified.

The WDL may only be issued after a successful on-site inspection of the wholesale distribution site by the BASG. The statutory timeframe for issuing a WDL is 90 days from the submission of a complete application. Any additional requests by the authority or missing information identified in the inspection will lead to a clock-stop.

The WDL is granted for a specific site and for specific distribution activities as specified in the application, and in principle for an unlimited period. However, the authorisation remains subject to regular Good Distribution Practice inspections by the BASG, and can be withdrawn in the case of any detected and non-remedied deficiencies.

For the distribution of medical devices, no licence comparable to the WDL is necessary. However, a trade licence and an appropriately qualified managing director under trade law are necessary.

Finally, according to Section 67 of the MPG, registration in the publicly accessible Medical Devices Register is mandatory for all persons or entities who are responsible for placing medical devices on the market for the first time in the European Economic Area (EEA) and who are domiciled in Austria.

5.2 Different Classifications Applicable to Pharmaceuticals

See **1.3 Different Categories of Pharmaceuticals and Medical Devices**.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The importation and transfer of "pharmaceutical products" (*Arzneiwaren*) is regulated under the AWEG. In this context, it should be noted that the term "pharmaceutical products" is not identical with the term "medicinal product" as defined in the AMG or Directive 2001/83/EC – rather, it is based on the customs tariff regulations of Regulation (EEC) 2658/87. The AWEG therefore does not apply to all medicinal products. Also, medical devices are explicitly excluded from its scope (Section 1, paragraph 2 of the AWEG).

Provisions for parallel imports of medicinal products are regulated in the AMG (in particular, Section 10c). Products that have been authorised for parallel import are exempt from the notification obligation under the AWEG. Furthermore, obligations for importers and exporters are provided by the AMBO (see, for example, Section 4a). Specific provisions for the importation of investigational medicinal products are regulated in the CTR (Articles 61 and 63). The transfer of investigational medicinal products within the EEA (and Switzerland) is exempt from the notification obligation under the AWEG (Section 6, paragraph 2 of the AWEG).

The BASG is competent to issue import certificates and receive notifications under the AWEG and to supervise compliance with the AMG, the AWEG and the CTR. In addition, certain powers are granted to the customs administration under the AWEG.

General and specific obligations with regard to the importation of medical devices and IVD devices are laid down in the MDR/IVDR (see, in particular, Articles 13 and 60 of the MDR and Articles 13 and 55 of the IVDR) and enforced by the BASG as the competent authority.

6.2 Importer of Record of Pharmaceuticals and Medical Devices

According to Section 4 of the AWEG, the following entities are entitled to apply for an import permit or carry out an importation notification for pharmaceutical products:

- public pharmacies;
- hospital pharmacies; and
- companies authorised to distribute pharmaceutical products in a state within the EEA.

The entitlement to apply for a parallel import authorisation is granted to the following entities, according to Section 9 of the AMG:

- professionals authorised to manufacture or wholesale the medicinal product concerned;
- operators of domestic public pharmacies; and
- pharmaceutical companies established within the EEA that are authorised to place the medicinal product concerned on the market.

Depending on their activities (eg, repackaging), importers may be subject to the operating licence requirement of Section 63 of the AMG (see also **4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices** and **5.1 Wholesale of Pharmaceutical and Medical Devices**).

The MDR and the IVDR do not provide for specific legal requirements to act as the importer of record of medical devices or IVD devices. However, they define the importer as "any natural or legal person established within the Union that places a device from a third country on the Union market". Importers must register in accordance with Article 28 of the MDR/IVDR.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Under the AWEG, importation of pharmaceutical products from a state outside of the EEA is subject to a prior importation permit issued by the BASG. Importation of pharmaceutical products from a state within the EEA must be notified to the BASG in advance.

Section 11 of the AWEG, however, provides for extensive exceptions to these requirements, including exceptions for:

- medicinal products for which a marketing authorisation or an authorisation for parallel import has been obtained;
- medicinal products for Named Patient Use;
- medicinal products for use in a Compassionate Use Programme;
- medicinal products needed in event of emergencies; or
- medicinal products for personal use, in an amount corresponding to the usual personal needs of the traveller concerned.

Parallel importation of medicinal products is subject to a prior authorisation by/notification to the BASG in accordance with Section 10c of the AMG (see also Article 57, paragraph 1(o) of Regulation (EC) 726/2004 for medicinal products authorised under the centralised procedure).

The importation of medical devices and IVD devices does not require any specific authorisation under the MDR/IVDR or the MPG.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Which products are subject to the restrictions under the AWEG is determined by the classification of goods according to the tariff and statistical nomenclature of the EU pursuant to Regulation (EEC) 2658/87. Only products that fall under the subheadings of the combined nomenclature taxatively listed in Section 2(1) of the AWEG (eg, subheading 3002 20, 3002 30, 3004) are to be considered "pharmaceutical products" within the meaning of the AWEG.

6.5 Trade Blocs and Free Trade Agreements

Austria is a member of the WTO. Furthermore, as a member state of the EU, Austria participates in free trade agreements concluded by the EU member states. It is worth noting that the current EU sanctions against Russia do not provide for trade blocs of medicinal products and medical devices.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

Medicinal Products

The price basis of a medicinal product is the manufacturer's factory or depot selling price (*Fabriksabgabepreis*/*Depotabgabepreis*, or FAP/DAP). Furthermore, the respective "mark-ups" (wholesale and pharmacy mark-ups, regulated by law) and VAT are added to this price. The FAP/DAP can be freely determined by the company authorised to distribute and the Ministry of Health needs to be informed of this price.

For those medicinal products that are included in the list of reimbursable medicinal products, the so-called Reimbursement Code (*Erstattungskodex*, or EKO), the "EU average price" is relevant. This average price constitutes the maximum possible FAP/DAP for reimbursable products. For the purpose of calculating the EU average price, the Price Commission of the Ministry of Health considers the medicinal products with the same active ingredient, active ingredient strength, dosage form and identical (or approximately identical) package size.

The determination of the EU average price by the Price Commission takes place six months after the application for inclusion in the EKO is submitted. This is repeated 18 months after the first price determination and 24 months after the second price determination. The Price Commission can initiate a new price determination 18 months after the third price determination.

In the case of medicinal products that are not included in the EKO but exceed an annual turnover of EUR750,000 at the expense of the public health insurance (based on the FAP, in the previous 12 months), the Umbrella Organisation of the Austrian Social Insurance (*Dachverband*, or DVB) must immediately notify the Price Commission, which then has eight weeks to determine an EU average price for the medicinal product. If the determined EU average price is lower than the applied price, the company authorised to distribute must reimburse the difference to the social insurance institutions within six months of the date on which the sales threshold was exceeded.

The DVB applies the principles of price determination in accordance with the rules of procedure for the issuance of the EKO, as well as the economic evaluation criteria of the Therapeutic Products Evaluation Commission, and negotiates the reimbursement price with the manufac-

turer on this basis. Once an agreement has been reached, the reimbursement price specified in the EKO is binding, albeit subject to adaptation in accordance with the EU average price. If, on the other hand, a medicinal product is removed from the EKO by decision of the DVB, the companies authorised to distribute the drug have the option to appeal to the administrative court.

Furthermore, specific price regulations apply if a successor product with the same active ingredient (generic or biosimilar) is available in the EKO.

Generics

With regard to generics, the price of the first generic successor product must be at least 50% below the price of the original branded product whose patent protection has expired. The price of the second generic successor product must be 18% lower than the price of the first successor product, and the price for the third successor product must be 15% lower than the price of the second successor product. The price of the original product must be reduced by at least 30% within three months of the inclusion of the first generic product in the EKO. If there is a third successor product, all other providers must reduce the price to the price of the third product. Additional successors must offer price reductions of at least EUR0.10 in order to be included in the EKO.

Biosimilars

With regard to biosimilars, the price of the first successor product must be at least 38% lower than the original product. The price of the second successor product must be at least 15% lower than that of the first successor product, and the price of the third successor product must be at least 10% lower than that of the second successor product. After that, the same regulation applies as for generics (ie, the original product must reduce its price by 30% within three months, etc).

Medical Devices and IVD Devices

No legal price control mechanisms are available, in principle, for medical devices and IVD devices.

7.2 Price Levels of Pharmaceuticals or Medical Devices

The price of a medicinal product can in principle be freely determined by the company authorised to distribute it but is limited by the EU average price of said product (as further detailed in **7.1 Price Control for Pharmaceuticals and Medical Devices**).

No legal price-control/price-setting mechanisms are available, in principle, for medical devices and IVD devices.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Medicinal Products

The Austrian General Social Security Act (*Allgemeines Sozialversicherungsgesetz*, or ASVG) states that, in case of illness, the insured person is entitled to health treatment comprising the provision of remedies (*Heilmittel*) – a term that includes medicinal products, in particular. According to the ASVG, the medical treatment must be sufficient and appropriate, but it must not exceed the extent of what is necessary.

Austria is one of the few EU countries in which the costs of reimbursable medicinal products prescribed by a physician are, in principle, covered in full for the patients insured in the public insurance system. Patients only have to pay a flat fee ("prescription fee") in pharmacies. Exemption from the prescription fee is possible under certain conditions.

Medicinal products that have been included in the EKO can be prescribed at the expense of the health insurance institutions (see **7.1 Price Control for Pharmaceuticals and Medical Devices**). Other medicinal products are only reimbursed in medically justified individual cases.

Medical Devices and IVD Devices

Regarding medical devices and IVD devices, no system comparable to the EKO exists. The Austrian Social Security Act does not refer to "medical devices" as such but to *Heilbehelfe* and *Hilfsmittel* (therapeutic aids), which are reimbursed – subject to a 10% deductible (or a current minimum of EUR40.40) – if they are prescribed by a physician. Typically, medical device/IVD device manufacturers sign contracts with the social insurance institutions in order to avoid the social insurance institutions requesting a cost estimate in advance regarding devices if no contract between the social insurance institutions and the manufacturer is in place.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Medicinal Products

Any entity authorised to distribute a medicinal product approved and available in Austria may apply for inclusion in the EKO. The medicinal products undergo a pharmacological, medical-therapeutic and health economic evaluation with regard to their eligibility for reimbursement. In this process, the DVB is supported by the Medicines Evaluation Commission (*Heilmittel-Evaluierungs-Kommission*, or HEK), an independent advisory body that is not bound by instructions. The HEK's recommendations form the basis of the DVB's decisions.

The EKO is divided into three areas (known as "boxes").

- The Green Box contains medicines that the health insurance institutions reimburse to the socially insured without special authorisation. These are freely prescribable.
- The Yellow Box includes those drugs that the social insurance institutions consider to have a significant additional therapeutic benefit for patients, but which were not included in the Green Box for medical or economic reasons. For these medicines, health insurers reimburse the insured if the prescription has been approved by their chief medical office (dark yellow area RE1). In some cases, a retrospective control is also accepted (light yellow area RE2).
- The Red Box contains medicinal products for a limited time while the company's request for inclusion in the EKO is being reviewed. During this period, the costs are covered only if there is approval from the chief medical office of the social insurance institutions.

Finally, even the so-called "no-box" medicinal products – ie, products for which no application has been made to be included in the EKO – can be reimbursed if the individual prescription has been approved by the chief medical office. As this option is usually chosen for very expensive medicines, the Austrian legislator has introduced a requirement that the EU average price will be relevant to these products if turnover exceeds EUR750,000 (see **7.1 Price Control for Pharmaceuticals and Medical Devices**).

Changes within the boxes and deletions from the EKO are possible both at the request of the company authorised to distribute the product and the DVB (supported by the HEK's recommendations).

If the social insurance institution refuses reimbursement in an individual case, the patient can

file an action before the civil courts. In these proceedings, the court reviews the social insurance institution's decision typically with the help of a specific expert and is entitled to decide on the reimbursement. The court's decision may be challenged before the Higher Regional Court and, eventually, before the Supreme Court.

Medical Devices and IVD Devices

Regarding medical devices and IVD devices, no system comparable to the EKO exists. For reimbursement of medical devices and IVD, see **7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds**.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Essentially, retailing of medicinal products may only be undertaken by pharmacies. Medicinal products requiring prescription may only be provided to patients upon prescription by a physician.

So far, the aut idem rule has not been implemented into Austrian law. Pharmacists are required to dispense to the patient the actual medicinal product prescribed (even if, for example, a generic product is available). The pharmacist can only offer the patient a pharmaceutical equivalent if the prescribed product is not available in the pharmacy.

Medical devices and IVD devices are not pharmacy-only products.

8. Digital Healthcare

8.1 Rules for Medical Apps

For medical apps that qualify as medical devices, the MPG as well as the MDR constitute the major regulatory framework.

Software (including apps) qualifies as a medical device if:

- it is intended for human use, as determined by the manufacturer;
- it is intended – alone or in combination – to fulfil one or more of the specific medical purposes listed in Article 2(1) of the MDR (see **3.1 Product Classification: Pharmaceuticals or Medical Devices**); and
- it does not achieve its principal intended action by pharmacological, immunological or metabolic means – in or on the human body – but may be assisted in its function by such means.

Guidance on the qualification and classification of software in Regulation (EU) 2017/745 and Regulation (EU) 2017/746 is provided in the "MDCG 2019–11".

In addition, medical apps may also be qualified as an "accessory of a medical device", according to Article 2(2) of the MDR. An accessory of a medical device is "an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s)".

8.2 Rules for Telemedicine

The term "telemedicine" is not defined by Austrian law. The Ministry of Health defines "telemedicine" as the provision or support of healthcare services using information and communication technologies, where either the patient and healthcare provider or two different healthcare providers are not present at the same location.

In the legislative materials to the most recent changes in the Austrian Physicians Act 1998 (*Ärztegesetz*, or ÄrzteG), the legislator states that "telemedicine is a multi-layered term that encompasses very heterogeneous automated medical services, but also processes in the healthcare system of a predominantly administrative nature".

The legal permissibility of telemedical services must be assessed on the basis of Section 49, paragraphs 1 and 2 of the ÄrzteG, according to which the medical profession must be practised lege artis as well as "directly and personally, but also by using telemedicine". The permissibility of telemedical applications in an individual case needs to be judged on the basis of whether the physician can obtain all the information necessary to clarify the state of health via the digital channel and whether the requirements of Section 49 of the ÄrzteG, as well as all other medical professional duties, are therefore fulfilled. In the context of telemedicine, the consideration of the "distance" factor must be taken into account as a significant deviation from a conventional setting.

According to the current specifications of the Austrian Health Insurance Fund (*Österreichische Gesundheitskasse*, or ÖGK), which is the largest Austrian health insurance fund, telemedical services may only be reimbursed if the patient concerned has already been treated personally by the specific physician conducting the telemedical service.

Furthermore, as regards the applicable legal framework for telemedicine from a data protection point of view, the GDPR, the DSG and the Austrian Health Telematics Act 2012 (*Gesundheits-Telematikgesetz*, or GTelG) must be observed.

8.3 Promoting and/or Advertising on an Online Platform

There are no special regulations for the promotion and advertising of medicinal products and medical devices on online platforms available in Austria. Therefore, the general requirements and restrictions (eg, prohibition of lay promotion for prescription-only medicinal products or medical devices) as set out in the AMG (for medicinal products) or in the MPG and MDR/IVDR (for medical devices/IVD devices) apply.

8.4 Electronic Prescriptions

Every person insured in the Austrian public social insurance system receives an "e-card", which provides information regarding the health insurance coverage of the respective person. Austria further provides for an optional, free-of-charge central digital health solution known as the Electronic Health Record (*Elektronische Gesundheitsakte*, or ELGA).

An electronic prescription (*e-Rezept*) is available in Austria for prescriptions issued for medicinal products at the expense of the social insurance institutions. These are no longer issued on paper, but electronically, and saved in the e-card system. The respective medicinal product can be collected at the pharmacy either with the e-card or the respective e-prescription code or the e-prescription ID. Paper prescriptions are still used for medicinal products that are not reimbursed by the social insurance institutions.

Electronic medication (*e-Medikation*) is an optional, free-of-charge application of ELGA that can be used to prevent unwanted interactions and multiple prescriptions of medications. Physicians and pharmacists thus have a better overview of which medications have been prescribed and dispensed for a patient. Patients can opt out of ELGA and *e-Medikation*.

8.5 Online Sales of Medicines and Medical Devices

The online sale of medicinal products is only permitted for pharmacies complying with the requirements set forth in the AMG and the corresponding Distant Selling Ordinance (*Fernabsatz-Verordnung*). The Ordinance sets out the quality criteria pharmacies must comply with if they wish to sell medicines via the internet.

The pharmacies willing to engage in online sales need to be registered with the BASG for this purpose. Only OTC medicinal products may be sold online; the online sale of medicinal products requiring a prescription is not permitted.

The online sale of medical devices/IVD devices is subject to the provisions set forth in Article 6 of the MDR/IVDR – in particular, medical devices distributed via online channels must comply with all obligations set out in the MDR.

8.6 Electronic Health Records

In Austria, ELGA is operated as a central electronic health record (see **8.4 Electronic Prescriptions**). The GTelG contains special regulations for the electronic processing of health data and genetic data by healthcare providers (see Article 4(13) and (15) of the GDPR). In the context of health telematics, a healthcare provider is a professional who – as a controller or processor (as defined in Article 4(7) and (8) of the GDPR) – regularly processes health data or genetic data in electronic form for the following purposes:

- medical treatment or care;
- nursing care;
- invoicing of health services;
- insurance of health risks; or
- exercise of patient rights.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices

The Austrian Patent Act (*Patentgesetz*, or PatG) is applicable in this regard. Medicinal products, medical devices and IVD devices can be protected by patents, in principle, if they fulfil the requirements as set forth in the PatG. There are no special requirements with regard to patents for medicinal products and medical devices. In Section 2 of the PatG, however, it is clarified that no patent protection is available for certain biotechnological inventions (such as cloning) or surgical or therapeutic procedures and diagnostic procedures, owing to ethical and social factors.

9.2 Second and Subsequent Medical Uses

The question of whether a second or subsequent medical use of a known product is patentable must be answered based on the principle requirements for patentability. In practice, the main obstacle to patentability might be the question of whether the subsequent indication is actually new.

New dosage regimes would not be patentable, even if these regimes make the medicinal product more effective. The discovery of the use for new patient populations might only be patentable if the new patient group can be clearly distinguished from the previously known group and therefore regarded as new (and where the use for this patient group is not already covered by the previous patent).

9.3 Patent Term Extension for Pharmaceuticals

An Austrian patent is granted for a maximum of 20 years. The patent holder may, however, apply for a so-called Supplementary Protection Certificate (SPC) to extend a patent for ingredients of medicinal products for up to five years in accordance with Regulation (EC) 469/2009 concerning the SPC for medicinal products (SPCR).

Third parties may challenge the granted SPC on the grounds of invalidity according to Article 15 of the SPCR, whereby the application must be filed with the Austrian Patent Office (Section 5 of the Austrian Supplementary Protection Certificates Act 1996 (*Schutzzertifikatsgesetz*)). For details of an exemption from SPC protection, see **9.7 Procedures Available to a Generic Entrant**.

Moreover, patented medicinal products that are suitable for use in children (ie, paediatric medicinal products) may be granted six months additional patent protection upon submission of a Paediatric Investigation Plan (PIP).

9.4 Pharmaceutical or Medical Device Patent Infringement

According to Section 22 of the PatG, the patent owner has the exclusive right to manufacture, place on the market, display or use the subject matter of the invention, or to import or possess it for the aforementioned purposes. Any infringement of that right without the consent of the patent owner constitutes a patent infringement.

However, the effect of the patent does not extend to studies or trials and related practical requirements, if these are necessary to acquire marketing authorisation, approval or registration under medicinal products law (as per the so-called Bolar provision implemented in the PatG in accordance with Directives 2004/27/EC and 2004/28/EC). Given that no marketing authorisation is required, no Bolar provision is available for medical devices.

The scope of protection of the patent is limited to the patent claims in the original patent application (rather than the entire content of the patent or the descriptions, which may nonetheless serve as interpretation guidance). In line with Section 22b of the PatG, the protection of a patent for biological material endowed with certain properties by virtue of the invention covers any biological material obtained from such biological material by generative or vegetative propagation in the same or a different form and endowed with the same properties.

In case of patent infringement, the patent owner is entitled to injunctive relief, removal of unlawful condition, damages/payment, and publication of the judgment. The PatG further provides the opportunity to ask for a preliminary injunction regarding the mentioned claims (except publication).

Injunctive relief may already be sought if the infringement is imminent – ie, if there are reasonable grounds to assume that a third party will interfere with the patent rights in the near future.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

As mentioned in **9.4 Pharmaceutical or Medical Device Patent Infringement**, studies, trials, and the resulting practical requirements therefrom are excluded from the effects of the patent as long as they are necessary for acquiring marketing authorisation, approval or registration under medicinal products law. The PatG does not otherwise differentiate between actual products

that can be protected by a patent and, as such, does not contain any rules specific to medicinal products (with the above-mentioned Bolar exemption) or medical devices.

The defendant in a patent infringement case will typically try to claim that the patent in question is null and void – for example, that the patent was granted in error because the invention was not new or is not patentable.

According to Section 36 of the PatG, the owner of a newer patent can claim a licence to a prior third-party patent – and consequently avoid patent infringement – if the newer invention constitutes important technical progress of considerable economic significance and cannot be realised without such licence. In case the patent owner of the older patent refuses to grant such licence, the Patent Office can decide on the granting of a licence (including appropriate remuneration therefor) upon the application of the patent owner of the younger patent.

The PatG further provides for compulsory licences in the context of plant variety rights, in case of public interest (see **11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments**) or because the third-party patent-holder is not exercising its patent invention in Austria accordingly.

9.6 Proceedings for Patent Infringement

In Austria, the patent-owner and the exclusive licensee may file a patent infringement action. The exclusively competent court for patent infringement cases is the Vienna Commercial Court (*Handelsgericht Wien*) – the decision of which may be challenged before the Higher Regional Court Vienna (*Oberlandesgericht Wien*) and, ultimately, before the Supreme Court (*Oberster Gerichtshof*).

The remedies available include claims for injunctive relief, removal of unlawful condition, damages/payment and accounting, and publication of the judgment.

In cases where the defendant claims that the allegedly infringed patent is null and void, the court may assess that question at its own discretion in the first instance and can suspend the proceedings if it regards the nullity to be likely. In such cases, the defendant must file a revocation action with the Patent Office within one month; otherwise, the court decides without further considering such defence.

9.7 Procedures Available to a Generic Entrant

Generic medicinal products can be approved in a related approval procedure if there is no patent or document protection and can be offered on the market after the patent of the original product has expired. Owing to the aforementioned Bolar provision (see **9.4 Pharmaceutical or Medical Device Patent Infringement**), studies or trials necessary to acquire marketing authorisation, approval or registration under medicinal products law do not infringe patent law and may therefore be carried out even though the patent is still in force.

Since 2019, an exemption from SPC protection – starting six months before the SPC expires – is available for generic production for the purpose of exporting and for generic production and storage for the first placing on the market in the EU. National patent offices must be informed about the production. An EU export logo (as applicable) must be indicated on the outer packaging for exports to third countries.

No patent linkage is in place – ie, the authorisation procedure for medicinal products and medi-

cal devices does not take patent protection into account.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Medicinal products and medical devices/IVD devices – in particular, their names, design and packaging – might be subject to trade mark, design or (eventually) copyright protection. Trade mark and design protection requires an application and registration, whereas copyright protection is granted from the date the copyrighted work is created.

In case the name, design or packaging is subject to such protection, the Austrian Trade Mark Act (*Markenschutzgesetz*, or MSchG), Design Act (*Musterschutzgesetz*, or MuSchG) and Copyright Act (*Urheberrechtsgesetz*, or UrhG) essentially provide for claims for injunctive relief, removal of unlawful condition, damages/payment, and publication of the judgment. Furthermore, trade mark, design and copyright infringement may even be criminally sanctioned (as a private prosecution offence). The laws provide for sanctions of imprisonment of up to two years or monetary fines of up to 360 daily rates (where the "daily rates" for payment of a fine are based on the individual situation/income of the convicted person).

In addition to the remedies provided under the respective IP laws, Regulation (EU) 608/2013 enables the right-holder of products protected by specific IP rights (trade marks, designs, patents, SPC) to prevent counterfeit products from being imported. The respective right-holder can request the customs authorities to detain products believed to infringe the right-holder's IP rights for further examination.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

As a general rule, medicinal products may not be marketed under names that are misleading, particularly with regard to the efficacy and safety of the product (Section 6 of the AMG).

Furthermore, the EMA has issued the "Guideline Regarding the Acceptability of Names for Human Medicinal Products Processed Through the Centralised Procedure". The BASG issued a similar guideline for nationally approved medicinal products ("Guideline on the Designation of Medical Specialties", version 9/2021).

As per the AMG for medicinal products, both the MDR and the IVDR prohibit in their (respective) Article 7 the use of any trade mark, name or text in the labelling, instructions claims, marketing and promotion if it could mislead the patient regarding the medical device's or IVD device's intended purpose, its safety or performance.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

The trade dress, design and packaging of medicinal products and medical devices may be protected by copyright and design rights – and, potentially, as trade marks – if the requirements for such protection are met and protection is sought for trade mark or design.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Data exclusivity (or dossier protection) is relevant for innovative (original) medicinal products. According to the data exclusivity rules, a generic applicant may not refer to the documents of an

original medicinal product until eight years after the first approval of the original product in the EU. The generic product may be marketed for the first time only after a further two years (ie, after ten years in total) – this is known as the "8+2 rule". If the marketing authorisation holder of an original product expands the authorisation to a new therapeutic indication within the first eight years of the first marketing authorisation, the data exclusivity period is extended from ten to 11 years (the "8+2+1 rule") – meaning the generic entry will be delayed for another year.

For medical devices and IVD devices, this is not applicable as no marketing authorisation is required.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

The COVID-19 pandemic resulted in a great number of new provisions in the Austrian legal system, which cannot be depicted in their entirety in this setting. However, with regard to medicinal products, medical devices and IVD devices, a number of special regulations can be highlighted.

Section 94d of the AMG provides for the authorisation of the Federal Minister of Health to establish complementary regulations to the general provisions of the AMG by ordinance in the case of epidemics and pandemics, if the necessary supply of medicinal products or active substances to the population is seriously and substantially endangered, and as long as special regulations are necessary owing to the specific situation. While this authorisation has been included in the AMG since 2005, a corresponding provision in the MPG was only introduced during the pandemic (now Section 81 of the MPG). The validity of such ordinances was initially limited to a maximum of six months and is now limited to a maximum of one year.

On the basis of these provisions, a number of implementing ordinances were issued in recent years, including an Ordinance on Provisional Measures to Ensure the Availability of Medical Devices (*Verordnung betreffend vorläufige Maßnahmen zur Sicherstellung der Verfügbarkeit von Medizinprodukten*, or VVMP), as well as several COVID-19 Medical Device Ordinances (*COVID-19 Medizinprodukte V*) and COVID-19 Medicinal Products Ordinances (*COVID-19 Arzneimitte IV*).

As of 1 January 2024, however, the special COVID regulations mentioned above are no longer in force.

11.2 Special Measures Relating to Clinical Trials

With regard to clinical trials of medicinal products, medical devices and IVD devices, the implementing ordinances mentioned in **11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices** provided certain special regulations, but these are no longer in force.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

Conditional Marketing Authorisation

With regard to medicinal products, Article 14-a of Regulation (EC) 726/2004 provides for a legal opportunity to obtain a "conditional marketing authorisation" if certain requirements are met. Specifically, the product in question must fulfil an unmet medical need, its benefit-risk balance must be positive, it must at least be likely that

the applicant will be able to provide comprehensive data post-authorisation, and the benefit of the product's immediate availability must outweigh the risk incurred by the fact that additional data is still required. The marketing authorisation holder must meet special obligations after the authorisation has been granted. The validity of a conditional marketing authorisation is one year, with the opportunity for annual renewal. During the pandemic, this procedure was applied in connection with the available COVID-19 vaccines and treatments.

Marketing Authorisation Under Exceptional Circumstances

The conditional marketing authorisation procedure is to be distinguished from that of the "marketing authorisation under exceptional circumstances" pursuant to Article 14, paragraph 8 of Regulation (EC) 726/2004. Such authorisation may be issued under exceptional circumstances if, for objective reasons, comprehensive data cannot be obtained even post-authorisation. In addition, Article 14, paragraph 9 of Regulation (EC) 726/2004 provides for the opportunity to request an accelerated assessment procedure if a medicinal product is of major interest from the point of view of public health and in particular, from the point of view of therapeutic innovation.

Marketing Authorisation in a Disaster

It should also be mentioned that Section 8, paragraph 1(4) of the AMG permits placing a medicinal product on the market in Austria even without marketing authorisation if it is to be used for the prevention of – or in connection with – a dangerous situation arising from a disaster, and success in this respect cannot be achieved with an authorised and available medicinal product. However, although this is an emergency regulation, it does not lead to (accelerated) approval. Once the particular conditions are no longer met, the product may no longer be placed on the market without marketing authorisation.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

In light of the difficulties arising from COVID-19, GMP certificates for sites (as well as time-limited manufacturing and import authorisations) were automatically extended until the end of 2023. These are therefore no longer applicable.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

At the EU level, several implementing regulations were adopted during 2021 that required an export authorisation for the export of vaccines against SARS-related coronaviruses and for the export of active substances used for the production of such vaccines. These have expired in the meantime.

11.6 Drivers for Digital Health Innovation Due to COVID-19

The GTelG, which regulates the electronic transmission of health data and genetic data by healthcare providers, included temporary provisions until 30 June 2022 in order to combat the spread of COVID-19. These provisions facilitated identity verification of patients in the context of remote prescriptions.

For more on the possibility of remote management and conducting clinical trials, see **2.4 Restriction on Using Online Tools to Support Clinical Trials** and **11.2 Special Measures Relating to Clinical Trials**.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

Even before the COVID-19 pandemic, the PatG provided for the possibility of granting compulsory licences to patented inventions in specific

cases (see **9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices**). Pursuant to Section 36, paragraph 5 of the PatG, everyone is entitled to a non-exclusive licence to a patented invention for their business, provided that the granting of the licence is required in the public interest. This also applies to the federal administration, although the latter does not have to prove the operation of a business.

In order to obtain a compulsory licence, the licence applicant must first seek to obtain the patent-owner's consent to the licence on market terms (Section 37, paragraph 1 of the PatG). If the patent-owner does not consent to such licence, the Austrian Patent Office will decide on the request of the licence applicant, and determine an appropriate remuneration for the compulsory licence. In the case of a national emergency or other circumstances of extreme urgency, the licence applicant will not be required to seek the patent-owner's consent first, and the Austrian Patent Office may immediately grant a provisional authorisation to use the invention (Section 37, paragraph 3 of the PatG).

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

As far as is evident, no liability exemptions for COVID-19 treatments or vaccines were introduced into Austrian national law during the pandemic. The Vaccine Damages Act (*Impfschadengesetz*, or ISG) outlines the preconditions for a legal claim against the Austrian Federation to compensation for vaccine damages, irrespective of the existence of fault. Applications for compensation of damage caused by COVID-19 vaccinations may also be filed on the basis of the ISG. Moreover, damages can be claimed on the grounds of the general rules of civil law and on the grounds of the Product Liability Act.

11.9 Requisition or Conversion of Manufacturing Sites

As far as is evident, no manufacturing sites were requisitioned or legally converted owing to COVID-19 in Austria.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

Special provisions regarding "emergency procurements", deadlines and online negotiation options for procurement procedures, and exceptions to the opposition procedure in the context of procurements were implemented in connection with COVID-19. However, these changes to procurement procedures expired on 30 June 2023.

CANADA

Law and Practice

Contributed by:
Jason Markwell, Dino Clarizio, Rebecca Crane and David Park
Markwell Clarizio LLP

Contents

Markwell Clarizio LLP is a Canadian law firm with extensive experience in intellectual property litigation and regulatory issues impacting the life sciences industry. The firm helps clients navigate the complex regulatory system governing the approval and sale of health products in Canada, including data protection, patent linkage, patent term restoration, pricing, formulary interchangeability, product listing agreements and advertising. Its counsel attend meetings with regulators and appear as litigation counsel at hearings before the Patented Medicine Prices Review Board (PMPRB) and judicial review applications. Markwell Clarizio LLP also represents clients in patent infringement and impeachment actions, injunction motions, appeals and interventions, including cases under the Patented Medicines (Notice of Compliance) Regulations. Its partners have appeared as counsel in many precedent-setting cases before the Supreme Court of Canada, the Federal Court of Appeal, the Federal Court and the PMPRB.

Authors

Jason Markwell is a partner at Markwell Clarizio LLP, and a leading patent litigation and drug regulatory lawyer in Canada. He has years of experience acting for the life sciences industry in drug regulatory disputes, patent litigation and appeals. Jason has appeared as counsel in precedent-setting cases before the Supreme Court of Canada, the Federal Court of Appeal and the Federal Court. He is active in various IP organisations, including the Intellectual Property Institute of Canada and the International Association for the Protection of Intellectual Property. He is a Senior Fellow of the Litigation Counsel of America and a member of the Advocates' Society.

Dino Clarizio is a partner at Markwell Clarizio LLP and a leading intellectual property litigation lawyer in Canada. He has practised exclusively in the field of intellectual property law for more than 30 years and his work includes all aspects of IP litigation, with a focus on patent litigation in the pharmaceutical, life sciences and chemical fields. Dino has acted as counsel in dozens of life sciences patent cases involving all aspects of patent law in Canada. He is the co-author of two of the leading textbooks on Canadian patent law, and of an annual consolidation of Canada's patent laws and regulations.

Rebecca Crane is a partner at Markwell Clarizio LLP who specialises in patent and drug regulatory work in the life sciences sector. She draws on her legal and scientific expertise to advise clients at all stages of health product development, as well as through the lifecycle of the products. Rebecca has significant expertise in litigation, regulatory and patent portfolio strategies in the areas of pharmaceuticals, life sciences and medical devices. She frequently represents life science industry clients in patent litigation matters and provides strategic product regulatory advice, including on matters related to Canada's Patented Medicines Prices Review Board (PMPRB).

David Park is an associate at Markwell Clarizio LLP and has experience in working on a wide range of intellectual property litigation matters. He has frequently assisted in pharmaceutical patent disputes. His interest in the life sciences sector stems from an academic background in biochemistry and from his experience working within the pharmaceutical industry.

Markwell Clarizio LLP

Commerce Court North
25 King Street West,
Suite 1101
Toronto, Ontario
M5L 2A1

Tel: +1 416 451 8400
Email: info@markwelllaw.com
Web: www.markwelllaw.com

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Health Canada regulates, evaluates and monitors pharmaceuticals pursuant to the Food and Drugs Act (FDA) and its associated regulations. It regulates controlled substances under the Controlled Drugs and Substances Act (CDSA) and its associated regulations. The Cannabis Act is the legislative framework for controlling the production, distribution, sale and possession of cannabis in Canada.

Medical devices are regulated under the FDA and the Medical Devices Regulations (MDR), administered by Health Canada.

The distribution of pharmaceuticals and medical devices is regulated federally and by territorial/provincial legislation and regulatory bodies, such as provincial colleges of pharmacy and public drug benefit formularies.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Health Canada has various internal complaint/appeal resolution processes to challenge its decisions. Once those internal resolution processes have been exhausted or where a decision is not subject to such resolution processes, a party with standing may challenge a Health Canada decision by filing an application to the Federal Court of Canada for judicial review.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Health Canada classifies health products into certain categories, such as drugs and medical devices. With respect to drugs, Health Canada further classifies products into subcategories such as controlled substances, biologic products, prescription drugs and non-prescription drugs.

Medical devices are categorised by Health Canada according to risk: Class I is the lowest perceived risk, while Class IV is the highest. The classification determines the type of submission and information that must be filed with Health Canada for marketing approval and post-market surveillance.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Health Canada regulates clinical trials/investigational testing of pharmaceuticals and medical devices through the FDA and its regulations.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Health Canada must authorise all clinical studies of authorised and unauthorised pharmaceuticals, biologic drugs and medical devices before they begin, with limited exceptions.

To perform a drug clinical trial, the sponsor must submit a clinical trial application (CTA) to Heath Canada. The sponsor must also have a Research Ethics Board (REB) Attestation and complete certain Qualified Investigator Undertaking forms and a Clinical Trial Site Information form. For biologics, Health Canada also requires that the lot release information is provided by the CTA sponsor/manufacturer before its use in the trial. A CTA is not required for phase IV clinical trials. If the CTA is approved by Health Canada, a No Objection Letter (NOL) will be issued.

To perform medical device investigational testing, the sponsor must submit an investigational testing application (ITA) to Health Canada. The ITA approval process is required for trials involving the use of all unlicensed Class II, III and IV medical devices. REB approval must be obtained prior to study initiation. An ITA is not required for Class I (low risk) medical devices, nor is it required for conducting a study using a licensed device according to its licensed indications for use. Under the MDR, only manufacturers and importers can apply for authorisation. If the ITA is approved by Health Canada, a Letter of Authorisation will be issued.

2.3 Public Availability of the Conduct of a Clinical Trial

In 2019, Health Canada launched its Public Release of Clinical Information initiative. Since then, Health Canada has developed a Clinical Trials Database (CTD), which provides certain publicly available information on phase I, II and III clinical trials of human pharmaceuticals and biological drugs. The information provided in the database includes drug name, medical condition, study population, study start/end dates and trial status. However, the database is not a registry and does not contain comprehensive information about each trial. The CTD also does not include information on clinical trials in healthy volunteers (eg, bioavailability/bioequivalence trials) or phase IV trials.

In addition, after a final regulatory decision, the following information (with certain exceptions) in respect of clinical trial and medical device applications will no longer be considered confidential business information and will be publicly available through Health Canada:

- clinical summaries; and
- reports and supporting data of clinical trials in support of a drug submission and clinical trials or investigational testing in humans in support of any Class III or Class IV medical device application.

Health Canada will not release individual patient records and clinical case report forms to the public.

2.4 Restriction on Using Online Tools to Support Clinical Trials

Online tools and systems to support clinical trials may be used so long as they comply with applicable requirements (privacy, confidentiality, informed consent, etc) and good clinical practices. For example, the sponsor should ensure that online tools conform with their established requirements for completeness, accuracy, reliability and consistency of intended performance.

2.5 Use of Data Resulting From Clinical Trials

Two federal privacy laws set out how federal government institutions and certain businesses must deal with personal information, including personal health information. The Personal Information Protection and Electronic Documents Act (PIPEDA) addresses the personal information handling practices of federal government departments, including Health Canada, and the Privacy Act regulates private businesses' data protection practices. Many provinces and territories also have laws that deal specifically with the protection of personal information, including health information. Whether data constitutes personal health information depends on several factors.

Personal data resulting from clinical trials is generally considered to be confidential, although in certain scenarios the sponsor and other agen-

cies will have access to such information, including patient-identifiable information, for analytical purposes. If the data is de-identified or anonymised, then it is generally not considered confidential.

Data can be transferred to a third party or an affiliate so long as the transfer is in accordance with all applicable privacy requirements, contractual agreements and informed consents.

2.6 Databases Containing Personal or Sensitive Data

A database containing personal or confidential data may be subject to contractual and statutory obligations, including certain security and privacy measures. For example, Ontario's Personal Health Information Protection Act requires custodians to take reasonable steps to ensure the personal health information they hold is always protected and secure.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

In general, classification decisions are made by the appropriate group at Health Canada upon the submission of required information or an application for market authorisation. In instances where a product could be classified in multiple ways, such as drug/device combination products, classification requests can be sent to the Office of Science within the Therapeutic Products Directorate of the Health Products and Food Branch at Health Canada for guidance.

Product classifications are based on the FDA and its associated regulations. The classification criteria are generally based on the product composition, product purpose and intended use, as well as product format and representations (eg, labelling claims and indications).

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Health Canada is responsible for the review and approval of new drug submissions (NDS), including those for biologic drugs.

To obtain marketing authorisation for a biologic drug (innovator or biosimilar), a manufacturer must file an NDS with the Health Products and Food Branch at Health Canada. The submission must include preclinical and clinical results to support the safety, efficacy and quality of the biologic. Given the nature of biologics, Health Canada requires more detailed chemistry and manufacturing information than it does for other drugs. An on-site evaluation may be conducted at the manufacturing site, and samples may be subject to evaluation through a lot release programme overseen by Health Canada to ensure the consistency of the manufacturing process.

A manufacturer can request a brief consult with the Biologic and Radiopharmaceutical Drugs Directorate of Health Canada to discuss the details of their submission and any areas of concern prior to filing.

Health Canada will issue a notice of compliance (NOC) and Drug Identification Number (DIN) upon satisfactory completion of the NDS review. The approval process typically takes one to two years. However, there are regulatory mechanisms for expediting the approval process in some cases.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

While there is no specific requirement to renew market authorisations for pharmaceuticals, a manufacturer of a drug must notify Health Canada each year before October 1st that the drug is still on the market and that all information previously provided is accurate and up to date.

The MDR require every manufacturer of a medical device to inform Health Canada each year before November 1st that the information contained in their licence application is accurate. Manufacturers of licensed Class II, III and IV medical devices are also charged an annual fee. Failure by the manufacturer to renew the licence application may result in cancellation of the licence.

There are circumstances when a marketing authorisation can be revoked – eg, failure to comply with the FDA or its regulations. Typically, Health Canada will attempt to work with manufacturers to obtain compliance before a suspension or revocation is issued.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

To obtain marketing authorisation for a drug, a manufacturer files an NDS with Health Canada, including preclinical and clinical data to support the safety, efficacy and quality of the product, as well as manufacturing details. Health Canada will issue an NOC and DIN upon satisfactory review of the NDS. This approval process generally takes one to two years but there are certain mechanisms to expedite the process in some cases. If the manufacturer changes the strength, format/dosage form or indications, etc, of the drug, then a Supplemental New Drug Submission (SNDS) must be approved by Health Canada.

Generic drugs are approved through an abbreviated new drug submission (ANDS) and are based in part on comparisons to the brand-name reference product. Supplemental abbreviated new drug submissions (SANDS) are required for certain product changes (eg, packaging, labelling) or new indications. As with an NDS, an applicant for an ANDS or SANDS will receive an NOC upon approval by Health Canada, subject to any patent issues.

Medical devices are categorised and regulated by Health Canada according to risk: Class I indicates the lowest perceived risk, while Class IV indicates the highest perceived risk. The classification determines the type of submission and information that must be filed with Health Canada for the device to be approved for marketing.

Generally, marketing authorisations can be transferred from one entity to another in situations where the only change to the product is the manufacturer's name, such as in a merger, buyout or other corporate restructuring. In such cases, a submission to Health Canada for each affected drug product must be filed, with supporting documentation.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

Healthcare professionals may access drugs and medical devices not currently authorised for sale in Canada through the Special Access Program (SAP) to treat patients with serious or life-threatening conditions where conventional treatments have failed, are unsuitable or are not available in Canada.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

In certain situations, an NOC with conditions may be granted by Health Canada with the condition that the sponsor undertakes additional studies to verify the clinical benefit of the drug.

For drugs, manufacturers are required to report all information related to serious adverse drug reactions (ADRs) that occurred in Canada and all serious, unexpected ADRs that occurred outside of Canada to the Canada Vigilance Program of the Marketed Health Products Directorate of Health Canada within 15 calendar days of receiving or becoming aware of the information. Manufacturers must prepare an annual summary of ADRs and serious ADRs during the previous 12 months.

For medical devices, records relating to complaints and incidents must be maintained by the manufacturers/importers and must be provided to Health Canada with an incident report if the medical device was sold in Canada and if the incident:

- occurs within Canada;
- occurs outside Canada for a Class I medical device;
- relates to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labelling or directions for use; and
- has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so if it were to recur.

The requirement to report an incident that occurs outside Canada does not apply unless the manufacturer has indicated to a regulatory agency in the country in which the incident occurred that it intends to take corrective action, or unless the regulatory agency has required the manufacturer to take corrective action.

In addition, certain holders of medical device authorisations in Canada must also notify Health Canada of certain foreign risks – ie, a Medical Device Licence (MDL) holder for a Class II to IV device, a Medical Device Establishment Licence (MDEL) holder that imports a Class II to IV device, and a holder of an ITA for a Class II to IV device.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

For drugs, Health Canada has a Submissions Under Review (SUR) list for new active substances (pharmaceuticals and biologics with active ingredients not approved in Canada) as well as SNDSs for new uses.

There are four SUR lists:

- NDSs currently under review;
- SNDSs currently under review;
- NDSs formerly under review; and
- SNDSs formerly under review.

For NDSs/SNDSs currently under review, the list includes:

- the medicinal ingredient(s);
- the month/year the submission was accepted for review; and
- the therapeutic area populated with the WHO Anatomical Therapeutic Chemical Code.

For any submission that was accepted into review on or after 1 October 2018, the SUR list also includes the company name and submission class (eg, extraordinary use submission; new active substance; biosimilar; review under

priority review; review under NOC with Conditions; review under submissions relying on third party data; aligned review with a health technology assessment organisation; and COVID-19 use).

For NDSs/SNDSs formerly under review, the SUR list includes:

- the medicinal ingredient(s);
- the month/year the submission was accepted into review and concluded;
- the therapeutic area based on the WHO Anatomical Therapeutic Chemical Code; and
- a hyperlink to the regulatory decision summary or cancellation.

There is a separate list for generic drug submissions (ANDS) accepted for review on or after 1 October 2018.

There is no corresponding publicly available list of medical device submissions. However, the Medical Devices Bureau at Health Canada maintains a list of all licensed Class II, III and IV medical devices marketed in Canada, as well as a list of active MDEL.

Confidential Business Information (CBI) is defined in the FDA as business information:

- that is not publicly available;
- in respect of which the person has taken measures that are reasonable in the circumstances to ensure that it remains not publicly available; and
- that has actual or potential economic value to the person or their competitors because it is not publicly available, and its disclosure would result in a material financial loss to the person or a material financial gain to their competitors.

Health Canada has discretionary authority to disclose CBI about a therapeutic product (including prescription, non-prescription drugs and medical devices) without notifying the person to whose business the information relates or obtaining their consent, if the purpose of the disclosure is related to the protection or promotion of human health or public safety and the disclosure is to:

- a government;
- a person from whom the Minister seeks advice; or
- a person who carries out functions relating to the protection or promotion of human health or the safety of the public.

Health Canada may also disclose CBI about a therapeutic product without notifying the person to whose business the information relates or obtaining their consent, if it believes that the product may present a serious risk of injury to human health.

Personal information in records considered for disclosure by Health Canada will be protected in accordance with federal privacy legislation and applicable provincial/territorial privacy laws.

3.8 Rules Against Illegal Medicines and/or Medical Devices

Health Canada monitors the marketing of drugs and medical devices and takes necessary enforcement actions to prevent the illegal marketing of products. It may take various types of enforcement action to address any such illegal activity, including imposing fines, undertaking activities related to the seizure, detention and forfeiture of products and recommending criminal charges, where appropriate.

In addition, physicians and healthcare professionals are required to adhere to provincial/territorial legislation and to meet their respective professional standards in handling drugs and medical devices.

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

Health Canada has the authority to take appropriate enforcement measures regarding the importation and sale of counterfeits. This responsibility is also shared with other provincial/territorial regulators, government bodies and healthcare professionals.

The sale of counterfeit health products also violates Canada's Criminal Code. As such, cases of suspected counterfeit health products are also referred to the Royal Canadian Mounted Police (RCMP) and the Canadian Border Services Agency (CBSA), where appropriate. The CBSA assists Health Canada with the administration and enforcement of regulated goods at the border.

4. Manufacturing of Pharmaceuticals and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

With respect to pharmaceuticals, the Food and Drug Regulations (FDR) require that an establishment engaged in fabricating and packaging/labelling drugs (among other activities) holds a drug establishment licence (DEL) issued by the Minister of Health. The process involves submitting an application, along with a prescribed fee payment, setting out certain required information.

It takes Health Canada approximately 250 days to consider the application, verify good manufacturing practices (GMP) compliance and determine whether to issue an establishment licence. An initial on-site inspection of the establishment will be performed during that period.

Once issued, a DEL authorises an establishment to perform one or more of the regulated activities (eg, fabricate, package/label) in respect of one or more categories of drugs (eg, pharmaceuticals, vaccines, biologics).

The FDR also require that drugs are fabricated in accordance with certain GMP. An establishment that holds a DEL is subject to inspection by the Minister of Health to verify compliance with GMP.

In order to maintain the DEL, the holder of the licence must submit an application to Health Canada before April 1st of each year for the review of their licence.

For medical devices, an MDEL is required for most classes of medical devices. The application for such a licence is submitted to Health Canada along with a prescribed fee payment. In order to maintain the MDEL, the holder of the licence must submit an application to Health Canada before April 1st of each year for the review of their licence.

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

A DEL is required (with some exceptions) to import, distribute and wholesale a drug. A completed application setting out certain required information, such as evidence of GMP, along with a prescribed fee payment, must be submitted to Health Canada. A licence review application must be submitted each year before April 1st by companies that hold a valid DEL.

Provincial/territorial drug legislation also applies to the wholesale distribution of drugs, including regulations issued by Colleges of Pharmacy and Pharmacy Boards.

For medical devices, an MDEL is required (with certain exceptions) for distributing medical devices in Canada. The application for an MDEL is submitted to Health Canada along with a prescribed fee payment. In order to maintain the MDEL, the licence holder must submit an annual review application to Health Canada before April 1st. Manufacturers of Class II, III or IV medical devices also require an MDL to import or distribute their medical devices in Canada, and such licences must be annually renewed before November 1st.

5.2 Different Classifications Applicable to Pharmaceuticals

Pharmaceuticals are classified at both the federal and provincial/territorial levels.

Health Canada classifies drugs into certain categories, such as controlled substances, biologic products, prescription drugs and non-prescription drugs. Controlled drugs listed in the schedules to the CDSA are not on the Prescription Drug List, but their prescription status is conferred by their respective regulations.

A drug with a prescription status at the federal level requires a prescription in all provinces/territories.

When a newly marketed drug is given a non-prescription (over the counter/OTC) status or is removed from the Prescription Drug List by Health Canada, the conditions of sale are determined at the provincial/territorial level. The National Drug Scheduling Advisory Committee (NDSA) reviews the submission and categorises the drug into National Drug Schedules that have been adopted to some extent by the provinces/territories, except Quebec, as follows:

- Schedule I drugs require a prescription and are provided by a pharmacist;
- Schedule II drugs are available only from the pharmacist and must be retained within an area of the pharmacy where there is no public access, but do not require a prescription;
- Schedule III drugs can be sold from the self-selection area of the pharmacy operated under supervision of the pharmacist, but do not require a prescription; and
- unscheduled drugs can be sold without professional supervision.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The import and export of pharmaceuticals and medical devices is regulated under the FDA and

its associated Regulations. Some health products have additional restrictions placed on them by other Acts, such as the CDSA.

The Medical Devices Directorate at Health Canada helps to ensure the safety, effectiveness and quality of medical devices sold in Canada. It works with other agencies, such as CBSA, to prevent the importation and exportation of medical devices that do not comply with the FDA and the MDR.

6.2 Importer of Record of Pharmaceuticals and Medical Devices

An importer of authorised pharmaceuticals and medical devices must have an establishment licence. Unauthorised drugs may be imported into Canada under certain conditions, such as when authorised under a clinical trial in Canada. Controlled substances have additional restrictions under the CDSA. For prescription drugs, the importer must (with certain exceptions) be a practitioner, drug manufacturer, wholesaler or pharmacist.

Anyone who imports a medical device into Canada must also meet the applicable requirements of the FDA, including the following:

- for Class I devices, the importer must have a valid MDEL, unless exempted;
- for Class II, III or IV devices, the device must be licensed by having an MDL and the importer must have a valid MDEL, unless exempted; and
- for all medical device classes, the importer must ensure that the company from which they import has an MDEL that cover the appropriate licensable activities, unless exempted.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Generally, the importation of pharmaceuticals and medical devices requires prior authorisations. However, there are certain exceptions for importers. Unlicensed medical devices and drugs may be imported through a request by a healthcare professional to the Special Access Program (SAP). Certain drugs may also be imported to address urgent public health needs through the Access to Drugs in Exceptional Circumstances regulatory pathway.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Upon entry into Canada, declaration forms must utilise the Harmonized Commodity Description and Coding System (HS) codes and provide information required by Health Canada. Such importations are subject to regulations issued by CBSA and Health Canada.

6.5 Trade Blocs and Free Trade Agreements

Canada is a member of the World Trade Organization and has free trade agreements with 51 different countries. Canada also has several Mutual Recognition Agreements with other countries (eg, EU, Switzerland, Australia, the UK) covering the GMP compliance programmes for drugs/medicinal products.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

In Canada, the Patented Medicine Prices Review Board (PMPRB) is governed by the Patent Act and the Patented Medicines Regulations, and

ensures that rights-holders do not sell patented medicines in Canada at an excessive price.

The PMPRB only has jurisdiction if there is a patent or certificate of supplemental protection pertaining to the medicine sold in Canada. It takes a very broad view of its regulatory powers. Rights-holders who are subject to the jurisdiction of the PMPRB (ie, patentees and Certificate of Supplementary Protection holders) must submit pricing information on a prescribed basis.

If the PMPRB has jurisdiction, it will review the prices at which the medicine is sold in any market in Canada to determine whether it is excessive. In doing so, it is empowered to consider several factors, including the price at which the medicine is sold in certain other countries, the price at which medicines in the same therapeutic class are sold, and the size of the market in Canada.

The price of generic medications is also regulated by some provinces. For example, in Ontario, regulations made under the Ontario Drug Benefit Act provide that generic medications will only be reimbursed by the public plan at a certain percentage of the price for the interchangeable innovative product. The permitted percentage depends on the dosage form (oral solid versus other) and the number of other generic versions on the market. In addition, certain designated molecules have lower percentage caps on their pricing.

Similar restrictions do not exist for medical devices.

7.2 Price Levels of Pharmaceuticals or Medical Devices

The PMPRB may consider domestic and international prices of the same medicine in other markets. As of 1 July 2022, the comparator countries are Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden and the United Kingdom (PMPRB11). As the PMPRB develops new pricing guidelines, new drugs with a list price above the Median International Price for the 11 comparator countries will remain "under review" until the new guidelines are in place. New drugs with a list price below the Median International Price will be deemed "reviewed".

The price of a medical device does not generally depend on its price in other countries.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Provincial health insurance plans reimburse the cost of some pharmaceuticals and medical devices in an outpatient setting. Some individuals (eg, indigenous people, military members and federal penitentiary inmates) are covered by federal plans. The eligibility requirements and coverage vary depending on the plan.

Public hospitals cover the cost of most medications/medical devices for inpatients.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Cost-benefit analyses are often applied in determining the reimbursement price of pharmaceuticals and medical devices on public and private drug benefit formularies. The specific rules vary by payor.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Many provinces and territories have implemented switching policies for generic drugs and biosimilars. Such interchangeabilities are governed

by specific provincial/territorial regulations and by rules adopted by provincial/territorial colleges or boards.

8. Digital Healthcare

8.1 Rules for Medical Apps

Health Canada has specific rules for medical apps. Software is deemed to be a medical device when the following conditions are met:

- it is intended to be used for one or more medical purposes as outlined in the definition of device in the FDA; and
- it performs these purposes without being part of a hardware medical device (ie, it is not necessary for a hardware medical device to achieve its intended medical purpose).

Health Canada generally interprets "medical purposes" to be those intended:

- to acquire, process or analyse a medical image, or a signal from an in vitro diagnostic device or a pattern/signal from a signal acquisition systems or imaging device; or
- for the purpose of supporting or providing recommendations to healthcare professionals, patients or non-healthcare professional caregivers about the prevention, diagnosis, treatment or mitigation of a disease or condition.

8.2 Rules for Telemedicine

The practice of telemedicine is regulated at a provincial/territorial level. The Colleges of Physicians and Surgeons in each province/territory also have policies regarding the practice of medicine, including telemedicine.

Generally, physicians may provide medical services through a mobile device if they follow the obligations and policies set by the Colleges and any applicable privacy legislation.

8.3 Promoting and/or Advertising on an Online Platform

There are no special rules for the online promotion or advertising of drugs and medical devices in Canada. The promotion and advertising of such products, whether by print, broadcast or internet, is regulated under the FDA and associated regulations. Only medical devices and prescription drugs that have been authorised for sale by Health Canada may be advertised legally in Canada. Additional regulatory restrictions apply for prescription drugs and opioids.

Market authorisation holders and advertisers can obtain advertising pre-clearance through various independent agencies, such as the Pharmaceutical Advertising Advisory Board.

8.4 Electronic Prescriptions

Electronic prescriptions are regulated primarily at the provincial/territorial level. For example, the Saskatchewan College of Pharmacy, relying on Health Canada's policies and provincial legislation, provides that an electronic prescription is equivalent to the written format and is acceptable if certain requirements are met. Health Canada has said that electronic prescriptions are permissible if they achieve the same objective as a written prescription.

8.5 Online Sales of Medicines and Medical Devices

Online sales of drugs and medical devices are permitted and regulated under the FDA. Additional requirements for the online sale of drugs have been set by some provinces/territories.

8.6 Electronic Health Records

Regulations and policies regarding the creation, maintenance, retention and destruction of hard copy medical records typically extend to electronic health records. Additional requirements for electronic health records may apply at the provincial and territorial level.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices

The Patent Act and its regulations, including the Patent Rules and the Patented Medicines (Notice of Compliance) (PMNOC) Regulations, govern patent protection in Canada. Canadian jurisprudence is also a source of patent law (eg, double patenting).

To be patentable, an invention must claim new, useful and non-obvious subject matter. There are no specific patentability requirements for pharmaceuticals or medical devices; however, various issues commonly arise in patent cases involving pharmaceuticals and medical devices, including whether the patent claims are directed to a method of medical treatment (not patentable) or are ambiguous, lack utility, or are invalid on the basis of anticipation, obviousness, insufficiency of written description or double patenting.

The PMNOC Regulations create a linkage regime that ties the approval of subsequent entry products (generics, biosimilars) to the patent status of the brand-name reference product.

The pricing of patented medicines is regulated by the PMPRB pursuant to the Patent Act and the Patented Medicines Regulations.

9.2 Second and Subsequent Medical Uses

Patent protection is available for new uses of known compounds, so long as they satisfy the requirements of patentability and are directed to new, useful and non-obvious subject matter. Methods of medical treatment and surgery are not considered to be patentable subject matter, whereas claims to the use of a vendible product are permitted. This distinction often turns on whether a specific dosage amount and/or specific administration is recited in the claims.

A new dosage regimen or use of a medicine in selected patient population may be patentable if it satisfies the requirements of patentability and does not require the exercise of skill and judgement by a physician such that it is considered a method of medical treatment.

Any activity that interferes with the full enjoyment of the monopoly granted by the patentee is an infringing activity. This can include both direct and indirect infringement by way of inducement. Three factors are required to establish indirect infringement:

- the act of infringement must have been completed by the direct infringer;
- the completion of the act of infringement must be influenced by the act of the alleged inducer to the point that, without the influence, direct infringement would not take place; and
- the influence must knowingly be exercised by the inducer.

9.3 Patent Term Extension for Pharmaceuticals

In Canada, a patentee or licensee may obtain a Certificate of Supplementary Protection (CSP) pursuant to the Patent Act and Supplementary Protection Regulations. CSPs provide a maximum of up to two additional years of patent-like protection for eligible patent claims directed to pharmaceutical products. To be eligible for a CSP, the patent must pertain to a medicinal ingredient or a combination of medicinal ingredients contained in a drug that is authorised for sale. The additional protection begins on the 20-year expiration date of the patent, provided it remained in force at that time. The CSP allows for the continued rights of the patentee; however, third parties are permitted to make, construct, use or sell the medicinal ingredient or combination of ingredients for export from Canada. Only one CSP is available for a given medicinal ingredient or combination.

The Patent Act gives the court the authority to declare that a CSP application is invalid or void. However, only CSP applicants that have a CSP application of the same priority may commence such a proceeding.

9.4 Pharmaceutical or Medical Device Patent Infringement

Infringement of a pharmaceutical or medical device patent includes any act that interferences with the full enjoyment of the monopoly granted by the Patent Office. This can include direct and indirect infringement by way of inducement.

A party can bring an action for a quia timet injunction in situations where it can be established that the anticipated infringing activity is imminent. There is a stringent test for such injunctions, and they are rarely granted.

The PMNOC Regulations also effectively allow for quia timet patent actions by permitting a patent owner to prevent the sale of unapproved biosimilars or generic drugs for up to two years.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

There are several exemptions to patent infringement in Canada in relation to pharmaceuticals and medical devices. Section 55.2 of the Patent Act permits the use of a patented invention to obtain governmental regulatory approval, and Section 55.3 further permits experimental use. There is also a common law exemption from infringement for experimental use.

The Patent Act also permits the government of Canada and any person specified in the application to make, construct, use and sell a patented invention to the extent necessary to respond to a public health emergency. A compulsory licence issued under such conditions may be active for up to one year. The Commissioner of Patents has the authority to grant a compulsory licence in certain cases of patent rights abuse.

9.6 Proceedings for Patent Infringement

An action for patent infringement may be brought by the patentee and all persons claiming under the patentee pursuant to Section 55(1) of the Patent Act. A person claiming under the patentee is someone who obtained rights to use the patented invention from the patentee – eg, exclusive and non-exclusive licensees. The patentee must be a party to any infringement action such that if they decline to be named as a co-plaintiff, they must be named as a defendant, or *mise en cause* under Quebec law.

The presumptive remedy for patent infringement is damages. However, the court may allow the

patentee to elect an accounting of the infringer's profits in some cases. The court also has jurisdiction to issue a permanent injunction and require the delivery up or destruction of any infringing goods.

The typical litigation process requires the patentee (or any person claiming under the patentee) to serve and file a Statement of Claim alleging one or more acts of infringement. Actions can be filed in the Federal Court of Canada or in the superior court of the province where the alleged infringement took place. The defendant may respond by serving and filing a Statement of Defence alleging non-infringement and/or patent invalidity as a common defence. The defendant will also typically allege by counterclaim that the patent is invalid (this relief may only be sought in the Federal Court). The defendant may also bring several preliminary motions, including a motion to strike and/or motion for summary judgment.

9.7 Procedures Available to a Generic Entrant

The PMNOC Regulations allow a subsequent-entry manufacturer (generic, biosimilar) to allege that patent(s) listed on a register against the brand-name reference product are not valid and/or would not be infringed by the manufacture, use or sale of the subsequent-entry product in Canada. Upon receipt of such an allegation, the patent owner may commence an infringement action against the subsequent-entry manufacturer in the Federal Court. By commencing an action, Health Canada's decision on whether to approve the subsequent-entry product is frozen for 24 months or until the disposition of the action in Federal Court, whichever is earlier. There are certain scenarios whereby a subsequent-entry manufacturer may launch its product "at risk", including instances in which the patentee waives its right to a 24-month stay.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

The sale of counterfeit pharmaceuticals and medical devices is governed primarily by the Customs Act, the Combating Counterfeit Products Act (CCPA), the Trademarks Act, the Patent Act, the Copyright Act and the Criminal Code. Counterfeit health products and associated activities also constitute violations of the FDA and its Regulations.

Through the CCPA, registered copyright and trade mark owners may obtain assistance from the CBSA by filing a Request for Assistance (RFA) for border officials to detain commercial shipments suspected of containing counterfeit goods. The RFA is valid for two years and can be renewed before expiry. Once an RFA is filed, the CBSA can provide information to the RFA holder in respect of shipments and samples of the suspect goods.

If counterfeit goods are discovered, customs officers are permitted to temporarily detain them for a period of five days in the case of perishable items, and ten working days for non-perishable items, and to provide information to the IP rights-holder about the items detained. To extend the detention period, the IP rights-holder must bring a court action to enforce the prohibitions on counterfeit goods and provide notice of the legal proceeding to the Minister before the detention period expires.

In addition, health products are examined for compliance at the border or at a Canadian establishment during compliance verifications or inspections. If the Health Products and Food Branch Inspectorate suspects or confirms counterfeit health products, then Health Canada

may take several types of enforcement action, including notifying the RCMP, recommending the refusal or seizure of imports at the border, or ordering the removal or destruction of imports at the border, as well as seizure and detention, forfeiture and destruction.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Under the FDR, Health Canada must approve a drug's proposed brand name. This process is distinct from the trade mark registration process conducted by the Canadian Intellectual Property Office. Both processes deal with the potential for consumer confusion, but Health Canada also examines the name from a health and safety perspective. A review of marks pursuant to the Trademarks Act is conducted based on the likelihood of confusion with another mark as to the source of origin.

Health Canada's approval for medical device names is not required.

There are no specific restrictions for parallel importation under the Trademarks Act. However, there are certain labelling and language requirements under the FDR for drugs and under the MDR for medical devices being imported into Canada.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

Certain trade dress or non-traditional marks can be protected under the Trademarks Act and at common law. Pursuant to the Trademarks Act, the requirements for non-traditional trade marks (eg, hologram, moving image, scent, taste, colour, shape, mode of packaging good and/or texture) will depend on the nature of the trade mark and will be subject to examination by the Trademarks Office for distinctiveness.

Unregistered trade dress may also be protected under the tort of passing off at common law. Generally, there are three necessary elements to establish passing off:

- the existence of goodwill or reputation in the trade mark;
- deception of the public due to misrepresentation; and
- actual/potential damage.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Canada provides eight years of data exclusivity for an "innovative drug" that contains a medicinal ingredient not previously approved and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. Data protection applies to chemical drugs and biologics.

Canada will not issue market authorisation for a drug based on a comparison, either direct or indirect, to an innovative drug for eight years from the issuance date of the innovative drug's first market authorisation. In addition, manufacturers that seek approval on the basis of a comparison are prohibited from filing a submission for a copy of that innovative drug until six years have elapsed since the first market authorisation.

The data protection period may be extended by a further six months if, within the first five years of the eight-year period, the results of paediatric clinical trials designed and conducted for the purpose of increasing knowledge of the use of the drug in paediatric populations are also submitted and found acceptable.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

Health Canada made various interim orders (IOs) to establish a temporary regulatory pathway for drugs and vaccines related to COVID-19 to expedite the authorisation thereof. Following these temporary measures, amendments to the FDR were introduced to facilitate the review, authorisation and oversight of COVID-19 drugs and vaccines.

On 22 February 2023, the Regulations Amending the MDR (Interim Order No 3 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19) was adopted to facilitate access to medical devices related to COVID-19. This created a permanent regulatory framework for COVID-19 medical devices while also maintaining most of the flexibilities introduced by earlier IOs for devices on the List of Medical Devices for an Urgent Public Health Need in Relation to COVID-19 (UPHN list).

On 3 January 2024, the Regulations Amending the Medical Devices Regulations (Medical Devices for an Urgent Public Health Need) came into force. These regulations were introduced to broaden the COVID-19 medical devices framework to apply to other medical conditions that present, or are the result of, a significant risk to public health in Canada, and require immediate action to deal with the risk.

Other IOs were adopted to prevent or ease shortages of drugs and medical devices by allowing the importation of foreign drugs and medical devices that met similar high quality and manufacturing standards as Canadian-approved products, in addition to other provisions. Another IO authorised the Minister of Health, under certain conditions, to compel anyone who sells drugs to provide information about shortages or potential shortages of that drug related to COVID-19. These provisions have since been incorporated into the amended FDR.

11.2 Special Measures Relating to Clinical Trials

Health Canada adopted special measures to assist with the running of ongoing clinical trials as a result of the pandemic. Sponsors were required to document any measure they took to reduce the risk of COVID-19 infection. If the physical site for visits changed, trial participants were required to consent to the transfer of any identifiers from the original site to the new site. Additional guidelines for the management of ongoing clinical trials included:

- consideration of safety monitoring measures;
- informing study participants of any changes to the study and monitoring plan; and
- identification of all participants affected by a COVID-19 study disruption with a unique participant identifier.

The interim IOs were replaced by the Clinical Trials for Medical Devices and Drugs Related to COVID-19 Regulations, which came into effect on 27 February 2022 and are intended to facilitate the regulatory pathway for clinical trials for drugs and medical devices related to COVID-19. The regulations are expected to remain in force until additional measures under Canada's Clinical Trials Modernization Initiative plan are adopted. Applicants for COVID-19 drug trials can apply for authorisation under either the FDR or the Clinical Trials for Medical Devices and Drugs Related to COVID-19 Regulations; trials under the latter are subject to modified requirements. Similarly, applicants for COVID-19 medical device trials

can apply for authorisation under either the MDR or the Clinical Trials for Medical Devices and Drugs Related to COVID-19 Regulations.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

IOs regarding the sale of drugs for use in relation to COVID-19 were put in place temporarily to facilitate the emergency approval of COVID-19-related drugs, including prescription and non-prescription pharmaceuticals, radiopharmaceuticals and biologic products. The FDR were subsequently amended to allow for modified requirements that facilitate the regulatory process for new COVID-19 drugs to receive an NOC through the NDS regulatory pathway. The amendments maintain some of the earlier mechanisms from the IOs, thus continuing to facilitate the approval of COVID-19-related drugs.

Similarly, IOs were put in place regarding the sale of medical devices for use in relation to COVID-19. On 22 February 2023, Health Canada introduced the Regulations Amending the Medical Devices Regulations (Interim Order No 3 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19), which provide for accelerated access to, and approval of, COVID-19 medical devices that have an urgent public health need. On 3 January 2024, the Regulations Amending the Medical Devices Regulations (Medical Devices for an Urgent Public Health Need) were introduced to broaden the COVID-19 medical devices framework to apply to other urgent public health needs.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

Health Canada introduced several temporary measures to provide greater regulatory flexibility for drug establishment licensing and GMP during the pandemic. This included accelerated regulatory pathways and modified schedules for Health Canada inspections related to drugs manufactured in Canada and abroad. The FDR were subsequently amended to allow for modified requirements that facilitate the regulatory process for new COVID-19 drugs. COVID-19-related DEL applications submitted under the amended Regulations are processed by Health Canada in an expedited manner on a case-by-case basis.

Similar amendments to facilitate the regulatory approval of medical devices, including DELs, were put in place through the Regulations Amending the Medical Devices Regulations (Interim Order No 3 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19).

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

IOs respecting the importation of drugs for use in relation to COVID-19 were put in place to facilitate the emergency approval of COVID-19-related drugs, including prescription and non-prescription professional use pharmaceuticals, radiopharmaceuticals, biologics such as vaccines and veterinary drugs. The FDR were subsequently amended to allow for modified requirements that facilitate the regulatory process for new COVID-19 drugs. The amendments maintain some of the mechanisms introduced through the IOs.

Similarly, IOs were put in place regarding the importation of medical devices for use in relation to COVID-19. On 22 February 2023, Health Canada introduced the Regulations Amending the Medical Devices Regulations (Interim Order No 3 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19), which provide for accelerated access to

COVID-19 medical devices that have an urgent public health need.

11.6 Drivers for Digital Health Innovation Due to COVID-19

Many measures have been put in place to accelerate the use of virtual and digital healthcare in light of COVID-19, including the following:

- a Virtual Care Task Force (VCTF) report was released by the Canadian Medical Association, the College of Family Physicians of Canada and the Royal College of Physicians and Surgeons of Canada on 11 February 2020, to provide a framework for expanding the use of virtual care;
- all jurisdictions in Canada revised their healthcare fee codes to facilitate the virtual delivery of care;
- a Virtual Care/Digital Table organised by all levels of government endorsed a policy framework for virtual healthcare services within Canada;
- a Canadian Network for Digital Health Evaluation was created to strengthen Canada's capacity to evaluate digital health interventions;
- the federal government signed several bilateral agreements with various provinces/territories, including Ontario, to enhance virtual health services at the provincial and territorial level; and
- several provinces and territories also developed virtual care action plans.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

The COVID-19 Emergency Response Act was enacted in response to the pandemic and provides that the Commissioner of Patents may, on the application of the Minister of Health, authorise the government of Canada (and any person specified in the application) to make, construct, use and sell a patented invention in order to respond to a public health emergency. Such an authorisation ceases after one year or after the day on which the public health emergency ends, whichever is earlier. The patentee is provided compensation by the government of Canada (or the person specified in the application) but the amount is discretionary, taking into account the economic value of the authorisation and the extent the patented invention is used.

The Patent Act also provides that the Commissioner of Patents may authorise the use of a patented invention by a provincial government or the government of Canada.

To date, there has been no public announcement of a compulsory licence being granted for COVID-19-related treatments in Canada.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

Canada did not invoke liability exemptions through the Emergencies Act in response to COVID-19.

11.9 Requisition or Conversion of Manufacturing Sites

Health Canada and other government departments collaborated with the health product industry to provide medical supplies, including manufacturing scale-up and re-tooling of sites.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

The federal and provincial/territorial governments made changes and updates to the systems of public procurement due to COVID-19.

At the federal level, the Treasury Board of Canada published a Contracting Policy Notice 2020-1 – Response to COVID-19 on 23 March 2020, which provided that the Board had approved time-limited increases to emergency contracting limits, including that the Minister of Public Services and Procurement had unlimited emergency contracting limits for the research, development, acquisition and deployment of vaccines related to COVID-19 until 31 March 2021. This Notice also set out that Public Services and Procurement Canada (PSPC) was co-ordinating the centralised purchase of specific goods, such as personal protective equipment, on behalf of the federal and provincial/territorial governments. In 2023, the emergency contracting limits were converted to "exceptional contracting limits" (which can be used for emergency contracts) and the PSPC was given a "sustained emergency of national importance exceptional limit" until 31 December 2023.

There were also some changes at the provincial/territorial level. For example, in Ontario, the Coronavirus (COVID-19) Response and Recovery Regulations (O. Reg. 92/20) were introduced under the Supply Chain Management Act. Under this regulation, the Ministry of Government and Consumer Services and the Ministry of Health were designated as the supply chain management entities for the purposes of responding to COVID-19. Quebec also authorised the Minister of Health Services and Social Services to enter into any contracts necessary to protect public health.

Trends and Developments

Contributed by:
Jason Markwell, Dino Clarizio, Rebecca Crane and David Park
Markwell Clarizio LLP

Markwell Clarizio LLP is a Canadian law firm with extensive experience in intellectual property litigation and regulatory issues impacting the life sciences industry. The firm helps clients navigate the complex regulatory system governing the approval and sale of health products in Canada, including data protection, patent linkage, patent term restoration, pricing, formulary interchangeability, product listing agreements and advertising. Its counsel attend meetings with regulators and appear as litigation counsel at hearings before the Patented Medicine Prices Review Board (PMPRB) and judicial review applications. Markwell Clarizio LLP also represents clients in patent infringement and impeachment actions, injunction motions, appeals and interventions, including cases under the Patented Medicines (Notice of Compliance) Regulations. Its partners have appeared as counsel in many precedent-setting cases before the Supreme Court of Canada, the Federal Court of Appeal, the Federal Court and the PMPRB.

Authors

Jason Markwell is a partner at Markwell Clarizio LLP, and a leading patent litigation and drug regulatory lawyer in Canada. He has years of experience acting for the life sciences industry in drug regulatory disputes, patent litigation and appeals. Jason has appeared as counsel in precedent-setting cases before the Supreme Court of Canada, the Federal Court of Appeal and the Federal Court. He is active in various IP organisations, including the Intellectual Property Institute of Canada and the International Association for the Protection of Intellectual Property. He is a Senior Fellow of the Litigation Counsel of America and a member of the Advocates' Society.

Dino Clarizio is a partner at Markwell Clarizio LLP and a leading intellectual property litigation lawyer in Canada. He has practised exclusively in the field of intellectual property law for more than 30 years and his work includes all aspects of IP litigation, with a focus on patent litigation in the pharmaceutical, life sciences and chemical fields. Dino has acted as counsel in dozens of life sciences patent cases involving all aspects of patent law in Canada. He is the co-author of two of the leading textbooks on Canadian patent law, and of an annual consolidation of Canada's patent laws and regulations.

Contributed by: Jason Markwell, Dino Clarizio, Rebecca Crane and David Park, **Markwell Clarizio LLP**

Rebecca Crane is a partner at Markwell Clarizio LLP who specialises in patent and drug regulatory work in the life sciences sector. She draws on her legal and scientific expertise to advise clients at all stages of health product development, as well as through the lifecycle of the products. Rebecca has significant expertise in litigation, regulatory and patent portfolio strategies in the areas of pharmaceuticals, life sciences and medical devices. She frequently represents life science industry clients in patent litigation matters and provides strategic product regulatory advice, including on matters related to Canada's Patented Medicines Prices Review Board (PMPRB).

David Park is an associate at Markwell Clarizio LLP and has experience in working on a wide range of intellectual property litigation matters. He has frequently assisted in pharmaceutical patent disputes. His interest in the life sciences sector stems from an academic background in biochemistry and from his experience working within the pharmaceutical industry.

Markwell Clarizio LLP

Commerce Court North
25 King Street West,
Suite 1101
Toronto, Ontario
M5L 2A1

Tel: +1 416 451 8400
Email: info@markwelllaw.com
Web: www.markwelllaw.com

Life Sciences in Canada: An Introduction

The life sciences sector is an important part of Canada's innovation economy. It employs hundreds of thousands of people and contributes billions of dollars to the gross domestic product. The life sciences ecosystem includes universities, public research institutions and private companies operating across a wide range of industries, including pharmaceuticals, biotechnology, medical devices, agriculture, agrifood, cosmetics and environmental technologies.

Several regulatory initiatives have been implemented or proposed in recent years at a national level to achieve certain public policy goals relating to life sciences, including a national life sciences strategy, pharmacare (in progress), dental care, drugs for rare diseases, pricing reform for patented medicines, bulk exports to the United States and a ban on animal testing for cosmetics. In addition, most provinces and many private insurers have implemented biosimilar switching policies to reduce the cost of certain drugs. Each of these topics is discussed below.

National life sciences strategy

Canada has a record of success in the development of new drugs. However, the COVID-19 pandemic highlighted the critical need to boost Canada's domestic biomanufacturing capabilities.

In June 2021, the federal government announced a ground-breaking "Biomanufacturing and Life Sciences Strategy" that was driven by two main objectives:

- to grow a strong, competitive domestic life sciences sector, with cutting-edge biomanufacturing capabilities, while creating good jobs for Canadians; and
- to ensure Canada is prepared for pandemics and other public health emergencies in the future.

This "new era of health innovation" consists of five pillars:

- strong and co-ordinated governance;
- strengthening research systems and the talent pipeline;
- growing businesses by "doubling down" on existing and emerging areas of strength;
- building public biomanufacturing capacity; and
- enabling innovation by ensuring "world-class regulation".

Since this strategy was announced, the government has invested billions of dollars in new life sciences projects across the country, including:

- the construction of a new Biologics Manufacturing Centre to produce large quantities of vaccines;
- the creation of a Bioscience Research Infrastructure Fund to support research institutions and hospitals;
- the instigation of a Stem Cell Network to support research in regenerative medicine; and
- investments in private companies to support scale-up and commercialisation.

National pharmacare

Universal public healthcare is a pillar of Canada's national identity. However, the federal healthcare system does not provide free drugs to most Canadians, and some stakeholders believe that drug prices are too high.

In 2015, the Liberal Party, led by now Prime Minister Justin Trudeau, promised that if it were to be elected to office, the government would

"make prescription drugs more affordable" by creating a national pharmacare programme with three foundational elements:

- a national agency to assess pharmaco-economic value and negotiate lower prices;
- a national formulary of insured drug products; and
- reform of the federal agency that regulates the prices of patented drugs (the Patented Medicine Prices Review Board – PMPRB).

This was said to be the "most significant suite of changes proposed [to health policy] in over two decades". The party was elected to a majority government in October 2015.

In February 2018, the Liberal federal government created an Advisory Council on the Implementation of National Pharmacare to "ensure every Canadian has access to the medicine they need" and to "make prescription drugs more affordable and accessible". This led to a sweeping report in June 2019 which held that the amount Canadians currently spend on prescription drugs is "unacceptable" and that the federal government should "work with provincial and territorial governments and stakeholders" to establish a universal, single-payer, public pharmacare system. This new programme would comprise a Canadian Drug Agency to negotiate prices on behalf of public payors, a national formulary of "essential medicines" and a national strategy for access to expensive drugs for rare diseases.

In April 2019, the federal government announced its intention to "move forward" with a national pharmacare programme and to work with provinces, territories and other partners in the "coming months" to "develop a vision and mandate" for a new Canadian Drug Agency. The Liberal party was re-elected to a minority government in October 2019.

Throughout 2020 and 2021, the federal government was focused on the COVID-19 pandemic and ensuring that Canadians had timely access to vaccines and other therapeutics. As such, most of the proposed healthcare reforms were put on hold, officially or otherwise, while the country addressed more urgent needs.

In September 2021, the Liberal party ran for re-election on a promise to "put health and safety first" and to "provide better healthcare for everyone". National pharmacare was mentioned briefly in the campaign platform but was not identified as a "top priority". Instead, the party noted that "[o]ne of the key lessons of COVID-19 is that fundamental science and research is vital to our long-term well-being and prosperity". The Liberal party was elected to form its second minority government in October 2021.

In March 2022, the Liberal government entered into an agreement with the left-leaning New Democratic Party (NDP) to secure the necessary votes to pass a budget and withstand a confidence vote. In return, the government promised to "make progress towards a universal national pharmacare programme by passing a Canada Pharmacare Act by the end of 2023 and then tasking the National Drug Agency to develop a national formulary of essential medicines and bulk purchasing plan by [June 2025]".

On 18 December 2023, the federal government announced the creation of the Canadian Drug Agency (CDA) and an initial investment of CAD89.5 million to "provide the dedicated leadership and co-ordination needed to make Canada's drug system more sustainable and better prepared for the future, helping Canadians achieve

better health outcomes". The CDA will be built from the existing Canadian Agency for Drugs and Technologies in Health (CADTH) and in partnership with provinces and territories. Once the CDA is operational, "it will take on a greater role in the drug system to ensure Canadians can have better health outcomes and access the medications they need now and into the future".

On 29 February 2024, the government of Canada tabled Bill C-64 entitled "An Act respecting pharmacare", aka the "Pharmacare Act". The Bill is not yet in force and must still go through the usual Parliamentary process for enacting legislation. However, on its face, the Bill purports to do five things:

- set out the principles that the Minister of Health is to consider when working towards the implementation of national universal pharmacare;
- give the Minster of Health the power to make payments, in certain circumstances, in relation to the coverage of certain prescription drugs and related products;
- set out certain powers and obligations of the Minister of Health, including the preparation of a list to inform the development of a national formulary and a national bulk purchasing strategy;
- require the Minister of Health to publish a pan-Canadian strategy regarding the appropriate use of prescription drugs and products; and
- provide for the establishment of a committee of experts to make certain recommendations.

It is too early to assess whether this Bill achieves its stated purpose (Section 3), or whether it is even a lawful exercise of federal power under the Constitution Act. These issues – and others – will no doubt be discussed at length in the upcoming Parliamentary debates and committee hearings.

National dental care programme

On 11 December 2023, the federal government made good on its election promise and its agreement with the NDP to provide dental care to uninsured Canadians.

The newly created Canadian Dental Care Plan (CDCP) will receive CAD13 billion in initial federal funding and will be administered by a public-private partnership of Health Canada, Service Canada and Sun Life Assurance Company of Canada. To qualify for the CDCP, an applicant must be a Canadian resident, with no access to dental insurance, of a prescribed age (qualifying teens and seniors) or living with a disability, and with a family income below a certain threshold (currently CAD90,000). The programme will take effect in May 2024, starting with seniors.

National strategy for rare diseases

In 2019, a federal advisory council recommended that Canada adopt a national strategy to provide fair, consistent and evidence-based access to expensive drugs for rare diseases. The federal government committed to invest up to CAD1 billion over two years, starting in 2022–23, with an ongoing investment of CAD500 million annually thereafter.

In January 2021, Health Canada "invited Canadians to share their ideas and views on what a national strategy [for rare diseases] could look like". Feedback received from over 650 individuals and organisations was reflected in a July 2021 report entitled "Building a National Strategy for Drugs for Rare Diseases: What We Heard from Canadians". Health Canada promised to continue discussions with stakeholders "over the summer" and to engage in further public consultation in the

fall "to build a strategy that will work for all Canadians", with a view "towards launching a national strategy for rare diseases in 2022".

In March 2023, Canada announced its first-ever National Strategy for Drugs for Rare Diseases. The goal of this initiative is to improve the health of patients across Canada by increasing access to, and the affordability of, effective drugs for rare diseases. The federal government will provide up to CAD1.4 billion to provinces and territories to improve access to new and emerging drugs, as well as enhanced access to existing drugs, early diagnosis and screening for rare diseases. The government will also invest approximately CAD100 million to help improve consistent access to drugs across Canada and to fund a programme for the benefit of First Nations and Inuit patients.

Pricing reform for patented medicines

The Liberal party promised in its 2015 election platform to reform the PMPRB, which is the federal agency that regulates the prices of patented drugs.

The PMPRB has a statutory mandate to ensure that patented medicines are not sold in Canada at an "excessive price". To meet this objective, patentees must submit ex-factory sale prices for medicines at launch and on a semi-annual basis thereafter. The PMPRB then compares the sale price of those medicines in Canada to the sale price in certain other industrialised nations. If the PMPRB believes that the Canadian price is "excessive", it may launch an investigation and start a quasi-judicial administrative proceeding to recover "excess revenue" from the patentee.

In May 2017, the Minister of Health announced consultations on a suite of regulatory changes related to the work of the PMPRB. This was followed by a white paper entitled "Protecting Canadians from Excessive Drug Prices: Consulting on Proposed Amendments to the Patented Medicines Regulations" and a consultation period in which the government heard from interested stakeholders.

In August 2019, the government proposed amendments to the Patented Medicines Regulations ("Regulations") to "provide the Board with new price regulatory factors and information to protect consumers against excessive prices of patented medicines". This included a new schedule of countries for international price comparisons and a pharmaco-economic analysis to assess value.

In February 2022, the Quebec Court of Appeal held that the proposed pharmaco-economic analysis and net price reporting requirements in the Regulations were not a valid exercise of federal jurisdiction under the Constitution Act. These same provisions were later held to be invalid by the Federal Court of Appeal. The revised basket of 11 comparator countries (PMPRB11) was upheld by both courts.

In April 2022, the federal government announced that it would abandon the impugned economic aspects of the Regulations and move forward only with the revised basket of comparator countries. Those provisions came into force on 1 July 2022.

In October 2022, the PMPRB released revised draft guidelines to explain how it would review prices under the new regime. Eighty-eight stakeholders provided feedback during the consultation period, including drug manufacturers (innovative and generic), patient advocacy groups and insurers (public and private).

In November 2022, the PMPRB suspended the guideline consultation process quite unexpectedly. Shortly thereafter, the Acting Chairperson, a member of the PMPRB and the executive director of the PMPRB resigned from their positions. This led to very contentious hearings by the House Standing Committee on Health, including testimony from the Minister of Health, to explore whether there had been inappropriate political interference with the PMPRB's operations.

In February 2023, the government appointed a new Chairperson with a background in law and intellectual property. This was followed by the appointment of a Vice Chairperson and two new members a few months later. A new Minister of Health, Mark Holland MP, was appointed after a cabinet shuffle in July 2023.

In September 2023, the PMPRB adopted an interim guidance document to provide clarity on when a price investigation will be initiated. In November 2023, the PMPRB published a "scoping paper" outlining the following six themes that would inform the development of new guidelines:

- efficient monitoring of prices without price setting;
- the transition to the PMPRB11 – new versus existing medicines;
- price reviews during the product life cycle;
- investigations and referrals to hearing;
- the relationship between the PMPRB and pan-Canadian health partners, insurers (private and public) and alignment with broader government initiatives; and
- engaging with patients, health practitioners, pharmacies and other stakeholders.

In December 2023, the PMPRB invited stakeholders to participate in a policy round table and to file written submissions. On 15 February 2024, the PMPRB issued an initial report summarising the feedback that it received during the policy round-table and said that it "will announce its next steps soon". No specific deadlines were provided.

Bulk export of drugs to the United States

On 27 November 2020, the Federal Minister of Health issued an interim order restricting the bulk export of drugs to the United States. This order was made in response to a US Rule pursuant to Section 804 of the Food, Drug and Cosmetic Act allowing for the importation of certain types of prescription drugs from Canada.

On 28 November 2021, the interim order was made permanent through amendments to the Food and Drug Regulations. The new enactment says that "[n]o person who holds an establishment licence shall distribute a drug for consumption or use outside Canada unless the licensee has reasonable grounds to believe that the distribution will not cause or exacerbate a shortage of the drug". Exporters are also required to create and maintain records for a prescribed period of time. Health Canada has since published a non-binding "Guide to distributing drugs intended for the Canadian market for consumption or use outside of Canada (GUI-145)" to help stakeholders understand their rights and obligations.

On 5 January 2024, the US Food and Drug Administration authorised an application by the Florida Agency for Health Care Administration to import certain types of prescription drugs from Canada. Health Canada immediately issued a press release stating that it "is actively monitoring the Canadian drug supply… to ensure that Canadians have access to the drugs that they need" and that it has "informed regulated parties of their obligations under Canadian regulations". Health Canada further said that it "will not hesitate to take immediate action to address

non-compliance, ranging from requesting a plan for corrective measures, issuing a public advisory or other forms of communication, to taking action on the licenses of regulated parties who contravene the export prohibition if warranted".

The Minister of Health has told his US counterparts and the US Ambassador to Canada that the federal government "will take all necessary measures to protect the Canadian drug supply". US and Canadian trade associations representing innovative pharmaceutical companies and several patient advocacy groups have raised strong objections to the proposed export of Canadian drugs to the US.

It is too early to assess the effect of the US Rule on the export of drugs from Canada, but this is an issue of great interest to stakeholders that will be watched closely in the coming year.

Ban on animal testing for cosmetics

On 27 June 2023, Canada banned the "cruel and unnecessary testing of cosmetic products on animals". Companies will no longer be allowed to test cosmetic products on animals nor sell cosmetics in Canada that rely on animal testing data to establish safety. This new policy was motivated by the global shift toward ethical cosmetic testing and to align with existing legislation in the EU, Australia, the United Kingdom and South Korea. Canada is working with the international scientific and regulatory community, including the OECD, to develop, validate and implement effective alternatives to animal testing.

Biosimilar switching policies

Biosimilar drugs have been available for sale in Canada since 2014.

Manufacturers that want to sell a biosimilar drug in Canada must file a new drug submission and demonstrate that their proposed product is of high quality and has a similar structure, function, safety and efficacy to a previously authorised reference biologic drug. Manufacturers must also comply with the federal Data Protection Regulations (six-year no filing; eight-year no approval) and Patented Medicines (Notice of Compliance) Regulations (patent linkage), if applicable. Once approved, each provincial/territorial government must decide whether pharmacists may dispense the biosimilar drug instead of the reference product (also known as interchangeability) and the reimbursement criteria.

To date, 54 biosimilars of 17 innovator reference products have been approved for sale, and eight submissions have been accepted into review but have not yet been approved. Eleven public drug plans, including those in the four most populous provinces (British Columbia, Alberta, Ontario and Quebec), and several large private insurers have implemented mandatory switching policies to reduce drug costs.

Conclusion

The life sciences industry is an important contributor to Canada's innovation economy. The federal government has shown a willingness to invest significant public funds in research and development, while at the same time implementing countervailing measures to advance other public policy goals, such as national pharmacare, national dentalcare, price controls for patented medicines and animal welfare. It remains to be seen whether these targeted legislative efforts will achieve their desired goals, but there is no question that they will shape the ongoing evolution of the industry in Canada. Likewise, it will be of interest to see how the recent willingness of certain US states, such as Florida, to allow the importation of drug products from Canada will affect the drug supply in Canada.

CHINA

Law and Practice

Contributed by:
Alan Zhou, Coco Fan, Stephanie Wang and Kelly Cao
Global Law Office

Contents

Global Law Office (GLO) has become one of the largest, leading Chinese law firms, with more than 500 lawyers practising in its Beijing, Shanghai, Shenzhen and Chengdu offices. Its life sciences and healthcare practice group was one of the first in China and provides "one-stop" legal services for every area of the industry, including M&A, investment and funding, licence in and out, daily operation, IP protection, and advice on compliance, including internal and government investigations as well as anti-bribery matters and dispute settlement. Under a changing regulatory environment, GLO's team has the perfect combination of international experience and local knowledge to support various innovation or pilot projects, including digital healthcare and MAH/cMAH trial cases. The team participates in the formulation of local codes of conduct and benchmark policies/rules, and also co-operates closely with associations such as the CPIA, the RDPAC and the ACCP.

Authors

Alan Zhou is the leading partner of the life sciences and healthcare practice group at Global Law Office and has a strong background in the area, routinely representing multinational corporations, well-known Chinese state-owned and private enterprises, and private equity/venture capital funds. As a participant or an external counsel, he has been engaged by local authorities and industrial associations to advise on legislation and industrial standards in the life sciences and healthcare industry, including guidelines on compliance and risk control, e-healthcare, medical insurance reform and medical representative administration. Alan has been widely published both at home and abroad.

Coco Fan is a partner in the life sciences and healthcare practice group at Global Law Office, and specialises in corporate, compliance, private equity, venture capital and M&A. Her experience covers prescription medicine, over-the-counter medicine, contract research organisations, medical devices, biopharmaceuticals, health foods, clinical supply, vaccines, animal health and hospitals. Coco has advised multinational and private companies and investors on risk assessment, health checks and tailored compliance training, including anti-corruption, antitrust and promotion. She also advises on establishing industrial compliance management standards for pharmaceuticals and medical devices.

Stephanie Wang is an of counsel in the life sciences and healthcare practice group at Global Law Office, and has more than ten years' experience. She has been actively involved in advising multinational pharmaceutical and med-tech companies on their corporate governance, daily operation and compliance. Stephanie has extensive knowledge and experience in the life sciences and healthcare industry, and routinely advises clients on a variety of commercial agreements relating to R&D, licensing, marketing authorisations and the manufacturing, distribution and promotion of medical products. She has also worked with notable private equity institutions on investment in various pharmaceutical enterprises.

Kelly Cao is a partner in the life sciences and healthcare practice group at Global Law Office. Her main practice areas encompass dispute resolution, compliance and risk control, as well as labour and employment. Kelly has advised major life sciences companies on general compliance and dispute resolution, and assists multinational enterprises and well-known domestic enterprises with their disputes in litigation and arbitration. She also provides legal services to multinational pharmaceutical corporations, assisting with their compliance system establishment and internal compliance investigations.

Global Law Office

36th Floor
Shanghai One ICC
No.999 Middle Huai Hai Road
Xuhui District
Shanghai 200031
China

Tel: +86 21 2310 8200
Fax: +86 21 2310 8299
Email: Alanzhou@glo.com.cn
Web: www.glo.com.cn

环球律师事务所
GLOBAL LAW OFFICE

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Legislation and Regulations

The primary statute regulating pharmaceuticals in China is the Drug Administration Law (DAL). Together with its implementing rules, the DAL governs various drug-related activities, including drug development, registration, manufacturing and distribution.

In order to address statutory requirements under the DAL, GxP (good practice) rules on laboratory, clinical trials, manufacturing, distribution and pharmacovigilance have also been enacted, as well as administrative measures on drug registration, manufacturing, distribution and recall, etc. Product-specific laws, rules and guidelines, such as the Vaccine Administration Law and the Administrative Measures on Blood Products, also apply to the respective products.

The Medical Devices Administration Law was included in the national legislative planning in 2023, and its legal hierarchy is higher than the effective Regulations for the Supervision and Administration of Medical Devices (RSAMD); it aims to better regulate the medical device market by consolidating the responsibilities of related parties. The RSAMD were amended in 2021 to officially incorporate marketing authorisation holder (MAH), conditional approval, emergency use, device unique identification, etc, into the regulatory frameworks. The amendments significantly increased administrative punishment for violation and imposed legal liabilities on the legal representatives and persons in charge of entities violating RSAMD. The development, registration/filing, manufacturing and distribution of medical devices are, like pharmaceuticals, regulated by GxP rules and administrative measures. Product-specific rules and guidelines have also been released and implemented.

Furthermore, the Administrative Measures on the Registration and Record-filing of Medical Devices ("Device Registration Measures") and the Administrative Measures on the Registration and Record-filing of In Vitro Diagnosis (IVD) Reagents were released to update and specify the regulatory procedure and requirements for medical device and IVD reagent registration and filing, respectively.

Regulatory Bodies

State Administration for Market Regulation (SAMR)

The SAMR is the national authority for the market supervision, administration and law enforcement of pharmaceuticals and medical devices, in the areas of anti-monopoly, product quality safety, food safety, fair competition and commercial bribery, the issuance of business registrations, and certifications and accreditations, among other things.

National Medical Products Administration (NMPA)

As a national bureau operating under the supervision of the SAMR, the NMPA regulates the registration, post-market risk management, administration of safety and quality, formulation of industrial/national standards, and supervision and inspection of pharmaceuticals and medical devices.

The NMPA also supervises permit/filing receipt issuance and law enforcement on pharmaceuticals and medical devices on the provincial level, while the local administrations for market regulation (AMR) are in charge of certain permit issuance and law enforcement on pharmaceuti-

cals and medical devices on the city and county levels.

National Health Commission (NHC)

The NHC is mainly responsible for national health policies, the reform of the medical and healthcare system, disease prevention and control, national drug policies and the national basic drug system. It supervises the National Administration of Traditional Chinese Medicine and the National Disease Control and Prevention Administration.

National Healthcare Security Administration (NHSA)

The NHSA is mainly responsible for the preparation and implementation of regulations and policies related to basic medical insurance (BMI), including policies regarding reimbursement, pricing and procurement for pharmaceuticals and medical services.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

The decisions of the regulatory bodies that apply and enforce regulations of pharmaceuticals and medical devices can be challenged through an administrative review or administrative litigation; these procedures also apply in general vis-à-vis administrative regulatory bodies for other regulated products.

Administrative review is the prepositive procedure to challenge regulatory body decisions. If the decisions made by the reviewing body are unacceptable, a lawsuit before the court could be filed, unless the administrative review decisions are final as prescribed by law. Alternatively, proceedings may be instituted directly with a court, except in certain circumstances in which an administrative review must first be applied for. Once the court accepts the case, no further administrative review could be resolved.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals

The DAL classifies and differentially regulates drugs as prescription drugs and non-prescription (over-the-counter – OTC) drugs. A patient must present prescriptions when purchasing prescription drugs, while OTC drugs can be bought without prescriptions. China further subdivides OTC drugs into Class A and Class B, according to their safety level.

Medical Devices

The RSAMD classify medical devices into three classes according to their risk levels and expected purposes, structural features, methods of use and other qualities. Class III medical devices have the highest risk level, and their safety and effectiveness should be ensured under strict control.

2. Clinical Trials

2.1 Regulation of Clinical Trials

The DAL and the Administrative Measures for Drug Registration establish the primary principles and statutory requirements for clinical trials. Guidance and technical review standards such as Good Clinical Practice (GCP) for Drug Trials and Pharmaceutical Research Information Guide for Phase III Clinical Trials of Innovative Drugs (Chemical Drugs) provide guidance detailing the obligations of the parties involved, operational procedures, technical requirements, etc. Notably, the newly issued Measures for the Supervision and Inspection of Drug Clinical Trial Institutions (Trial) tailor the rules on supervising compliance with the GCP for Drug Trials

and other relevant rules by the institutions in the process of filing and clinical trials. These Measures stipulate that provincial medical products administration (MPA) may employ various inspections to supervise clinical trial institutions. The MPA will require those institutions found to be "non-compliant" to suspend any new clinical trials for drugs.

The Frequently Asked Questions on Rapid Reporting of Safety Data during Drug Clinical Trials was updated to version 2.0 in 2023, aiming to align with the relevant International Council for Harmonisation regulations.

Likewise, the RSAMD and Device Registration Measures set out the legal framework on whether and how clinical trials of medical devices should be conducted, while an array of review standards and guidance, such as GCP for Medical Devices Trials, further specify operation guidance and technical requirements for conducting clinical trials. For clinical trials for IVD reagents, the NMPA provides special principles with a separate guideline.

The newly issued Trial Measures for the Review of Sci-tech Ethics Clinical requires that entities engaged in the life sciences, medicine and other sci-tech activities shall set up a sci-tech ethics (review) committee to assess the sci-tech ethics risks, conduct an ethical review, etc. As such, clinical trials for drugs and medical devices must comply with the relevant ethical review requirements.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Clinical trials for drugs are generally required before the sponsor applies for marketing authorisations, unless otherwise exempted by law (such as certain generic drugs and IVD). A clinical trial must be authorised by the Centre for Drug Evaluation (CDE) of the NMPA before its implementation. The general steps for securing pharmaceutical clinical trial authorisation are as follows:

- a review by an ethical committee prior to initiation;
- a sponsor may need to apply for a pre-consultation meeting with the NMPA;
- the sponsor may conduct a clinical trial if it has not received any objection or query from the CDE within 60 days of acceptance of the clinical trial application;
- if there is no objection from the CDE, the sponsor may implement the clinical trial after the 60-day period, which will be re-calculated if supplementary documents are required; and
- if the CDE issues an objection, the sponsor may reply in writing concerning all issues raised by the CDE and reapply for approval of the clinical trial. The CDE will further review and determine whether to approve that clinical trial within 60 days of receiving the reapplication, and the sponsor is only allowed to implement the clinical trial upon receipt of the CDE's written approval.

Clinical trial requirements for medical devices vary according to the relevant classification. Specifically, Class I medical devices are exempted from clinical evaluations, while Class II and III medical devices may undergo clinical evaluations or clinical trials subject to their safety and effectiveness.

- Clinical evaluation – unless otherwise exempt from a list issued by the NMPA, Class II and III medical devices are subject to clinical evaluation conducted by the NMPA.

- Clinical trial – if the existing clinical literature and clinical data are insufficient to demonstrate the safety and effectiveness of a medical device, a clinical trial should be implemented instead.

2.3 Public Availability of the Conduct of a Clinical Trial

The Drug Clinical Trial Registration and Information Platform (www.chinadrugtrials.org.cn) hosted by the NMPA is a public database providing detailed information regarding clinical trials of pharmaceuticals for the purpose of registration. The newly issued Specifications for Drug Clinical Trial Plan Submission and Review reiterate that an applicant shall register the drug clinical trial plan on the platform prior to conducting a drug clinical trial.

There is no publicly available database for clinical trials of medical devices in China.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no specific restrictions on using online tools to support clinical trials; using such tools is subject to generally applicable laws and regulations concerning personal information protection, online advertising, etc.

2.5 Use of Data Resulting From Clinical Trials

Raw data generated from clinical trials may include trial subjects' personal information, health data, genetic resources, etc.

The Personal Information Protection Law (PIPL) provides a legal framework for the administration of handling personal information. During clinical trials, sites, principal investigators, sponsor-designated monitors and other third parties may access trial subjects' personal information. However, sponsors will generally only receive anonymised data from the trial. Moreover, the sharing and transferring of personal data are subject to other statutory requirements, such as the receipt of data subjects' consent, restrictions on cross-border data transfer, etc.

Human genetic resource samples and data (HGR) are governed by the Biosecurity Law and the Administrative Regulation on Human Genetic Resources ("HGR Regulation"). Currently, foreign parties are only permitted to use Chinese HGR upon filing/approval by the HGR authority and are strictly prohibited from collecting or storing Chinese HGR in the PRC and transferring the Chinese HGR overseas. Failure to obtain such filing/approval may result in administrative liabilities or even criminal liabilities. The newly issued Implementation Rules on the HGR Regulation provide specific guidance on determining foreign parties and a more specific scope of HGR, excluding clinical data, imaging data, protein data and metabolic data on the top of the HGR Regulation.

2.6 Databases Containing Personal or Sensitive Data

In addition to the statutory requirements set out in **2.5 Use of Data Resulting From Clinical Trials**, the Guidelines for Clinical Trial Data Management issued by the NMPA set out the basic standards for the responsibility, qualification and training of parties responsible for data management, and requirements for the design of data management systems, the standardisation of clinical trial data, quality control and the assessment of clinical data.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The DAL defines a "drug" as a substance used to prevent, treat or diagnose human diseases and intended to regulate human physiological functions, for which usage and dosage are specified for indication/primary treatment. The list of types of drugs includes traditional Chinese medicines, chemical drugs and biological products. The CDE evaluates drug marketing authorisation applications submitted by manufacturers or development institutions.

The term "medical devices" refers to instruments, equipment, appliances, IVD reagents and calibrators, materials and other similar or related articles (including computer software) that can be used directly or indirectly with human bodies to achieve specified purposes (such as diagnosis, prevention and monitoring) and whose effectiveness is primarily achieved by physical or other similar means rather than by pharmacological, immunological or metabolic means (or under circumstances where these latter means serve only auxiliary functions).

The Center for Medical Device Evaluation (CMDE) of the NMPA is responsible for the technical evaluation of medical devices. The NMPA released Opinions on Further Strengthening and Improving Medical Device Classification Management in 2023, outlining critical tasks concerning medical device classification, including improving classification principles and catalogue and proposing to modify the classification-related rules. The NMPA has updated the Medical Device Classification Catalogue accordingly, indicating its commitment to maintaining the regulatory environment with the rapid development of medical device technologies and the industry.

The following applies to products containing both a drug and a device (ie, a combination product):

- if similar products on the market are categorised as a drug or a medical device, the product under discussion shall follow the same recognition standard for registration; and
- if no similar products are registered on the market, the applicant shall apply for the product attribute identification with the NMPA and submit a registration application accordingly.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Marketing authorisation applications for biologic medicinal products generally follow a similar process as mentioned in **3.1 Product Classification: Pharmaceutical or Medical Devices**. Having said that, it is compulsory to conduct verification and examination on manufacturing sites for biologic medicinal products being registered, while such verification and examination for other drugs are subject to the CDE's discretion.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

Marketing authorisations for drugs and Class II and III medical devices are valid for five years and can be renewed for another five years. Marketing authorisations for Class I medical devices (ie, filing receipts) do not expire.

The NMPA can revoke a marketing authorisation for reasons such as the conduct of clinical trials without pre-approval, the use of unapproved package materials or containers, the

use of unapproved labels or instructions, bribery, obtainment of a marketing authorisation by fraudulent means, etc. Conversely, the NMPA could cancel the marketing authorisation if an approved product lacks effectiveness, has material adverse effects or risks human health.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

There are three types of registration applications for drugs:

- drug registration applications;
- re-registration applications; and
- supplemental applications.

Drug Registration

The following steps are generally required in a drug registration:

- study prior to clinical trials;
- clinical trials;
- submission of a drug registration application;
- registration verification and examination; and
- registration inspection.

The NMPA provides four kinds of special procedures to shorten the time or facilitate the registration review, including:

- registration for drugs with breakthrough effects;
- registration for drugs with additional approval conditions;
- fast-track registration for drugs with obvious clinical values; and
- registration for drugs that are required to confront public health emergencies.

Specifically, the CDE has issued specifications on facilitating the registration review of marketing authorisation applications for innovative drugs that are specific to children, used for the treatment of rare diseases or applicable to special procedures for drugs with breakthrough effects. These specifications clearly outline the timeframe for communications (30 days) and registration review (130 days) for innovative drugs that fall within their scope.

Re-registration

This is applicable when renewing a valid drug marketing authorisation before expiry.

Supplemental Applications

These are generally required for changes to drugs with marketing authorisation, such as material changes in the drug manufacturing, changes related to drug effect and risks in the instructions, changes of the MAH, etc. Notably, when changing the MAH, the transferee must be capable of quality management, risk prevention and control, and of providing liability compensation to ensure drug safety, effect and quality control. For approved changes, the MAH may be granted a grace period of up to six months from the date of approval to implement the change, except for changes related to drug security.

The NMPA issued the Administrative Measures for Drug Standards in 2023, requiring MAHs to submit the proposed standards for drug registration during their applications or supplemental applications. Any change to registration standards requires a supplementary application, filing or report, depending on the risk levels.

Medical Devices

Class II and III medical devices are administrated by the registration process, while Class I medical devices are administrated by the filing process.

The following processes are generally required to obtain a new marketing authorisation:

- submission of a technical product testing report;
- submission of the clinical evaluation for the clinical data to confirm safety and effectiveness, if required by law;
- examination of the quality management system, which shall comply with good manufacturing practices;
- submission of the registration application documents; and
- regulatory review by the CMDE and the NMPA/provincial MPA.

There are certain special procedures to shorten the time or facilitate the registration review, under relevant regulations, including:

- a registration procedure for an innovative medical device;
- a priority registration procedure for medical devices that:
  (a) have obvious clinical advantages for certain diseases or are in urgent clinical demand without homogeneous approved medical devices; and
  (b) are listed in the national key R&D projects; and
- an emergency registration procedure for medical devices required in public health emergencies.

Changes to these marketing authorisations are divided into modification registration item variations (eg, change of product specification or technical requirements) and filing item variations (eg, change of the MAH's name or address). Currently, both need to be approved by the NMPA/provincial MPA. Changes to modification registration items may trigger an additional technical review by the CMDE. There is no definitive regulation to permit the transfer of the marketing authorisation of medical devices.

Regarding the application for Class I devices, the municipal MPA (for domestic devices) or the NMPA (for imported devices) shall be provided with the filing materials, which are generally as same as those for Class II and III medical devices administrated by the registration process. The MAH must file any changes to the filing items of Class I devices with the original filing authority.

Subject to the above procedures, the NMPA has required registration applications for drugs and certain medical devices to be conducted via the electronic system since 2022.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

The DAL explicitly establishes an expanded access programme allowing physicians and patients access to pre-approval, investigational drugs if:

- the drug is in a clinical trial;
- the drug is used for diseases that threaten life but lack effective treatment;
- the drug has potential effectiveness based on medical observations;
- the drug usage complies with ethical principles;
- the drug usage has been reviewed and the patient's informed consent has been obtained; and
- the drug is used only within the clinical trial site and is used on patients outside the clinical trial setting but with similar conditions.

In addition to the above requirements under the DAL, certain regions have introduced regional

rules for expanded access programmes. Both Tianjin and Shenzhen have issued Regulations on the Promotion of Cell and Gene Industries, which permit expanded access programmes regarding cell and genetic drugs held in Tianjin and Shenzhen Special Economic Zone on certain premises, such as approval for expanded clinical trials and submission of the marketing authorisation application to the CDE for such drugs.

The RSAMD also has similar requirements for an expanded access programme for investigational medical devices. Moreover, the newly issued Regulations for the Emergency Use of Medical Devices specify an emergency use system that permits the use of medical devices without marketing authorisations in public health emergencies, including implementing authorities and their responsibilities, detailed procedures for expert verification, etc.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

A drug MAH (and its local MAH deputy, if it is an overseas MAH) has the following post-marketing obligations under the DAL and the detailed Provisions on Supervision and Administration:

- implementing a pharmacovigilance system;
- conducting regular post-market launch appraisals;
- establishing a release process for drug market launches;
- establishing and implementing a drug-tracking system; and
- establishing an annual report system.

The NMPA has promulgated Guidelines on Pharmacovigilance Inspections and Good Practice for Pharmacovigilance Systems to guide a drug MAH in establishing a pharmacovigilance system.

To refine the quality and safety management throughout the entire drug life cycle and clarify the key responsibilities of an MAH, the newly issued Provisions on the Supervision and Administration of Drug Marketing Authorisation Holder Implementation of the Main Responsibility of Drug Quality and Safety summarise relevant provisions previously scattered across the DAL and other laws and regulations.

A medical device MAH is also responsible for post-marketing obligations, including:

- establishing and maintaining a quality management system;
- setting up and implementing the post-marketing research and risk management and control plan;
- monitoring and re-evaluating medical device adverse events; and
- establishing a tracking and recall system.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

The official websites for the CDE (for drugs), the CMDE (for medical devices) and the NMPA (for both drugs and medical devices) enable third party access to certain information regarding pending, rejected and approved marketing authorisations.

Pharmaceuticals

For drugs pending approval, information such as acceptance number, drug name, drug type, application type, registration category, company name, accepted date and registration application status is publicly available on the CDE's official website. The public can also access granted

marketing authorisation information such as approval number, manufacturing enterprise with production site, approved date, dosage form and specification via the relevant database on the NMPA's official website. Third parties can access refused application information on the NMPA's official website.

Medical Devices

Third parties can access less information about medical devices compared to drugs. The pending marketing authorisation information is only available to applicants. Refused marketing authorisation information for refused devices, including acceptance number, device name, the applicant and its local deputy (if it is an overseas medical device), can be accessed on the NMPA's official website. Marketing authorisation information for permitted devices is publicly available on the NMPA's official website, including the marketing authorisation number, the MAH's name and address, the manufacturing site, the device's name, type, specifications, structure, components, applicable scope and intended use, the approval date, the effective date and modified information.

The government is prohibited from disclosing any commercial secrets (such as manufacturing processes, key technical parameters, know-how, tests and data) or personal privacy accessed during review and examination, unless the rights-holder has granted its consent or unless non-disclosure will have a material adverse effect on public interests.

3.8 Rules Against Illegal Medicines and/or Medical Devices

The DAL and the RSAMD, respectively, regulate administrative penalties for:

- the production, distribution or use of counterfeit or substandard drugs and medical devices; and
- the production, importation or distribution of prohibited or unregistered drugs and medical devices.

Administrative penalties include warning, confiscation, suspension, fines and licence revocation. The personnel in charge and the legal representative of the violating entity could also face personal liabilities. Such wrongdoing may also trigger criminal liability.

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement") sets out the provisional measures and special requirements related to border measures and criminal procedures against counterfeited products. As a WTO member, China follows the obligations outlined by the TRIPS Agreement. Moreover, the Regional Comprehensive Economic Partnership requires that committed members, including China, have procedures in place to suspend the release of suspected counterfeit goods or to destroy counterfeit goods.

China Customs will help rights-holders to protect their IP under the Regulations of Customs Protection of Intellectual Property Rights and its implementing measures. If a rights-holder discovers infringing drugs or medical devices and provides certain evidence, it could request Customs to seize the infringing goods. Furthermore, voluntarily completing IP Customs Filing would obtain more assistance from Customs, which will proactively notify the rights-holder of suspected infringing drugs or medical devices upon discovery.

Customs will seize counterfeit goods if the rights-holder confirms and provides a bond. Besides, Customs is authorised to suspend imports or exports of counterfeit goods and to impose fines accordingly. Such wrongdoing may trigger criminal liability. The 2020 Economic and Trade Agreement between the PRC and the United States of America (the "China–US Trade Agreement") further strengthens China's obligation to implement border measures.

4. Manufacturing of Pharmaceuticals and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

Pharmaceuticals

Pharmaceutical manufacturing plants are required to obtain drug manufacturing licences, even for MAHs that lack manufacturing capacity and outsource manufacturing work to other manufacturers. In the event of outsourcing the manufacturing and/or sub-packaging, the manufacturing enterprise that carries out the manufacture and/or sub-packaging shall also obtain the corresponding manufacturing licence, which is valid for five years and is renewable for another five years six months before expiry.

To further implement the responsibility of MAHs in ensuring the quality and safety of outsourced drug manufacturing, since October 2023 the NMPA has imposed more stringent and detailed requirements in terms of licensing, quality management and supervision of outsourced drug manufacturing. The NMPA has developed corresponding on-site inspection guidelines, which ensure that MAHs and manufacturing enterprises have more detailed reference criteria.

Medical Devices

In accordance with the Measures for the Supervision and Administration of Medical Device Production (2022 revision), the types of authorisation for medical device manufacturers differ depending on the classification of devices.

- Class I devices: the manufacturer shall conduct a filing with the municipal MPA for the manufacturing of Class I devices.
- Class II and III devices: a manufacturing licence will be granted by the provincial MPA following the result of the review and on-site examination.

A filing for Class I devices does not specify the duration of authorisation, while a manufacturing licence for Class II and III devices is valid for five years and can be renewed for another five years within 30 to 90 working days prior to expiry.

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

Drug Distribution Licence

In support of the revised DAL (2019), the SAMR officially implemented the Measures for the Supervision and Administration of Drug Quality in Operation and Usage in January 2024. These measures govern matters related to drug distribution licences, and integrate and replace the earlier Measures for the Administration of Drug Operation Licences and Measures for the Supervision and Administration of Drug Circulation.

Generally, a wholesale drug distributor must maintain a drug distribution licence, with an exception for drug MAHs that sell their drugs as a wholesaler without obtaining a drug distribu-

tion licence. The licence is valid for five years and can be renewed within two to six months before expiry. The relevant provincial MPA will review the application, conduct on-site examinations and decide whether to approve it. An application for changes to licensed matters of a drug distribution licence must be submitted to the issuing authority, which will decide within 15 days from the date of receiving the change application. In addition, a wholesale drug distributor must have a self-operated warehouse that is appropriate for its range of products and scale of operations.

If a wholesale drug distributor (including an MAH) is an online seller, it shall report to the provincial MPA by filing an information report form.

Medical Devices

The wholesale distribution of Class I devices does not require authorisation. For Class II devices, a distributor should maintain a distribution filing receipt from the municipal MPA, which will grant the receipt if all the required documents are submitted. The wholesale distribution of Class III devices requires a distribution licence from the municipal MPA, which will review the application, conduct examinations when necessary and decide whether to approve the application.

A filing receipt for Class II devices does not specify a validity period, while a distribution licence for Class III devices is valid for five years and can be renewed for another five years, subject to an application for renewal within 30 to 90 working days before expiry.

Any violations of the Quality Management Standards for the Operation of Medical Devices may lead to the revocation of the wholesale medical devices distribution licence due to the impact on product safety and effectiveness. Thus, a wholesale medical device distributor is also required to comply with the revised Quality Management Standards for the Operation of Medical Devices, which will officially come into effect on 1 July 2024. This includes new requirements related to the establishment and improvement of the distribution quality management system.

If a medical device distributor (including an MAH) is an online seller, it shall complete the medical device online sales information form. This form requires pre-filing with the local municipal MPA, providing information such as the medical device manufacturing licence, the medical device distribution licence or medical device filing certificate number, etc. Any changes to the filed information should be promptly notified.

5.2 Different Classifications Applicable to Pharmaceuticals

For the different classifications that apply to pharmaceuticals (such as “available only on prescription”), see **1.3 Different Categories of Pharmaceuticals and Medical Devices**.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The import and export of pharmaceuticals and medical devices are subject to the Customs Law of the PRC, the DAL and various relevant regulations.

The SAMR, the NMPA, the NMPA’s designated drug test institutions, the Ministry of Commerce

of the PRC (MOFCOM) and China Customs all have the power to enforce relevant laws and regulations. The NMPA and its local counterparts govern the administration of the use of imported pharmaceuticals and medical devices.

6.2 Importer of Record of Pharmaceuticals and Medical Devices

An importer of record of pharmaceuticals and medical devices is required to conduct a filing with Customs as the Customs Declaration Enterprise (either as a customs broker or as a consignee of imported/ exported goods).

If the importer of record concurrently acts as the applicant for the NMPA's import filing (see **6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices**) and port inspection for imported pharmaceuticals, it must maintain a Drug Distribution Licence or a Drug Manufacturing Licence (for active pharmaceutical ingredients and intermediate agents).

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Prior Authorisations for Importation of Pharmaceuticals

The following require prior authorisation:

- in general, imported pharmaceuticals must obtain marketing authorisations from the NMPA prior to importation – an additional import permit issued by the NMPA is required for narcotic drugs and psychotropic drugs;
- in exceptional cases, pharmaceuticals can be imported by means of a special approval by the NMPA;
- a small number of drugs to be imported by a hospital and used for specific medical purposes due to urgent clinical needs;
- drug samples for drug registration purposes; and
- comparator drugs (except narcotic drugs and psychotropic drugs) for the purposes of drug registration or consistency evaluation of generic drugs.

Individuals bringing drugs to China for their personal use are exempted from the above requirements.

Prior Authorisations for Importation of Medical Devices

The following applies:

- imported medical devices shall first be filed/ registered with the NMPA and obtain marketing authorisations;
- if the imported medical devices fall into the Catalogue of Products Subject to the Compulsory Product Certification System, a China Compulsory Certification is required;
- if the imported medical devices fall into the Catalogue of Commodities Subject to the Automatic Import Licence Administration, an automatic import licence is required; and
- if medical devices are imported for emergency use, an approval from expert evaluation organised by the CMDE of the NMPA is required.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

The importation of drugs or medical devices is subject to registrations/permits, compulsory national or industrial standards, and specific regulations. To guarantee the public's safe use of pharmaceuticals and medical devices, the laws and regulations specify several reasons for prohibiting importing, including but not limited to uncertain curative effect, serious adverse reac-

tion, harm to the human body, expired, invalid, obsolete or used.

6.5 Trade Blocs and Free Trade Agreements

China has signed and acceded to various trade blocs and free trade agreements, including the Regional Comprehensive Economic Partnership, the Framework Agreement on Comprehensive Economic Cooperation with ten members of the Association of Southeast Asian Nations, the Preferential Trade Agreement (the Asia-Pacific Trade Agreement) and 17 bilateral Free Trade Agreements (FTAs). Based on the official website of the China FTA Network, several other FTAs are also under negotiation and consideration.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

Pharmaceuticals

The prices of most drugs are mainly determined by market competition, while the prices for narcotic drugs and Class I psychotropic drugs that are listed in the Central Pricing Catalogue are capped by the government.

Nonetheless, government policies may have a significant effect on the pricing of drugs. For example:

- prices for drugs reimbursed by the BMI funds are determined by authorities, including the NHSA, and prices for certain drugs covered by the BMI funds are fixed through negotiations between the NHSA and suppliers thereof;
- the government centralised procurement, which offers strong bargaining power to the procuring side, gives a favourable procurement price to hospitals and drug stores participating in centralised procurement, and may set pricing rules for manufacturers and wholesalers;
- the "Two-invoice System" eliminates multi-tiered distribution channels and lowers drug prices; and
- the enforcement of a "zero mark-up policy" means that public hospitals may not add any mark-up when selling drugs to patients.

Medical Devices

There is no nationwide regulation or policy specifically and directly controlling the pricing of all medical devices. However, the pricing of medical devices may be significantly influenced by regulatory factors, as follows:

- the pricing of certain medical devices is indirectly restricted because national and local rules limit the amount that a public hospital may charge patients for medical services, and the cost of medical devices used in such services may be included in those charges;
- the procurement of certain costly medical devices by hospitals is strictly controlled by planning at the central and provincial levels; and
- centralised procurement, the two-invoice system and the zero mark-up policy may also be applied to the procurement of certain high-value medical consumables by public hospitals, etc.

7.2 Price Levels of Pharmaceuticals or Medical Devices

PRC law does not require the prices of pharmaceuticals and medical devices to be benchmarked or otherwise set in reference to the prices of the same products in other countries. However, the NHSA does monitor drug prices

at home and abroad for the purpose of making timely warnings of any abnormal changes to drug prices and supply. Prices in other countries might also be used as references during negotiations between the NHSA and drug suppliers with respect to BMI funds coverage.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Pharmaceuticals

The NHSA and the Ministry of Human Resources and Social Security (MOHRSS) jointly issued the latest version of the National Reimbursement Drug List (NRDL) in 2023. Under the NRDL, pharmaceuticals are classified into Class A and Class B, with each class being reimbursed differently by the BMI funds. Patients assume full costs for drugs excluded from the NRDL.

The latest effective NRDL, officially implemented on 1 January 2024, reiterates that all provincial authorities shall implement the same NRDL with limited exceptions, including ethnic medicines, preparations of medical institutions and Chinese medicine tablets.

Medical Devices

Medical consumables may be considered "diagnosis and treatment items" or parts of such items for BMI reimbursement purposes. Certain local healthcare security administrations at the provincial level have promulgated effective lists of medical consumables that local BMI funds can reimburse.

As public hospitals are supported by state financial funds, the procurement of medical devices above the designated amount by public hospitals would be regulated by rules regarding government procurement.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Pharmaco-economic analysis would be employed when assessing which drugs are to be included in the NRDL and the price for NRDL negotiations. Pharmaco-economic materials may be required to be submitted by applicants to add a drug into the NRDL or to adjust its reimbursement coverage.

A cost-benefit analysis would also be considered when assessing which medical consumables are to be covered by BMI funds.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Physicians and pharmacists must follow the principles of safety, effectiveness and economy when issuing or dispensing prescriptions.

A physician may decide what drugs are to be prescribed based on such physician's professional judgement that the prescription is rational and appropriate to a patient's condition. In no event shall the prescription be formulated by artificial intelligence (AI). The quantity of drugs a physician may prescribe is specifically limited for each prescription, to avoid wasting medical resources or taking advantage of the BMI funds.

Government policies may affect or guide a physician's prescription decisions.

- The BMI funds indirectly require physicians to consider the BMI budget when prescribing drugs and to use medical consumables reimbursed by the BMI funds.
- Hospitals are required to prioritise drugs and medical consumables that are centrally procured.
- Diagnosis-related group payment methods (DRGs) and the big data diagnosis-inter-

vention package (DIP) are aimed to be fully implemented and expanded to all medical institutions by the end of 2025, and will pressure hospitals to control medical expenses so may influence physicians' prescription behaviours. The NHSA is building an intelligent monitoring system for BMI fund supervision of the DRGs and DIP payment methods.
- Local authorities of the NHSA – along with other departments – conduct examinations of the use of BMI funds through diverse inspections, such as daily supervision, special inspections, joint inspections, unannounced inspections and inspections based on whistle-blowing. The increasingly severe punitive measures imposed on designated medical institutions and drug retailers contracting with the agencies of the BMI, as well as the mechanism and rewards for reporting incompliant use of BMI funds, aim to restrain fraudulent activities in the use of BMI funds. The special rectification campaign to crack down on BMI fund fraud led by the NHSA focuses on acts of obtaining insurance benefits in a deceptive manner and monitors how the BMI funds are reimbursed on key drugs and medical consumables with top billing.

A pharmacist will dispense prescription drugs according to a physician's prescription. The examination of a prescription by an eligible pharmacist focuses on the appropriateness, rationality and correctness of a drug's use, rather than economic considerations.

8. Digital Healthcare

8.1 Rules for Medical Apps

Medical apps that have diagnostic or treatment functions that meet the regulatory definition of medical devices will be regulated as medical devices, and are subject to the same regulatory requirements as general medical devices. The NMPA and the CMDE have also promulgated specific guidelines to address the principles of reviewing the registration application and classification of AI medical apps.

8.2 Rules for Telemedicine

There are separate rules for telemedicine in the PRC.

Under the Measures for the Administration of Telemedicine Service, hospitals can provide hospital-to-hospital technical support for diagnoses and treatments by means of modern information and communication technologies.

Physicians can conduct online diagnoses and treatments for patients with common or chronic diseases whose first diagnosis is at an offline hospital for the same symptoms, provided that such online diagnoses and treatments comply with the Administrative Measures for Online Diagnoses and Treatment (Trial) and the relevant rules.

8.3 Promoting and/or Advertising on an Online Platform

Besides the general legal requirements on the promotion and/or advertising of pharmaceuticals and medical devices, online promotion and/or advertising are specifically regulated. Online advertisements for pharmaceuticals and medical devices are subject to the examination and approval of the relevant local AMR. An entity providing information on pharmaceuticals or medical devices via the internet to online users is subject to the Qualification for Internet Drug Information Services issued by the relevant provincial MPA. In any case, information on pharmaceuticals and medical devices presented online shall be accurate and science-based.

The Measures for the Administration of Online Advertising further prohibit the publishing of advertisements for pharmaceuticals and medical devices by claiming health and well-being knowledge.

8.4 Electronic Prescriptions

There are no national laws or regulations that specifically regulate the use of electronic prescriptions. In practice, all electronic prescriptions must be issued with a physician's e-signature and reviewed by a pharmacist.

For the online sales of prescription drugs, there are certain special rules related to the use of electronic prescriptions under Measures for the Supervision and Administration of Online Sales of Pharmaceuticals (MSAOSP):

- online retailers of pharmaceuticals shall be responsible for the authenticity and reliability of the electronic prescription sources, as well as the adoption of a real-name authentication system;
- the third-party platform for the online sales of pharmaceuticals shall be responsible for verifying the electronic prescriptions; and
- online retailers of pharmaceuticals shall mark used electronic prescriptions to avoid repeated use thereof.

As of 31 October 2023, electronic prescription centres have been deployed in all provinces and officially applied in more than 20 provinces.

8.5 Online Sales of Medicines and Medical Devices

According to the MSAOSP, online sales of drugs are generally permitted, except for drugs that are subject to special administration. The NMPA announced the first list of drugs prohibited for online sales in 2022. In addition to the requirements applied to an offline drug distributor, an online distributor of drugs is subject to the following further requirements:

- reporting certain information to the local MPA (ie, the website name, app name, IP address and domain name, among other information of the distributor);
- displaying certain information on the home page or the frontpage for distribution, such as its drug manufacturing or distribution permit information and the qualifications of designated pharmacists or other medical technical personnel; and
- being responsible for the authenticity, accuracy and legality of the information displayed.

If the drugs are sold to individuals, the distributor should also conduct a prescription examination, set up an online pharmaceutical service system and comply with special rules about the information displayed for the prescription drug.

The third party providing the platform for the online distribution of drugs is subject to filing requirements of recording its information with the local MPA, which will publish the filing information and be responsible for supervising the online distribution activities.

Online sales of medical devices are permitted. Besides the requirements applicable to a general medical device distributor, an online distributor is subject to additional filing requirements for its sales activities with the local MPA. Furthermore, relevant information regarding the online sale of a medical device shall be notified to the local MPA, except for the online sale of Class I medical devices and certain Class II medical devices, which are exempted from filing in offline sales.

8.6 Electronic Health Records

Electronic health records may contain the following data types:

- personal information – any collection, use, storage, processing, provision, disclosure, deletion or transfer of such data records is subject to the PIPL, and the processing of sensitive personal information shall be subject to more stringent requirements;
- medical records, the storage or use of which is subject to the Use and Administration Rules for Electronic Medical Records (for Trial Implementation) and the Provisions on the Administration of Medical Records of Medical Institutions;
- human genetic resources, which are subject to the restrictions under the Biosecurity Law and the HGR Regulation with its Implementation Rules (see **2.5 Use of Data Resulting From Clinical Trials**); and
- aggregated electronic health records in hospitals, which may be deemed population health information and medical big data.

Any health information and medical data of PRC citizens generated within the PRC shall be subject to national regulation and use based upon concerns regarding national security and citizens' lives and health. Medical big data must be stored in a reliable server located within the PRC, in a way that satisfies the national standards of data storage, disaster recovery, back-up and security management. Regarding the transfer of data, security assessment by cyberspace administration prior to the outbound transfer of important data and personal information is required. Furthermore, the Measures on the Standard Contract for Outbound Transfer of Personal Information promulgated in 2023 provide a more efficient way for the outbound transfer of data by entering the standard contract if certain conditions are met by the processor.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices

The main sources of legislation that govern patents in China are:

- the Patent Law;
- the Rules for the Implementation of the Patent Law;
- the Administrative Measures for Prioritised Patent Examination;
- the Administrative Measures for Centralised Examination of Patent Applications (for Trial Implementation);
- the Measures on Compulsory Patent Licensing;
- several Provisions and Interpretations issued by the Supreme People's Court on patent-related issues;
- the Guidelines for Patent Examination; and
- the Administrative Adjudication Measures for, and Measures for the Implementation of, the Early Resolution Mechanism for Drug Patent Disputes (for Trial Implementation).

Patent applications for pharmaceuticals and medical devices are most commonly rejected due to a lack of:

- inventiveness;
- enablement; or
- specifications' support on claims.

Generally speaking, an invention or utility model must possess novelty, inventiveness and usefulness in order to be patentable.

Supplemental Data

The extent to which applicants are allowed to submit supplemental data after the patent application date has always been a difficult point in the drug-related patent examination system. This issue was also raised in the China–US Trade Agreement. The Guidelines for Patent Examination, as amended in 2023, clearly provide that the examiner shall assess whether the supplemental data submitted by the applicant meets the requirements of the Patent Law after the filing date, and the technical effect proved by the supplemental data should be able to be obtained from the published contents of the patent application by persons skilled in the art.

In terms of patentability requirements that are specific to pharmaceuticals or medical devices, the following are not patentable:

- inventions or creations that are in violation of Chinese laws or social morality, or that are detrimental to public interests;
- inventions or creations that are accomplished by relying on the basis of genetic resources, where their acquisition or use breaches Chinese laws and regulations;
- scientific discoveries;
- rules and methods of intellectual activities; and
- methods for diagnosing or treating diseases.

9.2 Second and Subsequent Medical Uses

A second and subsequent medical use of a known substance that takes the typical written form of "use of substance X in the preparation of a medicament for the treatment of disease Y" (Swiss-style claims) could be patentable in China.

If new dosage regimes and new or selected patient populations are merely present in the course of administration as distinguishing features but fail to define the manufacturing procedure per se, a claim for such use does not possess novelty and thus is not patentable.

Exploitation of a patent on a second or subsequent use of a drug, such as making, utilising or selling without the permission of the patentee, may constitute an infringement of second and subsequent patents of pharmaceutical products.

9.3 Patent Term Extension for Pharmaceuticals

The Patent Law provides two situations for Patent Term Extension:

- to compensate for unreasonable delay during the patent examination process, applicable to all types of patents; or
- to compensate for the time spent during review and approval for new drugs – this only applies to invention patents related to new drugs. The compensatory term is up to five years and the total Patent Term of relevant new drugs upon marketing authorisation approval shall not exceed 14 years.

If the patentee or an interested party is dissatisfied with the decision of whether to grant patent term compensation, it may apply to the China National Intellectual Property Administration (CNIPA) for administrative reconsideration. Such reconsideration decision can be appealed in turn through an administrative action before the court.

9.4 Pharmaceutical or Medical Device Patent Infringement

Without the permission of the patentee, the following exploitation for production or commercial purposes may constitute an infringement of a patent:

- the manufacture, utilisation, offer for sale, sale or import of the pharmaceutical or medical device containing a patented invention or utility;
- the utilisation of the patented process of an invention or utility;
- the utilisation, offer for sale, sale or import of the pharmaceutical or medical device directly obtained through the patented process of invention or utility; or
- the manufacture, offer for sale, sale or import of any pharmaceutical or medical device containing the patented design.

The Patent Law provides an exemption from patent infringement where anyone manufactures, uses or imports patented drugs or medical devices to provide information that is necessary for the marketing authorisation (Administrative Approval Exemption).

Preliminary Injunctions

If a patentee or an interested party has evidence that proves the threatened infringement of a patent which, if not stopped promptly, will cause irreparable damage to its lawful rights and interests, it may apply to the court for a preliminary injunction and an order for the preservation of infringing evidence and assets, even prior to the commencement of the court action. To be actionable, such a threat of infringement is required to be "imminent".

The China IP court will take the following factors into consideration in granting a preliminary injunction:

- the factual and legal basis, including the stability and validity of the patents at issue;
- whether the applicant's legitimate interests would be irreparably damaged if no injunction were issued;
- whether the loss caused to the applicant would exceed the loss incurred by the respondents through the issuance of the injunction if no injunction were issued;
- whether the injunction would harm public interests; and
- whether the applicant provides a sufficient bond.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

The specific defences to patent infringement in relation to pharmaceuticals and medical devices include the Administrative Approval Exemption (see **9.4 Pharmaceutical or Medical Device Patent Infringement**) and Experimental Use Type Defences (where the alleged infringement is used for research and experimentation), which collectively could be equivalent to the Bolar exemption. The patent exhaustion defence, prior art defence and transit exception could also apply to pharmaceuticals and medical devices as a general defence.

Compulsory licences are available for pharmaceutical products and medical devices to be used in China in the following circumstances:

- if a patentee has failed to exploit a patent without justification for more than three years since the date of granting the patent right and four years since the patent application date;

- if the patentee's act of exercising the patent right is determined to be monopolistic, and a compulsory licence would remove or reduce the anti-competitive effects of such patent use;
- if it concerns a national emergency, extraordinary state affairs or the public interest;
- for the manufacture and export of patented drugs to countries or regions that comply with the relevant international treaties to which China has acceded for the purpose of public health; or
- if a patented invention or utility model representing major technical advancements with remarkable economic impact relies on earlier patents, a compulsory licence could be granted to exploit both earlier and later patents.

A party granted a compulsory licence enjoys neither an exclusive right of exploitation nor a right to authorise others to exploit, and such a party shall pay reasonable royalties to the relevant patentee. If dissatisfied with the compulsory license decision or royalties, the patentee or related parties may file a lawsuit.

9.6 Proceedings for Patent Infringement

The following main options are available to enforce patent rights in China:

- administrative actions:
  - (a) the patentee or any interested party can file complaints with competent evidence before the CNIPA (and its local counterparts), and the local IPA can also conduct regular investigations against patent infringements – remedies include ordering the infringers to cease the infringement, seizing/destroying infringing items, and the imposition of fines; and
  - (b) Customs – see **3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices** regarding the border measures that can be taken;
- civil litigation remedies include preliminary injunctions, permanent injunctions and monetary damages; and
- criminal penalties (in cases of severe patent counterfeiting).

For civil cases, the patentee or any interested party can bring proceedings for patent infringement. Interested parties can be the legitimate heirs of the property right of the patent or licensees.

The Infringement Proceeding Procedure

The typical procedure for a patent infringement proceeding is as follows:

- the claimant submits a pleading to the court and files a copy of the pleading for each defendant;
- the court will decide whether to accept the case:
  - (a) if not, it will issue an award within seven days notifying the unacceptance, which is appealable;
  - (b) if yes, the court will serve a copy of the pleading to each defendant within five days of accepting the case, and the defendant must submit a statement of defence within 15 days of receipt;
- the claimant and defendant submit evidence, and the court will arrange the exchange of evidence;
- the defendant may also choose to file a patent invalidation application with the Re-examination and Invalidation Department under the CNIPA; and
- the court will conduct oral hearings and make its decision.

Either party can file an appeal to a higher court within 15 days of receiving the judgment.

The typical procedure of administrative enforcement for a patent infringement action includes the following:

- an administrative complaint is lodged with the CNIPA or its local counterparts;
- the CNIPA or its local counterpart investigates and takes action to obtain evidence of infringement;
- the defendant can submit a formal defence and rebuttal evidence;
- oral hearings may take place;
- the CNIPA or its local counterparts issue a decision; and
- either party may choose to appeal the decision by filing an administrative lawsuit with the court.

An accused infringer will bring patent invalidation proceedings with the Re-examination and Invalidation Department of the CNIPA parallel with the civil litigation as a litigation strategy.

9.7 Procedures Available to a Generic Entrant

A potential generic entrant can conduct research and development and clinical trials, and file a product application with the NMPA under the Administrative Approval Exemption and Experimental Use Type Defences to patent infringement.

The Patent Law establishes the Chinese efficiency-first patent linkage system. Relevant implementation measures stipulate that an MAH shall register the patent information of the drug on the Chinese listed drug patent information registration platform, while a generic drug applicant should make one of the four categories of declarations with respect to the registered patents. Among others, the Category IV declaration claims that the registered patents should be declared invalid or that they do not cover the generic drug.

The patentee or the licensee of the patent or the MAH of the drug can challenge the Category IV declaration before the court (judicial link) or the CNIPA (administrative link) within 45 days after such declaration is published. Within 15 business days of the case being accepted by the court or the CNIPA, the patentee or the interested party should provide the evident documents to the NMPA, which will withhold the administrative examination of the application for the generic drug for up to nine months to wait for an effective judgment or administrative decision, during which time the technical examination of the application will not be ceased. A 12-month exclusive period will be granted following the issuance of the marketing authorisation to the first chemical generic to successfully challenge a patent. Marketing authorisation of generic drugs of the same kind will not be approved within the aforementioned exclusive period.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Regarding counterfeit pharmaceuticals and medical devices, the public interest and the lawful rights of the rights-holder may be protected in the following ways.

- Administrative proceeding – a consumer can file a complaint to the local AMR, and any party can file a whistle-blowing report with the administrative authorities, such as the local AMR, the local MPA, Customs, etc. After

investigations, the administrative authorities may issue a punishment ruling when infringement is affirmed. The dissatisfied rights-holder or the infringer can bring an administrative lawsuit to the court regarding the local authority's decision.
- Civil proceedings – the patentee and the interested party can bring infringement actions before the courts. Punitive damages are allowed under the Trademark Law.
- Criminal proceedings – the manufacture and distribution of counterfeit pharmaceuticals and medical devices constitute violations of the Criminal Law of the PRC.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Trade marks used for pharmaceuticals and medical devices are subject to the general requirements of the Trademark Law (such as prohibitions on containing fraudulent content). In addition, the NMPA places special restrictions on trade marks to be used for pharmaceuticals and medical devices. For example, pharmaceuticals' generic names cannot be registered as trade marks, and unregistered trade marks cannot be used in the specifications and labels of pharmaceuticals.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

IP protection is available for the trade dress or design of pharmaceuticals and medical devices under various PRC laws. Applicable laws prohibit any unauthorised use of a mark that is identical or similar to the package or decoration of another's commodity that is influential.

The patented design of pharmaceuticals and medical devices can be protected under the Patent Law. The trade dress or design of pharmaceuticals and medical devices could be protected as a copyrightable industrial design or product design under the Copyright Law and as a registered two-dimensional/three-dimensional trade mark under the Trademark Law.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Data exclusivity is currently only available for pharmaceuticals, not for medical devices. PRC law provides six-year protection from the date of the marketing authorisation, which prohibits unauthorised third parties from using undisclosed trial data and other data to apply for manufacturing or distribution approval of new chemical pharmaceuticals.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

During the COVID-19 pandemic, the distribution of medicines and medical devices was subject to distribution permits, as discussed in **5. Distribution of Pharmaceutical and Medical Devices**. China issued special regulations to severely crack down on the illegal manufacture and distribution of counterfeit and inferior pharmaceuticals, medical devices and hygienic materials, especially for pharmaceuticals and medical devices used for the treatment and prevention of COVID-19.

Since China announced its decision to manage COVID-19 with measures against Class B instead of Class A infectious diseases, the NMPA issued a special notice to emphasise the regulation on drug dividing distribution management (ie, the distribution of drugs by splitting the

minimum package) and to ensure the supply of drugs commonly used to treat COVID-19.

11.2 Special Measures Relating to Clinical Trials

To ensure the effectiveness of safety management of clinical trials during COVID-19, the CDE published guidelines to ensure the progress of clinical trials under the condition of protecting the trial subject from COVID-19, with key measures focusing on reducing the trial subject's exposure to the virus and controlling the spread of infection.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

Two regulatory pathways have applied for emergency approvals of pharmaceuticals or medical devices in China since before the outbreak of COVID-19: emergency approvals and conditional approvals.

Regulatory pathways for special approvals greatly reduce the time required for the approval of pharmaceuticals and medical devices due to a public health emergency.

Conditional approvals for pharmaceuticals often occur when pharmaceuticals (including vaccines) have curative effects and predictable clinical value based on the data in clinical trials, and when they are used for the treatment of serious life-threatening diseases with no effective therapeutic means or for those with urgent need of public health. Conditional approvals for medical devices often occur when medical devices are used for the treatment of rare diseases or serious life-threatening diseases with no effective therapeutic means or for those with urgent need of public health.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

During the COVID-19 pandemic, many provinces and cities introduced special regulations to facilitate the application for manufacturing permits for medical devices. For example, the registration and manufacturing of medical masks and medical protective clothing are no longer subject to approval by the provincial MPA: a simplified filing with the municipal MPA is sufficient.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

Importation

For importation, China Customs issued special regulations to ensure the rapid customs clearance of donations for COVID-19 research and treatment. Pursuant to the special regulations, the clearance of imported pharmaceuticals, disinfectants, protective clothing, rescue and treatment devices, and relevant materials may be carried out before the required customs procedures are completed.

Exportation

For exportation, China devotes greater efforts and adopts various measures to ensure the quality and safety of exported pharmaceuticals and medical devices. China Customs and its local counterparts have promulgated measures to accelerate the import and export process of COVID-19-related vaccines and reagents.

As the global health emergency status of the COVID-19 pandemic concludes, transitioning into the normalised management phase of epidemic prevention and control, the Chinese government has adjusted its quality supervision measures for the export of epidemic prevention materials since August 2023.

11.6 Drivers for Digital Health Innovation Due to COVID-19

China introduced certain rules to encourage digital healthcare innovation and digital transformation due to COVID-19, including online health assessment, health guidance, health education, follow-up visits for chronic diseases, etc. It specially proposes to actively develop telemedicine services and to standardise internet diagnosis and treatment consulting services.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

Compulsory licensing of IP rights is regulated in the Patent Law, as discussed in **9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices**.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

So far, COVID-19 treatments or vaccines are not exempted from liability under the PRC law.

11.9 Requisition or Conversion of Manufacturing Sites

In China, the Emergency Response Law and the Prevention and Treatment of Infectious Diseases Law provide that the requisition or conversion of manufacturing sites is allowed due to the outbreak of a public health emergency, including COVID-19.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

Generally, public hospitals shall purchase medicines and medical devices that have been listed on a centralised procurement platform. After the outbreak of COVID-19, many provinces and cities issued special measures to allow public hospitals to procure pharmaceuticals and medical devices to prevent and treat COVID-19 from certain suppliers directly.

Furthermore, to ensure the accessibility of COVID-19 therapeutic drugs, the NHSA issued the Guidelines for Price Formation for COVID-19 Therapeutic Drugs (for Trial Implementation).

To improve the pricing mechanism for COVID-19 therapeutic drugs, the NHSA further promulgated a regulation based on the aforementioned guidelines, which introduces a three-tiered classification system (A, B, C) for COVID-19 therapeutic drugs that are not included in the NRDL. The healthcare security department is allowed to implement temporary medical insurance payment policies in response to the needs of epidemic prevention and control.

Trends and Developments

Contributed by:
Min Zhu, Ya-ling Gon, Yang Gu, Chai Lu, Ying Li and Shiye Yuan
Han Kun Law Offices

Han Kun Law Offices is a leading full-service law firm in China, with over 800 professionals located in eight offices in Beijing, Shanghai, Shenzhen, Haikou, Hong Kong, Wuhan, Singapore and New York City. The firm's main practice areas include private equity, mergers and acquisitions, international and domestic capital markets, investment funds, asset management, antitrust/competition, banking and finance, aviation finance, foreign direct investment, compliance, private client/wealth management, intellectual property and dispute resolution. Han Kun provides a full range of legal services and business advice to Chinese companies and multinationals doing business in China. Over the years, it has been widely recognised as a leader in complex cross-border and domestic transactions that cover foreign investment access, industry compliance, labour and national security review, taxation, foreign exchange and intellectual property.

Authors

Min Zhu has extensive legal practice experience in the life sciences and healthcare industries. He has served life sciences and healthcare companies in different stages of development, including financing and licensing deals for start-ups, mergers and acquisitions, and various regulatory and compliance matters, such as anti-corruption and anti-bribery, clinical trials, drug and medical device registration, distribution, advertising and promotion, as well as medical and healthcare data compliance. Prior to joining Han Kun, Min practised law for many years at another leading Chinese firm and also in the Shanghai office of an international law firm.

Ya-ling Gon (Michelle) focuses on representing clients in complicated and challenging compliance and regulatory matters, including anti-corruption, unfair competition, anti-monopoly, anti-fraud, export control and trade sanction areas. She is well respected for being personally devoted to her clients and offering practical advice on resolving complex legal issues. Most of Michelle's clients are leading multinationals doing business in China or large, China-based multinationals doing business globally across a wide range of industries, including pharmaceuticals, medical devices, life sciences, healthcare, agriculture, food-related products, wine and spirits, hospitality, cruise lines, manufacturing, IT and hi-tech.

Contributed by: Min Zhu, Ya-ling Gon, Yang Gu, Chai Lu, Ying Li and Shiye Yuan, **Han Kun Law Offices**

Yang Gu focuses on corporate, regulatory compliance and transactional services for the life sciences, biopharmaceutical, medical and healthcare industries, including biosecurity and human genetic resource issues, clinical trial matters, product marketing authorisations, GxP compliance, drug licensing and collaboration, as well as regulatory issues involved in venture capital and private equity investments, M&A, and foreign and outbound investments in the life sciences industries. He also provides advocacy advice on draft laws and regulations released by the NMPA and other Chinese governmental authorities.

Chai Lu focuses on public and private M&A transactions, private equity transactions, securities offerings and exchange listings. She has advised a number of clients in Greater China on cross-border M&A, SEC-registered and non-registered securities offerings, and listings on the Stock Exchange of Hong Kong. She also advises clients on ongoing regulatory and reporting requirements. Chai has represented many Chinese and international clients in a broad range of transactions in different industries, including financial services, insurance, telecommunications, TMT, consumer goods, mining, power and energy, manufacturing and healthcare.

Ying Li specialises in patent prosecution, invalidation, litigation and IP counselling, with a notable record in aiding clients to secure patents in China. Before joining Han Kun, she amassed 16 years' experience at CCPIT Patent and Trademark Law Office. Her expertise extends to patent mining, drafting, office action responses and conducting prior art and freedom-to-operate searches, particularly using the STN database for small molecule drugs and biological macro-molecules. Ying is recognised for her outstanding case management and communication skills, and has successfully represented clients before the China National IP Administration and in court, earning widespread trust and commendation for achieving excellent outcomes.

Shiye Yuan has led Han Kun Law Offices' tax practice since 2020, after a 15-year tenure with the Big Four accounting firms, including as an M&A tax partner at KPMG. He started his tax career in 2004 and specialises in PE/VC tax optimisation, offering stable solutions amidst changing tax laws. In M&A and capital markets, he devises tax-efficient, compliant structures for transactions, balancing savings with regulatory acceptance. For wealth management and stock option incentives, Shiye crafts personalised tax plans that consider tax efficiency and asset protection, catering to the individual needs of various stakeholders.

Han Kun Law Offices

9/F, Office Tower C1
Oriental Plaza
1 East Chang An Ave
Dongcheng District
Beijing 100738
PRC

Tel: +86 10 8525 5500
Fax: +86 10 8525 5511/5522
Email: beijing@hankunlaw.com
Web: www.hankunlaw.com/en

Life Sciences in China: An Introduction

The market rebound that was anticipated in pharmaceutical investment and finance following the end of the pandemic did not materialise in 2023, due to factors such as stringent anti-corruption policies in the pharmaceutical industry and the changing dynamics of international politics. Nevertheless, amidst this shifting landscape, there were still notable deals and opportunities. Companies with robust innovation capabilities and promising product pipelines have continued to attract substantial investment.

Overall, the post-pandemic period has brought forth an era of both transformation and uncertainty. Navigating these changing dynamics requires a keen understanding of regulatory changes and geopolitical influences, and an unwavering commitment to innovation and quality within the industry.

Pharmaceutical Industry Transactions in the Post-Pandemic Period

IPOs

The pharmaceutical industry in China experienced a significant contraction in IPOs in 2023, with only 22 companies listing compared to 50 the previous year. Total IPO financing dropped sharply from RMB76.51 billion to RMB22.32 billion, representing a 70.8% decline. In addition, terminated IPO projects surged to 38, almost double the number recorded in 2022. Chemical pharmaceuticals accounted for the most IPOs, with nine listings, followed by biopharmaceuticals and medical devices, each with four listings.

The slowdown in IPOs was primarily due to stricter regulatory scrutiny focused on financial performance, promotional expenses and technological innovation criteria. These developments suggest a move towards more rigorous market entry standards, which may pose a challenging outlook for pharmaceutical IPOs in 2024, amidst continued stringent policies and increasing complexities in the industry.

VC/PE financing

Although it was anticipated that the relaxation of pandemic control measures would stimulate a resurgence in VC/PE investment activities, 2023 did not fully meet these expectations. In the Chinese market, the number of financing events in Q1-3 increased to 962, marking a 12.01% increase from the previous year, but

the total financing amount for Q1-Q3 2023 was only RMB85.02 billion, representing a significant decrease of 25.1% compared to the same period in 2022.

Despite the overall subdued market conditions, companies demonstrating strong innovation capabilities and high-quality product pipelines continued to attract substantial investment. This trend underscores that, in the pharmaceutical industry and particularly in innovative drugs and biotechnology, investors prioritise innovation and technological potential over general market sentiment.

License-in/out

In 2023, China's pharmaceutical industry achieved record numbers of license-out deals, with over 40 significant collaborations covering nearly 50 innovative drugs. Thirteen of these transactions exceeded USD1 billion, marking a new high in deal volume and financial vigour. While small molecule targeted drugs and antibody drugs were in high demand, the most notable transaction was an USD8.4 billion deal in the antibody-drug conjugate (ADC) sector involving BeiGene. This deal not only highlighted the rising global value of Chinese ADC products but also suggested the sector's potential for future breakthroughs. The pivot of biosimilars towards emerging markets such as Argentina, the Philippines and Thailand also indicated a strategic shift to uncharted territories, demonstrating the Chinese biopharmaceutical industry's adaptability and ambitious global outreach.

Alongside its remarkable license-out achievements, China's pharmaceutical industry actively engaged in license-in transactions. In 2023, there were more than 170 such deals, including partnerships with entities from the US, Japan, the UK and Switzerland. Although there was a slight drop in the number of transactions compared to the previous year, the overall financial commitment remained strong. Most of these license-in agreements focused on innovative drugs, particularly in the pre-clinical stage. This reflects China's strategic emphasis on early-stage pharmaceutical development and its continued integration into the global biotech innovation network.

Mergers and acquisitions

In 2023, China's pharmaceutical industry maintained a steady yet cautious pace in M&A, with most deals staying within the RMB1 billion range. Local pharma companies focused on sales collaborations and over-the-counter (OTC) channel integrations, showing less interest in acquiring innovative businesses compared to their global counterparts.

The medical device industry saw more diverse M&A activity, with a focus on market integration and technology enhancement. Small or medium-sized domestic companies led most of these deals, which often did not exceed RMB100 million, indicating a trend of smaller-scale, strategic acquisitions in China's evolving healthcare sector.

Regulatory Trends

In 2023, Chinese regulatory authorities updated a number of notable laws and regulations to keep up with the rapid development of the life sciences industry. Among the regulatory trends, significant updates included new rules on human genetic resources (HGR), ethics review, promotion and advertising, and imported drugs and medical devices for urgent clinical use.

Regulatory authorities made diligent efforts to protect national biosecurity and regulate HGR-related activities by adopting a set of new rules

and standards in 2023. To further refine the Regulations on Administration of Human Genetic Resources, promulgated in 2019, the Ministry of Science and Technology (MOST) issued the Implementation Rules for the Regulation of Human Genetic Resources Administration (Implementation Rules), which clarify the scope of HGR information, narrow down the scope of "foreign entities" and update requirements for collection and biobanking, international collaboration, etc. MOST also released new administrative guidelines and updated frequently asked questions, which serve to make further clarification in, for example, the determination of specific samples and regulatory procedures. China's new HGR regulations clarify many practical and key issues in industry practices for utilising HGR and still feature high standards and strict supervision.

Regulatory authorities have placed increasing focus on ethics review by releasing two new rules in 2023. The Measures for the Ethics Review of Life Sciences and Medical Research Involving Humans have expanded the scope of application and clarified requirements in informed consent and exemptions, etc, while the Scientific and Technological Ethics Review Regulation has introduced new procedures for scientific and technological ethics review. Notably, the regulation stipulates that entities in the life sciences sector must establish an internal scientific ethics (review) committee if their research falls under sensitive fields in scientific ethics. Relevant industry players should monitor these trends closely in stricter ethics review supervision.

In 2023, the State Administration for Market Regulation (SAMR) released the Measures for Administration of the Review of Advertisements for Drugs, Medical Devices, Health Foods, and Food Formulas for Special Medical Purposes (Draft for Comment) (Draft), which would revise existing rules originally promulgated in 2019. To respond to practical needs, the Draft introduces several provisions in livestream advertisements and those with website links and QR codes. The Draft also proposes new requirements for labelling obligations and clarifies procedures for advertising approvals.

Chinese regulatory authorities have also explored the feasibility of the importation and use of drugs and medical devices for urgent clinical use. In early 2023, a pilot regulation was released and applied in the Hainan Free Trade Port, which introduced several requirements for the acceptance of real-world data as registration materials for regulatory approvals and also updated provisions on taking away for use and measures under occurrence of major safety events. Based on the pilot regulation, the National Medical Products Administration (NMPA) released a draft of administrative requirements for medical devices for urgent clinical use in late 2023, which could be applied nationwide in the future.

According to the NMPA at a national conference on drug supervision and administration in January 2024, the major regulatory focuses in 2024 will be on the management of safety risks of drugs, the continuing reform of the drug and medical device review system, and the enhancement of regulatory informatisation.

In addition to the general introductions to policy updates that are applicable to both drugs and medical devices, the following regulatory highlights apply to drugs or medical devices respectively.

Drug highlights

During 2023, several guidelines were released to enhance the regulation of clinical research into

drugs. On 18 August 2023, the China Medicinal Biotechnology Association was commissioned by the National Health Commission to issue the Guidelines on the Clinical Research of Somatic Cell (Trial), which have refined the regulatory requirements for clinical research programmes for somatic cell therapies such as CAR-T/NK. To establish a more complete and systematic regulatory system for the supervision of drug clinical trial institutions, the NMPA released the Measures for Supervision and Inspection of Drug Clinical Trial Institutions (Trial) and its supplemental technical guidelines on 3 November 2023, which officially came into effect on 1 March 2024.

Relevant authorities released several regulations and documents regulating drug distribution. On 27 September 2023, the SAMR released the Measures for Quality Supervision and Administration of Drug Distribution and Use. These measures became effective on 1 January 2024 and outline the obligations regarding drug distribution and the use of marketing authorisation holders (MAH), distributors and medical institutions.

Following the implementation of the Provisions for Supervision and Administration of Online Drug Sales, the NMPA has been enhancing the regulation on online drug sales. A notice on the NMPA's official website in June 2023 required companies and platforms to rectify information displays regarding prescription drugs. The release of the Guidelines for Inspection of Third-Party Platforms for Online Drug Sales (Trial) in December 2023 strengthened the supervision of online platforms in fulfilling their responsibilities.

Medical device highlights

China is currently working on a pre-legislative study of the Law on Medical Device Administration. On 7 September 2023, the 14th National People's Congress Standing Committee released the legislative agenda for 2023–2028, wherein the Law on Medical Device Administration was included for the first time. When this law is adopted in the future, it will provide an authoritative framework for medical device regulation.

The regulatory framework for China's laboratory developed tests (LDT) industry continues to mature. Shanghai launched its LDT pilot programme in March 2023, following a national pilot programme that began at the end of 2022. These two pilot regulations provide comprehensive and detailed guidelines on the use of LDT products, paving the way for future exploration in the development of a more mature regulatory regime.

As for the regulations over medical device distribution, the NMPA released the newly revised Good Supply Practice for Medical Devices (GSP) on 4 December 2023, which will come into force on 1 July 2024. The new GSP, which replaced the 2014 version, is more consistent with the 2021 Regulations for the Supervision and Administration of Medical Devices and will strengthen the requirements for quality management.

Compliance Practices

Commercial bribery in medical and healthcare industries

Rigorous monitoring and enforcement of commercial bribery is expected to continue, with a focus on the healthcare sector, including dawn raids, cross referrals of cases to other competent agencies, and collaboration among different government agencies to crack down on corruption and bribery. As law enforcement efforts against commercial bribery intensify, an increasing number of complex hidden bribery schemes are being identified and penalised by law enforcement agencies. Such schemes

include tailor-made bidding, bid rigging, exclusive profit sharing, and entertainment and kickbacks disguised as speaker fees for training or experience sharing at various conferences, as well as using ad hoc rebates and discounts to distributors for indirect payments to healthcare professionals, etc.

The National Health Commission has explicitly clarified that academic conferences and normal medical activities conducted in compliance with relevant national regulations should still be positively supported and encouraged. However, the regulatory authorities will actively rectify those bribery activities associated with academic conferences – eg, providing inappropriate benefits by fabricating academic meetings, or unlawful misappropriation of the sponsorship fees for academic conferences that do not take place as planned.

In sum, the payment of speaker fees in relation to academic conferences is not completely prohibited, but it remains one of the key compliance issues for healthcare companies to carefully review the process and collect the relevant event photos and materials for future internal audit or external inquiries by the enforcement agencies.

Strengthening regulation of national medical insurance fund usage

To increase scrutiny of medical insurance fund usage, new regulation methods will be piloted, including increasing unannounced inspections and fraud prevention mechanisms based on data collection from mobile applications and new payment methods for off-site supervision.

Continuous advancement of national centralised procurement of medical devices and pharmaceuticals

National centralised procurement became institutionalised in 2021, and remarkable achievements and valuable experience have been obtained in pharmaceutical chemicals and high-value consumables such as coronary stents and artificial joints. Deeper coverage of national centralised procurement over regular pharmaceutical chemicals is expected. Companies should enhance self-monitoring of compliance efforts to prevent procurement issues related to commercial bribery or taxation issues. Law enforcement agencies hope that the reduced profit margins due to centralised procurement will lead to less commercial bribery by life sciences companies involving healthcare professionals.

Trade secret protection

In 2022, relevant policies regarding trade secret protection were initiated at both national and local levels. Enterprises are encouraged to enhance internal control mechanisms, self-protection capabilities and management organisation, for the purpose of establishing systematic compliance. Meanwhile, local governments intend to strengthen the protection of key and specialised industries, especially new industries, new business models and trends. Priority will be given to the protection of knowledge- or technology-intensive, innovative and time-honoured businesses.

Changes in Chinese Intellectual Property Laws and Regulations

Revision of patent-related laws and regulations

On 21 December 2023, after five revisions, the State Council promulgated new rules for the implementation of the Patent Law of the People's Republic of China; on the same day, the

China National Intellectual Property Administration (CNIPA) published revised guidelines for patent examination. Both of these sets of changes came into effect on 20 January 2024.

The amendments to the rules relate mainly to optimising the patent application filing process, relaxing the provisions on the grace period for novelty, and improving the priority-related system. The changes also include aspects related to patent application filing, such as introducing the principle of good faith, adding a delayed examination system and improving the patent re-examination system. Other amendments include refining the patent term compensation system, improving the patent dispute handling and mediation system, and clarifying the criteria for defining patent infringement disputes with significant domestic impact. The revision of the CNIPA examination guide corresponds to these changes.

The biggest change related to life sciences is that specific content related to patent term extension and patent linkage are stipulated in Articles 77–84 of the new Rules for the Implementation of the Patent Law of the People's Republic of China, and a new chapter – "Several Provisions on the Examination of Patent Applications for Inventions in the Field of Traditional Chinese Medicines" – is added to Part II of the "Substantive Examination" of the Patent Examination Guidelines as Chapter 11. Regarding the examination of patent applications in the field of traditional Chinese medicines, the new Chapter 11 was added to make detailed and clear provisions on the examination standards for the subject of patent protection for traditional Chinese medicine inventions, as well as on the specification, claims, novelty, inventiveness and utility.

Changes in the number of patent applications and objects of patent protection

China's invention patent applications have continued to increase. According to nationally reported statistics, the number of valid domestic invention patents reached 4.015 million by the end of 2023, representing a year-on-year increase of 22.4% and making China the first country in the world where the number of valid domestic invention patents exceeded 4 million.

China's pharmaceutical-related patent applications have also continued to increase. In 2023 alone, the number of published drug-related patent applications in China, including chemical drugs, biopharmaceuticals and traditional Chinese medicines, reached 58,000, an increase of more than 3,000 compared with the 55,000 in 2022. Of this total amount, the number of published antibody-related patents alone reached about 13,000 in 2023.

In the field of life sciences, the objects of patent application protection have changed significantly. In addition to the traditional drugs themselves, strong innovation in the digital economy and the rapid development of artificial intelligence have played an important role. In recent years, the average annual growth rate of patent applications in the medical and healthcare industry using artificial intelligence technology has exceeded 32%, with the number of applications related to health monitoring and medical image processing technology increasing significantly.

The pharmaceutical and medical industries also represent a large part of the patent-intensive industry inside China. According to an explanation by CNIPA, patent-intensive industries rely on intellectual property rights to participate in market competition.

According to data released in January 2024, the added value of China's patent-intensive industries in 2022 was RMB15.3 trillion, an increase of 7.1% over the previous year. Of this amount, the contribution from the pharmaceutical and medical industry was RMB1.288 trillion. According to the growth trend of patent publications in 2023, the added value of the pharmaceutical and medical industry to China's GDP in 2023 continued to maintain its growth trend.

Tax Concerns

As one of the most encouraged sectors currently in China, healthcare and life sciences companies may enjoy a wide range of tax incentives, mainly including the following preferential tax treatments.

High and new technology enterprise (HNTE)

The HNTE policy offers a reduced 15% corporate income tax rate (as opposed to 25% for normal enterprises). Many life sciences companies find it relatively easy to qualify for this tax preference, although certain others may encounter difficulties, particularly PRC subsidiaries of multinationals, due to a lack of PRC-generated IP. Over the past few years, more pharmaceutical companies, particularly biotechnology start-ups, have devoted themselves to developing first-in-class or best-in-class drug products, which places them in a better position to enjoy HNTE tax incentives.

R&D expense super-deduction

China's R&D expense super-deduction policy is similar to those of many other jurisdictions and allows an extra deduction for qualified expenditures. Life sciences companies are qualified to enjoy a 100% extra deduction by being recognised as either a "manufacturing enterprise" or a "small and medium technology enterprise".

Input VAT refunds

In terms of VAT treatment, a major incentive is the input VAT refund mechanism, under which small-scale or manufacturing life sciences companies can have their qualified accumulated input VAT refunded. This is particularly beneficial for life sciences companies that incur significant input VAT out of payments due to R&D or licence activities during their early stages when they have no chance to book revenue.

From a transaction perspective, it is also important to have a proper understanding of the relevant tax implications. For example, for in-license deals, apart from the potential input VAT refunds, one of the key tax considerations is the identification of a permanent establishment for overseas licensors that plan to assign personnel to work in China for the licence project. The entire revenue package of the licensor may be subject to 25% PRC corporate income tax if the entity is deemed to have set up a permanent establishment in China.

Tax incentives extended

From 2023, the economic environment in China has proven to be mixed. In order to promote business development, the PRC government and tax authorities have extended many tax incentives, including those designed for small and medium companies. Such incentives are not only applicable to life sciences companies but they do significantly reduce the tax burden for start-up companies.

GERMANY

Law and Practice

Contributed by:
Martin Altschwager, Thilo Räpple and Zahra Zaatan
Baker McKenzie

Contents

Baker McKenzie was founded in 1949 and is one of the world's largest and most effective law firms, with more than 12,000 employees across 74 offices. The German offices seek to play their part in fulfilling the global vision of the firm's two founders – Russell Baker and John McKenzie. More than 200 lawyers (spread across Berlin, Düsseldorf, Frankfurt am Main and Munich) can represent clients' interests not only in Germany, but also beyond its borders, by combining comprehensive expertise with long-standing experience. As one of Germany's leading law firms, Baker McKenzie advises national and international companies and institutions on all aspects of commercial and tax law. In so doing, the firm concentrates on understanding the economic background to the work, while remaining focused on helping clients realise their business goals.

Authors

Martin Altschwager is a partner and a member of Baker McKenzie's pharmaceuticals and healthcare practice group in Frankfurt. Martin advises national and international clients on all aspects of European and German pharmaceuticals and medical device law, covering market access, manufacture, distribution, promotion and advertising of medicinal products, medical devices and digital health services. Martin has significant experience in managing the regulatory aspects of large M&A transactions and corporate reorganisations of pharmaceutical and medical device companies. Martin is the author and co-author of several life sciences publications, speaks regularly on the topic, and is recognised as a next-generation lawyer in the field in Germany.

Thilo Räpple has been a partner at Baker McKenzie since 1995 and is consistently recognised as one of the leading life sciences lawyers in Germany. Thilo focuses his practice on the pharmaceutical and medical industry sector, and has substantial experience in handling matters that deal with pharmaceuticals, medical devices, and regulatory law, as well as pharmaceutical advertising, law and industry-specific compliance issues. He regularly advises on regulatory aspects of M&A deals relating to the purchase or sale of pharma and medtech companies. Thilo is the author of several publications relating to life sciences and he also co-chairs the leading German pharma law congress.

Zahra Zaatan is an associate in the pharmaceuticals and healthcare practice group at Baker McKenzie in Frankfurt am Main. Zahra advises national and international clients on all aspects of German and European pharmaceuticals and medical device law, including market access, manufacture, distribution, marketing and reimbursement of medicinal products, medical devices and digital health services.

Baker McKenzie

Junghofstrasse 9
60315
Frankfurt/Main
Germany

Tel: +49 69 299 08 202
Fax: +49 69 299 08 108
Email: martin.altschwager@bakermckenzie.com
Web: www.bakermckenzie.com/en/locations/emea/germany

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Pharmaceuticals for human use are governed by the German Drug Act (*Arzneimittelgesetz,* or AMG), which primarily implements the Directive on the Community code relating to medicinal products for human use (Directive 2001/83/EC). In addition, several important German regulations govern the manufacture and distribution of pharmaceuticals and the pricing of prescription-only pharmaceuticals. Since 28 January 2022, pharmaceuticals for veterinary use have been governed by the Regulation on veterinary medicinal products (Regulation (EU) 2019/6), which is complemented by the German Veterinary Drug Act (*Tierarzneimittelgesetz*, or TAMG).

Since 26 May 2021, medical devices have been governed by the Regulation on medical devices (Regulation (EU) 2017/745) (MDR), which is complemented by the German Medical Device Law Implementation Act (*Medizinprodukterecht-Durchführungsgesetz*, or MPDG) as well as several further implementing German regulations. Since 26 May 2022, in vitro diagnostics have been governed by the Regulation on in vitro diagnostic medical devices (Regulation (EU) 2017/746) (IVDR), which is also complemented by the MPDG. For legacy medical devices and in vitro diagnostics, transitional provisions apply.

Regulatory oversight both of pharmaceuticals and medical devices is divided between federal authorities and state-level authorities.

With regard to pharmaceuticals, the federal regulatory authorities *Bundesinstitut für Arzneimittel und Medizinprodukte* (BfArM) and Paul-Ehrlich-Institut (PEI) are responsible for issuing national marketing authorisations (MAs), for approving clinical trials, and for pharmacovigilance. The PEI assumes these responsibilities for biological pharmaceuticals, such as vaccines and advanced therapy medicinal products (ATMP), whereas the BfArM is responsible for all other pharmaceuticals (centralised MAs are issued by the EC based on the evaluation of the European Medicines Agency (EMA) under the Regulation (EC) No 726/2004). The state-level authorities are responsible for issuing manufacturing, wholesale distribution and import licences, as well as for overseeing, ascertaining (through inspections) and enforcing compliance with applicable pharmaceutical laws.

As regards medical devices, the BfArM is responsible for classification decisions, clinical trial approvals and vigilance. Meanwhile, the state-level authorities are responsible for general oversight, inspections and enforcement.

The BfArM and the PEI are independent federal authorities within the portfolio of the Federal Ministry of Health and are subject to its oversight. The Federal Ministry of Health has the authority to issue directives to the BfArM and the PEI. The same applies mutatis mutandis to state-level authorities.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Enforceable decisions by regulatory bodies qualify as administrative acts, which can be challenged by the addressee (or by a third party with standing) by lodging an objection with the regulatory body that has issued the administrative act. By default, the objection has suspensory effect and impedes enforcement of the challenged administrative act. However, the regulatory body can order the immediate exe-

cution of the administrative act, notwithstanding the pending objection. In such case, the addressee of the administrative act (or a third party with standing) can submit a request to the competent administrative court to (re-)establish the suspensory effect of the objection, which (if successful) precludes enforcement until a final decision is obtained – either the objection is sustained by the regulatory body or, upon filing a lawsuit against the administrative act and the unsuccessful objection proceeding, the administrative act is either confirmed or lifted by the administrative courts.

Objections against administrative acts, as well as requests for the (re-)establishment of suspensory effect and lawsuits, must be lodged in writing or electronically and within one month of notification of the decision to be challenged.

The aforementioned procedure applies to pharmaceuticals and medical devices as well as to other regulated products.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals may qualify as prescription-only, pharmacy-only, and freely sellable pharmaceuticals. Prescription-only medicinal products also qualify as pharmacy-only at the same time and may not be advertised to the public and, as with pharmacy-only pharmaceuticals, can only be dispensed by pharmacies (including online/mail-order pharmacies).

The same three-pronged distinction applies to medical devices. However, unlike pharmaceuticals, most medical devices are freely sellable and not qualified as prescription-only or pharmacy-only.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Since 31 January 2022, clinical trials of pharmaceuticals have been governed by the Regulation on clinical trials on medicinal products for human use (Regulation (EU) No 536/2014) (CTR) and new complementing provisions in the AMG. However, in certain scenarios, ongoing clinical trials of pharmaceuticals may continue to be conducted under the legacy national AMG rules during a three-year transition period that expires on 30 January 2025 (see **2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial**).

Since May 2021, clinical trials of medical devices have been governed by the MDR and the MPDG. The same governance applies for clinical trials of in vitro diagnostics as of 26 May 2022.

Clinical trials require prior authorisation by the BfArM (or, in the case of biological pharmaceuticals such as vaccines, ATMPs and certain in vitro diagnostic medical devices, by the PEI) and – as part thereof or a prerequisite thereto – a positive opinion by the competent ethics committee. The focus of the authorisation procedure before the federal regulatory authority is the quality, efficacy/performance and safety of the investigational pharmaceutical or medical device. The focus of the review by the ethics committee is the ethical and scientific justification of the clinical trial – in particular, taking into account the rights of the trial participants.

Non-interventional clinical studies are excluded from the scope of the aforementioned regulations, but may, under the applicable state laws and regulations, require involvement of the ethics committee of the local physicians' association.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

For clinical trials of pharmaceuticals under the CTR, the sponsor must – as of 31 January 2023 – submit an application dossier electronically through the newly established Clinical Trials Information System (CTIS), which is the single-entry point for the submission of clinical trials under the CTR. Since 31 January 2023, clinical trials can no longer be commenced under the legacy AMG rules. Clinical trials authorised under the AMG rules that are expected to continue beyond 30 January 2025 need to be transitioned to the CTR/CTIS.

Applications through the CTIS will cover both the scientific review of the clinical trial by the competent federal regulatory authority (the BfArM or the PEI) as well as the ethical review by the competent ethics committee.

Applications for authorisation of clinical trials of medical devices by the BfArM, as well as for the prerequisite positive opinion by the competent ethics committee, must be submitted electronically through the German Medical Devices Information and Database System (*Deutsches Medizinprodukte-Informations- und Datenbanksystem*, or DMIDS) portal. The new application procedure established under the MDR and the IVDR is not yet applicable because the necessary new European Database on Medical Devices (Eudamed) is not yet fully functional and currently is not expected to become functional until 2027.

The competent federal regulatory authority (and, if applicable, the ethics committee) must acknowledge receipt within ten days and, in the case of formal deficiencies, request their remediation within ten days (14 days under the legacy AMG rules).

The assessment of formally completed applications for clinical trial authorisations will be completed by the competent federal regulatory authority within 45 days following the validation of the application (different timeframes apply under legacy AMG rules). Up to five days after the assessment phase, the decision on whether the clinical trial can be conducted will be issued. The relevant authority or ethics committee may request additional information from the applicant; until the receipt of any such information, the clock is stopped.

Subsequent significant changes to the approved clinical trial may only be implemented following prior approval by the federal regulatory authority (and/or the competent ethics committee, if applicable), depending on the subject matter of the change.

Clinical trial authorisations, as well as favourable ethics committee opinions, can be suspended or revoked if the conditions for approval of the clinical trial are no longer met.

In January 2024, the German Ministry of Health published a draft Act on Medical Research (*Medizinforschungsgesetz*) to strengthen the pharmaceutical industry in Germany. This provides for certain measures to streamline and accelerate the clinical trial authorisation procedure.

2.3 Public Availability of the Conduct of a Clinical Trial

For pharmaceuticals, information on approved clinical trials performed under the legacy AMG rules are publicly accessible under the EU Clinical Trials Register. For clinical trials approved under the CTR, information is available on the CTIS platform.

Sponsors of clinical trials of pharmaceuticals must submit a report of the clinical trial results to the CTIS within one year of completion (or within six months for clinical trials governed by legacy AMG rules). This report is then published on the aforementioned databases.

In accordance with its Policy 0070, the EMA already publishes clinical data that pharmaceutical companies have submitted to support their centralised MA applications on its website.

Information on clinical trials of medical devices is currently not made available in free public databases. However, the MDR and the IVDR provide for the transparency of clinical trial information through the Eudamed database. The obligations of sponsors of clinical trials of medical devices to submit clinical trial results will come into force six months after publication of the EC notice that the clinical investigations and performance studies module of the Eudamed database has achieved full functionality. The EC recently announced the module will not be completed before the third quarter of 2026.

2.4 Restriction on Using Online Tools to Support Clinical Trials

At the present time, there are no German regulations on the use of online tools to support clinical trials. However, in the light of experiences resulting from the hybrid clinical trial set-ups borne out of necessity during the COVID-19 lockdowns (and the emerging discussion on decentralised or entirely siteless clinical trials), guidance in this field can be expected in the future. Specifically, the recently proposed draft Act on Medical Research (see **2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial**) explicitly allows that the consent of the trial participant may also be given electronically, provided it is signed through a qualified electronic signature. Generally, any use of clinical trials must comply with data protection requirements under the EU General Data Protection Regulation (GDPR) and applicable implementing and complementing German laws at federal and state level.

2.5 Use of Data Resulting From Clinical Trials

The clinical trial data directly generated in the trial – whether in "raw" form, as maintained at the clinical trial site, or in pseudonymised form, as subsequently transferred from the clinical trial centre to the sponsor – is considered "special category data". Its processing is conditioned to higher requirements set out in Article 9(2) of the GDPR. Only anonymised data does not fall under the requirements of the GDPR, but anonymised clinical data is of limited use and the requirements for anonymisation are set at a high level. German law requires that clinical trial participants not only provide their informed consent to their participation in the clinical trial, but also provide their consent to the processing of their data by signing informed consents as approved by the competent ethics committee in the clinical trial authorisation procedure.

A transfer of clinical data that falls under the GDPR (ie, non-anonymised data) is generally only possible if covered by the informed consent of the trial participants. Whether – in the absence of express informed consent by the trial participants – the transfer of such data can also be justified by the purposes of scientific research under Article 9(2) lit. j of the GDPR depends on the specific situation.

2.6 Databases Containing Personal or Sensitive Data

The creation of a database containing personal data of trial subjects would need to comply with

the requirements set out in the GDPR. Notably, the trial participants need to be informed about the use and storage of their data in such a database, and the database must meet applicable data security requirements. To the extent that the database is operated by a third party, that third party must itself comply with the GDPR. To the extent that the database is hosted outside the EU, or data are otherwise transferred outside the EU, the rules and ECJ case law regarding the transfer of personal data out of the EU must be complied with. Further data protection regulation is to be expected once the EC's draft regulation to establish a European Health Data Space (EHDS), which includes the secondary use of data, comes into force.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

German law defines pharmaceuticals as substances or preparations made from substances that are intended to treat, mitigate or prevent diseases or to restore, correct or modify physiological functions through a pharmacological, immunological or metabolic effect, or to make a medical diagnosis. Medical devices are defined as products – including devices, instruments, in vitro diagnostics, software, but also substances – that are intended for a medical use, but which achieve their principal intended action in or on the human body by means other than pharmacological, immunological or metabolic means.

Accordingly, the key criteria for classifying borderline products as either a pharmaceutical or a medical device relates to:

- identifying the principal intended purpose; and
- analysing whether such purpose is achieved by pharmacological, immunological or metabolic means.

Guidance on the interpretation of these terms has been published by the Medical Devices Coordination Group (MDCG), an EU expert body established under the MDR. The MDCG Guidance 2022–25 carries substantial weight and is available in its most current (April 2022) version via the EC website. Further guidance with specific examples can be found in the so-called "Borderline Manual" (current Version 3 of September 2023), also prepared by MDCG.

The responsibility for classifying a product appropriately lies with its manufacturer. If a product is granted an MA as a pharmaceutical, it will be considered as a pharmaceutical as long as the MA is in force. Conversely, however, Conformité Européenne (CE)-marking a product after conformity assessment in accordance with medical device law does not ensure that the implied classification as a medical device will be upheld if challenged by regulators or by competitors in court. Nevertheless, a manufacturer or the state supervisory authorities can apply to the BfArM for a binding decision as to whether the product in question qualifies as a medical device. The BfArM, in turn, may refer any such request to the EC for a decision by way of implementing the acts pursuant to Article 4 of the MDR.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

German law does not, in principle, provide for different MA procedures for biological medicinal products (unlike, for example, the USA). However, the requirements regarding the contents of the dossier are different from those for biologi-

cal medicinal products, owing to the importance of the manufacturing process of the biological medicinal product. Similarly, the MAs of biosimilars require substantially more documentation than MAs for generics of non-biological originator medicines.

Procedurally, MAs for biological medicinal products – provided they are not authorised by the EC under an EU-wide centralised MA – are granted by the PEI rather than the BfArM (see **1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices**).

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

MAs are issued for an initial period of five years. If renewed upon request, at least nine months prior to the expiry of its initial term, the MA remains valid for an unlimited period of time. The MA may, upon renewal, be limited again for a five-year period only if the initial five-year period did not provide sufficient real-life data to guarantee the safety of the medicinal product.

An MA can be suspended or revoked if legal requirements for the MA – for example, safety, efficacy and quality – are not met or are no longer met. Furthermore, an MA can be revoked under the "sunset clause" if the authorised pharmaceutical is not placed on the market within three years of the issuance of the MA or if the marketing of a pharmaceutical placed in the market is suspended for three successive years.

For medical devices, certificates issued by notified bodies that support the CE-marking of the medical device by the manufacturer are valid for up to five years. Certificates issued by notified bodies can be reduced in scope, suspended or revoked by the notified body if the requirements for issuance of the certificate are not met or are no longer met.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

An MA for a pharmaceutical for human use can be obtained by the following means.

- Centralised procedure – through an application to the European Medicines Agency (EMA), with a view to obtaining a centralised MA valid in the entire EU/European Economic Area (EEA). The EMA shall give an opinion on the application within 210 days and the opinion is the basis for the decision by the EC to grant the centralised MA.
- National procedure – through an application to the BfArM (or to the PEI for biological pharmaceuticals), with a view to obtaining a national MA valid in Germany. The statutory timeframe for issuing the MA is seven months upon receipt of a completed application. Where a national MA is to be applied for in several member states (decentralised procedure, or DCP), the reference member state will draw up a draft assessment report within 120 days and each member state shall take a decision within 90 days of receipt of these drafts. Where a national MA for the medicine has already been issued in another member state, that member state must submit an up-to-date assessment of the approved assessment to the German authority, which will make a decision on the application based on the other state's assessment within another 90 days (mutual recognition procedure, or MRP).

Changes to MAs for pharmaceuticals are submitted electronically to the competent regulatory authority (the EMA, the BfArM, or the PEI).

Depending on their impact on the safety, quality and efficacy of the product, variations are classified as IA, IB or II. The former only require a notification, whereas the latter require prior approval.

Centralised MAs can be transferred following the procedure set out in Regulation (EC) No 2141/96. MAs issued by German authorities are transferred by contractual agreement between the current holder and future holder, and the new MA holder is subsequently notified to the competent federal regulatory authority (the BfArM or the PEI).

For medical devices, the CE mark may be affixed to the device once the manufacturer has conducted a conformity assessment. Depending on the risk-classification of the medical device, the conformity assessment requires the involvement of a notified body and the issuance of the certification by that notified body. A transfer of the CE mark is not possible legally; rather, the new manufacturer of the medical device must obtain and meet all the requirements necessary to CE-mark the medical device under their own name.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

Besides clinical trials, pharmaceuticals that require an MA but are not authorised (yet) may only be supplied to patients in the following scenarios.

- Compassionate-use programmes – for patients with a chronically or seriously debilitating disease (or whose disease is considered to be life-threatening) who cannot be treated satisfactorily by an authorised medicinal product. The pharmaceutical concerned must either be the subject of a pending MA application or must be undergoing clinical trials. In Germany, pharmaceuticals supplied under a compassionate-use programme may only be supplied free of charge.
- Named-patient programmes – upon prescription for a specific patient, pharmacies may import and dispense to that patient a limited quantity of medicinal products that are authorised in the country of export (but not in Germany) if no comparable medicines are available in Germany. A named-patient programme does not need to be authorised or notified to a regulatory authority.

German medical device law does not provide for compassionate-use programmes or named-patient exceptions for medical devices that need to bear a CE mark. However, the BfArM may – upon request in individual cases – authorise the use of non-CE-marked devices under Section 7 of the MPDG (see Article 59 of the MDR) if their use is in the interest of public health or patient safety or health.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

For pharmaceuticals, the MA holders must fulfil several ongoing obligations, including the following:

- to keep the dossier of the product up to date and notify, or submit variations to, the competent regulatory authority if the particulars set out in the MA change;
- to set up, maintain and audit a pharmacovigilance system, appoint a qualified person for pharmacovigilance (*Stufenplanbeauftragter*), maintain a pharmacovigilance master file, operate a risk management system for the pharmaceuticals, document and report suspected adverse reactions, monitor scien-

tific literature for safety signals, prepare and submit periodic safety update reports;
- to appoint an information officer (*Informationsbeauftragter*) who is responsible for ensuring that the product labelling, package-insert leaflets, and summary of product characteristics, as well as all promotional material, is in line with the terms of the MA; and
- to take out and maintain product liability insurance that fully covers the specific statutory no-fault liability of the MA holder under the AMG.

Similarly, manufacturers of medical devices – ie, those who are indicated as the manufacturer in the labelling – are subject to a number of obligations under the MDR/IVDR, including the following:

- to keep the technical documentation of the device up to date;
- to appoint a person responsible for regulatory compliance (PRRC);
- to maintain and provide unique device identifier (UDI) information to improve the traceability of medical devices; and
- to comply with technovigilance reporting obligations, conduct post-market clinical follow-up (PMCF) activities, prepare post-market surveillance (PMS) reports or regular periodic safety update reports (PSUR), and prepare trend reports on safety signals. Further ongoing obligations for post-market surveillance can be derived from the manufacturer's quality system, which typically implements the requirements of the harmonised technical standard ISO 13485:2016.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

Although the EMA does publish a list of "medicines under evaluation", the German federal regulators do not proactively publish pending MA applications under review. Details about approved pharmaceuticals are available in the public section of the database "AMIce" (*Arzneimittel-Informationssystem*).

Requests for information about pending, granted or rejected MA applications can be submitted to the BfArM or the PEI under the German Freedom of Information Act (*Informationsfreiheitsgesetz*, or IFG). However, to the extent that the requested information contains personal data, is protected by IP rights or constitutes confidential business information, that information will be redacted or will not be disclosed. The authority will typically ask the MA holder whether they consent to the requested disclosure and will allow for comment on the proposed redactions. Generally, the German regulatory authorities are more protective of the MA holder's information than the EMA.

As medical devices are not subject to a governmental approval process under current medical device law, any information about medical devices undergoing conformity assessment remains with the manufacturer and the notified body, who – as private parties – are not subject to the Freedom of Information Act. For medical devices placed on the market in Germany and notified to the BfArM, a limited set of information is available on the DMIDS database (accessible through the BfArM website). Under the MDR and the IVDR, certain information about medical devices is already made publicly available through the Eudamed database – namely, basic information about the economic operators (manufacturers, importers, distributors), about devices and

about CE certificates issued by notified bodies. Eudamed will be expanded in the coming years to make certain clinical trial and performance evaluation data, PMS and vigilance information (such as field safety notices), and market surveillance information of the supervisory authorities publicly available also.

3.8 Rules Against Illegal Medicines and/or Medical Devices

With regard to pharmaceuticals, the EU Falsified Medicines Directive (Directive 2011/62/EU) has been implemented into German drug law on the following basis.

- To prevent falsified prescription-only medicines entering the supply chain, prescription-only medicines must bear an anti-tampering device (eg, a sealing strip), which allows verification that the pack has not been opened, and a unique identifier to verify the authenticity of the pack (serialisation) – the details are set forth in the Delegated Regulation (EU) 2016/161.
- The import and distribution of falsified pharmaceuticals in Germany is expressly prohibited and is subject to penal sanctions. The regulatory authorities are authorised to take enforcement action against falsified medicines, including seizure.
- MA holders, wholesale distributors, and pharmacies are subject to increased control and notification obligations to identify and report falsified medicines.

Under the MDR and the IVDR, importers and distributors of medical devices have the obligation to inform the competent authorities of suspected falsified devices. The authorities may, where necessary to protect public health, confiscate, destroy or otherwise render inoperable any such falsified devices.

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

The Federal Ministry of Finances and the customs authorities are responsible for enforcing German drug law with regard to pharmaceuticals imported from (or exported to) non-EU countries. The customs authorities will verify upon import the relevant import documentation, including whether a certificate attesting that the manufacture in the country of export complies with good manufacturing practices. If in doubt, the German customs authorities will liaise with the German regulatory authorities. German customs authorities regularly report on the numbers and types of intercepted counterfeit pharmaceuticals.

Similarly, the German customs authorities are responsible for enforcing compliance of imported medical devices with the applicable law, in accordance with Regulation (EC) No 765/2008. When determining further action, the German customs authorities will liaise with the competent German regulatory surveillance authorities if a medical device:

- displays characteristics that give cause to believe that the device presents a serious health or safety risk;
- is not accompanied by the required documentation or not marked as required; or
- has a CE mark that has been affixed to the device in a false or misleading manner.

In addition to the foregoing, border measures can be based on IP rights (see **10.1 Counterfeit Pharmaceuticals and Medical Devices**).

4. Manufacturing of Pharmaceuticals and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

The manufacture of pharmaceuticals (which also includes packaging, labelling and final release of the finished product) is subject to a manufacturing authorisation. The authorisation is granted by the competent authority of the federal state in which the manufacturing site is located. In order to obtain a manufacturing authorisation, the applicant must:

- appoint a Qualified Person (QP), as well as a Head of Production and a Head of Quality Control, each of whom must be appropriately qualified – the QP must also be experienced and reliable, to be evidenced through a clean criminal record certificate;
- have other appropriately qualified and trained personnel to conduct the manufacturing activities;
- have the appropriate premises for performing the manufacturing activities; and
- set up and maintain a quality system, consisting of standard operating procedures, which covers the manufacturing activities, and have the staff trained to its content.

The manufacturing licence will only be issued after a successful on-site inspection of the manufacturing premises by the regulatory authority. The statutory timeframe for issuing a manufacturing licence is three months from the submission of a complete application. However, follow-up requests by the authority or deficiencies identified in the inspection will stop the clock.

The manufacturing authorisation is granted for a specific site and typically for specific manufacturing activities and types of medicines – sometimes only covering individually specified medicinal products. It is issued for an unlimited time but remains subject to regular Good Manufacturing Practice (GMP) inspections by the competent authority.

The manufacture of medical devices is not subject to a governmental authorisation. The quality of the manufacturing processes is regulated indirectly through the conformity assessment of the respective device and the manufacturer's quality system, which supports the conformity assessment.

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

The wholesale distribution of pharmaceuticals is subject to a wholesale distribution licence (WDL). Wholesale distribution is not limited to the physical handling and storage of pharmaceuticals. A WDL is also needed for procuring, selling and supplying pharmaceuticals, even when the physical handling and logistics are outsourced to a third party. However, a manufacturer does not need a WDL for supplying and distributing pharmaceuticals that it has manufactured – any such supply and distribution is covered by the manufacturing licence.

The WDL is granted by the competent authority of the federal state in which the wholesale distribution site is located. In order to obtain a WDL, the applicant must:

- appoint a Responsible Person (RP) for wholesale distribution, who must be appropriately qualified, experienced and reliable – the latter to be evidenced through a clean criminal record certificate;
- have other appropriately qualified and trained personnel to conduct the wholesale distribution activities, as necessary;
- have the appropriate premises for performing the wholesale distribution activities; and
- set up and maintain a quality system, consisting of standard operating procedures, which covers the manufacturing activities, and have the staff trained to its content – this quality system shall in particular ensure that medicines are only sourced from (and supplied to) entities that are authorised to supply or procure such medicines, that all procurement and supply of pharmaceuticals is properly documented, and that recalls can be implemented.

The WDL will only be issued after a successful on-site inspection of the wholesale distribution site by the regulatory authority. The statutory timeframe for issuing a WDL is three months from the submission of a complete application. However, follow-up requests by the authority or deficiencies identified in the inspection will stop the clock.

As with a manufacturing authorisation, the WDL is granted for a specific site, for specific distribution activities and for specific types of medicines (including or excluding, for example, blood products, controlled substances, or temperature-controlled products). It is issued for an unlimited time, but remains subject to regular GDP inspections by the competent authority.

The distribution of medical devices is not subject to a governmental authorisation. However, under the MDR/IVDR, distributors are subject to certain obligations to ensure that only compliant medical devices are made available on the market (see Article 14 of the MDR/IVDR).

5.2 Different Classifications Applicable to Pharmaceuticals

See **1.3 Different Categories of Pharmaceuticals and Medical Devices**.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The import and export of pharmaceuticals is governed by the AMG – notably, its Sections 72 et seq.

The import of medical devices and in vitro diagnostics is regulated in the MDR and IVDR, respectively, by assigning regulatory responsibilities and duties to the importer where the manufacturer is not established in the EU and has not assigned an authorised EU representative (see **6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices**).

6.2 Importer of Record of Pharmaceuticals and Medical Devices

In order to import from outside the EU and EEA member states into Germany or to export from Germany outside the EU/EEA, an operator is required to have an EORI-number (EU-wide applicable customs registration number). Applying for a customs credit (deferred payment) and possibly providing a customs guarantee may allow the applicant to benefit from simplified

customs operations (eg, electronic customs declarations, payment of duties online, simplified procedures). In addition, an operator may choose to apply for the status of Authorised Economic Operator (AEO), which should entail a pre-approval for most customs authorisations.

With regard to regulatory requirements, see **6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices**.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Pharmaceuticals may only be imported from outside the EU and the EEA member states (Norway, Iceland and Liechtenstein) into Germany if an MA for any such pharmaceutical is in place and if the importer holds an import authorisation. The issuance, scope and resulting obligations of an import authorisation are analogous to a manufacturing authorisation (see **4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices**). Exemptions from the requirements of an MA and an import authorisation requirement apply, inter alia, to:

- pharmaceuticals for the importer's own scientific use (except for clinical trials);
- pharmaceuticals imported in small quantities by the MA holder or an authorised manufacturer as samples or for analytical purposes;
- pharmaceuticals imported by an authorised manufacturer for further processing;
- pharmaceuticals imported by an MA holder, authorised manufacturer or wholesale distributor intended for further shipment into other EU member states;
- pharmaceuticals imported in small quantities for personal use;
- samples imported for use by regulatory authorities; and
- imports by pharmacies in connection with a "named-patient programme" (see **3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations**).

The import of medical devices from outside the EU and the EEA member states into Germany does not require a governmental authorisation. However, the imported medical devices must be lawfully CE-marked (based on a complete conformity assessment) and the importer will bear the regulatory responsibility for the device if the manufacturer is based outside the EU/EEA and has not appointed an authorised representative. Under the MDR/IVDR, the importer is subject to additional obligations to ensure that only compliant medical devices are imported and made available on the market (see Article 13 of the MDR/IVDR).

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

The applicable non-tariff regulations depend on whether an imported product qualifies as a pharmaceutical, a medical device or another type of product. This in turn depends on whether that product meets the statutory product definition under the AMG or the applicable medical device regulations (for details, see **1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices** and **3.1 Product Classification: Pharmaceuticals or Medical Devices**).

6.5 Trade Blocs and Free Trade Agreements

Germany is a member of the EU and thus participates in the free trade arrangements concluded by the EU. It is also a member of the World Trade Organization (WTO).

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

Pharmaceuticals

The AMG (notably, its Section 78) and the German Drug Pricing Regulation (*Arzneimittelpreisverordnung*, or AMPreisV) set out whether pharmaceuticals are subject to price controls and, if so, also set out the price margins of wholesalers and pharmacies. Generally, only prescription-only pharmaceuticals that are dispensed in pharmacies are subject to price controls and fixed margins. Non-prescription pharmaceuticals, as well as prescription-only pharmaceuticals dispensed directly to hospitals, are exempt from the general statutory price controls.

Under German constitutional law, the pharmaceutical company is free to set its sales price. However, the public health insurance funds are not obliged to reimburse such prices in full. Rather, for pharmaceuticals that are subject to price control under the German AMG and German AMPreisV, the German Social Code V (*Sozialgesetzbuch V*, or SGB V) – which regulates the public health service and the public health insurance system that covers approximately 90% of the German population – provides for several price control mechanisms.

Early benefit assessment and reimbursement price negotiations (AMNOG)

As of 1 January 2011, the so-called AMNOG Act has introduced a price control mechanism for pharmaceuticals with a new active substance. Reimbursement prices for such innovative pharmaceuticals are negotiated between the MA holder and the Central Federal Association of Health Insurance Funds (*GKV-Spitzenverband*) on the basis of a so-called "benefit assessment". As of 12 November 2022, the Act to Stabilise the Financing of the Public Health Insurance (*GKV-FinStG*) has materially tightened the AMNOG rules with an effort to curb public prescription-drug spending.

The process has two consecutive preparatory phases of six months each, as follows.

- Phase 1 (one to six months after product launch in Germany) – upon the launch of the medicine on the German market, the MA holder must submit a dossier demonstrating (through clinical evidence) the additional therapeutic benefit of the new medicinal product in comparison with the so-called appropriate comparator therapy, ie current standard treatment. Orphan drugs enjoy certain exemptions from this requirement if the annual outpatient turnover in Germany does not exceed EUR30 million (EUR50 million prior to the *GKV-FinStG*). Based on the assessment of the data in the submitted dossier, the Federal Joint Committee of the German public health insurance system (*Gemeinsamer Bundesausschuss*, or GBA) determines the scope and degree of the additional therapeutic benefit of the new medicine.
- Phase 2 (seven to 12 months after product launch in Germany) – the additional therapeutic benefit determined by the GBA is a key factor for subsequent reimbursement price negotiations between the MA holder and *GKV-Spitzenverband* during the seven to 12 months following the launch. The *GKV-FinStG* has emphasised the prejudicial nature of the additional therapeutic benefit assessment on the negotiable reimbursement price by establishing several mandatory price ceilings linked to certain assessment outcomes. By way of example, if no additional therapeutic benefit is found and the comparator therapy is still

patent-protected, the negotiated reimbursement price for the new medicinal product must result in annual therapy cost that is at least 10% lower than the patent-protected comparator therapy, effectively penalising the new medicinal product. The agreed reimbursement price will apply retroactively for all patients in Germany (including those privately insured) from the seventh month of the market launch onwards (before the *GKV-FinStG* only from the 13th month onwards). If the MA holder and *GKV-Spitzenverband* fail to agree on a reimbursement price for the new medicine, a reimbursement price will be unilaterally set by an arbitration board, with retroactive effect to the seventh month since the market launch.

In the first year of the marketing, and until the reimbursement price kicks in at the beginning of the seventh month following the market launch, the new medicinal product will by default be reimbursed at the price set by the MA holder. With the new EU Health Technology Assessment (HTA) Regulation (EU) 2021/2282, the benefit assessment of new therapies will gradually be regulated for the first time at an EU level. Starting with new oncology pharmaceuticals and ATMPs only in January 2025, the assessment will take place in parallel with the EU regulatory MA process. The scope of the EU HTA process will be expanded to orphan drugs in January 2028 and to all other medicines in January 2030. As a result, the German AMNOG assessment procedures are expected to be adjusted to ensure a seamless link of the EU and national assessment procedures.

Reimbursement price caps for established therapeutic classes

The GBA can establish therapeutic classes of pharmaceuticals that cover a group of pharmaceuticals of similar or comparable active substance and comparable therapeutic effect. For each class, the GBA will set (and review annually) reimbursement price caps, which generally lie in the lower third of the range between the lowest price and the highest price of all pharmaceuticals in that class. Public health insurance will only reimburse these pharmaceuticals up to the cap; if the MA holder sets a higher price, the patient will need to pay the difference. This price control primarily, but not exclusively, affects generics.

Statutory rebates

MA holders must reimburse a statutory rebate of 7%, temporarily raised to 12% for the 2023 calendar year by the *GKV-FinStG*, (for patent-protected pharmaceuticals) and 16% (for generics and the corresponding off-patent reference pharmaceuticals) to public health insurance funds. Statutory rebates do not apply for pharmaceuticals in established therapeutic classes subject to the reimbursement price caps.

Price freeze

Since 1 August 2010, MA holders must pay back to public health insurance funds any increase in price beyond the price effective on 1 August 2009. Since 1 August 2018, the reference price level is adjusted annually for inflation. The price freeze, which has been prolonged until end of 2026 by the *GKV-FinStG,* does not apply where a reimbursement price is set based on the early benefit assessment or capped for an established therapeutic class. Current legislative initiatives seek to exempt supply-critical, off-patent pharmaceuticals without a therapeutic alternative from the price freeze.

The prices for pharmaceuticals that are not covered by Section 78 of the AMG and AMPreisV

(mainly non-reimbursable medicines) can be set or negotiated freely.

Medical Devices

German medical device law does not provide for price controls. German public healthcare law, in turn, does not provide for a common reimbursement and pricing mechanism for all medical devices. Rather:

- where medical devices are part of the outpatient medical therapy (eg, ophthalmic medical devices that can be implanted in an outpatient setting), the healthcare provider is generally reimbursed for the purchase price by the public health insurance fund – however, regional collective agreements may provide for particular reimbursement requirements and price caps; and
- medical devices prescribed by a healthcare provider that serve to secure the medical therapy, or mitigate or compensate the effects of injuries, are qualified as auxiliary devices (*Hilfsmittel*). Suppliers of auxiliary devices must meet pre-qualification requirements and enter into supply agreements with public health insurance funds in order to be entitled to supply (and be reimbursed for) auxiliary devices to insured patients. Furthermore, auxiliary devices may be grouped in established therapeutic classes similarly to pharmaceuticals, with a view to capping the reimbursement price.

7.2 Price Levels of Pharmaceuticals or Medical Devices

The actual sales price in other EU countries will be taken into account in the AMNOG reimbursement price negotiations for innovative pharmaceuticals (see **7.1 Price Control for Pharmaceuticals and Medical Devices**).

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

90% of the German population is enrolled in the statutory health system. These patients have a right to be provided with all treatments (including pharmaceuticals and medical devices), which are medically necessary, sufficient and cost-effective. This means that the coverage of pharmaceuticals is generally limited to prescription-only medicines, and the cost is controlled through various statutory price control mechanisms (see **7.1 Price Control for Pharmaceuticals and Medical Devices**) and by tenders of the statutory health insurance funds.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

The additional benefit of novel pharmaceuticals by comparison to the standard therapy is a key factor in negotiating the reimbursement price (see **7.1 Price Control for Pharmaceuticals and Medical Devices**).

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Physicians are subject to various mechanisms to ensure that their prescribing of pharmaceuticals is cost-efficient. Physicians who prescribe excessively may be required to pay damages to the public healthcare system.

In order to curb pharmaceutical spending, pharmacies must observe several substitution rules designed to increase the dispensing of generics or cheaper parallel-imported pharmaceuticals rather than originator products. A pharmacist who fails to comply with those substitution rules must pay back to the public healthcare system the full price of the dispensed product, without the option to offset the theoretical cost of the

cheaper alternative that should have been dispensed under the substitution rules.

8. Digital Healthcare

8.1 Rules for Medical Apps

Medical apps may qualify as medical devices if the app meets the definition of a medical device (see **3.1 Product Classification: Pharmaceuticals or Medical Devices**). The MDCG Guidance 2019-11 on the qualification and classification of software offers additional criteria to operationalise the general medical device definition for software. A key criterion within the five-step decision tree proposed by the MDCG Guidance 2019-11 is whether the app performs actions on data for a specific patient that go beyond mere storage, archival, lossless compression, communication, or simple search. One test is whether the app creates or modifies medical information through its own algorithm.

Many medical apps that were classified as risk class I before the MDR may classify as class IIa or higher under the MDR. As a result, their re-certification under the MDR will require the involvement of a notified body (see **3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices**). Until (re-)certification under the MDR, such apps may continue to be marketed under their pre-MDR certification until 31 December 2028 – subject to several conditions, including that their design and intended purpose are not significantly changed.

If a medical app qualifies as a medical device of class I, IIa or IIb, that medical app can qualify as a Digital Health Application (DiGA) and be eligible for prescription by physicians and reimbursement by the public health insurance system ("app on prescription"). This reimbursement mechanism for medical apps was introduced in late 2019 and is the first statutory reimbursement mechanism for medical apps in the world. In order to be included in the DiGA Directory of reimbursable apps, the manufacturer of the DiGA must submit an application to the BfArM, showing that:

- the main function and medical purpose of the DiGA is based on digital technologies and functions;
- beyond security and functionality (evidenced through the CE mark), quality, data protection, data security and inter-operability requirements are met; and
- the use of the DiGA provides positive healthcare effects (patient-relevant medical benefit, structural and procedural improvements in healthcare) – as to medical devices of class IIb, the use must provide a medical benefit.

If positive care effects are not excluded, but supporting data is not yet available, DiGAs can be temporarily admitted to the DiGA Directory for up to 12 months (in exceptional cases, 24 months) to generate that data. Once the data is available, the reimbursement price for the DiGA will be negotiated in a process that is comparable to the AMNOG procedure for novel pharmaceuticals (see **7.1 Price Control for Pharmaceuticals and Medical Devices**). In 2021, the DiGA concept was extended to Digital Nursing Apps (DiPA), such as fall prevention apps or personalised memory games for people with dementia.

8.2 Rules for Telemedicine

German doctors may provide telemedicine services where face-to-face patient contact is not medically required. In 2019, the anachronistic prohibitions to advertise for such telemedicine services and to dispense medicines prescribed

through a telemedicine service have been lifted. However, the promotion of telemedicine services remains challenging because new case law only allows the promotion of telemedicine services to the extent that it is proven that the promoted service complies with generally accepted professional standards.

In the public healthcare system, the telemedicine services that are reimbursed to the doctors are growing. Pushed forward with the recently passed Digital Act, telemedicine will become an integral part of statutory healthcare. To this end, the previous quantity restriction on video consultations (previously a maximum 30% of all treatment cases) has been lifted. At the same time, medical remuneration is more strongly oriented towards quality features. The collective agreement between *GKV-Spitzenverband* and the doctors' head association sets out requirements on patient authentication, data privacy and quality requirements for the telemedicine service provider that must be complied with in the public healthcare system.

8.3 Promoting and/or Advertising on an Online Platform

There are no special rules for the online promotion and/or advertising of medicines and medical devices. Rather, companies promoting their medicines or medical devices online must comply with all applicable requirements, including advertising limitations set forth in the Health Product Advertising Act (*Heilmittelwerbegesetz*, or HWG), pharmacovigilance obligations, and data privacy and telecommunications laws.

8.4 Electronic Prescriptions

From a regulatory perspective, German drug law (the German Drug Prescription Regulation (*Arzneimittelverschreibungsverordnung,* or AMVV)) and German medical device law (the German Medical Device Dispensing Regulation (*Medizinprodukte-Abgabeverordnung*, or MPAV)) already allow prescriptions to be issued electronically and be signed by electronic qualified signature.

For patients insured in the public health insurance system (see **7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds**), the issuance of e-prescriptions for prescription-only drugs is obligatory as of January 2024. The e-prescription issued by the physician is stored and encrypted in a central database of the federal government's telematics infrastructure provided by the National Agency for Digital Medicine (*gematic*), which pharmacies can access. Patients can thus redeem their e-prescription (consisting of a token) either via app, electronic health card or via paper printout at their preferred pharmacy. It is also possible to integrate e-prescriptions into the electronic patient record. The scope is likely to be gradually expanded to all pharmaceuticals.

8.5 Online Sales of Medicines and Medical Devices

Medicines and medical devices may be sold online. German pharmacies may also sell both prescription-only and pharmacy-only medicines online if:

- the pharmacist also holds a mail order pharmacy permit (*Versandhandelserlaubnis*); and
- the mail order business is conducted "out of the pharmacy" in addition to the retail pharmacy business.

Mail order pharmacy activities are not permitted in Germany without running a "bricks-and-mortar" pharmacy.

In addition to German pharmacies, several Dutch online pharmacies located at the Dutch/German

border supply the German market, leveraging the free movement of goods within the EU.

8.6 Electronic Health Records

In the public health system, which covers approximately 90% of the German population, the electronic patient record (ePA) is currently being rolled out and will be implemented nationwide and automatically for all publicly insured persons by 2025. The Digital Act provides for an opt-out procedure to enhance the amount of users. The ePA is regulated in the Social Code V (see **7.1 Price Control for Pharmaceuticals and Medical Devices**). In addition to the German legislation, the digitalisation of health records is currently enhanced by the EC's proposal for the EHDS, which primarily aims to facilitate cross-border access to and exchange of health data (so-called primary use of data).

As electronic health records qualify as "special category data" under the GDPR, the considerations on clinical trial data in **2.5 Use of Resulting Data From Clinical Trials** apply mutatis mutandis to electronic health records.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices

In Germany, the Patent Act contains the relevant provisions for patents.

There is a huge variety of general patent law issues that can become relevant for pharmaceuticals and medical device products, ranging from the determination of the widest possible scope when applying for a patent to a potential infringement under the doctrine of equivalents in infringement proceedings. In addition, the specific provisions regarding a second and subsequent medical use – as well as the extension of the patent term by way of a supplementary protection certificate set out in **9.3 Patent Term Extension for Pharmaceuticals** – often play an important role. Not strictly resulting from patent law provisions, yet of great relevance in patent strategies and litigation, agreements between originators and generic entrants may also be considered as anti-competitive.

There are no specific patentability requirements for pharmaceuticals or medical devices as such. Even though methods for treatment by surgery or therapy and diagnostic methods are not patentable, the use of substances in these methods is explicitly not covered and thus patentable. Further restrictions regarding patentability relate to processes for cloning human beings and for modifying the germinal genetic identity of human beings.

9.2 Second and Subsequent Medical Uses

A second or subsequent medical use is patentable if the medical indication is new. Therefore, the type of application or the area of use must not be previously known.

However, generally, it is not sufficient to modify the dosage regime even if this improves the effectiveness of the drug. Notwithstanding, the discovery of the use for new patient populations is patentable if the new patient group can be clearly distinguished from the previously known group.

The preparation and use of the drug for the claimed (second or subsequent) use constitutes patent infringement regarding the (new) patent. Preparation for such use can result from instruc-

tions for use delivered with the drug. Nevertheless, the drug can be used in a non-infringing manner for the previously known purpose, provided that this application is not protected (anymore). If there is a prior product patent with broad claims, the patent covering a second or subsequent use may be a dependent invention.

9.3 Patent Term Extension for Pharmaceuticals

The patent holder of an authorised medicinal product can apply for a supplementary protection certificate (SPC) within six months following the grant of the MA. The SPC can extend the protection term by the time that elapsed between the application for the patent and the MA, reduced by five years. This potential extension is limited to five years, plus six months in cases with completed studies in compliance with an agreed paediatric investigation plan. For each medicinal product, only one SPC can be granted, and the product must be covered by a first MA.

Generally, the certificate confers the same rights as the basic patent, with certain limitations regarding the intended export of the products.

Any third party can bring an action for declaration of invalidity of the certificate before the German Federal Patent Court, according to Section 81 of the German Patent Act.

9.4 Pharmaceutical or Medical Device Patent Infringement

As for any product patent, infringing actions include the manufacturing, offering, placing on the market or use of a product, as well as importing or possessing it to these ends. Advertising a product may also infringe a patent, even if the advertising only relates to subsequent distribution after the lapsing of the patent.

In order to get injunctive relief, the infringement must be (at least) imminent. The application for an MA is not considered to fulfil the requirement of imminent infringement.

In the case of a medical product that has been authorised more than a year before the term of the patent, but which has not been brought on to the market since, the Higher Regional Court of Düsseldorf found that the grant of the authorisation was generally not sufficient to show that infringement was imminent. Thus, the court rejected imminent infringement, provided that the authorisation would not be withdrawn if it were not used until the end of the patent term.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

The German Patent Act provides for an experimental use exemption and, in particular, for the "Roche-Bolar" exemption, which allows the generic entrant to proceed with the application for an MA before the expiry of the patent. The exemption covers all actions that are necessary in order to receive the MA.

Furthermore, there is a (theoretical) option for compulsory licences based on Section 24 of the German Patent Act. Even though this option is not strictly limited to pharmaceuticals or medical devices, the only case in which such a compulsory licence has been granted by the Federal Patent Court (upheld by the Federal Court of Justice) was related to a pharmaceutical product (an anti-retroviral HIV/AIDS medicinal product called "Isentress"). The interested licensee must apply for the grant of the compulsory licence and demonstrate:

- that they failed to receive a licence in compliance with reasonable and common business

practices after having tried to receive that licence throughout a reasonable period of time; and
- that the public interest requires the granting of a compulsory licence.

9.6 Proceedings for Patent Infringement

Typically, the patent holder and the exclusive licensee can bring proceedings for patent infringement. The action can include claims for injunctive relief, rendering of accounts, and recall and destruction of infringing products, as well as damages.

The typical procedure begins at one of the most commonly used regional courts for patent litigation, which are Düsseldorf, Mannheim and Munich. The first-instance decision, which is provisionally enforceable, will be reached within eight to 15 months, depending on the court. This decision can be appealed before the higher regional court.

These actions can be requested as preliminary measures – in which case, the courts would generally require that the patent in suit has survived an inter partes validity attack. However, this requirement is often not applied to preliminary measures against generic entrants, meaning preliminary injunctions can be granted. In spring 2021, the Higher Regional Court of Munich requested a preliminary ruling of the ECJ on whether the general requirement of inter partes validity proceedings in order to grant a preliminary injunction is compliant with the IP Enforcement Directive.

Given that Germany has a bifurcated patent system, invalidity is not available as a defence in infringement proceedings on the merits. The alleged infringer must bring a separate nullity action before the Federal Patent Court to invalidate the patent. This nullity action usually takes more than two years, resulting in a so-called injunction gap between the (provisionally) enforceable infringement decision containing injunctive relief and the potential declaration of nullity of the patent in suit. A legislative reform in summer 2021 tightened procedural timelines to close this injunction gap – the statement of defence against a nullity action must now be filed within two months and, as of spring 2022, the German Federal Patent Court will provide a "qualified notice" containing its preliminary assessment of a pending nullity action within six months from filing the action.

9.7 Procedures Available to a Generic Entrant

Even though German courts tend to be strict when granting preliminary injunctions if the patent has not been confirmed in inter partes validity proceedings, they often make an exception for cases against generic entrants. Therefore, if a generic entrant wishes to enter the market before the expiry of the originator's patent, they could file a nullity action before the Federal Patent Court in order to make sure that the potentially infringed patent will be invalidated before market entry. However, this option is very expensive and time-consuming.

There is no patent linkage system in place. Patent law and the laws governing the MA of a generic drug are separate in Germany.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Other than using patent law, an IP rights holder can take action against counterfeit pharmaceu-

ticals and medical devices primarily based on trade mark law.

Trade mark infringement grants the rights holder various remedies, including claims against the counterfeiter to cease and desist infringing the trade mark, claims for damages and siphoning off the profits, and claims for destruction of the infringing products. In order to prevent counterfeit medicines from being imported, the rights holder can also (under Regulation (EU) No 608/2013) request the customs authorities to detain products suspected of infringing the holder's trade marks for further determination. Furthermore, trade mark infringement can be criminally sanctioned and expose the counterfeiter to imprisonment of up to three years or to monetary fines.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Pharmaceuticals may not use names which are misleading, particularly regarding the efficacy and safety of the product (Section 8 of the AMG). Similarly, Article 7 of the MDR and the IVDR prohibit the use of any trade mark, name or text in the labelling, instructions claims, marketing and promotion that may mislead the patient regarding the device's intended purpose, safety or performance.

The regulatory authorities have issued guidelines specifically in relation to pharmaceuticals on the acceptability of names or human medicinal products. For pharmaceuticals to be authorised centrally by the EC, the guideline by the EMA applies. For pharmaceuticals to be approved nationally, the guideline by the BfArM and the PEI applies. Both guidelines set out further requirements and recommendations for developing an invented name for the pharmaceutical. The German guideline also addresses under which conditions one brand name can be used as an umbrella brand for several products of a product family.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

The trade dress and design of pharmaceuticals, medical devices and their packaging may be protected by design rights and by copyright (and potentially also by trade marks). This protection will depend on whether the trade dress or design in question meets the criteria for any such protection. Registering design rights may present a relatively inexpensive way to protect the design of pharmaceuticals and particularly medical devices. Furthermore, the Act against Unfair Trade Practices (*Gesetz gegen den unlauteren Wettbewerb*, or UWG) may afford the product owner claims against competitors who pass off their products as the original products.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

For pharmaceuticals, the data provided by the MA holder in support of the MA application is protected by regulatory data exclusivity for eight years following the granting of the MA. For this eight-year period, other applicants may not cross-refer to the original clinical and pre-clinical data in support of an MA application for a generic copy of the pharmaceutical.

Furthermore, a generic product for which an MA has been granted through reference to the originator MA data may only be placed on the market ten years after the granting of the original MA. If, during the first eight years, a new therapeutic indication has been added to the original MA that brings a major clinical advantage in comparison to existing therapies, the marketing exclusivity can be extended by up to one more year

to 11 years (this is known as the "8+2+1" rule). These rules apply equally to chemical drugs and biologics.

This regulatory data protection and marketing exclusivity periods are expected to be reduced – or conditioned on additional requirements – in the future, as part of the EU's proposed revision of its general pharmaceutical legislation (the so-called EU Pharma Package). In order to promote the availability of pharmaceuticals across the EU, the proposal of the EC conditions the eight-year regulatory data protection period to the pharmaceutical being made available in all EU members states within the first 24 months of launch, lest the regulatory data protection period be reduced to six years. Counter-proposals by the EU Parliament point in opposite directions. The ultimate impact of the EU Pharma Package on data and market exclusivity periods will depend on the outcome of the upcoming political negotiations in the EU.

For medical devices, no data exclusivity rules apply because medical devices do not require an MA.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

On the basis of the amended German Protection Infection Act, the BfArM has been granted authority to grant exemptions from various requirements of German drug law. This included, where necessary, granting:

- exemptions from requirements applicable to clinical trials, MA applications, import of medicines, and compassionate-use programmes; and
- permissions to distribute medicines:
  (a) with non-compliant labelling;
  (b) that had not been manufactured in full compliance with GMP; or
  (c) that were past their expiry date.

This authority expired on 31 December 2023.

As regards medical devices, based on the Commission Recommendation 2020/403, special temporary regimes allowing for the placing on the market of face masks that were not CE-marked were in place until late summer 2020 and enforcement against non-compliant face masks was limited to those presenting a health hazard. Since face masks are no longer in short supply, regulatory enforcement against non-CE-marked face masks has increased (see also the updated Commission Recommendation (EU) 2021/1433).

11.2 Special Measures Relating to Clinical Trials

The EMA issued guidance on the management of clinical trials during the COVID-19 pandemic, to which the BfArM issued complementing guidance. The EMA guidance provided that, subject to a number of specific circumstances, patients participating in clinical trials may have investigational medicines delivered to their homes – with that delivery to be carried out by the trial sites or hospital pharmacies or, exceptionally, through distributors.

As a result of the COVID-19 pandemic, decentralised clinical trials have become more and more relevant. To facilitate the conduct of such clinical trials, the current draft Act on Medical Research (*Medizinforschungsgesetz*) foresees the direct dispensing of pharmaceuticals by

doctors to participants in clinical trials, provided that the safety and pseudonymisation of the participants and the validity of collected data are guaranteed and approval has been granted by the competent higher federal authority.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

In 2022, importers and manufacturers of face masks requested that the BfArM exempt them from performing a full conformity assessment for non-CE-marked imported masks under the legacy medical devices rules applicable before 26 May 2021 (see Article 59 of the MDR, which is currently applicable) and permit them to rely on a fast-track assessment by certain notified bodies. Given that face masks are no longer in short supply, this pathway is no longer permitted.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

Generally, GMP certificates for manufacturing and importing sites in the EEA have been automatically extended until the end of 2024.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

In March 2020, the German government issued a temporary decree imposing an export ban on certain personal protective equipment such as protective masks. Subsequently, the enforcement of the regulations applicable to face masks imported into the EU and Germany was temporarily halted but has resumed since (see **11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices**).

11.6 Drivers for Digital Health Innovation Due to COVID-19

The German healthcare system is undergoing a concerted digitalisation effort, including the wider use of telemedicine (enhanced by the recently passed Digital Act), which had been initiated before and independently of COVID-19. According to public polls, however, COVID-19 has sparked both more doctors to provide – and more patients to use – telemedicine services.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

The German government has not announced any intention to issue compulsory licences for treatments or vaccines related to COVID-19. However, the German Infection Protection Act states that the Federal Ministry of Health is entitled to issue an order whereby an invention is to be used in the interest of the public welfare (Section 13 of German Patent Act). Revisions on the compulsory licensing of IP rights at an EU level can be expected – initiated by the EC's EU patent reform proposal (the so-called EU Patent Package), which aims to tackle cross-border crises within the EU, including public health emergencies.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

No liability exemptions have been introduced for COVID-19 treatments or vaccines. The general liability rules for pharmaceuticals apply. As an exception thereto, liability exemptions applied to pharmaceutical companies whose COVID-19 treatments or vaccines had been procured and supplied by the Germany government despite not meeting certain requirements of applicable drug law; those liability exemptions expired on 31 December 2023.

11.9 Requisition or Conversion of Manufacturing Sites

No manufacturing sites in Germany have been requisitioned or converted due to COVID-19.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

The general rules governing public procurement have not been changed owing to COVID-19. Based on the amendments to the German Infection Protection Act in response to the COVID-19 pandemic, the federal government can promulgate regulations allowing the government to take measures for procuring and stockpiling drugs and other necessary products should an epidemic situation of national scope be announced by the German Parliament.

In May 2020, the German Parliament passed a regulation permitting the central procurement of certain medical products (including pharmaceuticals, medical devices, and laboratory diagnostics) by the Federal Ministry of Health. The regulation expired on 31 December 2023. A number of tenders suggest that public purchases are increasingly placing stronger emphasis on more local manufacture and supply chain resilience.

Trends and Developments

Contributed by:
Ulrich Grau, Constanze Püschel and Tobias Volkwein
D+B Lawyers

D+B Lawyers was established in 1997 as Dierks + Bohle and has since grown into a legal firm with eight equity partners. As part of a collective experience within the firm, each partner contributes to D+B's expertise and continuity. Specialising solely in healthcare law, the firm's team of 34 lawyers offers advisory services, focusing particularly on areas such as statutory health insurance, data protection, and digital health. D+B's clients include pharmaceutical companies, medical technology firms, healthcare practitioners, and governmental bodies. The firm operates across three core departments: pharmaceuticals and pharmacies, panel doctor legal affairs, and hospital law. Headquartered in Berlin, with additional offices in Düsseldorf and Brussels, D+B Lawyers aims for both national and international expansion, continually strengthening its network and team to address legal needs. Recently, D+B Lawyers has provided legal assistance to clients such as ALK Abelo, PINK! gegen Brustkrebs GmbH, Sanero Medical GmbH, SOFY GmbH, and the state hospital associations of Berlin and Brandenburg.

Authors

Ulrich Grau is a partner at D+B Lawyers, where he specialises in a range of legal areas, including supplement pharmaceuticals and medical device law, protection of industrial property, medical/therapeutic services law, hospital law, and public procurement law. Ulrich has been recognised for his expertise and is ranked in Chambers and Partners' Europe 2024 Guide. Actively involved in legal associations such as the German Association for the Protection of Intellectual Property and the Chamber of Attorneys in Berlin since 1999, Ulrich is known for his dedication and contributions to the legal field.

Constanze Püschel is a legal professional known for her expertise in supplement pharmaceuticals and medical device law, biotechnology, medical law, and regulatory consultation. With a Doctor of Laws degree from Hamburg University and more than two decades of experience, she has been recognised for her contributions, including being acknowledged by Handelsblatt as one of the "Best Lawyers in Germany 2024" for biotechnology. As a partner at D+B Lawyers, Constanze's industry knowledge and commitment to excellence have positioned her as a notable figure in the legal landscape, especially within the healthcare and biotechnology sectors.

Contributed by: Ulrich Grau, Constanze Püschel and Tobias Volkwein, **D+B Lawyers**

Tobias Volkwein is recognised for his expertise in medical law and regulatory consultation. Tobias obtained his Doctor of Laws degree from the University of Cologne in 2009 and was admitted to the Bar in 2010. Throughout his career, Tobias has held various legal positions, including serving as in-house counsel for an international biotechnology company. With his extensive experience and specialisation in medical law, Tobias contributes significantly to the legal field as a partner at D+B Lawyers.

D + B Lawyers

Kurfürstendamm 195
D-10707
Berlin
Germany

Tel: +49 30 327787-0
Fax: +49 30 327787-77
Email: office@db-law.de
Web: www.db-law.de

D+B LAWYERS

An Introduction to the German Life Sciences Industry in 2024

Overview of Germany's healthcare system

For more than 100 years, Germany's healthcare system has been based on statutory health insurance (*gesetzliche Krankenversicherung*, or GKV). Today, approximately 74 out of 83 million inhabitants are covered by statutory health insurance, whereas only 10 million patients are privately insured. Statutory health insurance funds spend almost EUR300 billion per year on services for their insured. Hence, statutory health insurance funds have an important impact on all stakeholders in the life sciences industry. This leads to a highly regulated life sciences sector, with a major emphasis on the cost-benefit ratio of services provided.

Impact of statutory health insurance

In addition to the density and quantity of regulations, life sciences is one of the most complex and rapidly changing regulatory branches. An almost disruptive change to the statutory health insurance system, in particular, was observed during the legislation when Jens Spahn was Minister of Health between mid-2017 and the end of 2021. Since 2020, the COVID-19 pandemic situation has emerged as the leader in terms of actions by the legislator – refreshed by the Minister of Health, Professor Karl Lauterbach, who was installed at the end of 2021.

Digitisation initiatives and regulatory changes

Focus is still on the acceleration of digitisation, including installing electronic health records or electronic prescriptions. The further development of Digital Health Applications (DiGA) continues to raise a lot of specific questions following their introduction at the end of 2019, particularly with regard to reimbursement schemes. However, the implementation of the main digitisation instruments faced a lot of resistance in the past few years.

Finally, the e-prescription has been fully applicable since the beginning of 2024. With the adoption of the Health Data Use Act (*Gesundheitsdatennutzungsgesetz*, or GDNG) and the Digital Act (*Digital-Gesetz*, or DigiG) in February 2024, the German legislator took two further important steps on its digitisation path.

Focus on financial stability and medicinal supply

Another focus is the financial situation of the statutory health insurance system, which has worsened in the past years (most recently, during the COVID-19 pandemic). At the end of 2022, the legislator therefore introduced a strict law – the *GKV Financial Stabilisation Act (GKV-Finanzstabilisierungsgesetz*, or GKV-FinStG) – to stabilise statutory health insurance funding by avoiding a permanent rise in the premiums to be paid by its members. This had many impacts, particularly on the (lower) reimbursement of medicinal products in Germany.

Influence of EU directives on regulation

A third focus is the maintenance of a sustainable availability of (specifically, generic) medicines – again, something that has worsened in recent years. Therefore, at the beginning of 2023, the legislator published the Drug Delivery Shortage Control and Supply Improvement Act (*Arzneimittel-Lieferengpassbekämpfungs- und Versorgungsverbesserungsgesetz*, or ALBVVG).

Current developments and challenges for the industry

The regulatory framework for the life sciences industry is widely influenced by EU directives and regulations, especially concerning the marketability of pharmaceuticals and medical

devices. All in all, legal advice must cover many areas. This obviously includes legal know-how and expertise on life sciences regulations and extends to – inter alia – M&A, antitrust and competition, public procurement and data protection.

Evolution of market access and reimbursement

Manufacturers of pharmaceuticals have to deal with frequently amended regulations on market access and reimbursement of their products without losing sight of the fact that the German prices are a very relevant reference point for prices in many European countries, as well. The benefit assessment by the Federal Joint Committee (*Gemeinsamer Bundesausschuss*, or G-BA), based on the Act on the Reform of the Market for Medicinal Products (*Arzneimittelmarkt-Neuordnungsgesetz*, or AMNOG), has the greatest influence on the reimbursement prices.

Nevertheless, the GKV-FinStG of 2022 could essentially change the established system, which is mainly based on the benefit of the respective medicinal product as assessed by the G-BA. Instead, the GKV-FinStG widely introduces a schematic price corridor system linked to comparator drugs. According to the first evaluation at the end of 2023, the legislator currently does not deem it necessary to reconsider its "new approach", however.

Impact of legislative changes on pharmaceutical pricing

Further, in terms of of Advanced Therapy Medicinal Products (ATMPs), the pharmaceutical industry strives to adapt to the benefit assessment regulation and procedures. In this field, another deep impact of the GKV-FinStG has been felt. The sales threshold for Orphan Medicinal Products (OMPs), which are subject to a regular benefit assessment, will be reduced from EUR50 to EUR30 million.

Adaptations for Advanced Therapy Medicinal Products

Furthermore, the Regulation 2021/2282 on Health Technology Assessment (the "HTA Regulation") gets closer – in calling for a more collaborative framework in the EU – to improving business predictability and avoiding duplication of work and discrepancies between HTA mechanisms. The HTA Regulation will apply from 12 January 2025, starting with cancer medicines and ATMPs, before expanding to cover OMPs in 2028 and finally to cover all centrally authorised medicinal products in 2030.

In June 2023, an implementation rolling plan for 2023-24 was published. The European-wide orientation includes huge challenges for the German life sciences industry – as well as for G-BA, which organised a first information day in December 2023 for all affected stakeholders.

Challenges in clinical trials and regulatory simplification

As regards clinical trials, the implementation of the Clinical Trials Regulation (CTR) – and of its Clinical Trials Information System (CTIS), in particular – is still causing many practical issues for the industry. The good news is that the legislator published a draft for the Medical Research Act (*Medizinforschungsgesetz*) on 26 January 2024, aimed at simplifying and accelerating the approval procedures for clinical trials.

Another innovation for Germany in this field was the publication of Model Contract Clauses for Clinical Trials With Drugs, Conducted Under the Responsibility of a Pharmaceutical Company in November 2023. This joint initiative by German University Medicine (*Deutsche Hochschulmedi-*

zin, or DHM), KKS Network (academic clinical study centres), the pharmaceutical industry associations vfa and BPI, and the Federal Association of Contract Research Organisations (*Bundesverband Medizinischer Auftragsinstitute*, or BVMA) also aims to make Germany more attractive in this regard.

Anticipating the EU pharmaceutical law package

The "next big thing" for pharmaceutical entrepreneurs at a European level, behind the further legislative progress of the regulation introducing the European Health Data Space (EHDS), surely lies in the new EU pharmaceutical law package. On 26 April 2023, the EC presented the following legislative proposals for the revision of the EU medicinal products legislation:

- first, a proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use; and
- second, a proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency.

The proposals intend to repeal several European legal acts, including Directive 2001/83/EC and Regulation (EC) 726/2004. This revision is part of the implementation of the Pharmaceutical Strategy for Europe and aims to promote innovation while reducing the regulatory burden and environmental impact of medicinal products. Undoubtedly, this will also have a huge impact on the pharmaceutical industry in Germany and the proposals have already been heavily discussed.

Challenges for medical device manufacturers under the Medical Devices Regulation

Manufacturers of medical devices still face the challenge of adapting to the Medical Devices Regulation (MDR), which sets the regulatory frame for the marketability of their products. This demands an understanding of the new legal requirements and the implications for the certification process and the design of quality management systems. The industry in Germany was also relieved by the good news that, after months of discussions, the transitional provisions of the MDR were extended. However, even with more time, the preparation for stricter regulations remains challenging for the industry – with many questions still unanswered.

IRELAND

Trends and Developments

Contributed by:
Karen Gallagher, Hannah McLoughlin, Jane Bourke and Neil Keenan
Pinsent Masons (Ireland)

Pinsent Masons (Ireland) is a solutions-driven life sciences team that brings together experts in the field to provide clients with solutions to unprecedented legal challenges. Working in 20 EMEA offices, the team comprises more than 120 sector-focused lawyers, who understand the technical as well as legal issues – with many having scientific backgrounds, in-house industry experience and strong relationships with industry bodies. Pinsent Masons' team acts for some of the most innovative life sciences companies in the world, including pharmaceuticals, generic and biosimilar, biotech and medtech companies. The work aligns with the firm's purpose, leading on precedent-setting litigation and market-leading transactions that make a real difference in the world. Pinsent Masons offers businesses a holistic approach, with transactional, tax, competition, IP, medicines regulatory, dispute resolution, employment, product liability, cyber and data, public policy and compliance professionals working seamlessly together to support life sciences companies that push the boundaries of science and law.

Authors

Karen Gallagher is a partner at Pinsent Masons (Ireland), where she leads the patents and life sciences practice. Karen has more than ten years' experience in contentious IP work, providing strategic advice to clients in complex patent disputes and trade mark, design and copyright litigation. Her clients include global pharmaceuticals companies, generics and biosimilar clients, international brands, and technology and media companies. She has represented clients in precedent-setting patent infringement and revocation proceedings (with a particular focus on life sciences patent cases), trade mark infringement disputes, trade mark appeals, copyright and database rights disputes, and passing-off claims.

Hannah McLoughlin is an associate in the Pinsent Masons (Ireland) IP team. Hannah has acted as the lead associate in a number of high-profile pharmaceutical patent cases before the IP division of the Irish Commercial Court and the Court of Appeal, managing the day-to-day work on these matters. She has also advised clients on trade mark infringement and copyright licensing matters, as well as domain name dispute resolution procedures and social media take down requests. Hannah holds a diploma in IP and technology from the Law Society of Ireland.

Contributed by: Karen Gallagher, Hannah McLoughlin, Jane Bourke and Neil Keenan, **Pinsent Masons (Ireland)**

Jane Bourke is a senior associate in the Pinsent Masons (Ireland) IP team and has diverse experience of advising on contentious and non-contentious IP matters for life sciences clients. Jane holds a master's degree in IP and IT from University College Dublin and is a registered Irish trade mark agent. She lectures on trade marks, database rights and copyright issues as part of the Law Society of Ireland's IP and technology diploma. Jane is a previous chair and current member of the Law Society of Ireland's Technology Committee and also sits on MARQUES' Famous and Well-Known Marks Committee.

Neil Keenan is a corporate partner in Pinsent Masons (Ireland), where he leads on life sciences corporate work. Neil has 30 years' experience in M&A, venture capital, private equity, corporate governance and share schemes, acting on complex transactions in life sciences and other sectors. He has acted on several transactions for life sciences and healthcare companies, including recently for Sandoz in the acquisition of the remaining shares in Rowex. Neil is a member of the Irish Company Law Review Group and the Institute of Directors and is a member (and former chair) of the Law Society of Ireland's Business Law Committee.

Pinsent Masons (Ireland)

1 Windmill Lane
Dublin 2
Ireland

Tel: +353 1 553 8600
Email: amanda.daly@pinsentmasons.com
Web: www.pinsentmasons.com

Contributed by: Karen Gallagher, Hannah McLoughlin, Jane Bourke and Neil Keenan, **Pinsent Masons (Ireland)**

Ireland as a Life Sciences Hub

Ireland has a highly developed and vibrant life sciences sector. It is home to most of the leading multinational pharmaceutical, medical devices and medtech companies, as well as boasting a thriving medical device and medtech start-up community. Key life sciences hubs have developed around Dublin, Cork and Galway.

2023 was a year of continued growth for the life sciences industry in Ireland. During the past year, companies such as Astellas, Bristol Myers Squibb, Jazz Pharmaceuticals, Pfizer, Gilead, and EirGen Pharma have announced plans to open new or extend existing facilities in Ireland. Several significant deals concluded in the past 12 months and the Irish courts have been busy dealing with a number of high-profile pharmaceutical patents disputes.

Irish life sciences companies are adapting to an evolving regulatory landscape, driven by the introduction of new EU legislation. They are also innovating with the use of AI, particularly in the drug development and diagnostics areas.

In other developments, Ireland was due to hold a referendum in June 2024 on ratification of the Unified Patent Court (UPC) Agreement (the "UPC Agreement"). Ratification would be good news for patent-rich life sciences companies in Ireland. The referendum has now been postponed as the government has said more time is needed to inform and engage the public on the Unitary Patent and the UPC.

This article summarises the key trends and developments in the life sciences sector in Ireland during the past 12 months.

Some statistics on the Irish life sciences sector

According to figures from the Industrial Development Agency (IDA), Ireland is now home to more than 90 pharmaceuticals companies. Leading originator companies AbbVie, Bristol Myers Squibb, Novartis, Pfizer, Astrazeneca, MSD, Janssen, Sanofi and Lilly and top generics and biosimilars companies such as Teva, Sandoz (Rowex), Viatris, Accord and Stada (Clonmel Healthcare) have significant operations in the country. Ireland has also established itself as a global player in the medtech space, with more than 300 medtech companies operating in the country, including 14 of the 15 top global medtech companies.

Ireland is the world's third largest exporter of pharmaceuticals, according to the UN International Trade Statistics database. Annual exports of pharmaceuticals amount to more than EUR116 billion.

Unified Patent Court and Referendum

Ireland is one of the signatories to the UPC Agreement; however, a referendum is needed before Ireland can formally ratify and participate in the UPC. In June 2024, Irish citizens were set to be asked to vote on an amendment to the Irish Constitution, which would enable Ireland to ratify the UPC Agreement. This in turn would allow Ireland to join the Unitary Patent and UPC system, which became operational across 17 EU member states on 1 June 2023. The date of the referendum has now been postponed, owing to the lack of public awareness concerning the unitary patent. The Irish government, in a statement on 16 April 2024, announced that it continues to believe that participation in the UPC is "essential" and that the referendum should be pursued – although "more time was needed for

public discourse and engagement on the matter to help inform the debate".

Why is a referendum necessary?

Article 34(1) of the Irish Constitution states that justice shall be administrated in courts established by law by judges appointed in a manner provided by the Irish Constitution. The UPC Agreement provides for the setting up of an international court between contracting states. As the UPC Agreement involves the transfer of judicial powers from the Irish courts to the new international court, it is necessary to amend Article 29 of the Irish Constitution to allow this. The Irish Constitution can only be amended by popular vote.

If the referendum is passed, legislation will be introduced allowing Ireland to ratify the UPC Agreement. Steps will then be taken to open a local division of the UPC in Dublin. This is expected to attract international patent litigation (including in the life sciences sector) to Ireland and thus provide a considerable boost to the Irish economy.

Benefits of joining the UPC

The UPC represents a significant opportunity for Ireland to further increase its reputation as global innovation hub and to continue the flow of foreign direct investment into the country. The Irish Business and Employers Confederation (Ibec), a representative body for Irish businesses, noted in a statement on 24 January 2024 that "a conservative estimate of the value add to the Irish economy for (Ireland's) participation in the UPC could be worth as much as EUR1.66 billion per annum".

If Ireland ratifies the UPC Agreement, this will have a significant impact on the sector. It will offer global pharmaceuticals companies a common law, English-speaking route into the UPC and scope for indigenous pharmaceuticals and medtech companies to obtain protection for their innovative products on a much wider scale.

M&A and Investment Activity

Many spin-off businesses have developed from the multinational pharmaceuticals sector in Ireland. While decisions to locate in Ireland may initially have been tax-driven, the sector is now well established and has the advantages of Ireland's well-educated workforce, an English-speaking common law jurisdiction that is within the EU, and access to governmental supports through the IDA. The pharmaceuticals sector generates high levels of employment in Ireland and is a very significant contributor to Ireland's corporation tax revenues.

In addition, a large cohort of medical devices, biotech and medtech businesses has developed in Ireland. A significant number of these are concentrated in Galway and the west of Ireland. This is due in part to some large multinational companies such as Boston Scientific, which was established in Galway in 1994. Galway also has a very good ecosystem of accelerator programmes such as Bioinnovate and the Excel programme developed by the National University of Galway (NUIG), with the availability of support from governmental agencies such as the Western Development Commission. Many successful Irish life sciences businesses have been spun off from technologies developed in universities such as NUIG, Trinity College Dublin, University College Dublin and University College Cork.

The fundraising environment is active and, despite being subject to the same funding constraints that all industries have experienced during the couple of years as a result of global uncertainty and a higher interest rate environ-

ment, the life sciences sector has weathered this better than some other sectors. The funding environment in Ireland is categorised by good support for very early-stage companies, with Enterprise Ireland and the Atlantic Bridge University Bridge Funds focusing on university spin-offs. The next stages of fundraising can be more difficult and many businesses rely on a cohort of high net worth investors for funding. There are two venture capital life sciences funds, Seroba and Fountain Healthcare, that are particularly active in the Irish market and private equity is increasingly becoming a feature of life sciences transactions.

There have been a number of quite significant transactions and developments in the market during the past 12 months to April 2024. Notable deals include the purchase of Amryt Pharma by Chiesi Farmaceutici.

The acquisition of County Galway-based Chanelle Pharma by private equity fund Exponent is notable as an example of international private equity becoming a feature of the Irish market. Also of note is Amgen's acquisition of Horizon technologies, a significant fundraising by Luma Vision (which was originally a spin-off from Bioinnovate), and the acquisition by Sandoz of the stake of its former joint venture partner Rowa in County Cork-based generic drug company Rowex Limited.

Key Life Sciences Patent Cases

The past two years have seen high levels of activity before the Irish Commercial Court and Court of Appeal, with several life sciences companies involved in patent infringement and revocation proceedings. Notably, there has been a series of decisions on preliminary injunctions in infringement proceedings that have shed further light on the interpretation of the 2019 Supreme Court decision in Merck Sharp & Dohme Limited v Clonmel Healthcare Limited (2019) IESC 65, (2020) 2 IR 1 (MSD v Clonmel) and the circumstances in which a generic pharmaceuticals company will be injuncted pending trial in patent infringement proceedings.

The judgment in the long-running Norton (Waterford) Limited t/a Teva Pharmaceuticals Ireland v Bristol Myers Squibb Holdings Ireland Unlimited (2023) IEHC 744 (Teva v BMS) revocation proceedings was handed down in December 2023. This was the first Irish judgment to consider the European Patent Office (EPO) Enlarged Board of Appeal decisions on G2/21/Sumitomo on plausibility and G1/22 on priority.

Finally, Ireland almost played host to the first EU case in relation to the supplementary protection certificate (SPC) manufacturing waiver when Jannsen sued Amgen in relation to Amgen's attempted reliance on the manufacturing waiver to produce a generic Ustekinumab product. That case was settled in May 2023 following a global compromise of the litigation.

Focus on preliminary injunctions

Prior to the Supreme Court decision in MSD v Clonmel in 2019, it was traditionally quite difficult for pharmaceuticals companies to obtain preliminary injunctions against generic competitors pending trial in Irish patent infringement proceedings.

Before MSD v Clonmel, the applicable test in interim and interlocutory injunctive proceedings in Ireland was taken from American Cyanamid Co v Ethicon Ltd (1975) AC 396, adopted as the Campus Oil test (Campus Oil v The Minister for Industry (No 2) (1983) IR 88). This was essentially a three-stage test, comprising the following steps:

- the court should consider whether there is a serious issue to be tried;
- the court should consider whether damages would be an adequate remedy for the applicant or the defendant; and
- if damages would not adequately compensate either party, the court should consider where the balance of convenience lies and whether to preserve the status quo.

Most applicants fell at the second hurdle, as it was understood that a patentee's loss was generally capable of being compensated in damages. Under the reformulated test, the Supreme Court noted that adequacy of damages should not be treated in isolation and must be assessed as part of the balance of convenience, and that difficulty in calculating damages – as opposed to impossibility of calculating damages – may be sufficient to tip the balance in favour of the applicant when weighed together with other factors.

The Supreme Court referred to several factors that might be weighed in assessing the balance of convenience in appropriate cases, including:

- whether the generic company has taken steps to clear the way;
- the difficulty in calculating damages for either party;
- the loss of first-mover advantage by the generic;
- the presumptive validity of the patent/SPC;
- the strength of any invalidity arguments, including with reference to successive decisions in other jurisdictions in relation to the validity of the patent.

In the recent cases of Biogen MA Inc & Anor v Laboratories Lesvi SL & Anor (2023) IECA 71 ("Biogen v Neuraxpharm"), Merck Sharp & Dohme LLC v Mylan Ire Healthcare Limited & Others (2023) IEHC 24 ("MSD v Mylan"), and Bristol Myers Squibb Holdings Ireland Unlimited v Norton (Waterford) Limited t/a Teva Pharmaceuticals Ireland (2023) IEHC 159 ("BMS v Teva"), the Irish courts appear to have taken a more patentee-centred approach in relation to preliminary injunctions pending trial. However, there has been a divergence with regard to the issue of whether a preliminary injunction should be granted following a finding of invalidity at first instance and pending appeal.

In Biogen v Neuraxpharm, Neuraxpharm were successful in defending Biogen's preliminary injunction application at first instance. The case concerned a Biogen divisional patent that protected its dimethyl fumarate product Tecfidera. The High Court judge appeared to be heavily persuaded by arguments that the parent patent had been found invalid and that there was a public interest factor in having the generic proceed to market – namely, savings to the taxpayer. The Court of Appeal overturned this decision, finding that the threshold test for invalidity in injunctive proceedings is high and that there must be successive determinations on the merits invalidating the patent in suit in order to outweigh the presumptive validity of a patent in the balance of convenience.

In MSD v Mylan, MSD were successful in obtaining a preliminary injunction against Mylan in the Commercial Court restraining Mylan from infringing MSD's SPC for Janumet. The court found that, although successive determinations of invalidity might weigh against the grant of an injunction in an appropriate case, the results in foreign proceedings concerning the patent were mixed in this case. The court was also persuaded by the fact that Mylan had not taken steps to clear the way in Ireland.

In BMS v Teva, the Commercial Court went even further. In that case, Teva had issued revocation proceedings in relation to the compound patent and SPC protecting BMS' apixaban product Eliquis. The revocation proceedings had been ongoing for two years by the time the preliminary injunction application was heard.

As regards adequacy of damages, the Commercial Court judge felt that neither party had demonstrated that it would be more or less difficult to compute damages. The court also considered the fact that an equivalent patent had been found invalid in England. However, factors such as the fact that the English case was under appeal at the time of the decision and the patent and SPC remained presumptively valid in this jurisdiction undermined this argument. The injunction was therefore granted. The Court of Appeal upheld the decision of the Commercial Court, citing the importance of the presumption of validity of a patent/SPC.

Following the substantive decision in the case, where the patent and SPC were found to be invalid, BMS applied to the Commercial Court again for an injunction against Teva pending BMS' appeal to the Court of Appeal. This injunction was refused, with the Commercial Court noting that the presumption of validity of the patent and SPC had been displaced by the Commercial Court judgment finding the patent invalid. The Commercial Court also noted that the refusal of an injunction against Teva would not necessarily mean that injunctions would not be granted against other generics companies, who had not been party to the revocation proceedings. This decision is currently under appeal to the Court of Appeal.

Regulatory Landscape

Reform of EU pharmaceuticals legislation

There has been a mixed reception in Ireland to the proposed EU legislative reforms concerning pharmaceuticals. Specifically, the IDA has raised concerns that the new reforms are making Europe more burdensome for pharmaceutical companies, who may favour the "more agile" regulatory system in the USA. That said, Ireland continues to be an attractive destination for life sciences companies to locate, owing to its favourable tax regime, educated workforce and strong links with Europe, the UK and the USA.

As part of the Pharmaceutical Strategy for Europe, on 26 April 2023 the EC adopted a proposal for a new Directive and a new Regulation, which aim to reform and replace general existing pharmaceuticals legislation on authorisation and supervision of medicinal products for human use (eg, Regulation 726/2004 and Directive 2011/83/EC) and legislation on medicines for children and for rare diseases (Regulation 1901/2006 and Regulation 141/2000/EC). These changes will focus on affordability, accessibility, innovation, environmental sustainability, and antimicrobial resistance.

It is anticipated that legislative change may include differentiated incentives for drug development, reductions of marketing exclusivity periods, and the introduction of a conditional data protection system. The latter development could see a company's IP rights being linked to the launch of a pharmaceuticals product in all participating EU member states within two years, at the risk of reducing the length of exclusivity available for new drugs.

Investment in generics

In recent years, the Irish Health Service Executive (HSE) has been grappling with how best to make

use of resources available to fund the national medicines bill. Professor Michael Barry, Clinical Director of the National Centre for Pharmacoeconomics (NCPE), has called for an increase in use of and investment in generics and biosimilars in Ireland, noting that the percentage of generics and biosimilars used in Ireland is much lower than its European counterparts. The argument is that increased use of generics leaves more budget available to fund investment in new drugs.

It appears that the Health Products Regulatory Authority (HPRA) has taken note. In 2023, the HPRA took the unprecedented step of designating a drug as "interchangeable" in circumstances where the SPC protecting the branded product remained in force and thus no generic products were permitted on the market.

In order for medicines to be designated interchangeable, they must have the same composition of active substances, pharmaceutical form and mode of administration. Once medicines are designated interchangeable, pharmacies are required to offer a patient the lowest-cost interchangeable medicine, even where a prescription is written with reference to a medicine's brand name as opposed to its active ingredient. Traditionally, the HPRA has only designated medicines as interchangeable once a number of generic competitors have entered the market.

AI and Life Sciences

Artificial Intelligence (AI) is driving a major transformation in the global life sciences sector, with Ireland at the forefront. Despite regulatory risks and challenges, AI – along with Machine Learning (ML) – offers significant benefits to the life sciences sector and is revolutionising various processes, from drug discovery to supply chain management.

However, a key concern regarding the use of AI in the life sciences sector is how to use AI safely and ethically. Regulatory compliance will become increasingly important, owing to the rapid pace and scale of AI-enabled life sciences development. This makes it challenging for regulators to ensure safety, transparency, model validation, patient safety, and date security. The recently adopted EU AI Act is welcomed by industry and regulators alike, as it provides clarity on the regulatory regime applying to AI. In the life sciences sector, the US Food and Drug Administration and the European Medicines Agency have been in the procress of consulting with industry, academic and other groups to develop AI/ML guidelines for drug development.

AI is making a significant impact in drug development and diagnostics. AI aids in discovering new drug candidates, thus reducing the time and cost of bringing drugs to market by improving clinical trial and manufacturing processes. AI's ability to analyse large patient data sets and to identify those likely to respond well to specific drugs makes previously incurable conditions potentially treatable.

In Ireland, the HSE is deploying various AI devices in test trials. One device monitors patients with deterioriating respiratory conditions and uses a sensor to relay data, triggering nurse intervention when the data deviates from the baseline. Moreover, the HSE has begun installing sensors in patients' homes to track their activities and send alerts if no or unusual movement is detected for an extended period. This can save valuable time in emergency response situations.

On the diagnostics side, APC Microbiome (a Cork research centre for food and medicine) has developed an AI system for ulcerative colitis management. This tool expedites the prediction

of patient outcomes and reduces biopsy evaluation errors in a clinical setting.

Conclusion

Despite competition from the USA and Asia-Pacific, Ireland remains a popular jurisdiction within which to do business for life sciences companies. Ireland is an attractive base for multinationals and a fertile environment for indigneous life sciences start-ups.

Life sciences companies are continuing to litigate in Ireland and, if Ireland ratifies the UPC, this trend is expected to continue. It will be interesting to see what influence Irish common law judges have on the jurisprudence of the UPC.

Home not only to most of the world's major life sciences companies, but also boasting the EU headquarters of major tech companies such as Google, Meta and Microsoft, Ireland is a prime location for pharma and tech collaborations in areas such as AI. The authors expect to see further developments in this space in 2024 and beyond.

ITALY

Law and Practice

Contributed by:
Diego Vaiano and Francesco Cataldo
Studio Legale Vaiano Cataldo

Contents

Studio Legale Vaiano Cataldo is based in Rome and consists of a team of 15 administrative lawyers headed by Professor Diego Vaiano and by Francesco Cataldo. The firm specialises in the legal field of life sciences, with particular regard to pharmaceutical law and medical devices, in relation to which it provides judicial and extrajudicial advice and assistance to the most important companies operating in the sector. The firm also provides legal counselling on public procurement, in particular on services and supplies, offering support at every stage of the procedure, from the study of tender deeds to the preparation of any requests for clarification or quotation documents, up to the executive phase. Where necessary, the firm offers assistance before the Regional Administrative Courts, the Council of State and the ordinary civil jurisdiction. The firm also boasts expertise in the administrative licensing of public goods and services, trade and production activities, environment, construction and urban planning, public competitions and arbitration.

Authors

Diego Vaiano is a partner at Studio Legale Vaiano Cataldo and has been a member of the Rome Bar since January 1994. He practises in the fields of healthcare and life sciences, and is considered to be one of the leading Italian experts in pharmaceutical and medical devices law. In the last two decades, he has defended the pharmaceutical industry in some of the most challenging litigation in the sector. He was also involved in major negotiations with the Italian Medicines Agency. He has been a member of the Farmindustria Board of Arbitrators since 2008, also acting as a consultant for Confindustria – Medical devices. He is a full professor of administrative law at the University of Viterbo – La Tuscia and is the author of many scientific publications on this subject.

Francesco Cataldo is a partner at Studio Legale Vaiano Cataldo and has been a member of the Rome Bar since 2008. An expert in administrative law, Francesco works mainly in the fields of healthcare and life sciences, public procurement, concessions of public goods and services and trade and production activities, dealing with both counselling and litigation before the administrative and the civil courts. He is an expert in administrative law at the La Tuscia University of Viterbo, and has been a lecturer in public, constitutional and parliamentary law at the Faculty of Law of the Roma Tre University. He frequently speaks at conferences on public procurement and administrative procedural law issues and is the author of several scientific publications on the subject. He also acts as a consultant for parliamentary study and work groups.

Studio Legale Vaiano Cataldo

Lungotevere Marzio, n. 3
00186
Roma
Italy

Tel: +39 06 68 74 772
Fax: +39 06 68 74 870
Email: studiolegale@vaianocataldo.it
Web: www.vaianocataldo.it

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

For medicinal products for human use, the main regulatory reference in Italy is Legislative Decree No 219/2006, issued in the implementation of Directive 2001/83/EC (Community code relating to medicinal products for human use).

The matters not directly governed by the aforementioned Legislative Decree – such as, those relating to the National Health Service's (NHS's) drug pricing and reimbursement conditions or to the evaluation of the therapeutic equivalence between different active ingredients – find their discipline within an objectively very vast and inhomogeneous series of norms.

With regard to medical devices, the application of the European Regulations 2017/745 (MDR) and 2017/746 (IVDR) has now taken place. The application of the first of these was initially planned to start on 26 May 2020, but was subsequently extended by one year, in light of the COVID-19 emergency. The second Regulation, relating to in vitro medical diagnostic devices, has been in force since 26 May 2022. Until these dates, the previous Community Directives (90/385/EEC, 93/42/EEC and 98/79/EC) – and the Legislative Decrees that transpose their provisions at a national level – continued to apply.

The authorities responsible for the application and verification of compliance with the aforementioned Regulations are:

- the Ministry of Health, which exercises, among others, the functions of the State with regard to protection of human health, co-ordination of the NHS, veterinary healthcare, as well as the supervision and monitoring of the circulation of medical devices; and
- the Italian Medicines Agency (AIFA), a body with legal status under public law, which operates on the basis of the guidelines and supervision of the Ministry of Health and the Ministry of Economy and Finance, and which has the function of ensuring the consistency of the pharmaceutical system, as well as the task of establishing, through negotiations with pharmaceutical companies, the price and reimbursement conditions for medicinal products.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

The decisions of the regulatory bodies in pharmaceutical matters are administrative acts or measures. As such, they can be challenged within 60 days of their communication or publication, with an appeal before the Regional Administrative Courts (TARs). Sentences pronounced by the TARs are appealable before the Council of State. Decisions made at appeal level can be challenged before the Supreme Court for reasons relating to jurisdiction only.

As an alternative to the appeal to the TAR, it is possible to file an extraordinary appeal with the President of the Republic within 120 days from the date of publication of the provision.

These remedies are applied identically for the challenge of any other administrative measure and, therefore, also with regard to medical devices.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals are classified in different ways, according to their reimbursement and supply status.

For the purposes of reimbursement, the AIFA classifies drugs in the following categories:

- Class A – essential medicines and drugs for the treatment of chronic diseases, the cost of which is borne by the NHS;
- Class H – medicines dispensed in the hospital, or in a similar facility, with costs to be borne by the NHS; and
- Class C – medicines not reimbursed by the NHS.

For the purposes of supply, the regimes currently provided for by the legislation are as follows:

- medicines subject to medical prescription;
- medicines subject to medical prescription to be renewed from time to time;
- medicines subject to special medical prescription;
- medicines subject to restrictive medical prescription, including:
  - (a) medicines that can be sold to the public subject to prescription by hospital healthcare professionals (HCPs) or specialists;
  - (b) medicines that can only be used in a hospital (or similar) environment; and
  - (c) medicines that can only be used by specialists;
- medicines not subject to medical prescription, including:
  - (a) over-the-counter (OTC) or self-medication drugs; and
  - (b) the remaining non-prescription medicines.

As far as medical devices are concerned, the national legislation follows that of the Community directives. There are, therefore, three categories of products:

- active implantable medical devices, ie, devices requiring some form of energy to function and meant to be entirely or partially implanted, by surgical or medical intervention, in the human body;
- medical devices (in general); and
- in vitro medical diagnostic devices, intended for in vitro use for the examination of specimens from the human body, including donated blood and tissue.

The first two categories of medical devices are grouped into different classes, according to their

complexity and the potential risk for the patient (Classes I, IIa, IIb and III).

A different risk classification is instead provided for in vitro diagnostic devices.

Again, with reference to medical devices, a further classification exists, for nomenclature purposes, called CND, or national classification of medical devices. This classification was selected by the Medical Device Co-ordination Group of the European Commission as a useful basis for developing the nomenclature for the European database EUDAMED, in consideration of its peculiarities in terms of structure, purpose and usability.

2. Clinical Trials

2.1 Regulation of Clinical Trials

The regulatory framework governing clinical trials of medicinal products for human use, currently in a transition phase, is the result of a progressive stratification of national and community regulations.

Among these are, in particular:

- Legislative Decree No 211/2003, which implemented Directive 2001/20/EC;
- Legislative Decree No 200/2007, which implemented the subsequent Commission Directive 2005/28/EC;
- Legislative Decree No 158/2012, which provided for the reorganisation of the Ethics Committees (independent bodies responsible for ensuring the protection of subjects enrolled in clinical trials); and
- Legislative Decree No 52/2019, which provided for the reorganisation of the legislation, introducing co-ordination provisions with (EU) Regulation No 536/2014.

This latest Regulation, which will abrogate the aforementioned Directive 2001/20/EC, aims to harmonise the procedures and requirements applicable to clinical trials in the various member states. The Regulation was published on 27 May 2014, but its application is subject to the activation of the database and the EU portal of clinical trials. These systems, after several extensions, became operative in January 2022.

For medical devices, the legislation on clinical investigations is currently contained in the Legislative Decrees which implement the Community directives in force on the subject. Furthermore, since 26 May 2021, these directives have been regulated by the new EU MDR (Articles 62 to 82 and Annex XV). Finally, Article 15 of the European Delegation Law 2019-2020 (Law No 53 of 22 April 2021) provided that the government adopts one or more legislative decrees for the reorganisation and adaptation of national legislation to the new regulation, dictating a series of principles and guiding criteria that must be followed for this purpose.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

The authorisation procedure for clinical trials is divided into several phases, within which the foreseeable risks and inconveniences are carefully evaluated with respect to the expected benefit.

The bodies involved in the procedure are the following:

- the AIFA, for the issuing of the authorisation;

- the Italian National Institute of Health (*Istituto Superiore di Sanità*), for the advisory opinion on Phase I studies and amendments;
- the Ethics Committees, for the opinions on the merits in the healthcare facilities where the clinical study is carried out;
- the general managers of the healthcare units, for the stipulation of contracts; and
- the EudraVigilance (European Union Drug Regulating Authorities Pharmacovigilance) network, for the reporting of adverse reactions.

As previously mentioned, the publication of EU Regulation No 536/2014 – which will be fully operational with the activation of the database and the EU portal – started a reform process, leading to the issue of Legislative Decree No 52/2019, of which, however, the implementing decrees (which will concretely redefine the procedures in force) are still pending.

The discipline relating to clinical investigations relating to medical devices is also in a transition phase.

According to the discipline dictated by the new EU MDR, in general and subject to exceptions, clinical investigations are mandatory for implantable and Class III medical devices, while for other devices they are necessary only if the clinical data found in other available sources is not sufficient to prove compliance with the general safety and performance requirements.

The procedural process outlined by the new EU Medical Device Regulation (MDR) (Regulation (EU) 2023/607) involves the submission of an application by the sponsor of the clinical investigation. The member state concerned is required to communicate whether the application is complete within ten days from the date of receipt. At this point, if no additional information is requested and if the application concerns a low-risk device among those mentioned in Article 70, paragraph 7, letter (a) of the MDR, the sponsor can start the clinical investigation on the same date as the validation of the application, provided that no negative opinion has been expressed by the competent Ethics Committee.

For the other medical devices, however, the initiation of the investigation requires prior notification of the authorisation by the member state.

Alongside this procedure, the new EU MDR governs specific procedures for the clinical investigations relating to devices already in possession of the marking (Article 74), for the clinical investigations conducted for purposes other than compliance assessment (Article 82), as well as a co-ordinated assessment procedure for clinical investigations conducted in more than one member state (Article 78).

These procedures differ, in some respects, from that currently in force at national level, which does not require an actual application, but rather a notification to be sent to the competent ministerial direction which, for medical devices belonging to Classes I, IIa and IIb (excluding implantable and long-term invasive devices), allows the relevant sponsor to start the investigation immediately, provided that it has the favourable opinion of the competent Ethics Committee.

2.3 Public Availability of the Conduct of a Clinical Trial

As of 21 July 2014, the funders of a study or clinical trial relating to medicinal products for human use are required to publish its results on the European database managed by the European Medicines Agency (EMA). Through this

database, it is possible to obtain information on the objectives of the study and the main results achieved.

This obligation is reinforced in the new Regulation (EU) No 536/2014, which – as mentioned in **2.1 Regulation of Clinical Trials** – entered into force on 31 January 2022. This Regulation expressly establishes that a summary of the results of the clinical trial and an abstract presented in terms understandable to laypersons are to be made available in the EU database, regardless of the outcome of the clinical trial.

Similarly, the new EU MDR requires the sponsor to submit a report on the investigation, within one year of its conclusion, regardless of its outcome.

2.4 Restriction on Using Online Tools to Support Clinical Trials

The guidelines for the collection of the informed consent to participation in clinical trials – drawn up by the National Co-ordination Centre of Ethics Committees – recommend that the consent collection process also include "telematic" tools, in order to facilitate a full understanding by the participant. The same guidelines clarify that "in selected situations, to be assessed on a case-by-case basis, to facilitate the participation of all potentially interested patients, interactive telematic tools can be used for the patient information process and/or for the collection of their consent".

2.5 Use of Data Resulting From Clinical Trials

Pursuant to the General Data Protection Regulation (GDPR), data resulting from clinical trials falls within the scope of "particular categories of personal data".

As such, it can be transferred to third parties or affiliates only in compliance with the provisions of the aforementioned Regulation. Depending on the case, it may be necessary for the trial promoter to enter an agreement (possibly autonomous), with these subjects on the processing of personal data.

2.6 Databases Containing Personal or Sensitive Data

The creation of a database containing particular categories of personal data should take place in compliance with the technical and organisational measures provided for by the GDPR, in particular in order to guarantee the safety of the processing and compliance with the principle of data minimisation.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The European legislation, implemented at national level, defines the characteristics that medicines and medical devices should possess to be considered as such.

The main criterion that is used to distinguish a medicine from a medical device is the method by which the product pursues its intended purpose. Unlike medicines, in fact, medical devices must exert their action through methods that are not mainly pharmacological or immunological, nor through metabolic processes.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Regulation (EC) No 726/2004 requires applicants to use the centralised procedure co-ordinated

by the EMA for the authorisation of medicinal products derived from the following biotechnological processes:

- recombinant DNA technologies;
- controlled expression of genes carrying codes for biologically active proteins in prokaryotes and eukaryotes, including transformed mammalian cells; and
- hybridoma- and monoclonal antibody-based methods.

In addition, the registration of other biological drugs, not derived from the aforementioned procedures, may be requested through national, decentralised or mutual recognition procedures. In the case of biological or biotechnological originators, the application to be submitted to the AIFA for registration purposes is that based on a complete dossier, pursuant to Article 8 of Legislative Decree No 219/2006.

The same legislation, however, provides that the dossier to be presented in these cases is supplemented by additional information, precisely indicated in the Annex to Legislative Decree No 219/2006, which is justified in consideration of the peculiarities of biological medicines and their sensitivity to changes in raw materials or production processes. These peculiarities are also reflected in the registration requirements of biosimilar medicines, which may be more demanding than those necessary for the "simplified" authorisation of generic medicines (Article 10, paragraph 7, Legislative Decree No 219/2006).

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

The marketing authorisation (MA) has an initial five-year validity period. It can be renewed, at the request of the holder, with an application to be presented at least six months before the expiry date, on the basis of a new assessment of the risk/benefit ratio carried out by the AIFA. In cases in which this assessment gives a positive result, the MA is renewed with unlimited validity, unless the AIFA, for pharmacovigilance-related reasons, decides to proceed with a further five-year renewal. In the event that the risk/benefit assessment is not favourable, the interested party can submit to the AIFA an opposition to the refusal provision, on which the latter decides, within 90 days, after consulting the Italian National Institute of Health. If even this last decision is not favourable, the AIFA notifies the holder and announces with a press release that the medicine can no longer be marketed.

Once the MA has been issued, it can be revoked, suspended or modified in the cases established by Article 141 of Legislative Decree No 219/2006 (eg, when the medicine is harmful, it does not allow the effect for which it is authorised to be obtained, the risk/benefit ratio is not favourable and in the other cases indicated by the law).

In addition to the foregoing, any MA issued loses its validity if it is not followed by the effective marketing of the medicinal product on the national territory within the following three years, or if an authorised medicinal product already present on the market is no longer effectively marketed for three consecutive years. However, these provisions can be derogated from by the AIFA for public health reasons.

For medical devices, the EC Certification (or CE Statement) and the underlying compliance assessment issued by the notified bodies have a maximum validity of five years (renewable). The MDR confirmed these validity periods, and regulated a transitional regime for the marketing of

certified products in compliance with the Directives currently in force.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

For medicinal products, the authorisation procedures are divided into:

- a centralised procedure, aimed at obtaining an MA valid in all EU countries, which is coordinated by the EMA and its Committee for Medicinal Products for Human Use (CHMP), and ends with the issuing of a decision by the European Commission;
- a mutual recognition procedure, which allows the extension to one or more EEA countries of an MA already granted by a member state;
- a decentralised procedure, which allows an MA to be obtained that is simultaneously valid in two or more EEA countries on the basis of identical documentation; and
- a national procedure, which allows a valid MA to be obtained within the Italian state only.

In order to initiate the procedure, the applicant is required to submit an application for authorisation to the competent authority, attaching a dossier containing the information required by Annex I to Directive 2001/83/EC.

Once the application is received, the competent authorities analyse its compliance and verify the existence of the conditions for issuing the MA. The legislation provides for a maximum term of 210 days, starting from the date of presentation of the valid application, for the conclusion of centralised, decentralised and national procedures. The mutual recognition procedure, however, provides for a term of 180 days.

The procedures for changing the terms of an MA are governed by Commission Regulation (EC) 1234/2008. These procedures are different, depending on the variation requested.

Type IA variations, which have little or no impact on the quality, safety and effectiveness of the medicinal product, can be implemented even before being notified to the competent authorities (these include, for example, administrative changes relating to the identity or address of the MA-holder or the manufacturer).

For the implementation of the other variations, however, it is necessary to wait for the completion of the silent consent (Class Ib variations), or the express authorisation from the competent authorities (Class II variations, relating, for example, to the addition of an indication or to the production process).

With regard to medical devices, the marking procedures differ according to the relative risk class.

For the lowest risk class (Class I), it is generally possible to mark the device on the basis of a declaration of compliance with the essential requirements provided for by the legislation, a declaration that can be made by the manufacturers themselves.

For the other classes of devices, and for sterile devices or devices with a measuring function, also in Class I, the assessment procedure provides instead for the involvement of a notified body, from which the manufacturer is required to request the issue of a certificate of compliance.

In general, any variations to the approved device require a new approval by the notified body that issued the EU technical documentation assessment certificate, if they may affect the safety and

performance of the device or the conditions of use prescribed for that device.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

When certain conditions are met, the national legislation allows free access to a drug therapy that has not yet received the AIFA's authorisation.

According to Law No 648/1996, this possibility is provided for, provided that there is no valid therapeutic alternative:

- for innovative medicines authorised in other states, but not in Italy;
- for medicinal products not yet authorised, but undergoing clinical trials; and
- for medicinal products to be used for a therapeutic indication other than that authorised.

Medicines that can be used pursuant to the aforementioned Law No 648/1996 are included in a special list of the AIFA, and can be prescribed at the total expense of the NHS for all the subjects who, in the national territory, are affected by the condition identified in the provision.

Early access to the drug is also allowed under "compassionate-use" programmes, for drugs still undergoing clinical trials, in patients suffering from serious or rare diseases or whose lives are in danger, when, in the physician's judgement, there are no further valid therapeutic alternatives. Access to the investigational drug requires a favourable opinion from the Ethics Committee, subject to confirmation of the pharmaceutical company's availability to supply the drug free of charge.

Subject to the authorisation of the Ministry of Health and the favourable opinion of the Ethics Committee, the possibility of resorting to compassionate use is also provided for medical devices in exceptional cases of necessity and urgency, in the interest of protecting the health of an individual patient and in the absence of valid therapeutic alternatives.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

After the granting of the MA, the holder takes into account any scientific and technical progress, and introduces the changes necessary for the medicine to be produced and controlled according to generally accepted methods.

In addition, pursuant to Legislative Decree No 219/2006, the same holder is obliged to inform the AIFA immediately of any prohibitions or restrictions imposed by the competent authorities of any country in which the medicine is marketed, as well as any other new data that may affect the risk-benefit assessment of the same.

In terms of pharmacovigilance, the legislation requires the MA holder (MAH) to record suspected adverse reactions in detail, and to notify with the utmost urgency those characterised as serious.

This information must be collected and submitted by the MAH in the form of Periodic Safety Update Reports (PSURs).

Similarly, vigilance obligations are envisaged for medical-device manufacturers or their authorised representatives, starting with the immediate communication to the competent authority of all the incidents of which they have become aware and of all the corrective actions that have been

undertaken to avoid or reduce the risks associated with the use of a medical device.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

The AIFA has adopted a regulation for the access to documents created or held permanently by itself. The regulation provides that the Administration may limit access to a document, obscuring some of its contents, when this is necessary to protect the confidentiality of persons, groups or companies. The same regulation excludes, in principle, from the right of access the documentation concerning the production methods and the know-how on the manufacture of pharmaceutical products. In principle, the jurisprudence denies the right of third parties to access any information relating to any confidential discounts granted by pharmaceutical companies to NHS bodies in the context of pricing and reimbursement contracts stipulated with the AIFA.

The situation is different for the authorisation procedures for generic medicines. In such cases, the jurisprudence has recognised the right of access to Marketing Authorisation Applications (MAAs) and bio-equivalence tests by the companies that market the reference medicine, noting that the latter have an interest worthy of protection in verifying the actual equivalence between their patented medicinal products and the generic ones that are the subject of the MAA.

For medical devices, the provisions of the general legislation on the right of access apply (Article 22 et seq, Law No 241/1990).

3.8 Rules Against Illegal Medicines and/or Medical Devices

Directive 2011/62/EU and delegated Regulation 2016/161 have integrated the regulatory system, providing for specific provisions to oppose the inclusion of counterfeit medicines into supply chains.

In order to counteract these phenomena, it was decided, in particular, to equip the packaging of the medicines with a unique identifier and an anti-tampering device.

The application of a Unique Device Identifier (UDI), including a product and production identifier, is also required for medical devices under Article 27 of the new EU MDR. Article 94 of the same Regulation requires the competent authorities of the member states to draw up annual market surveillance activity plans and to allocate sufficient resources to carry out such activities.

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

A national anti-forgery Task Force is active in Italy. The main institutions involved in this Task Force and in the drug counterfeiting issue are the AIFA, the Ministry of Health, the National Institute of Health, the Illegal Traffic of Medicines (*Nuclei Antisofisticazioni e Sanità*) (*Carabinieri*), the Ministry of Economic Development (*Ministero dello Sviluppo Economico*) and the Customs and Monopoly Agency.

Part of the control activity carried out concerns the management of reports relating to the discovery of suspicious products at customs. Specifically, this activity takes the form of a series of checks which have the purpose of ascertaining the origin of the products and their relative composition by means of laboratory analyses.

For medical devices, customs surveillance is mainly carried out by the Maritime, Area and Border Health Offices of the Ministry of Health.

The surveillance activity is carried out through three levels of verification (documentary, identity, material), to ascertain the compliance of medical goods with the requirements and prescriptions provided for by national and community regulations.

4. Manufacturing of Pharmaceuticals and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

Pursuant to Legislative Decree No 219/2006, the production of medicines and medical devices requires the authorisation of the AIFA and the Ministry of Health, respectively. The authorisation, which does not expire, is issued after an inspection aimed at ascertaining that the applicant has qualified personnel and technical-industrial means compliant with the regulations.

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

The wholesale distribution of medicines is subject to authorisation by the Regions, and requires the availability of suitable premises and adequately trained personnel (Legislative Decree No 219/2006).

The legislation on medical devices does not regulate the wholesale market.

5.2 Different Classifications Applicable to Pharmaceuticals

For the classification of medicines for supply and reimbursement purposes, see **1.3 Different Categories of Pharmaceuticals and Medical Devices**.

On the basis of these classifications and the relative conditions of use, medicines can be assigned to the following distribution channels.

- Hospital distribution, for medicines used in hospital. The distribution regime applicable in these cases requires hospital pharmacies to dispense medicines to hospitalised patients, subject to direct purchase from pharmaceutical companies following the outcome of public tenders.
- Territorial distribution, for chronic medicines or even short-term therapies and for clinical situations that do not require hospitalisation. The distribution regime applicable in these cases provides that the medicine is purchased by the wholesaler, dispensed by local pharmacies and, where included in reimbursement Class A, reimbursed to the subjects in question by the NHS according to the relative amounts due provided for by law.
- Direct distribution, for medicines which, although not intended for hospitalised patients, meet the criteria of differential diagnostics, of therapeutic criticality, and of periodic control by the specialist structure. These medicines are purchased and dispensed by health facilities according to the scheme illustrated above for the hospital distribution, and are delivered to patients by hospital pharmacies. However, in some regions, there are agreements entered into with the pharmacist trade associations, based on which patients can collect these drugs at some affiliated pharmacies that are authorised to supply

them. These cases fall within the "distribution on behalf of the health facility".

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The import and export of medicines are governed by Legislative Decree No 219/2006.

For medical devices, it is necessary to refer to the European directives, the national implementing legislation and the new EU MDR. Articles 13 and 60 of that Regulation are specifically dedicated to import and export activities.

The competent authorities for implementing the regulation are the AIFA and the Ministry of Health.

6.2 Importer of Record of Pharmaceuticals and Medical Devices

In general, the compliance with authorisation requirements and obligations similar to those envisaged for the production activity is required for subjects importing medicines.

For the parallel import of medicines registered in a member state, for which a similar medicine exists in the Italian market, the importer must have the regional authorisation for wholesale distribution. Moreover, for each workshop that carries out the re-labelling or repackaging of the product, a production authorisation is required.

There is no specific authorisation for subjects importing medical devices. However, they are responsible for the compliance of the product marketed in the Union.

Since 26 May 2021, with the full operation of the EU MDR, importers of medical devices have been required to comply with the obligations set out in Article 13 of the EU MDR itself (the obligation to verify CE marking, EU declaration of compliance, labelling, etc).

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Imports of medicines must be previously authorised by the AIFA.

Notwithstanding this general rule, the importation for personal use of medicines duly authorised in a foreign country is allowed in the following cases:

- medicines for which a valid therapeutic alternative does not exist or is not accessible in Italy, upon request and under the responsibility of the attending physician; and
- medicines personally imported by the traveller upon entering the national territory, provided they are intended for personal use for a treatment not exceeding 30 days.

The import of medical devices is subject to supervision by the Maritime, Air and Border Health Offices of the Ministry of Health. The surveillance activity ends with the final issue of an import-authorisation measure, or with a non-importation measure in the case of failure to pass the controls.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

The import of goods into the EU is regulated by a standardised classification system, which identi-

fies products on the basis of a tariff code. The classification is based on the harmonised system managed by the WHO (HTS, first six digits of the code), on the further subdivisions applied by the Union Combined Nomenclature (CN) and, finally, on the Community Customs Tariff (TARIC). The TARIC code, consisting of ten digits, identifies the applicable rates, any preferential duties and a whole series of other measures (temporary suspensions, quotas, ceilings, etc) specifically applicable to the product being imported.

6.5 Trade Blocs and Free Trade Agreements

The EU manages trade relations with third countries in the form of trade agreements designed to create better trade opportunities and to overcome trade barriers. Among the other agreements worth of mention here are the CETA (EU-Canada) and the JEFTA (EU-Japan); the latter entered into force on 1 February 2019, with a negotiated free trade area of more than 635 million people. The agreement includes, among others, the pharmaceutical sector, to the regulation of which a specific chapter is dedicated.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

The price of medicines not reimbursed by the NHS is established by the MAHs, and can only be increased in January of each odd year.

The price of the medicines reimbursed by the NHS is defined through negotiation between the companies and the AIFA.

The criteria with which the AIFA must comply during the negotiation are established by the Decree of the Ministry of Health of 2 August 2019, published on 24 July 2020.

The discipline dictated by the Decree in question provides that the negotiation is initiated by the pharmaceutical company by submitting a specific request, accompanied by the documentation listed in Article 2, paragraph 2 of the same Decree.

For the conclusion of the procedure, a term of 180 days is provided for, the suspension of which is allowed for a period not exceeding 90 days.

In the case of lack of agreement, the procedure ends negatively, with the classification of the medicine in Class C. In the case of a positive outcome, the procedure is finalised by an agreement between the AIFA and the pharmaceutical company defining the price and reimbursement conditions applicable to the medicine.

The negotiated price is valid for a period of 24 months, unless otherwise agreed by the parties, but the AIFA can still restart the negotiation before the deadline in the event of particular "market changes", in the case of "new evidence" on the positioning in therapy or on the estimated benefits, or if a shortage of the medicine on the Italian market occurs.

The negotiated price represents the maximum price for the sale of the drug to the NHS bodies, on which further discounts can be negotiated during the tender. In addition to this price, in the market segment of territorial distribution, VAT and the profit margins envisaged by the law in favour of pharmacists and wholesalers are added. The sum of these components thus determines the retail price of the medicine (ie, the price reimbursed to the pharmacist by the NHS),

which is divided among the players in the supply chain on the basis of the following quotas: 66.65% for the manufacturing pharmaceutical companies, 6.65% for wholesalers and 26.7% for pharmacists. For the transfer of equivalent medicines referred to in Article 7, paragraph 1, of Legislative Decree No 347/2001, not originally covered by a patent or licences deriving from that patent and assigned to the territorial distribution circuit, the quota attributable to the pharmaceutical company is reduced from 66.65% to 58.65% and the corresponding percentage of eight points that is released is divided between pharmacists and wholesalers, according to market rules.

For medical devices, there are no price-negotiation procedures similar to those for medicines. Prices are set by the producers and, for the supplies to NHS bodies, they are negotiated upon the outcome of public tenders between the supplying companies and the regional purchasing centres.

7.2 Price Levels of Pharmaceuticals or Medical Devices

The prices of medicines and medical devices marketed in Italy are not strictly bound to those quoted, for the same products, in other European countries and in the rest of the world. Nonetheless, Ministerial Decree of 2 August 2019 provides that the information on the "marketing, consumption and reimbursement in other countries" must be communicated by pharmaceutical companies during the negotiation of the price and reimbursement conditions of medicines, and are taken into consideration by the AIFA during the negotiation process.

A reference price system is instead envisaged in the public contracts sector, to contain the variability of the regional award prices of certain products which have a high impact in terms of cost for the NHS. Following this system, Legislative Decree No 95/2012 introduced the institution of "renegotiation" of existing contracts, which NHS bodies are required to exercise in the event of a deviation of more than 20% of the award price compared to the price of reference. In the case of failure of a renegotiation agreement, the NHS bodies have the right to withdraw from the contract without any charge. This system, however, has not so far found concrete application in the pharmaceutical sector, but in exceptional cases only.

Additional control systems of award prices, starting prices and the renegotiation of existing contracts have been provided for, in the case of medical devices, by Law No 296/2006 and by Legislative Decree No 78/2015.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Medicines are eligible for reimbursement by the NHS if they are deemed by the AIFA to be indispensable for the treatment of chronic or serious diseases, after negotiating the relative price and reimbursement conditions with the company holding the MA.

For the governance of pharmaceutical expenditure, the State makes use of various instruments, among which the most incisive is certainly the setting of an overall expenditure ceiling, equal to 15% for the year 2022, 15.15% for the year 2023 and 15.30% thereafter from the year 2024, divided into a ceiling for the pharmaceutical expenditure under agreement and a ceiling for pharmaceutical expenditure for direct purchases (drugs purchased directly from the NHS bodies). The current legislation provides that pharmaceutical companies must participate in the

settlement of the overspending of the aforementioned ceilings to varying degrees, depending on the ceiling that has been overrun. For the direct purchases' ceiling, in particular, pharmaceutical companies must participate in the settlement for an amount equal to 50% of the relative overrun (so-called pharmaceutical pay-back), in proportion to their market-share.

While the ceiling for the pharmaceutical spending under agreement has always proved to be capacious, the one intended for direct purchases has proved to have been seriously underestimated over the years, recording, starting from 2013, overspends for increasingly greater amounts, exceeding EUR1 billion per year. The requests for pharmaceutical pay-back have been the subject of extensive litigations, which are still pending before the administrative justice bodies, and have been so for some years.

With the latest in a long series of regulatory interventions, the legislator (Article 1, paragraph 281, Law No 234/2021) provided that, starting from 2022, the expenditure ceiling for the direct purchases expenditure will be equal to 8% for the year 2022, 8.15% for the year 2023 and 8.30% from the year 2024, with an increase compared to past values.

The legislation also provides for a ceiling and a settlement mechanism for the expenditure on medical devices. Each company contributes to the settlement in a measure equal to the percentage incidence of its turnover on the total expenditure for the purchase of medical devices to be paid by the NHS, as established by an agreement during the State-Regions Conference.

This system has been implemented from 2015 to 2018 and has been challenged by many companies before the TAR Lazio. The Tribunal has now referred to the Constitutional Court the question of the constitutional legitimacy of the aforementioned payback due to its doubtful violation of several articles of the Italian Constitution. The hearing is scheduled for 22 May 2024 and a decision is expected by the end of July 2024.

Futhermore, it has been established an annual contribution imposed on companies supplying medical devices to the NHS to an extent equal "to 0.75 per cent of the turnover, net of value added tax, from the sale of medical devices and large equipment to the SSN by companies that manufacture or market medical devices".

This "Fund", in particular, was established by Article 15, paragraph 2 of Law No 53 of 22 April 2021, by Article 28 of the Legislative Decree No 137/2022 and by Article 24 of Legislative Decree No 138/2022 for in vitro diagnostic medical devices; these provisions have provided that the Fund must be "fuelled by an annual share of 0.75% of the turnover, net of value added tax, from the sale to the NHS of medical devices and large equipment by companies producing or marketing medical devices" then delegating to a decree of the Minister of Health, in agreement with the Minister of Economy and Finance, the task of defining "the criteria and methods for the payment of annual instalments, for monitoring, as well as for the management of the fund".

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

The cost-benefit analysis and the "added therapeutic value" of a medicine in relation to the therapeutic alternatives available are the evaluation criteria adopted by the AIFA when negotiating the price conditions of the medicines reimbursed by the NHS.

For medical devices, the 2016 Stability Law assigned to a "Control Room" the task of carrying out a multi-dimensional technical assessment of medical devices, based on the criteria of relevance, safety, effectiveness, economic impact and organisational impact of the devices themselves, consistent with the relevant European guidelines (EUnetHTA). The rules provide that the individual NHS bodies can no longer carry out this activity autonomously, but must resort to evaluating structures established at a regional or national level, which must in any case operate under the co-ordination and on the basis of the priorities identified by the Control Room.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

For the governance of pharmaceutical expenditure, the AIFA makes use of additional instruments related to the expenditure ceilings, that specifically affect the phases of prescription, dispensing and reimbursement of the medicines whose costs are borne by the NHS.

Among these, the so-called "AIFA Notes" are particularly important: they are a regulatory tool aimed at limiting the scope of reimbursement of certain medicines by defining the indications and/or limitations that every physician should comply with in order to be able to prescribe the drug with costs borne by the NHS. At the time of the prescription, the doctor records the number of the Note on the prescription itself, thus certifying that the conditions provided for by that Note are met for the prescription of the medicine with costs borne by the NHS. The Notes are periodically reviewed in order to update the indications and limitations provided therein according to the new evidence available in the scientific literature.

Further regulatory instruments concern the prescription and dispensing of originator medicines and their equivalent counterparts included in the "transparency list" referred to in Article 7 of Legislative Decree No 347/2001. The following mechanisms apply to the medicines included in the list in question:

- limitation of the maximum reimbursement price by the NHS, which is reduced to the price of the cheaper equivalent drug based on the same active ingredient included in the transparency list; and
- automatic replacement of prescriptions, by virtue of which the pharmacist is obliged to dispense to the patient the aforementioned drug included in the transparency list with the lowest price, unless the treating physician has expressly added the "No Replaceability" clause to the prescription, or unless the patient has insisted in any case on obtaining the dispensing of the most expensive drug, in both cases personally paying the price difference.

Finally, there is a regional practice which tends to orient/encourage/discourage doctors' prescribing choices on the basis of measures that presume an evaluation of the therapeutic equivalence between medicines containing different active ingredients. This is the case, for example, of the decisions concerning:

- the promotion of the prescription of certain active ingredients, less expensive, in place of others; and
- the creation of tenders for the competing purchase of medicinal products based on different active ingredients.

Over the years, a practice has emerged that has seen the regions adopt decisions of this type with a certain frequency, and in no particular order, with the consequent creation of inequali-

ties of treatment among the patients in accessing pharmaceutical care services included in the essential levels of care. To resolve the matter and ensure uniformity in the access to services, the legislator has therefore intervened on the regulatory level, establishing that the aforementioned decisions, which require an evaluation of the therapeutic equivalence between medicines containing different active ingredients, can be adopted by the regions only "on the basis of the justified and documented assessments expressed by the Italian Medicines Agency" (Article 15, paragraph 11-ter, Legislative Decree No 95/2012).

In implementing the aforementioned Article 15, paragraph 11-ter, the AIFA adopted guidelines that identified the criteria for establishing, in practice, the therapeutic equivalence between medicines based on different active ingredients.

8. Digital Healthcare

8.1 Rules for Medical Apps

In October 2019, the European Commission's Medical Devices Coordination Group published a guideline on the qualification and classification of software as medical devices. The document reaffirms the general principle according to which the purpose given by the manufacturer to the software is the main criterion that must be used for the purposes of its qualification and classification as a medical device. Consequently, it must be considered that software used solely for research or information retrieval activities cannot be classified as medical devices. Conversely, software intended for the analysis and processing of health information for medical purposes can be qualified as medical devices, and classified in risk Class IIa, or in higher classes, if the decisions to be made on the basis of the software itself can seriously impact the health status of the user.

8.2 Rules for Telemedicine

On 17 December 2020, the State-Regions Conference approved a document containing "national guidelines for the provision of telemedicine services". The guidelines govern, in detail, the telemedicine activities that can be included in the essential levels of care (in particular, televisits, medical tele-consultation, medical health tele-consultation, tele-assistance by healthcare professionals, tele-reporting), and their limits and possibilities of use, as well as the applicable rules in terms of tariffs, accountability and necessary technological standards.

8.3 Promoting and/or Advertising on an Online Platform

Advertising to the public is allowed, subject to authorisation by the Ministry of Health, for medical devices and Standard Operating Procedure (SOP)/OTC medicines. Advertising can also be carried out via the internet, but it must comply with the rules established in the guidelines specifically issued by the Ministry of Health. These guidelines, however, almost completely prohibit the possibility of advertising medicines via social networks, with an exception only for Facebook desktop (right column) and YouTube.

8.4 Electronic Prescriptions

The COVID-19 pandemic gave a particular impulse to the process of dematerialisation of prescriptions.

The Ordinance of the Head of Civil Protection of 19 March 2020 introduced, for the emergency phase, alternative methods to the paper prescription, in order to reduce travel and the number of visits to NHS GPs' offices.

Further, the inter-ministerial decrees of 25 March 2020 and 30 December 2020 extended the use of electronic medical prescriptions to other types of medicines, including those not reimbursed by the NHS, while disciplining the dematerialisation of prescriptions and also the relative reminders for the post-emergency phase.

8.5 Online Sales of Medicines and Medical Devices

The online sale of medicines is governed by Legislative Decree No 17/2014 and is thereby permitted only for SOP/OTC drugs, and only in the online shops of pharmacies and parapharmacies, subject to authorisation by the region of competence and registration in the list of authorised subjects, kept by the Ministry of Health.

For medical devices, online sales are permitted under Article 6 of the new EU MDR.

8.6 Electronic Health Records

The Italian electronic health record (*Fascicolo Sanitario Elettronico*) (EHR) is managed by the Regions in compliance with the general rules established by Article 12 of Legislative Decree No 179/2012 and by the current legislation on the protection of personal data. The EHR collects all the health and social health data and digital documents generated by clinical events concerning the patient. The consultation of the data present in the EHR can be carried out only with the consent of the patient, and always in compliance with professional secrecy.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices

The main regulatory reference on the subject is the industrial property code (Codice Proprietà Industriale – CPI). There are specific regulations which integrate the CPI for the pharmaceutical sector and which concern, among others, the release of Supplementary Protection Certificates for medicines (SPCs, Regulation (EC) No 469/2009) and the legal protection of biotechnological inventions (Directive 98/44/EC).

9.2 Second and Subsequent Medical Uses

The possibility of obtaining patents for second medical use is generally recognised, provided that the patentability requirements are met, and it is therefore possible to demonstrate the innovative nature of the new use compared to the previous one.

The patent coverage of the new use inevitably expires after the initial one. Consequently, in the period between the first and second deadlines, a somewhat hybrid situation arises, during which generic medicines can be marketed, but not for the second use, which is protected by the patent issued subsequently. This particular dynamic has also meant that in Italy, as in many other countries, second- and subsequent-use pharmaceutical patents have been the subject of litigation.

9.3 Patent Term Extension for Pharmaceuticals

Pharmaceutical companies can apply for a Supplementary Protection Certificate(SPC), which allows them to extend the duration of the basic

patent. These certificates are governed by Regulation (EC) No 469/2009 and have a duration equal to the time elapsed between the filing of the patent application and the granting of the first European MA, minus five years. In any case, the certificate can never have a duration exceeding five years from the expiry of the basic patent.

On 1 July 2019, Regulation (EU) 2019/933 entered into force, which amended Regulation (EC) No 469/2009, providing for some exceptions to the protection provided by the SPC. In particular, it has been possible to produce a generic – or biosimilar – version of a medicine protected by a certificate, during its period of validity, in the following cases:

- for the purpose of exporting to a non-EU market where the protection conferred by the certificate has expired or never existed; and
- for the purpose of creating, in the six months preceding the expiry of the certificate, a stock intended to be marketed in the EU immediately after the expiry of the certificate.

9.4 Pharmaceutical or Medical Device Patent Infringement

The conducts subject to violation are identified, mainly, in the production, use, marketing, sale, import of the protected product/procedure, without the consent of the relative owner. The supply – or the offer to supply – to subjects other than the right-holders the means relating to an indispensable element of the invention, necessary for its implementation, also constitutes a patent infringement.

The owner of an industrial property right can request that the injunction be ordered for any imminent violation of their right and the continuation or repetition of the violations in progress and, in particular, can request the prohibition of manufacture, marketing and use of the things constituting a violation of the law, and the order to withdraw these activities from the market.

For the coverage offered by SPCs and for the exemptions provided for by Regulation (EU) 2019/933, see **9.3 Patent Term Extension for Pharmaceuticals**.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

The main defensive exceptions that can be raised in the pharmaceutical and medical devices sector are based on the classification of the contested acts as:

- acts carried out in the private sphere and for non-commercial purposes;
- acts performed on an experimental basis relating to the subject of the patented invention;
- studies and trials aimed at obtaining, even in foreign countries, an MA for a drug and the consequent practical requirements, including the preparation and use of the pharmacologically active raw materials strictly necessary for this purpose; and
- extemporaneous, and per unit, preparation of medicines in pharmacies upon medical prescription, and the medicines thus prepared, provided that industrially manufactured active ingredients are not used.

The legal system envisages the possibility of requesting compulsory licences for the non-exclusive use of the invention, but the conditions provided for the granting of such licences are extremely restrictive and stringent (eg, in the case of failed implementation of the invention, for dependent patents, or for health emergencies according to the Agreement on Trade-

Related Aspects of Intellectual Property Rights (TRIPS Agreement)).

9.6 Proceedings for Patent Infringement

The actions that can be carried out by the owner of the right or its exclusive licensee include actions to ascertain a counterfeiting, a paternity and claim action, condemning actions upon the cessation of counterfeiting and compensation for damages, typical precautionary actions governed by the CPI (injunction, description, seizure, etc), other precautionary actions contemplated by the CPC and, finally, executive actions.

For its part, the other party, in addition to explaining defences and exceptions, can challenge the validity of the patent by counterclaiming.

9.7 Procedures Available to a Generic Entrant

For the purposes of the marketing of generic medicines, no preventive judicial or extra-judicial actions are required. However, generic companies have the right to promote such actions to request, for example, the assessment of the invalidity of the title, or its forfeiture.

Without prejudice to data exclusivity (see **10.4 Data Exclusivity for Pharmaceuticals and Medical Devices**), according to the Italian legislation an application for an MA for a generic medicine cannot be rejected or deferred by the AIFA for reasons relating to patent coverage. Furthermore, the authorised equivalent medicinal product cannot be classified as a drug dispensed with costs borne by the NHS with effect prior to the expiry date of the patent or the Complementary Protection Certificate (*Certificato Complementare di Protezione* – CCP), published by the Ministry of Economic Development.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Counterfeiting gives rise to criminal – as well as civil – liability, integrating the criminal offences envisaged by Article 473 of the Italian Criminal Code, punished with imprisonment from six months to four years and with a fine from EUR2,500 to EUR35,000.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

The verification of the commercial name of a medicinal product falls within the competence of regulatory agencies only to the extent that its use could cause a safety or public health risk.

As regards the parallel import of medicines, the principles affirmed by EU and national jurisprudence provide that the medicine imported from abroad normally retains the trade name registered in the country of origin. The latter can be changed with a name coinciding with that with which the same drug is marketed in the country of destination only in the event that:

- there are regulations or practices in the country of destination that prevent the marketing of the product with the trade mark used in the country of origin; and
- the use of the designation of origin can create a confounding risk for public health.

Conversely, the change of destination is not permitted if the replacement of the trade mark is exclusively due to the desire, on the part of the parallel importer, to achieve a commercial advantage.

Article 7 of the new EU MDR also regulates the aspects in question for medical devices, prohib-

iting the use of texts, names, trademarks and signs that could mislead the user with regard to the destination, safety and performance of the device.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

IP Protection is potentially applicable to the graphic layout or design of pharmaceutical products to the extent that they meet the requirements of the legislation for the granting of such protection (eg, novelty, lawfulness).

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

According to Article 10 of Legislative Decree No 219/2006, the simplified application for the registration of a generic medicinal product cannot be submitted before eight years have elapsed from the issue of the first MA in Europe of the reference medicinal product ("data exclusivity"). Furthermore, the generic medicine thus authorised cannot be marketed before ten years have elapsed, again starting from the first MA of the reference medicine ("market protection"). If, in the first eight years, the reference medicine has obtained an extension of its therapeutic indications, the market protection period is increased by one year.

These protection regimes are calculated independently of patent protection, and can be opposed to the marketing and registration applications of generic, biosimilar and hybrid medicines, which are similarly based on the identification of a reference medicine and on the use of the (protected) data which supported its marketing authorisation.

The same protection regimes can also be benefited from by the MAHs relating to medicinal products containing a fixed-dose combination.

There are no similar protection regimes for medical devices.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

The end of the national state of emergency, and most of the special and derogatory measures authorised under it, came on 31 March 2022.

That said, in 2020 and 2021, the emergency legislation provided for numerous measures aimed at addressing the extraordinary needs deriving from the COVID-19 pandemic. Among these, the following are worth mentioning:

- VAT exemption or a reduced rate of 5% for a series of instruments and products used for the containment of the COVID-19 pandemic (eg, masks, lung ventilators for intensive care);
- the possibility of administering vaccines for SARS-CoV-2 in pharmacies open to the public;
- provisions to ensure the local availability of medical devices for oxygen therapy, also on an experimental basis, through the network of service pharmacies; and
- suspension of the ordinary rules (except for the general principles stated in Article 30) dictated by the code of public contracts for the award of contracts for works, services and supplies.

11.2 Special Measures Relating to Clinical Trials

In order to improve the ability to co-ordinate and analyse the available scientific evidence, the emergency legislation authorised the AIFA to access all the data from experimental and observational clinical studies and from compassionate therapeutic-use programmes activated for COVID-19 patients.

Furthermore, for the same purposes, the Ethics Committee of the National Institute for Infectious Diseases (Lazzaro Spallanzani) was identified as the single national body in charge of the evaluation of clinical trials, observational studies and programmes of compassionate therapeutic use of medicines for COVID-19 patients.

Finally, the AIFA was entrusted with the task of publishing a simplified procedure for the acquisition of clinical trial applications and for the modalities of enrolment in the studies.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

Article 15 of Legislative Decree No 18/2020 provides for an exceptional authorisation procedure for the production of surgical masks and PPE. Based on this procedure, manufacturers who intend to make use of this derogation send the surgical masks and PPE to the ISS and the *Istituto nazionale Assicurazione Infortuni sul Lavoro* (INAIL), respectively, self-certifying that they comply with the safety requirements established by current legislation. Within three days, the ISS and the INAIL release their decisions, based on the self-certification and the technical documentation received from the manufacturer. From June 2021, the extraordinary authorisation procedure ceased. The certificates issued on the basis of the aforementioned procedures in any case remained valid until the end of the state of emergency, on 31 March 2022.

As regards the approval of medicinal products, the applicable legislation already provided for the possibility of granting MAs subject to specific obligations in exceptional circumstances ("conditional MA"). This procedure was followed by the EMA for the purpose of issuing the MAs of the currently available COVID-19 vaccines.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

In order to reduce travel and visits to GPs' offices, the legislation adopted for the emergency period has extended the terms of validity of the restrictive prescriptions of Class A drugs. In addition, the duration of the therapeutic plans that include the provision of aids, disposable devices and other prosthetic devices and that expire during the state of emergency was automatically extended.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

In order to address any shortage of medicines, the AIFA authorised the import of foreign packs of medicines for the supplies to the NHS structures.

Furthermore, Article 66-bis of Legislative Decree No 34/2020 introduced provisions on the simplification of the procedures for the import and validation of surgical masks and PPE.

11.6 Drivers for Digital Health Innovation Due to COVID-19

See **8.2 Rules for Telemedicine**.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

Article 56-quater of the Decree-law No 77 of 31 May 2021 has inserted a new provision in the industrial property code entitled "compulsory licence in case of national emergency". Under that provision, in the case of the declaration of a national state of emergency motivated by health reasons, to cope with proven difficulties in procuring specific medicines or medical devices deemed essential, in compliance with international and European obligations, compulsory licences may be granted for non-exclusive, non-transferable and predominantly direct use to the supply of the internal market, of patents relevant for production purposes, which have validity bound to the continuation of the emergency period or up to a maximum of 12 months from the termination of that emergency period.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

Article 3-bis of the Decree-law No 44/2021, converted, with modifications, by Law No 71/2021, introduced a provision which limits the punishment, by way of manslaughter or negligent personal injury, for acts committed in the exercise of a health profession during the epidemiological state of emergency since COVID-19. On the basis of paragraph 1 of the provision, the aforementioned crimes become punishable only in cases of gross negligence. Furthermore, the following paragraph 2 provides that, for the purposes of assessing the degree of the fault, the judge takes into account, among the factors that can exclude its severity, the limited scientific knowledge on the pathologies deriving from the SARS-CoV-2 infection, as well as the scarcity of human and material resources concretely available, and, in addition, the lower degree of experience and technical knowledge possessed by unskilled personnel employed to deal with the emergency.

For people damaged by the anti-SARS-CoV-2 vaccine, Decree-law No 4 of 2022 authorised the payment by the State of the indemnities established, for the other vaccines, by the current legislation.

11.9 Requisition or Conversion of Manufacturing Sites

Article 5 of Legislative Decree No 18/2020 assigned to the extraordinary Commissioner for the management of the emergency the task of providing incentives (also non-repayable) of EUR50 million in order to support projects for the expansion or conversion of activities aimed at the production of medical devices and PPE.

The subsequent Article 6 of Legislative Decree No 18/2020 attributed to the Head of the Civil Protection Department the power to dispose, with their own decree, the requisition in use or ownership, from any public or private entity, of health and medical-surgical facilities, as well as movable property of any kind, necessary to deal with the aforementioned health emergency. For the owners of the assets acquired, the Law provided for the recognition of a requisition indemnity calculated according to the market value of the assets as of 31 December 2019.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

The emergency regulation authorised the extraordinary Commissioner to purchase PPE and other medical devices in derogation from the procurement code, also through advance payments of the entire supply.

Furthermore, with Law Decree No 76/2020, a series of provisions of a temporary nature were introduced, aimed at achieving – pending the emergency – a simplification of the procedures regarding public contracts.

JAPAN

Law and Practice

Contributed by:
Kenji Utsumi and Kensuke Suzuki
Nagashima Ohno & Tsunematsu

Contents

Nagashima Ohno & Tsunematsu is widely recognised as one of Japan's leading international law firms, specialising in all aspects of business and commercial law. The firm represents domestic and foreign clients involved in every major industry sector, including many of the largest and most influential companies, funds and organisations in Japan. The firm has structured and negotiated many of Japan's largest and most significant corporate and finance transactions, and has extensive expertise across all its practice areas. The pharmaceutical and healthcare team is based in the Tokyo office and consists of more than 14 lawyers, including eight partners. Key areas of the firm's practice relating to the life sciences sector include pharmaceutical and healthcare, risk and crisis management/compliance, corporate/M&A, data protection and privacy, IP, antitrust/competition, consumer law (consumer litigation), dispute resolution, and labour and employment.

Authors

Kenji Utsumi is a partner and co-chair of Nagashima Ohno & Tsunematsu's pharmaceutical and healthcare team. His areas of specialisation include pharmaceutical and medical regulations, commercial, licensing and distribution transactions, and M&A. Kenji serves as an adjunct professor of law at the University of Tokyo School of Law and is also a member of the Daiichi Tokyo Bar Association.

Kensuke Suzuki is a partner and co-chair of Nagashima Ohno & Tsunematsu's pharmaceutical and healthcare team. His areas of specialisation include pharmaceutical, medical device, food, medical and healthcare regulations, cross-border corporate transactions, securities regulations, and fund-related businesses. Kensuke served as a special adviser to the Ministry of Health, Labour and Welfare from 2014–15. He is a member of the Tokyo Bar Association.

Nagashima Ohno & Tsunematsu

JP Tower
2-7-2 Marunouchi
Chiyoda-ku
Tokyo
100-7036
Japan

Tel: +81 3 6889 7000
Fax: +81 3 6889 8000
Email: info@noandt.com
Web: www.noandt.com/en

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the "Pharmaceuticals Law"), together with related cabinet and ministerial orders, is the primary law that governs pharmaceuticals and medical devices in Japan.

The Ministry of Health, Labour and Welfare (MHLW) is the principal regulatory body for pharmaceuticals and medical devices. The MHLW is the national government body that issues most of the Pharmaceuticals Law-related ministerial orders and administrative guidelines, and drafts relevant cabinet orders. Prefectural governments (ie, independent local governments such as the Tokyo Metropolitan Government) are primarily responsible for monitoring pharmaceutical and medical device marketers, manufacturers and distributors in their respective jurisdictions on behalf of the MHLW. The Pharmaceuticals and Medical Devices Agency (PMDA), a Japanese independent administrative agency that receives financial support from the Japanese government to cover its operational costs, also plays a key role in reviewing marketing authorisation applications for new pharmaceutical and medical devices.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

If a pharmaceutical or medical device firm violates the Pharmaceuticals Law or any related regulation, the MHLW or a prefectural government may issue an administrative order to that firm. The recipient may challenge the administrative order through an administrative complaint review process provided under the Administrative Complaint Review Act. A pharmaceutical or medical device firm served with an administrative order may also commence a legal action for the revocation of the administrative order with a competent court in accordance with the Administrative Case Litigation Act. These challenge procedures are also generally applicable in cases involving the issuance of administrative orders for violations of laws concerning other regulated products (eg, certain food products). Recently, a few leading generic drug manufacturers received business suspension orders due to their violations of pharmaceutical regulations, resulting in significant shortages in certain sectors of the generic drug market in Japan.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals are categorised into two classes: prescription pharmaceuticals and OTC pharmaceuticals. Prescription pharmaceuticals may only be used by doctors or used in accordance with a doctor's prescription. OTC pharmaceuticals can be purchased at drug stores or other non-licensed stores. OTC pharmaceuticals are further classified into several sub-categories and, depending on the relevant sub-category, may have certain sales restrictions – for example, a requirement that they be sold only at establishments at which a pharmacist (or other designated licensed personnel) is present.

Medical devices are categorised into three classes:

- specially controlled medical devices (classes III and IV of the Global Harmonisation Task Force (GHTF) international classification structure);
- controlled medical devices (class II of the same); and

• ordinary medical devices (class I of the same).

Depending on the relevant class of medical devices, a marketer and a distributor will need to obtain different business licences, as appropriate.

2. Clinical Trials

2.1 Regulation of Clinical Trials

The Pharmaceuticals Law, together with the Good Clinical Practice (GCP) ministerial order issued by the MHLW, is the principal law regulating clinical trials. The MHLW and the PMDA are the main regulatory authorities that oversee clinical trials.

Japan requires all drugs to be tested through clinical trials and approved for marketing in Japan. Even new drugs that have undergone clinical trials and received marketing approval in foreign jurisdictions are required to undergo separate clinical trials in Japan in order to verify such drug's effectiveness and safety when given to Japanese people. Even for COVID-19 vaccines supplied to Japan, the Japanese government required that a limited number of separate clinical trials be performed in Japan based on this policy.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

To conduct a clinical trial, an applicant (a pharmaceutical or medical device marketer) must prepare a protocol and receive approval for such protocol from an institutional review board (IRB). The applicant is also required to register the protocol with the MHLW through the PMDA. In practice, the applicant consults with the PMDA informally about its draft protocol before formally registering the protocol with the MHLW.

2.3 Public Availability of the Conduct of a Clinical Trial

The website of the National Institute of Public Health discloses certain basic information regarding clinical trials conducted in Japan, including:

• the title of the study;
• the subject material of the study;
• a brief summary of the study;
• information about the monetary sponsor, the relevant IRB, and other organisations involved;
• contact information for the parties involved; and
• a summary of the results.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There is no apparent prohibition on using online tools to support clinical trials. Clinical trials are generally required to be conducted by doctors or hospitals and include in-person interviews with, and written informed consents from, clinical trial subjects. Recruiting clinical trial subjects can be conducted online. In addition, under a guideline from the MHLW, if an approved protocol for a clinical trial provides for online medical checks in the clinical trial, such medical checks can be conducted on an online virtual examination basis.

2.5 Use of Data Resulting From Clinical Trials

Raw data obtained from clinical trials is considered to be sensitive data of clinical trial subjects. Therefore, clinical trial data obtained by a doctor or hospitals (investigators) is usually converted into a form that prevents the identities of clinical trial subjects from being discoverable and only such anonymised information or data is provided to the sponsor of the clinical trial. Furthermore,

upon commencement of a clinical trial, investigators must obtain an informed consent letter from each trial subject regarding the use and treatment of such subject's sensitive personal data.

2.6 Databases Containing Personal or Sensitive Data

As mentioned in **2.5 Use of Data Resulting From Clinical Trials**, it is common practice for resulting data to be anonymised, and in such form the data is not regulated as strictly as sensitive data. Disclosure of original, non-anonymised data (raw data) is heavily regulated as sensitive information under the Act on the Protection of Personal Information (APPI).

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The term "pharmaceutical" is defined under the Pharmaceuticals Law as:

- items listed in the Japanese Pharmacopoeia;
- items that are intended for use in the diagnosis, medical treatment or prevention of disease in humans or animals; or
- items that are intended to affect the structure and functioning of a human's or animal's body.

However, quasi-pharmaceutical products and cosmetics are excluded from the definition of pharmaceutical.

The term "medical device" is defined under the Pharmaceuticals Law as appliances, instruments or similar items that are intended for use in the diagnosis, medical treatment or prevention of disease in humans or animals – or that are intended to affect the structure or functioning of the bodies of humans or animals – and that are specified by cabinet order.

The relevant cabinet order specifying medical devices is so broadly worded that it is not clear whether each and every medical appliance, instrument or similar item is classified as a medical device. Software that is intended for use in the diagnosis, medical treatment or prevention of disease in humans or animals can also be classified as a medical device.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

To market a pharmaceutical or medical device, the initial marketer is required to obtain marketing authorisation. Key factors that are taken into account when reviewing an application for marketing authorisation or marketing certification are:

- the quality, effectiveness and safety of the pharmaceutical or medical device;
- the applicant's marketing business licence;
- the manufacturer's manufacturing business licence; and
- the manufacturer's compliance with the good manufacturing practice (GMP) regulation.

To obtain marketing authorisation for a biological pharmaceutical, certain additional requirements must be fulfilled, such as:

- a manufacturer of a biological pharmaceutical must comply with more stringent management and safety requirements; and
- packaging/packaging inserts of a biological pharmaceutical must indicate that it is a biological product.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

The period of validity of a marketing authorisation is not indefinite. Depending on the type of medical product, an authorisation for a new pharmaceutical is generally subject to re-examination four to ten years after the initial authorisation. Additionally, the MHLW occasionally conducts a re-evaluation of pharmaceuticals based on the recommendation of its advisory board.

A marketing authorisation can be revoked by the MHLW and other competent authorities. A marketing authorisation can be revoked when, for example, it is found that:

- the relevant pharmaceutical does not have the efficacy or produce the effects indicated in the application; or
- the relevant pharmaceutical has no value because the harmful effects associated with such product outweigh the efficacy or beneficial effects.

Additionally, a marketing authorisation can be revoked if the responsible party has not marketed the relevant authorised pharmaceutical or medical device for three consecutive years without any reasonable justification. The MHLW may vary parts of a marketing authorisation for pharmaceuticals and medical devices if, in the MHLW's view, it is necessary to do so in light of health or hygiene considerations.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

Submission of Application

An application for marketing authorisation must be submitted to the MHLW or – in the case of certain pharmaceuticals and all medical devices (other than medical devices with a GHTF classification of class IV) – to the relevant prefectural government or a particular registered certification body. With regard to an application for a pharmaceutical or medical device that must be submitted to the MHLW, the application must be submitted through the PMDA. The MHLW's review of applications for marketing authorisation for new medicinal products is substantially outsourced to the PMDA. Once the PMDA is satisfied with the application, the application is forwarded to the MHLW, which then obtains a recommendation from the Council of Pharmaceutical and Food Sanitation before approving the application.

Required information

A marketing authorisation application must include, as an attachment, data concerning the results of clinical trials and other pertinent data – except where the application is for a medicine that is subject to a conditional early approval for market authorisation (an expedited process).

Variation of a marketing authorisation

Variation of a marketing authorisation – such as a change in the therapeutic indication, formulation, dosage, patient population, packaging or labelling – requires the marketing authorisation-holder to complete a formal process. Depending on the materiality of the change, the variation may require approval from the relevant authority or the mere submission of a report.

Transferral of a marketing authorisation

It is permissible for market authorisation to be transferred from the current marketing authorisation-holder to a transferee. A transferee of a marketing authorisation must notify the relevant authority of the transfer at least one month prior to the date of transfer.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

The Pharmaceuticals Law provides for an exceptional procedure to allow the importation of a pharmaceutical or medical device that has received foreign marketing authorisation for compassionate use if:

- the foreign marketing authorisation was obtained in a country with a marketing authorisation system equivalent to the system in Japan;
- immediate use of the pharmaceutical or medical device is necessary to prevent a pandemic that could cause death or serious harm to the health of Japanese citizens; and
- the pharmaceutical or medical device is specifically designated under an administrative order.

This special procedure was once used to import an influenza vaccine produced by a foreign manufacturer. It is also used for vaccines and therapeutic drugs for COVID-19 that are produced by foreign manufacturers and supplied for use in Japan.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

After the marketing of a pharmaceutical or a medical device commences, the marketing authorisation-holder is required to conduct post-marketing pharmacovigilance and technovigilance. If any issue relating to the effectiveness or safety of the marketed pharmaceutical or medical device is discovered during the post-marketing authorisation surveillance period, the marketer must conduct a pharmaceutical or medical device recall campaign, report the discovery to the PMDA, issue public notices, and take other appropriate measures to prevent patients suffering further damage or losses.

An applicant for a marketing authorisation must typically complete all clinical trials first and then submit its application with the complete accompanying data. However, in the case of conditional early approval for market authorisation for an innovative product exempted for a part of its clinical trials, post-marketing phase IV clinical trials must be performed.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

In general, third parties can access information about applications for marketing authorisations by making a request under Japan's information disclosure law. Under the Act on Access to Information Held by Administrative Organs, anyone may request the disclosure of administrative documents held by an administrative organ.

Under this law, the MHLW is essentially required to disclose an application for marketing authorisation if properly requested. However, the application may include or refer to the IP or confidential information of an applicant, and the disclosure of such information to a third party may result in serious damage to an applicant's rights and competitiveness. Therefore, disclosure of an application is usually made after the relevant sensitive information contained in it has been redacted or masked.

3.8 Rules Against Illegal Medicines and/or Medical Devices

To market a pharmaceutical or a medical device, the initial marketing entity must obtain marketing authorisation for the pharmaceutical or medical device under the relevant regulation. Falsification or illegal distribution of pharmaceuticals

or medical devices (including distribution by a party without first having obtained marketing authorisation) are violations of this regulation. The MHLW may order the responsible party to recall all such falsified or illegal products from the market, impose administrative sanctions against such responsible party, and even refer the violation to the public prosecutor for investigation and potential prosecution for criminal sanctions.

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

With regard to counterfeit pharmaceuticals and medical devices, the owner of an infringed patent or other IP right can file an application for an importation suspension of counterfeit products with the Japanese customs authorities. The IP rights-holder may also file an application for an import ban or provisional disposition order, or file a lawsuit with a court in Japan seeking similar relief.

4. Manufacturing of Pharmaceuticals and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

Pharmaceutical Manufacturers

A manufacturing business licence is required in order to manufacture pharmaceuticals in Japan. If a manufacturer of an imported product is located outside Japan, said manufacturer will be required to obtain accreditation as a foreign manufacturer. A manufacturing business licence is granted by the relevant prefectural government and such accreditation is granted by the MHLW. Once an application for a manufacturing business licence is formally submitted, the prefectural government reviews the application and – in most cases – conducts an on-site inspection of the applicant's manufacturing premises. The period of validity of a manufacturing business licence and an accreditation is five years.

Medical Device Manufacturers

Unlike pharmaceutical manufacturers, a medical device manufacturer – whether located in Japan or outside Japan – is only required to satisfy a prior registration (ie, registration with the MHLW as a medical device manufacturer). The registration must be renewed every five years.

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

In order to market pharmaceuticals or medical devices, the initial marketing entity must hold a marketing business licence and have marketing authorisation for each of the relevant products. A marketing business licence is granted by the relevant prefectural government. Once an application for a marketing business licence is formally submitted, the prefectural government reviews the application and – in most cases – conducts an on-site inspection of the applicant's office or factory.

Marketing business licences are generally valid for five years; however, the actual validity period will depend on – among other things – the type of pharmaceutical or medical device to be distributed by the applicant. Wholesalers and retailers of pharmaceuticals and medical devices are also required to obtain a distribution business licence.

5.2 Different Classifications Applicable to Pharmaceuticals

There are two types of marketing business licences for pharmaceuticals: Type 1 and Type 2. A Type 1 marketing business licence is required for marketing prescription pharmaceuticals. A Type 2 marketing business licence is required for marketing other pharmaceuticals (ie, non-prescription ethical pharmaceuticals and OTC pharmaceuticals).

There are three types of marketing business licences for medical devices:

- a Type 1 medical device marketing business licence is required for marketing medical devices with a GHTF classification of class III or IV;
- a Type 2 medical device marketing business licence is required for marketing medical devices with a GHTF classification of class II; and
- a Type 3 medical device marketing business licence is required for marketing medical devices with a GHTF classification of class I.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The Pharmaceuticals Law governs the import and export of pharmaceuticals and medical devices. Imports of pharmaceuticals and medical devices from outside Japan are, in principle, subject to the same marketing regulations applicable to products manufactured in Japan. Importers of these products are subject to requirements regarding marketing authorisation, marketing business licences and accreditation as a foreign manufacturer.

A manufacturing business licence is required for the manufacture of pharmaceuticals or medical devices that are to be exported from Japan. Although marketing authorisation is not necessary, a separate registration for manufacturing pharmaceuticals or medical devices for export is required.

The relevant prefectural government regulates marketing business licences, whereas the MHLW regulates accreditations for foreign manufacturers.

6.2 Importer of Record of Pharmaceuticals and Medical Devices

An importer of pharmaceuticals or medical devices must obtain a marketing business licence, except in the case of the importation of small amounts of these products by an individual for their personal use. An importer must present certificates of the marketing business licence and the marketing authorisation for each particular imported product to the relevant customs house.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Importation of pharmaceuticals or medical devices is not permitted unless the importer on record possesses a marketing business licence and a marketing authorisation for each particular imported product – except where small amounts of these products are imported by an individual for their personal use. As regards permitted exceptions in the case of emergency situations, see **3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations**.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

In addition to obtaining a marketing business licence and marketing authorisation when importing pharmaceuticals or medical devices, it may be necessary to change the product's packaging to conform to product description information and requirements provided under the relevant marketing authorisation. By way of an example, packaging and product labelling – and the explanatory written material provided with the products (such explanatory information is usually available online) – must be provided in Japanese and satisfy the requirements under the relevant marketing authorisation. Changing a product's packaging is considered part of the manufacturing of the product and, as such, the entity responsible for performing such changes is required to possess a manufacturing business licence.

6.5 Trade Blocs and Free Trade Agreements

As of December 2023, Japan has signed 21 economic partnership agreements/free trade agreements with other countries. Among others, Japan is a signatory to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (TPP) and the Regional Comprehensive Economic Partnership (RCEP).

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

Prices for the substantial majority of medical services provided and prescription pharmaceuticals sold in Japan are reimbursed by the Japanese universal healthcare system, and the substantial majority of legal residents of Japan participate in and are covered by Japan's national health insurance system. The cost of prescription pharmaceuticals to be paid through the national health insurance system corresponds to the prices for the relevant pharmaceuticals listed on the drug tariff.

Listing of a prescription pharmaceutical's price on the drug tariff is based on the Health Insurance Act and is a separate procedure from the marketing authorisation procedure provided under the Pharmaceuticals Law. The profit margin of the hospitals and the pharmacies is usually the difference between the prices at which the pharmaceuticals are purchased by the hospitals and the pharmacies (such price is usually lower than the price listed on the drug tariff) and the prices at which the products are sold by the marketer of prescription pharmaceuticals.

7.2 Price Levels of Pharmaceuticals or Medical Devices

The listing of pharmaceuticals on the drug tariff and the price designated for each of the pharmaceuticals listed are determined by the MHLW after reviewing the applications submitted by the market authorisation-holders of such pharmaceuticals. The price of the same product in other countries is one element of background information considered when determining the listing price. The drug tariff is reviewed and updated basically every two years.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

A substantial part of the costs of pharmaceuticals and medical treatments is covered by the health insurance scheme. For the majority of Japanese residents, 70% of these costs are covered by health insurance.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

The MHLW considers cost-benefit analysis as a key factor when evaluating new pharmaceuticals.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Historically, Japanese hospitals prescribed and dispensed pharmaceuticals themselves. However, in an effort to address excessive pharmaceutical-related spending, the MHLW began incentivising hospitals to separate the prescription and dispensing of pharmaceuticals functions so that pharmaceuticals are not prescribed unnecessarily.

8. Digital Healthcare

8.1 Rules for Medical Apps

The parts of software in medical hardware devices used for data processing are categorised as medical devices. Depending on its function, purpose, data-processing results and other factors, a software application (or relevant parts thereof) designed to run on a smartphone, tablet or other similar device may be categorised as a medical device if it is intended for use in the diagnosis, treatment or prevention of disease in humans.

8.2 Rules for Telemedicine

As a general principle, the law essentially requires medical diagnosis to be performed by a physician through a face-to-face consultation with a patient. However, a guideline issued by the MHLW provides guidance on the permissible scope of telemedicine services and legitimises the provision of such services in cases where conducting a face-to-face consultation would be practically difficult or where such services are to be provided for a patient with a chronic – yet stable – condition. Under the MHLW guideline, it is generally required that physicians using telemedicine for initial consultations with the patient be primary care physicians who are familiar with the subject patient.

8.3 Promoting and/or Advertising on an Online Platform

Regulations addressing the promotion or advertising of pharmaceuticals and medical devices apply equally to online promotion and advertising (eg, through online portals, company web pages and social networking websites). An advertiser's web page containing hyperlinks to other web pages may be considered collectively as a single advertisement and, as a whole, may violate regulations concerning advertisements – even if each web page on its own would not violate these regulations.

8.4 Electronic Prescriptions

The MHLW has issued a guideline addressing electronic prescriptions, which emphasises the merits of these. The issuance of electronic prescriptions through email is prohibited, given the risks associated with transmission of information electronically – for example, unintentional information disclosures or unlawful theft of information. The MHLW promotes the use of electronic prescriptions through an online management system administered by the national health insurance payer, which commenced operations in January 2023.

8.5 Online Sales of Medicines and Medical Devices

Almost all OTC pharmaceutical products are marketable online, with the exception of certain potent pharmaceuticals and OTC pharmaceuticals that were formerly classified as ethical pharmaceuticals (a classification that typically indicated a prescription was required).

8.6 Electronic Health Records

The use of electronic health records is an accepted practice in Japan and almost all large hospitals have adopted the use of these records, with smaller hospitals following their lead. Health-related information generally falls within the scope of "sensitive data" as defined under the APPI and is subject to stricter regulations. A person will, in principle, not be allowed to obtain sensitive data concerning an individual unless the individual's consent has been obtained.

The APPI requires appropriate security measures to be implemented for the handling of personal data. A specific guideline has been published regarding:

- the use of cloud platforms in relation to medical data; and
- the security measures to be implemented for the protection of medical data stored on such cloud platforms.

The transferral and storing of patients' sensitive data on cloud platforms is generally not prohibited, provided the relevant cloud platform meets and complies with the various requirements set out in the specific guideline.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices

The Patent Act is the primary law that applies to patents. The Patent Act allows for patent term extensions for pharmaceutical patents and, as a result, commonly encountered issues include:

- whether or not a pharmaceutical patent qualifies for a patent term extension; and
- the extent to which protections under the Patent Act continue to apply in the case of a patent term extension.

As regards the issuance of patents, there are no requirements that relate specifically or exclusively to pharmaceuticals or medical devices.

9.2 Second and Subsequent Medical Uses

The novelty of a pharmaceutical invention (a requirement for a patent to be granted for such invention) is generally judged based on the following two points:

- a compound having a specific attribute; and
- a medicinal use based on such attribute.

Accordingly, second and subsequent medical uses of a known pharmaceutical product can be granted patents if the relevant usage is considered novel and other relevant conditions and requirements are satisfied.

In this respect, medicinal use includes new dosage regimes and new or selected patient populations, and therefore can be patented if considered novel. Second and subsequent patents of pharmaceutical products can be infringed if the patented invention is exploited by a third party without authorisation during the term of the patent – for example, if a patented product is sold for the patented use without authorisation from the relevant patent-holder.

9.3 Patent Term Extension for Pharmaceuticals

For patented pharmaceuticals, the term of the patent can be extended upon request by the patent-holder to the Japan Patent Office, and

the fulfilment of relevant procedures. The term of the extension, which cannot exceed five years, is generally equivalent to the period of time during which the patent-holder was prevented from exploiting the invention while awaiting medicinal product approval in accordance with the Pharmaceuticals Law. Patent term extensions can be challenged by third parties – for example, a third party may commence a legal proceeding with the relevant court seeking invalidation of a patent term extension registration.

9.4 Pharmaceutical or Medical Device Patent Infringement

Infringement of a registered pharmaceutical or medical device patent occurs when a person exploits the patented invention during the term of the patent without the patent-holder's permission. This includes, for example, the unauthorised production, usage, sale, import or export of a patented product. The Patent Act provides for injunctive relief as a remedy that can be sought where there is an imminent threat of infringement, as opposed to the occurrence of actual infringement. In order for injunctive relief to be granted by a court, the threat of infringement must be present from an objective standpoint.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

Protections established by a patent do not restrict exploitation of the patented invention for experimental or research purposes. Accordingly, experimental use can be asserted as a defence to a claim of patent infringement in relation to pharmaceuticals and medical devices. The Patent Act provides for the granting of compulsory licences to patents in certain situations, including – but not limited to – patents for pharmaceutical products and medical devices. A compulsory licence can be granted by the Commissioner of the Japan Patent Office in prescribed cases, such as where a patented invention has not been exploited in Japan for three years.

9.6 Proceedings for Patent Infringement

If a patent is infringed or there is a present threat of infringement, the patent-holder can seek injunctive relief through a civil court proceeding to force the infringing party to cease and desist and to destroy infringing articles. The patent-holder can also assert a monetary compensation claim in a civil court proceeding against the infringing party for damages that it incurred from the infringement.

The Patent Act includes special provisions intended to facilitate a patent-holder's recovery of damages incurred by the infringement of its patent. By way of an example, under the Patent Act, a person who infringes a patent is presumed to have acted negligently in relation to the infringement. This presumption shifts the burden of proof from the patent-holder to the infringing party; therefore, in order for the infringing party to prevail, it must prove that there was no negligence on its part in relation to the infringement. Invalidity of the subject patent is an available defence and can be asserted in patent infringement litigation.

9.7 Procedures Available to a Generic Entrant

In order for the producer of a potential generic entrant to establish that the action it proposes to take is lawful under patent law, it may initiate litigation against the patent-holder of the relevant brand-name pharmaceutical in order to obtain a court decision confirming the non-existence of a patent infringement claim based on the generic market entry. However, obtaining a court order through this type of lawsuit is not a requirement for generic market entry under the Japanese

pharmaceutical regulations. It is generally considered that the existence of a potential patent infringement claim is taken into account when undergoing the marketing authorisation examination procedure.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

The Pharmaceuticals Law prohibits the sale of counterfeit drugs and medical devices. As such, violators will be subject to criminal penalties. In addition, counterfeit drugs and medical devices may infringe registered trade marks and possibly registered patents. Furthermore, the import and export of IP-infringing goods may be illegal, and violators will be subject to criminal penalties. Criminal investigations of possible violations are typically conducted by the police. The import and export of infringing goods is policed by the Japanese customs authorities.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

There are no specific restrictions on the trade marks that can be used for pharmaceuticals or medical devices under the Trade Mark Act. In general, a medicinal product brand can be registered as a trade mark. There are a number of excluded categories of marks that cannot be granted trade mark rights or protections, such as a sign that:

- is the same as, or similar to, a national flag;
- is deceptive or contrary to public policy; or
- is not legally distinguishable from:
  (a) signs or marks used to identify widely recognised brands; or
  (b) other trade marks that were filed earlier.

The owner of an infringed IP right, including a trade mark owner, can seek to suspend the import or export of counterfeits that infringe its IP right by filing an application for suspension with the Japanese customs authorities.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

IP protection is available for trade dress and designs of pharmaceuticals and medical devices, as well as their packaging. Trade dress and designs can be registered and protected as trade marks under the Trade Mark Act. The Trade Mark Act stipulates a number of legal criteria to be met in order to register a trade mark, including the requirement that the relevant mark or sign is capable of distinguishing the subject goods or services from those of other manufacturers or merchants or service providers.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

There is no data exclusivity available under Japanese law for pharmaceuticals and/or medical devices. An abridged procedure for obtaining marketing authorisation for generic drugs is not available until the re-examination period for the original drug has expired. This effectively operates as a time barrier that prevents a generic drug product from receiving marketing approval until such re-examination period for the original drug has expired. The same re-examination period rules apply for chemical drugs and biologics.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

The MHLW has announced that it will prioritise the review of marketing authorisation applications for medicines and medical devices to be used for the treatment of COVID-19. The MHLW will also consider measures to streamline the process by reducing and facilitating the preparation of application materials for such medicines and medical devices. Amendments were made to relevant Japanese rules in order to broadly abolish various regulatory filing requirements that mandated the submission of documents in hard copy with the company seal affixed thereto.

11.2 Special Measures Relating to Clinical Trials

The MHLW has issued guidance addressing various special measures that can be taken in relation to clinical trials for the COVID-19 pandemic. The MHLW guidance sets out criteria to allow for, among other things, delivery of the test drug to the test subject's residence by mail, alternatives to in-person institutional review board meetings, alternatives to on-site trial monitoring, and the use of telemedicine in clinical trials.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

The Pharmaceuticals Law provides for a special emergency approval process whereby the MHLW may grant exceptional approval for pharmaceuticals and medical devices developed to address an urgent need relating to the prevention of the spread of disease or other health hazards that may pose a serious threat to the lives and health of the general public, where no suitable alternative is available other than the use of such pharmaceuticals/medical devices. In order to be granted this exceptional approval, the pharmaceuticals/medical devices must either:

- be presumed to have the efficacy or effects indicated in the application (and not be presumed to have no value as pharmaceutical/medical device products, owing to harmful effects that outweigh their efficacy or effects); or
- be authorised to be marketed in a foreign country (provided the foreign country's marketing approval system is recognised by the MHLW as being substantially equivalent to Japan's marketing approval system in terms of assessing the quality, efficacy, and safety of the pharmaceuticals/medical devices).

The MHLW has granted marketing authorisation through the exceptional emergency approval process for Remdesivir, a medication that may be used in the treatment of COVID-19.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

During the COVID-19 pandemic, various regulatory filing and inspection processes relating to manufacturing business licences for pharmaceuticals and medical devices were revised to allow for electronic processing. Additionally, amendments were made to relevant Japanese rules in order to broadly abolish various regulatory filing requirements that mandated the submission of documents in hard copy with the company seal affixed thereto.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

In March 2020, the MHLW announced that it would permit companies to import disinfectant products produced outside Japan for use within their companies to protect employees from

COVID-19. This announcement was made as a measure to:

- address the significant increase in demand for disinfectants due to the COVID-19 pandemic; and
- allow Japanese companies to procure, from outside Japan, the supplies of disinfectant products necessary for the continuation of their business operations.

11.6 Drivers for Digital Health Innovation Due to COVID-19

The MHLW took measures to facilitate the use of telemedicine services in Japan during the COVID-19 pandemic. As mentioned in **8.2 Rules for Telemedicine**, initial consultations between physicians and patients were generally not permitted to be conducted online prior to the pandemic. However, this prohibition was temporarily suspended during the COVID-19 pandemic, and telemedicine services were broadly permitted from the initial consultation.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

The Patent Act allows for compulsory licensing in cases where the implementation of a patented invention is especially necessary in the public interest. In such cases, a person may request the patentee to participate in consultations concerning the granting of a non-exclusive licence to use the patented invention and may further request an order from the Minister of Economy, Trade and Industry for an order compulsorily granting a non-exclusive licence to use the invention for a specified purpose. There have been discussions on whether compulsory licences under the Patent Act should be granted to ensure a stable supply of products used for COVID-19 treatments; however, no such compulsory licence has been granted thus far.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

In December 2020, the Japanese government enacted an amendment to the Immunisation Act, thereby allowing the government to enter into contracts with vaccine manufacturers and agree to indemnify the manufacturers for losses incurred from compensating victims who sustained harm to their health after receiving the manufacturer's COVID-19 vaccine in Japan. Based on this provision, the Japanese government has reportedly been negotiating indemnification agreements with pharmaceutical companies that are to supply COVID-19 vaccines to Japan.

Despite the measures put in place by the government concerning compensation for vaccine recipients who sustained health-related harm, and pharmaceutical company indemnification for damages attributable to COVID-19 vaccinations in Japan, Japanese law does not grant immunity to pharmaceutical companies supplying COVID-19 vaccines. Consequently, vaccine recipients are not precluded from asserting claims directly against these pharmaceutical companies for damages attributable to the harm their health suffered from the vaccine.

11.9 Requisition or Conversion of Manufacturing Sites

In the event that the Japanese government declares a state of emergency in response to COVID-19, the government can designate individual manufacturers of pharmaceuticals and medical devices and require the designated manufacturers to take the necessary measures to ensure continued manufacturing and sales of specified pharmaceuticals and medical devices. It is generally considered that the measures contemplated to be taken by the designated manufacturers would typically include measures

necessary for ensuring the prevention of COVID-19 infection and an adequate supply of pharmaceuticals and medical devices for COVID-19 treatment. The Japanese government declared a state of emergency from April to May 2020, from January to March 2021, and from April to September 2021, respectively.

Pursuant to a recent amendment, the Japanese government is able to request that manufacturers promote and co-operate with the manufacturing of pharmaceuticals and medical devices if a shortage of product could make it difficult to prevent the spread of infectious disease and this could materially affect the lives and health of the Japanese people.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

As is the case in other countries, the Japanese government has actively sought to procure stocks of COVID-19 vaccines from various vaccine-producing pharmaceutical companies so that the administration of vaccines can be implemented in Japan. According to press reports, the Japanese government has entered into agreements with Moderna and Takeda Pharmaceutical, as well as with AstraZeneca and Pfizer, for the procurement of COVID-19 vaccines.

MALAYSIA

Law and Practice

Contributed by:
Timothy Siaw and Hon Yee Neng
Shearn Delamore & Co

Contents

Shearn Delamore & Co was established in 1905 and is one of the leading law firms in Malaysia. With more than 100 lawyers, the firm has the resources to run and manage the most complex projects, transactions and matters. It maintains extensive global network links with foreign law firms and multilateral agencies, including the World Law Group, the World Services Group and the Employment Law Alliance. Shearn Delamore & Co. formed an alliance with Drew & Napier LLC, Makarim & Taira S., Martinez Vergara & Gonzalez Sociedad and Tilleke & Gibbins to launch a blue-chip legal network named Drew Network Asia. The healthcare and life sciences team provides a full range of legal advice to innovative pharmaceutical, medical device and biotechnology companies and industry investors at every stage of the product life cycle, from intellectual property protections to commercial transactions and M&A. The firm's partners and lawyers have both legal and technical qualifications in the life sciences (including biochemistry, medical biochemistry and industrial biotechnology).

Authors

Timothy Siaw is a partner in the intellectual property, healthcare and life sciences team at Shearn Delamore & Co., and in the TMT and data protection practice groups. He has degrees in Science (majoring in Biochemistry) and Law from Monash University, Australia. Tim has been practising as an IP and technology lawyer for over 30 years, and has particular expertise in laws and regulations governing businesses in the life sciences industry.

Hon Yee Neng is an associate at Shearn Delamore & Co. She graduated from the University of London with an LLB (Hons) and has been admitted as an advocate and solicitor of the High Court of Malaya. She specialises in the areas of intellectual property, healthcare and life sciences, data protection, and technology, media and telecommunications.

Shearn Delamore & Co

7th Floor
Wisma Hamzah-Kwong Hing
No 1 Leboh Ampang
50100
Kuala Lumpur
Malaysia

Tel: +603 2027 2727
Fax: +603 2072 2758
Email: timothy@shearndelamore.com
Web: www.shearndelamore.com

Shearn Delamore &CO.

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Pharmaceuticals and medical devices in Malaysia are governed by the following legislation and regulations:

- the Sale of Drugs Act 1952;
- the Control of Drugs and Cosmetics Regulations 1984 (CDCR 1984);
- the Dangerous Drugs Act 1952;
- the Poisons Act 1952 (PA 1952);
- the Medicines (Advertisement and Sales Act) 1956 (MASA 1956); and
- the Medical Device Act 2012 (MDA 2012).

The main regulatory bodies for pharmaceuticals and medical devices are:

- the Drug Control Authority (DCA);
- the Pharmacy Board;
- the National Pharmaceutical Regulatory Agency (NPRA);
- the Medicine Advertisement Board; and
- the Medical Device Authority (MDA).

All of the above legislation and regulatory bodies are under the purview of the Malaysian Ministry of Health (MOH).

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Appeals may be made against the decisions of the regulatory bodies in accordance with the procedure set out in the applicable act or regulations.

Under Regulation 18 of the CDCR 1984:

- any person aggrieved by the decision of the DCA or the Director of Pharmaceutical Services may make a written appeal to the Minister of Health for Malaysia;
- all notice of appeals shall be made within 14 days from the date of notification from the DCA; and
- any decision of the Minister made on an appeal shall be final.

Similarly, under Section 47 of the MDA 2012, a person aggrieved by the decision of the MDA may appeal to the Minister of Health for Malaysia.

A person who is adversely affected by a decision, action or omission in relation to the exercise of a public duty or function shall also be entitled to make an application to the court for judicial review, pursuant to Order 53 of the Rules of Court 2012. The following remedies may be sought under the judicial review application:

- mandamus (peremptory or mandatory order);
- certiorari (quashing order);
- prohibition (prohibition order); and
- damages.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceutical products are categorised into:

- those containing the scheduled poison(s) listed in the PA 1952, which are categorised into the following different groups, which each have different registration requirements:
  (a) Group A for products with high toxicity;
  (b) Group B for prescription medicines;
  (c) Group C for non-prescription medicines; and

(d) Group D for products for laboratory use; and
- those containing active ingredients that are not listed in the PA 1952 and that are not categorised as health supplements, natural products or cosmetics which may be freely available over the counter.

The wholesale and retail sale of pharmaceutical products are governed by Sections 15 and 16 of the PA 1952, respectively.

Medical devices are classified into four categories: Class A, B, C or D. The classification of these devices is detailed in the First Schedule of Medical Device Regulations 2012 and further elaborated in the Guidance on the Rules of Classification for General Medical Devices.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Malaysia does not have specific legislation to regulate clinical trials or research.

Clinical trials are regulated in Malaysia by the NPRA or the MDA, and are reviewed by Institutional Review Boards/Independent Ethics Committees (IRBs/IECs) of the organisation conducting the trials. Approvals from the Medical Research & Ethics Committee (MREC) for trials are required for trials using MOH facilities.

The NPRA ensures the quality, efficacy and safety of pharmaceuticals in Malaysia prior to release in the Malaysian market, and acts as a Secretariat to the DCA.

Pursuant to the Medical Device (Exemption) Order 2016, medical devices that are intended for clinical research or performance evaluation are exempted from the registration requirement under the MDA 2012.

The National Committee for Clinical Research is a steering committee empowered to establish policies and guidelines to enhance and regulate clinical research practice in Malaysia.

The DCA is empowered to review matters related to product registration, and to approve or reject applications for the following:

- a clinical trial import licence (CTIL), which is issued for the import of any product for purposes of clinical trials; or
- a clinical trial exemption (CTX), which is the authorisation to manufacture any product(s) solely for the purpose of producing samples for clinical trials.

Guidelines

The applicable clinical trial guidelines in Malaysia are as follows:

- the Malaysian Guideline for Good Clinical Practice, Fourth Edition, which adopts the basic principles outlined by the International Committee on Harmonisation of Good Clinical Practice, but with appropriate modifications to suit local requirements, effective since January 2018;
- the Malaysian Guideline for Application for Clinical Trial Import Licence and Clinical Trial Exemption in Malaysia, Edition 8.0, effective since March 2024;
- the Malaysian Guideline for Independent Ethics Committee Registration and Inspection, First Edition, effective since May 2016;
- the Malaysian Guidelines on the Use of Human Biological Samples for Research;
- the Guidelines for Good Clinical Practice (GCP) Inspection, Edition 2.1;

- the Malaysian Guideline for Phase I Unit Inspection and Accreditation Programme;
- the Malaysian Guideline for Independent Ethics Committee Registration and Inspection, First Edition;
- the Malaysian Guideline for BE Inspection, First Edition;
- the Malaysian Guideline for Safety Reporting of Investigational Products, First Edition; and
- Guidance Document and Guidelines for Registration of Cell and Gene Therapy Products (CGTPs) in Malaysia.

Directives

Directives from the Director of Pharmaceutical Services of the Pharmacy Board on the regulation of clinical trials include the following:

- all ethics committees that approve clinical trials in Malaysia must be registered with the DCA to regulate the quality, safety and efficacy of pharmaceutical products;
- all clinical trials requiring a CTIL/CTX must be registered with the National Medical Research Register (NMRR); and
- all bio-equivalence (BE) research conducted for the purpose of registering a product in Malaysia must be carried out in a BE research centre that has been listed in the NPRA's BE Centre Compliance Programme.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Before commencing any clinical trial involving product(s), the investigator/sponsor/contract research organisation (CRO) must have secured the approval of the relevant IRB/IEC and the CTIL/CTX for the importation/manufacturing of the product locally for the study.

The following products will require a CTIL/CTX:

- a product, including a placebo, that is not registered with the DCA and is intended to be imported for clinical trial purposes;
- a product with a marketing authorisation when used or assembled (formulated or packaged) in a different way from the approved form, and when used for an unapproved indication or to gain further information about an approved use for clinical trial purposes;
- a traditional product with a marketing authorisation with an indication for "traditionally used" when used for unapproved indication/therapeutic claims for clinical trial purposes; and
- an unregistered product, including a placebo, that is manufactured locally for the purpose of the clinical trial.

IRBs/IECs

The committees to which the application should be submitted will depend on the location or facility where the clinical trial will be conducted.

Government health facilities under the MOH

Under the Malaysian National Institutes of Health's Guidelines for Conducting Research in MOH Institutions and Facilities, all clinical trials involving MOH facilities must register with the NMRR and obtain prior approval from the MOH. The following requirements also apply:

- a government employee intending to act as an investigator for the clinical trial must sign an investigator agreement and obtain approval from the head of their department and the organisational or institutional director of the relevant government department – permission must be obtained to conduct research at the respective facilities/institutions;

- where a private institution undertakes collaborative research with the MOH, a Memorandum of Understanding and a Research Agreement must be executed between the related MOH institution or division and the private institution; and
- the NMRR will review the documents submitted – if it is satisfied with the registration application, the NMRR will forward them to the MREC for its review and approval.

Universities or private institutions

Applications are to be submitted to the respective IRB/IEC of the university or institution, which will review and approve the trial proposal as per the functions of the MREC. If the university or institution concerned does not have its own IRB/IEC, applications can be submitted to the MREC or any such committees of other universities or private institutions.

All ethics committees must be registered with the DCA.

The application to the IRB/IEC is made by the investigator – ie, the person responsible for the conduct of the trial or, where conducted by a team, the person who is the leader of the team (principal investigator), subject to the particular policies of that IRB/IEC.

Section 3.1.2 of the Guideline for Good Clinical Practice provides for the list of documentation to be submitted to the IRB/IEC for approval, which includes the following:

- trial protocol;
- written informed consent form;
- consent form updates;
- subject-recruitment procedures and other written information to be provided to subjects; and
- an investigator's brochure, which is a compilation of the clinical and non-clinical data on the trial drug relevant to its study in human subjects.

2.3 Public Availability of the Conduct of a Clinical Trial

There are no statutory requirements for clinical trials, nor for the results to be made publicly available.

Nevertheless, the NMRR online platform offers a publicly accessible database of medical research and clinical trials conducted in Malaysia. Additionally, some organisations also voluntarily publish their data on their websites – eg, Novartis provides technical results and trial summaries for patients from Phases 1 through 4 of interventional trials for innovative products within one year of trial completion, at their website.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no restrictions on using online tools to support clinical trials. Volunteers may be recruited through various online portals, such asClinical Research Malaysia and GSK Malaysia.

2.5 Use of Data Resulting From Clinical Trials

The data resulting from clinical trials would be considered "sensitive personal data" under Section 4 of the Personal Data Protection Act 2010 (PDPA 2010), which defines sensitive personal data as any personal data consisting of information on the physical or mental health or condition of a data subject.

Under Section 40 of the PDPA 2010, any disclosure or processing of sensitive personal data may only be made if the data subject has given their explicit consent to do so, or if any of the

special circumstances set out in Section 40(1)(b) of the PDPA 2010 are satisfied.

2.6 Databases Containing Personal or Sensitive Data

The creation of a database containing personal or sensitive data constitutes the "processing" of data under the PDPA 2010 and would therefore be subject to the seven Personal Data Principles, as set out in Sections 5 to 12 of the PDPA 2010:

- the General Principle;
- the Notice and Choice Principle;
- the Disclosure Principle;
- the Security Principle;
- the Retention Principle;
- the Data Integrity Principle; and
- the Access Principle.

Furthermore, a data user/processing body that falls under any of the classes under the Personal Data Protection (Class of Data Users) Order 2013 would also need to obtain a certificate of registration in accordance with Sections 12 to 20 of the PDPA 2010 prior to processing personal data.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The NPRA uses the following criteria to assist in the classification of products as either pharmaceuticals or medical devices:

- the primary intended purpose of the product;
- the primary mode of action/the principal mechanism of action by which the claimed effect or purpose of the product is achieved – a drug is based on pharmacological, immunological or metabolic action in/on the body, whereas a medical device does not achieve its primary mode of action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its intended function by such means;
- the active ingredient, indication and pharmaceutical dosage form (these are the main criteria for classification of the drugs); and
- the classification of the products in reference countries.

Medical devices are classified into Class A, B, C or D, based on the risk associated with the vulnerability of the human body, the technical design and the manufacture of the medical device, with different registration requirements and registration fees. The classification rules are based on:

- intended use;
- duration of use (transient, short-term and long-term); and
- the part of the human body (non-invasive or invasive with respect to body orifices, surgically invasive interventions, central circulatory system, central nervous system, etc).

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

The NPRA's requirements for the registration of biologic/biopharmaceutical products are aligned with the scientific guidelines and recommendations established by the World Health Organization, the European Medicines Agency and the International Conference of Harmonisation (ICH). These standards cover quality, clinical effectiveness and safety.

Every biologic is regulated as a new product. Both substance and drug-product production must comply with Good Manufacturing Practice strictly and in accordance with the ASEAN Common Technical Dossier (ACTD) format.

Biologics such as vaccines, biotechnology products and blood products have special registration requirements which are detailed in the Drug Registration Guidance Document, Third Edition.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

Registration/marketing authorisations for pharmaceutical and medical devices are valid for five years (unless they are suspended sooner or cancelled by the relevant authority). The renewal of a pharmaceutical registration should be submitted within six months prior to the expiry of the validity period, while a medical device re-registration can be submitted within one year prior to the expiry date, together with the appropriate fee.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

To obtain a marketing authorisation for both pharmaceuticals and medical devices, the product must be registered with the relevant authorities.

Pharmaceuticals

The registration process for pharmaceuticals may be summarised as follows.

Pre-submission of Application

The applicant needs to determine the category of the product – ie, whether it is a:

- new drug product;
- biologic;
- generic;
- health supplement; or
- natural product.

Method of Evaluation

There are four methods of evaluating the application:

- full evaluation;
- full evaluation (conditional registration), for a product that must be registered in at least one DCA reference agency; a conditional registration is valid for two years and may be renewed twice (with the possibility of two extensions of two years each);
- full evaluation via abbreviated and verification review, for a product that has been evaluated and approved by one reference drug regulatory agency – the verification review applies to a product that has been evaluated and approved by two reference drug regulatory agencies; and
- abridged evaluation.

The following general requirements for full evaluation are in accordance with ACTD/ASEAN Common Technical Requirements or ICH guidelines:

- Part I Administrative data and product information;
- Part II Data to support product quality (Quality Document);
- Part III Data to support product safety (Non-clinical Document); and
- Part IV Data to support product safety and efficacy (Clinical Document).

For an abridged evaluation, a bio-availability study and a bio-equivalence study are required.

Submission of Application

An application for product registration shall be submitted only via the online QUEST3+ System. To conduct transactions via the QUEST3+ System, the applicant must first register membership with the National Pharmaceutical Control Bureau and purchase a USB Token that contains a User Digital Certificate, which shall be installed on the applicant's computer. Once the Digital Certificate is installed, the applicant may conduct transactions for product registration and licensing in the system.

Decisions of the Authority

A regulatory decision shall be made based on the outcome of the evaluation of the submitted documentation, and samples (if applicable). An application may be approved or rejected by the DCA, and the DCA's decision will be sent via email/official letter to the product registration-holder. Every registered product is accompanied by a registration number which must be printed on its label or package.

Post-registration Process

After the product is registered, the applicant must apply for a manufacturer, import or wholesale licence and shall fulfil all commitments and conditions imposed during the approval of the product registration, and be responsible for the maintenance of the product in terms of quality, safety and efficacy throughout the validity period of registration. Failure to do so may result in the rejection of an application for the renewal of a product registration. The DCA shall also be notified of any changes to the product's efficacy, quality and safety.

Any person who is aggrieved by the decision of the DCA or the Director of Pharmaceutical Services may make a written appeal to the Minister of Health Malaysia. The re-submission of product registration that was rejected for reasons of safety and efficacy shall not be accepted within two years after the rejection. However, if the product is registered in the reference countries, the submission of an application can be made earlier.

Variation of Marketing Authorisation

Two types of variations may be made to a marketing authorisation:

- major variation (MaV) – this is a variation to a registered pharmaceutical finished product that may significantly and/or directly affect the aspects of quality, safety and efficacy and does not fall within the definition of minor variation and new registration – change-of-content of product labelling, change of batch site of sterile drug product, etc; or
- minor variation (MiV-N & MiV-PA) – this is a variation to a registered pharmaceutical finished product in terms of administrative data and/or changes with minimal/no significant impact on the aspects of efficacy, quality and safety – change of product name, the specification of drug substance, etc.

Medical Devices

The registration process for medical devices may be summarised as follows.

Pre-submission of application

The applicant should first determine the device's classification according to the First Schedule of Medical Device Regulations 2012. Thereafter, a conformity assessment shall be undertaken to collect the evidence of conformity, which shall be verified by a registered Conformity Assessment Body (CAB). The CAB will subsequently issue a certificate of conformity and a report for the purposes of submission for registration.

Submission of application

Application for registration of a medical device may be made after supporting documents are available. Application for medical device registration shall be submitted online through MeDC@St2.0+. The form consists of eight parts as follows:

- general information of the device;
- information of manufacturer;
- grouping of device;
- Common Submission Dossier Template (CSDT) which can be found in Appendix 2 of Third Schedule of the Medical Device Regulations 2012;
- supporting documents for CSDT;
- post-market vigilance history;
- declaration of conformity in accordance with Appendix 3 of Third Schedule of the Medical Device Regulations 2012; and
- attestation for medical device registration application.

Decisions of the authority

The MDA may reject an application if it lacks sufficient information or includes incorrect documentation. Applicants will receive the decision through email and will be given an opportunity to resubmit the requested information within the request date. Every registered product is accompanied by a registration number which must be printed on its label in a manner that is legible, permanent and prominent.

Transfer of marketing authorisation

It is permissible to transfer the market authorisation from one marketing authorisation holder to another. Upon the approval of the transfer of marketing authorisation, the former product registration holder shall no longer have marketing authorisation over the registered product.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

The licence required to manufacture or supply a product does not apply to the dispensing of any drug for the purpose of it being used for the medical treatment of a patient or animal by a pharmacist, a fully licensed medical, dental or veterinary practitioner or a person employed in a governmental hospital or dispensary to dispense drugs.

Under Regulation 15(6) of the CDCR 1984, any person who wishes to import or manufacture any product solely for the purpose of treating any person suffering from a life-threatening illness may, upon application, be exempted from having to obtain marketing authorisation.

The Medical Device (Exemption) Order 2016 has provided for medical devices to be exempted from registration requirement if they are used for personal use, educational, investigational, or other specific defined purposes. The manufacturer or supplier seeking to supply such medical device must first submit a notification to the MDA for an exemption.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

Product registration holders of pharmaceutical products are required to carry out pharmacovigilance. Pursuant to the CDCR 1984, product registration holders shall inform the Director of Pharmaceutical Services immediately of any adverse reaction arising from the use of the registered product.

All product registration holders must ensure that the company has a pharmacovigilance system in

place and that appropriate action is taken, when necessary.

Product registration holders are required to monitor and report any product safety issues that arise locally or internationally to the NPRA, and to comply with all safety-related directives issued by the NPRA.

The product registration may be cancelled if the product registration holder fails to inform the NPRA of any serious adverse reactions upon receipt of such reports. For further information, reference may also be made to the Malaysian Guidelines on Good Pharmacovigilance Practices (GVP) for Product Registration Holders, First Edition, which contains guidelines for the establishment of a pharmacovigilance system.

The Malaysian Adverse Drug Reactions Advisory Committee is an advisory body to the DCA to supervise pharmacovigilance activities for medicinal products registered in Malaysia.

In relation to medical devices, Section 38 of the MDA 2012 requires the holder of a marketing authorisation to monitor the safety and performance of the medical device, and to put a post-market surveillance system in place.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

All information declared in the registration form for marketing authorisations of pharmaceuticals is confidential and is not accessible to third parties.

In relation to medical devices, the applicant must apply to the MDA for any information relating to the application to be kept confidential. The grant of confidentiality is at the discretion of the MDA, and consideration will be given to the criteria stated in Section 68(3) of the MDA 2012. If confidentiality is not granted, Section 69 of the MDA 2012 stipulates that, subject to the discretion of the MDA, the public may have access to such information relating to the application.

Information relating to individuals is governed by the PDPA 2010. Any disclosure or processing of sensitive personal data may only be made if the data subject has given their explicit consent to do so. Notwithstanding the requirement for explicit consent from the data subject, Section 40 of the PDPA 2010 also allows the processing of sensitive personal data where:

- the processing is necessary for the following reasons:
  - (a) to exercise or perform any right or obligation that is conferred or imposed by law on the data user in connection with employment;
  - (b) in order to protect the vital interests of the data subject or another person, in a case where consent cannot be given by or on behalf of the data subject or the data user cannot reasonably be expected to obtain the consent of the data subject;
  - (c) in order to protect the vital interest of another person, in a case where consent by or on behalf of the data subject is unreasonably withheld;
  - (d) for medical purposes and the processing is undertaken by a healthcare professional;
  - (e) for any legal proceeding;
  - (f) to obtain legal advice;
  - (g) for the administration of justice;
  - (h) for the exercise of any functions conferred by law;
  - (i) for any purpose the Minister deems fit; or

- the information contained in the personal data has been made public as a result of steps taken deliberately by the data subject.

3.8 Rules Against Illegal Medicines and/or Medical Devices

Pharmaceutical Products

Regulations 7 and 18A of the CDCR 1984 prohibit the illegal distribution of drugs and cosmetics products. A person who commits an offence under the CDCR 1984 is liable to a fine not exceeding MYR20,000 or to imprisonment for a term not exceeding three years, or to both.

Medical Devices

Section 5(2) of the MDA 2012 provides that any person who imports, exports or places on the market an unregistered medical device commits an offence, and shall be liable to a fine not exceeding MYR2 million or to imprisonment for a term not exceeding three years, or to both.

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

Issues relating to counterfeiting are dealt with under the Trademarks Act 2019, under Section 82(1) which states that any person may file an application to the Registrar, stating that:

- they are the registered proprietor, or the licensee having the power to file such application;
- at a time and place specified in the application, goods infringing the registered trade mark are to be imported for the purpose of trade; and
- they object to that importation.

Upon approval by the Registrar, the importation of any infringing goods into Malaysia for the duration of the period specified in the approval shall be prohibited. An approval shall remain in force until the end of a 60-day period commencing on the day of the approval, unless withdrawn earlier by the applicant. Where goods have been seized pursuant to the application, the applicant must take action for infringement within the retention period, otherwise the goods shall be released back to the importer and the applicant may be further liable for loss or damage suffered by the importer as a result of the seizure.

4. Manufacturing of Pharmaceuticals and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

Under Regulation 7(1) of the CDCR 1984, except as otherwise provided therein, no person shall manufacture, sell, supply, import, possess or administer any product unless the product is a registered product and the person holds the appropriate licence required and issued under the Regulations. Thus, any company carrying out the manufacture, import or wholesale of any registered products must hold a manufacturer's licence, import licence or wholesale licence. The Director of Pharmaceutical Services grants the authorisation.

An application for a manufacturer's licence for pharmaceutical products can be made online through the QUEST3+ System. To qualify for the application, the company must be a Product Registration Holder or is appointed by the holder as a contract manufacturer for registered products. Additionally, the manufacturing site must meet the standards of Good Manufacturing Practice and Good Distribution Practice. If the establishment intends to handle scheduled poisons listed under the First Schedule of the PA

1952, it is mandatory to appoint a pharmacist who has a Type A Poison License.

Once the manufacturer's licence is granted, the applicant can manufacture registered products in their premises and can sell by wholesale, or supply the registered products.

The manufacturer's licence for pharmaceutical products is valid for one year, from 1 January to 31 December of the same year.

Medical Devices

All establishments (ie, manufacturer, authorised representative, importer and distributor) must apply for an establishment licence. However, only manufacturers and authorised representatives need to apply for medical device registration under Section 15 of the MDA 2012. The MDA grants the authorisation of an establishment licence.

The application for an establishment licence can be made at MeDC@St2.0+. A flow chart of the application process is provided on the website. With the establishment licence, the manufacturer can import, export or place any registered medical device on the market.

The establishment licence is valid for three years, and an establishment can start to renew the licence one year prior to the expiry date.

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

Establishments engaged in the wholesale of pharmaceutical products are required to obtain a wholesale licence under the CDCR 1984. An application for a wholesaler licence for pharmaceutical products can be made online through the QUEST3+ System. If the establishment intends to handle scheduled poisons listed under the First Schedule of the PA 1952, it is mandatory to appoint a pharmacist who has a Type A Poison License.

The Guideline on Application of Manufacturer's, Import and Wholesaler's Licenses for Registered Products, Second Edition details the procedures for application of the licences for registered products.

Once the wholesaler's licence is granted, the licence holder can sell by wholesale or supply registered products from their premises. The licence holder is also required to comply with the principles of Good Distribution Practice. The Wholesaler's Licence for pharmaceutical products is valid for one year, from 1 January to 31 December of the same year.

Medical Devices

For medical devices, a distributor shall obtain an establishment licence to conduct its activity. With an establishment licence, a distributor can import, export or place any registered medical device on the market.

5.2 Different Classifications Applicable to Pharmaceuticals

The classifications of drugs can be found in the First Schedule of the PA 1952, where drugs are classified into the following:

- Group A Poison – high-toxicity medicines – eg, alclofenac, amidopyrine, avoparcin;
- Group B Poison – used in treatment where a doctor's diagnosis is needed to recognise the symptoms, and can be dispensed only

against prescription – eg, nifedipine, olanzapine, ramipril;
- Group C Poison – used in treatment where the symptoms are easily recognised, and can be dispensed without prescription – eg, ibuprofen, piroxicam, mefenamic acid; and
- Group D Poison – chemicals for laboratory use – eg, cetyl chloride, ethylidene diacetate, methyl bromide.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The CDCR 1984 governs the import and export of pharmaceuticals. Under Regulation 7(1) of the CDCR 1984, except as otherwise provided therein, no person shall manufacture, sell, supply, import, possess or administer any product unless the product is a registered product and the person holds an import licence required and issued under these Regulations.

An application for an importer's licence for pharmaceutical products can be made online through the QUEST3+ System. To qualify for the application, the company must be a Product Registration Holder or is appointed by the holder as a contract manufacturer for registered products. Additionally, the importer's premise must meet the requirements of Good Distribution Practice. If the establishment intends to handle scheduled poisons listed under the First Schedule of the PA 1952, it is mandatory to appoint a pharmacist who has a Type A Poison License. With an import licence, the licence holder can import or sell by wholesale or supply registered products.

Section 12 of the Dangerous Drugs Act 1952 prohibits the import of any dangerous drugs specified in Parts III, IV and V of the First Schedule thereof and the export of any dangerous drug specified in Parts III and IV unless otherwise authorised by the Minister of Health.

Medical Devices

The MDA 2012 governs the import and export of medical devices. The importation, exportation, or placement of a medical device in the Malaysia market requires the medical device to be registered under MDA 2012. Importers are also required to obtain an establishment licence.

A special exemption exists for exportation of export only medical devices. Pursuant to the Circular Letter of Medical Device Authority No 4, medical devices intended solely for export are exempted from the registration requirements under the MDA 2012. Instead, an exporter need only apply for an Export Only Medical Device Exemption Letter issued by the MDA.

Over and above, it is pertinent to note that at the point of entry, import regulations are applied and enforced by the Royal Malaysian Customs Department, specifically the Import Management & Enforcement Unit and the Export Management & Enforcement Unit under the Customs Division.

6.2 Importer of Record of Pharmaceuticals and Medical Devices

For a CTIL (for the import of any product for purposes of clinical trials, notwithstanding that the product is not a registered product), only an investigator or an authorised person from a locally registered pharmaceutical company/sponsor/CRO with a permanent address in Malaysia can act as an importer of record of pharmaceuticals and medical devices in the country.

An application for a CTIL/CTX containing a "poison/drug" should be made by a Poison Licence Type A holder for a pharmacist in the private sector or an Annual Retention Certificate holder for a public pharmacist. However, it should be noted that the holder of a CTIL/CTX for a particular product need not necessarily conduct the clinical trial themselves.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

The importation of pharmaceuticals and medical devices is subject to prior authorisation, as stated in Regulation 7 of the CDCR 1984, Section 8 of the PA 1952 and Section 15 of the MDA 2012.

There are exemptions regarding those authorisations. Special exemptions for the importation of products that are not registered with the DCA may be granted for the treatment of life-threatening illnesses, as provided under Regulation 15 (6) of the CDCR 1984.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Licences are required prior to the importation of any poison into Malaysia, under Section 8 of the PA 1952.

The categories of licences can be found in Section 26(2)(a) of the PA 1952:

- Type A licence issued to a pharmacist to import, store and deal in all poisons generally by wholesale and retail or by wholesale only or by retail only, subject to this Act;
- Type B licence issued to any person who is deemed fit or a responsible officer of a company to import, store and sell by wholesale any such poisons (not being a Group A Poison) as may be specified in such a licence;
- Type C licence issued to any person (in this Act referred to as "a listed seller") the licensing officer considers to be a fit and proper person to hold such a licence, to store and sell by retail Group F Poisons only;
- Type D licence issued to any person the licensing officer considers to be a fit and proper person to hold such a licence, to store and sell by retail any such Part II Poisons as may be specified therein; and
- Type E licence issued to any person who, in the course of their business, uses sodium hydroxide in such a substantial quantity that the licensing officer deems it appropriate to issue them a licence to import, store and use sodium hydroxide.

Section 30 of the PA 1952 further states that any psychotropic substances listed in the Third Schedule of the Act cannot be imported, exported, manufactured, compounded, mixed, dispensed, sold, supplied, administered, possessed or used, unless it is in accordance with the regulations applicable under the PA 1952.

Section 12 of the Customs Act 1967 further prohibits the importation and exportation of any dangerous drugs specified in Parts III, IV and V of the First Schedule thereof, unless otherwise authorised by the Minister.

6.5 Trade Blocs and Free Trade Agreements

Malaysia has already signed and implemented seven bilateral free trade agreements (FTAs), with Japan, Pakistan, India, New Zealand, Chile, Australia and Turkey.

At the ASEAN level, Malaysia has nine regional FTAs, with China, Korea, Japan, Australia, New Zealand Hong Kong and India, as well as the ASEAN Free Trade Agreement (AFTA), Regional

Comprehensive Economic Partnership (RCEP) and Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP).

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

The prices of pharmaceuticals and medical devices are not regulated in Malaysia.

In 2006, the Malaysian government introduced the Malaysian National Medicines Policy to promote equitable access and rational use of medicines for public health. The policy is revised and reissued every four years. Aligned with this Policy, various strategies have been introduced to ensure medicine prices are fair and affordable for Malaysians. Among these strategies, the Pharmaceutical Services Programme offers a list of medicines prices on its website which aims to assist the public with purchasing medicines in the private sector. This consumer price guide offers details on the availability and suggested retail prices of medicines as determined by the product registration holder, enabling consumers to make informed decisions. In the public sector, the MOH indirectly controls and reduces medicine prices with bulk purchases through concession supply and national tenders to provide accessible and affordable medicines.

7.2 Price Levels of Pharmaceuticals or Medical Devices

Currently, the price level of a pharmaceutical or medical device does not depend on the prices for the same product in other countries.

In the Medicine Price Monitoring Report 2020 issued by the MOH, a comparison was made between the international reference price and the procurement price in the public and private sectors in Malaysia. Pursuant to this, there have been discussions on the introduction of drug price regulations, but no concrete actions have yet been taken.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

In Malaysia, the government-based and publicly funded sectors provide health services that are tax-funded and administered by the MOH through its central, state and district offices. The policies and programmes are centrally formulated, funded and administered.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

There is no formal reimbursement system in Malaysia for pharmaceuticals or medical devices.

Although health technology assessments play a role in the formulation of drug policies in Malaysia, cost-effectiveness evidence is currently not mandatory, although it is of interest to decision-makers.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

In Malaysia, the prescription and dispensing of pharmaceuticals are currently governed by the PA 1952, the Poisons Regulations 1952 and the Poisons (Psychotropic Substances) Regulations 1989.

The Guide to Good Dispensing Practice 2016 establishes guidelines and procedures for good dispensing practice. It categorises the dispensing process into the following key areas: screening of prescriptions, preparation of medicines,

supplying the medicines, recording and counselling.

The Guide also emphasises the importance of proper record keeping. It mandates that whenever any poison is sold or supplied as a dispensed medicine or as an ingredient in a dispensed medicine, the seller or supplier shall record certain information in a Prescription Book, which includes the date of sale, the serial number of the entry, the name of the poison and the ingredients of the medicine, the quantity supplied, etc.

8. Digital Healthcare

8.1 Rules for Medical Apps

There are no specific rules that govern medical apps in Malaysia. However, the definition of medical devices under Section 2 of the MDA 2012 includes:

- any software for the purpose as specified in paragraphs (i) to (vii) of Section 2 that does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its intended function by such means; or
- any software to be used on the human body, which the Minister may, after taking issues of public safety, public health or public risk into consideration, declare to be a medical device by an order published in the Gazette.

As such, the MDA 2012 shall apply to medical apps that are used for purposes within the definition of a medical device under the Act. The application for the registration of a medical device is, in turn, governed by Section 6 of the MDA 2012.

8.2 Rules for Telemedicine

The Telemedicine Act 1997 was introduced in 1997 but is not yet in force. Telemedicine is defined as the practice of medicine using audio, visual and data communications.

Section 3 of the Telemedicine Act provides that only a fully registered medical practitioner holding a valid practising certificate or a medical practitioner who is registered or licensed outside Malaysia and holds a certificate to practise telemedicine issued by the council and practises telemedicine from outside Malaysia through a fully registered medical practitioner holding a valid practising certificate is authorised to practise in Malaysia.

8.3 Promoting and/or Advertising on an Online Platform

Section 2 of the MASA 1956 defines an advertisement to include any notice, circular, report, commentary, pamphlet, label, wrapper or other document, and any announcement made orally or by any means of producing or transmitting light or sound. The Guideline on Advertising of Medicines and Medicinal Products to General Public lists online advertising as an example of advertisement under the definition in Section 2.

The MASA 1956 governs any online advertising of medicines and medical devices in Malaysia. As advertising on online platforms is regulated, conditions imposed by the MASA 1956 shall be followed. Accordingly, online advertisement is subject to approval by the Medical Advertisement Board.

The Medical Device (Advertising) Regulations 2019 govern matters relating to the contents and conditions for the advertising of medical devices and provide that approval must be obtained to advertise a registered medical device.

8.4 Electronic Prescriptions

Electronic prescriptions are now allowed via the amendments under the Poisons (Amendment) Act 2022.

Pursuant to the amendments brought under the Poisons (Amendment) Act 2022, electronic prescriptions are now allowed for Group B Poison. Section 21(2A) of the PA 1952 provides that every electronic prescription shall adhere to the following:

- created and dated in electronic form;
- signed with a digital signature by the prescriber;
- sent to a registered pharmacist as an electronic message;
- state the name and address of the prescriber;
- state the name and address of the patient or, in the case of a prescription by a registered veterinary surgeon, the name and address of the person to whom such medicine is to be delivered;
- indicate the total amount of medicine to be supplied and the dose; and
- specify the number of times (not exceeding three) the medicine may be dispensed and, if dispensed more than once, at what intervals.

8.5 Online Sales of Medicines and Medical Devices

Under Section 13 of the PA 1952, it is against the law to sell or supply medicine without a licence. Violators may face fine up to MYR50,000 or receive a term of imprisonment not exceeding five years or both. Similarly, under Section 5 of the MDA 2012, selling unregistered medical device attracts a fine not exceeding MYR 200,000 or imprisonment for a term not exceeding three years or both.

While the sale of medicines and medical devices online is not regulated by any specific piece of legislation, the seller must comply with the Consumer Protection (Electronic Trade Transactions) Regulations 2012.

8.6 Electronic Health Records

Health-related information is regulated as sensitive personal data, as defined in Section 4 of the PDPA 2010. Sensitive personal data includes personal data consisting of information on the physical or mental health or condition of a data subject.

The processing of such information is governed by Section 40 of the PDPA 2010, which states that sensitive personal data may only be processed if the data subject has given their explicit consent or if the processing is necessary under certain circumstances set out in the PDPA 2010.

In terms of the storing of information in cloud platforms, the Malaysian Department of Personal Data Protection issued a Personal Data Protection Standard in 2015, which states that the transfer of personal data through cloud platforms is not permitted unless written consent is obtained from an officer authorised by the top management of the data user organisation. The transfer of personal data through cloud platforms must comply with personal data protection principles in Malaysia, and with the personal data protection laws of other countries.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices

Patent rights in Malaysia are governed by the Patents Act 1983 (PA 1983), together with the Patents Regulations 1986.

The issue most commonly encountered by pharmaceutical and medical devices products under the legislation is patent infringement.

There is no specific patentability requirement for pharmaceuticals or medical devices.

9.2 Second and Subsequent Medical Uses

The patenting of second and subsequent medical uses is expressly permitted under Section 14(4) of the PA 1983. Inventions in relation to new dosage regimes or selected patient populations are patentable in Malaysia if they satisfy the novelty and inventiveness patentability requirements.

A patent is infringed when a product or process falling within the scope of the protection of the patent, as defined by the claims in the patent, is exploited without the patentee's consent.

9.3 Patent Term Extension for Pharmaceuticals

Section 35 of the PA 1983 states that the term of protection of a patent shall be 20 years. There is currently no provision for patent term extension in Malaysia.

9.4 Pharmaceutical or Medical Device Patent Infringement

The patentee's exclusive right to exploit a patent allows them to exclusively use the patented product or patented process and to make, import, offer for sale or sell the patented product and any product obtained directly by means of the patented process. A patent is infringed when there is any unauthorised exploitation thereof.

However, Section 37(1A) of the PA 1983 provides that "the rights under the patent shall not extend to acts done to make, use, offer to sell or sell a patented invention solely for uses reasonably related to the development and submission of information to the relevant authority either in Malaysia or outside Malaysia which regulates the manufacture, use or sale of pharmaceutical products". Accordingly, applications for marketing authorisations for pharmaceutical products (but not medical devices) will not infringe the patent.

A cause of action for "imminent infringement" is also available in Malaysia, as provided for under Section 59(2) of the PA 1983. It is arguable that an application for marketing authorisation constitutes "imminent infringement" of a subsisting patent in relation to the product. However, this interpretation should be read in light of Section 37(1A) of the PA 1983.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

In Malaysia, the Bolar exemption is encapsulated in Section 37(1) of the PA 1983, which limits the rights under the patent to acts done for industrial or commercial purposes and not to acts done only for experimental or scientific research. Section 37(1A) of the PA 1983 further provides that a patentee's rights shall not extend to acts done

in relation to a patented invention solely for uses reasonably related to the development and submission of information to the relevant authority either in Malaysia or outside Malaysia that regulates the manufacture, use or sale of pharmaceutical products. It should be highlighted that the applicability of Section 37(1A) of the PA 1983 is limited to pharmaceutical products; it does not cover medical devices.

As a pre-emptive measure, an interested person may apply to court against the patent owner for a declaration under Section 62 of the PA 1983 that the performance of a specific act does not constitute an infringement of a patent.

Defences

The following defences to a patent infringement action are available:

- the claims of the patent allegedly infringed are invalid;
- the product complained of was not obtained by the patented process or, at any rate, not directly;
- the patentee has exhausted their rights – ie, the patented product or product obtained directly by means of the patented process was produced in Malaysia or elsewhere by or with the consent, conditional or otherwise, of the owner of the patent or of their licensee;
- the acts complained of were done privately either for purposes that are not industrial or commercial, or for scientific research relating to the subject matter of the invention;
- the acts complained of were reasonably related to the development and submission of information to the relevant authority that regulates the manufacture, use or sale of drugs (Bolar exemption);
- the acts complained of were done in connection with a foreign vessel, aircraft, spacecraft or land vehicle temporarily in Malaysia;
- the acts were done after notification in the Gazette that the patent has lapsed and before notification in the Gazette that the patent has been reinstated;
- the rights were done pursuant to a compulsory licence;
- the act was authorised by the government; and
- the "Gillette" defence, under which the alleged infringement is old or obvious – ie, what the defendant is doing differs from what was known before the date of the patent only in non-patentable variations.

Compulsory Licences

Under Section 49 of the PA 1983, an application for a compulsory licence may be made after the expiration of three years from the grant of patent or four years from the filing date of the patent application, whichever is the later, on the following grounds:

- where there is no production of the patented product or application of the patented process in Malaysia without any legitimate reason; or
- there is no product produced in Malaysia under the patent for sale in any domestic market, or there are some but they do not meet the public demand without any legitimate reason.

Notwithstanding the above, a compulsory licence may be granted any time after the grant of patent in the following circumstances:

- where the patented products are sold in the domestic market at unreasonably high prices without any legitimate reason; or

- for the purposes of production of a pharmaceutical product in Malaysia and the exportation of such pharmaceutical product to an eligible importing country to deal with its public health problem.

Prior to making an application to the Patent Registrar for a compulsory licence, the applicant shall first attempt to obtain authorisation from the owner of the patent on reasonable commercial terms.

Under Section 84 of the PA 1983, a government agency may exploit a patented invention under a government-use licence without the consent of the patent owner if there is a national emergency or where such is required by public interest; or where a judicial or relevant authority has determined that the manner of exploitation by the patent owner or their licensee is anti-competitive.

9.6 Proceedings for Patent Infringement

A patentee may bring a civil action against an infringer at the High Court. A patent infringement action generally begins by filing a writ of summons against the infringer. The procedure to be complied with for an action by writ is governed by Orders 6 and 10 of the Rules of Court 2012.

Remedies

A plaintiff in an infringement action may claim and obtain the following:

- an injunction (including a quia timet, interlocutory injunction and permanent injunction) restraining the defendant from any act of infringement or imminent infringement;
- an order for the delivery up or destruction of any patented product in relation to which the patent is infringed or any article in which that product is inextricably comprised;
- damages in respect of the infringement;
- alternatively, an account of the profits derived by the defendant from the infringement;
- a declaration that the patent has been infringed by the defendant and (if validity has been successfully contested) that the patent is valid;
- interest on any sum found payable; and
- further or other relief and costs.

Invalidation

A defendant in an infringement action may counterclaim for an invalidation of the patent on the following grounds:

- that it is not an invention – ie, not an idea that permits, in practice, a solution to a specific problem in the field of technology;
- that it is not patentable – the alleged invention is excluded from being patentable with reference to the following:
  (a) discoveries, scientific theories and mathematical methods;
  (b) plant or animal varieties or essentially biological processes for the production of plants or animals, other than manmade living micro-organisms, microbiological processes and the products of such micro-organism processes;
  (c) schemes, rules or methods for doing business, performing purely mental acts or playing games; and
  (d) methods for the treatment of human or animal bodies by surgery or therapy, and diagnostic methods practised on the human or animal body;
- that it is contrary to public policy – ie, the performance of any act in respect of the claimed invention would be contrary to public order or morality;
- that it is not new – ie, the alleged invention has been anticipated by prior art, which is defined as everything disclosed to the public,

anywhere in the world, by written publication, by oral disclosure, by use or in any other way, before the priority date of the claim;
- that there is no inventive step – the invention is obvious, having regard to what was known or used before the priority date;
- that it is not industrially applicable – the invention cannot be made or used in any of kind of industry;
- that the description or claim does not comply with the Patents Regulations 1986 – the specification is ambiguous or does not sufficiently and fairly describe the invention and the method by which it is to be performed, or does not disclose the best method known to the applicant for the patent and for which they were entitled to claim protection;
- that the drawings that are necessary for the understanding of the claimed invention have not been furnished;
- that the patentee is not entitled – ie, the right to the patent does not belong to the person to whom the patent was granted; and
- that there is incomplete or incorrect information – false or incomplete information has been deliberately provided, or caused to be provided, to the Registrar when filing a request for substantive examination by the patentee or their agent.

9.7 Procedures Available to a Generic Entrant

At the pre-submission stage of the application to the NPRA, the potential generic entrant shall provide the NPRA with a declaration that it shall comply with all legal provisions in Malaysia and conform to the PA 1983, and that it shall not market, sell, offer for sale or store any registered product containing any patented active ingredient(s) for which the patent duration has yet to expire.

A potential generic entrant who qualifies as an interested person shall have the right to apply for a declaration from the court against the owner of a patent that the performance of a specific act does not constitute an infringement of the patent, provided that the act in question is not already the subject of infringement proceedings. These proceedings for a declaration of non-infringement may be instituted together with the invalidation proceedings.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Issues of counterfeits are generally dealt with under the Trademarks Act 2019. In addition to civil remedies pursuant to trade mark infringement, any person who counterfeits a registered trade mark commits an offence and would be liable to criminal sanctions as well.

Issues of counterfeiting may also infringe the intellectual property rights residing in the packaging/container of the pharmaceutical and medical device – eg, design rights under the Industrial Designs Act 1996 and copyrighted works in the literary and artistic works in the package inserts. An infringement proceeding for industrial designs is by way of a civil action taken by the owner against any person who has infringed the rights conferred by the registered industrial design, as provided under Section 33 of the Industrial Designs Act 1996.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

The Trademarks Act 2019 does not impose any restrictions on trade marks that can be used for pharmaceuticals and medical devices.

In the now-repealed Trade Marks Act 1976, parallel imports were allowed on the principle of the exhaustion of rights, which is encapsulated in Sections 40(1)(d) and 40(1)(dd) and reads:

"(1) Notwithstanding anything contained in this Act, the following acts do not constitute an infringement of a trade mark:

(d) in relation to goods connected in the course of trade with the registered proprietor or a registered user of the trade mark if, as to those goods or a bulk of which they form part, the registered proprietor or the registered user in conforming to the permitted use has applied the trade mark and has not subsequently removed or obliterated it or has at any time expressly or impliedly consented to the use of the trade mark;

(dd) the use by a person of a trade mark in relation to goods or services to which the registered proprietor or registered user has at any time expressly or impliedly consented to…".

However, only Section 40(1)(dd) was retained in the new Trademarks Act 2019, in Section 55(3)(c), so it is unclear whether the previous case law discussing Sections 40(d) and 40(dd) remains applicable.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

The Trademarks Act 2019 allows for the shape of goods or their packaging to be registered as a trade mark, as long as it fulfils the general requirements for registration. Therefore, a registered mark for the shape or packaging will be granted trade mark rights.

Unregistered trade dress or design for pharmaceuticals, medical devices or their packaging may be protected in Malaysia under the common law tort of passing off. To establish a claim for passing off, the following elements must be satisfied:

- the plaintiff has sufficient reputation or goodwill in the mark;
- the defendant has misrepresented to the relevant members of the trade/public, as a result of which they are misled or likely to be misled into believing that the goods are endorsed, permitted and/or licensed by the claimant or affiliated with the claimant; and
- the plaintiff has suffered or is likely to suffer damage or injury to its business or goodwill by reason of the defendant's misrepresentation.

Trade dress or design of pharmaceuticals and medical devices such as tablets may further be registered and protected under the Industrial Designs Act 1996, as they fall under the definition of "features of shape, configuration, pattern or ornament applied to an article by any industrial process or means".

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

In Malaysia, undisclosed, unpublished and non-public domain pharmaceutical test data is protected under Directive No 2 on Data Exclusivity 2011, which was issued by the Director of Pharmaceutical Services under Regulation 29 of the CDCR 1984. The Directive provides data exclusivity for new chemical entities and second indications only.

The data exclusivity period runs from the date the new drug or the second indication is first registered or granted marketing authorisation and data exclusivity or test data protection in the country of origin or any country recognised

by the Director of Pharmaceutical Services. The period for which data exclusivity is granted is determined on a case-by-case basis by the Director of Pharmaceutical Services; it shall not be more than five years for a new drug product containing a new chemical entity, and three years for the second indication of a registered drug product.

Data exclusivity is not automatically conferred upon approval of a drug. The interested party must make a separate application for data exclusivity.

An application for data exclusivity can be made via a Letter of Intent in conjunction with the application for registration of a new drug product containing a new chemical entity or the application for a second indication of a registered drug product.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

Various regulations and guidelines have been issued concerning the commercialisation and distribution of medicines and medical devices aimed at handling COVID-19 in Malaysia. These include the following.

- The MDA's Guideline on Conditional Approval for COVID-19 Rapid Test Kit (Self-Test) established a temporary approval method for COVID-19 test kits to expedite the registration process of this medical device. Under this initiative, the requirement for the CAB to conduct conformity assessments on medical devices is waived. Instead, a COVID-19 Expert Committee was established to assess and evaluate the test kits to ensure their compliance with the established requirements of quality for use. The conditional approval is valid for one year and may be revoked if concerns are raised about the device's safety and/or the applicant's non-compliance with the requirements of the conditional approval.
- The NPRA issued the Guidance and Requirements on Conditional Registration for Pharmaceutical Products During Disaster to provide expedited access to pharmaceutical products such as vaccines during a disaster. Under this scheme, all registration applications for pharmaceutical products that fulfil the stipulated conditions will be given priority review, in which evaluation will be completed within 70 working days instead of the standard 210 working days. Products that have been conditionally approved by any DCA reference country or the WHO will be given top priority. Pursuant to this guidance, the standard requirements for the registration of pharmaceutical products have been relaxed. For instance, an application for pharmaceutical product registration may now be made for a pharmaceutical product that has not completed the Phase III clinical study.
- The DCA issued Decision NPRA.600-1/9/7(41), which exempted all registered COVID-19 vaccine products from the requirement to conduct physical tests for lot release activities. Pursuant to this decision, the requirement for the National Regulatory Authority or National Control Laboratory to evaluate an individual lot of a registered vaccine has been waived.

11.2 Special Measures Relating to Clinical Trials

During the COVID-19 pandemic, the NPRA allowed sponsors to distribute investigational products directly to trial subjects without the

need for site visitation or personal contact ("Direct-to-Patients"). The sponsor shall notify this arrangement to the NPRA and document each delivery in an accountability report for regulatory inspections.

The investigational product accountability report shall include a comprehensive record of the standard operation procedure for delivery, the manner of delivery, the storage requirements, the subject receiving adequate training on self-administration of the investigational products, and the employees processing the subject's personal data.

When implementing the Direct-to-Patients option, the following must be observed:

- the sponsor holds a valid CTIL or CTX with an approved import quantity;
- the investigational products shall only be distributed from Malaysian sites to trial subjects;
- the delivery of the investigational products shall not raise any new safety risks;
- subjects understand and provide consent that the investigational products will be delivered directly to their homes;
- the sponsor has investigated the viability of alternative distribution via an investigator or hospital pharmacy; and
- the sponsor shall ensure the conduct of appropriate alternative safety monitoring if subjects are not able to come to the investigational site.

The NPRA has also issued a Special Directive to accept applications for CTX from local manufacturers to manufacture unregistered COVID-19 vaccine products for the purposes of conducting research and development in Malaysia involving First-in-Human (FIH) studies. It must be noted that the regulatory requirements for clinical trials remain applicable.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

The NPRA issued Directive NPRA.600-1/9/13 (19), which grants conditional registration for COVID-19 vaccines supplied through the COVID-19 Vaccines Global Access (COVAX) Facility. The vaccine will be conditionally registered by the NPRA using the recognition mechanism that has been approved by the WHO Emergency Use Listing. The conditional registration of the vaccine under the COVAX Facility is for one year from the date the vaccine is registered and can be renewed.

The MDA issued guidelines for the importation and placing in the market of medical devices during an emergency situation through special access notification. The relevant guidelines are as follows.

- The Medical Device Guidance Document (Special Access – Notification – General Requirements) allows the MDA to issue a "no restriction letter" to an applicant for the purposes of importation and placement of the special access medical device in the Malaysian market. These medical devices are exempted from registration with the MDA and can be imported into Malaysia based on special access. The Guidance identified the following situations in which medical devices are eligible for special access:
  (a) when medical devices are to be used in an emergency situation that poses an immediate risk to a patient's life or long-term health where the required medical devices are not available in Malaysia;
  (b) where there is an absence of alternative treatment options or where available alter-

native treatments failed or were deemed ineffective or unsuitable for the patient according to the medical practitioner's clinical judgement;
(c) where the medical device is needed to minimise disruption to the continued supply of a similar medical device; and
(d) where the design and/or operation of a device is likely to support or enhance the outcomes of the procedure or treatment for the patient.

- The Medical Device Guidance Document (Special Access – Requirements For Ventilator During Emergency Situation) allows an applicant to import and/or sell ventilators in the Malaysian market via a "special access notification". Pursuant to this Guidance, certain registration requirements are modified to ensure speedy approvals of such applications.
- Guideline for Registration of COVID-19 IVD Test Kits allows the MDA to grant conditional approval or special access notification to establishments to register COVID-19 test kits as medical devices.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

The NPRA has introduced new guidelines to modify Good Manufacturing Practice and Good Distribution Practice inspections, to enable inspections to be carried out despite the physical restrictions caused by the COVID-19 pandemic. Instead of on-site inspection, the NPRA has implemented off-site inspection mechanisms such as remote and hybrid inspection to carry out national and foreign Good Manufacturing Practice inspections.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

The Royal Malaysian Customs Department did not grant any import or export exemptions in relation to medicines or medical devices. However, the Customs Department granted an exemption from import duty and sales tax for the following:

- medical equipment, lab equipment, Personnel Protective Equipment (PPE) and COVID-19 consumables for the MOH; and
- raw materials for the manufacture of hand sanitisers such as undenatured ethyl alcohol and denatured ethyl alcohol.

11.6 Drivers for Digital Health Innovation Due to COVID-19

The Malaysian Medical Council issued an Advisory on Virtual Consultations, which provides guidance on the provision of virtual consultations during the COVID-19 pandemic. The Advisory highlights that, while virtual consultations can only be provided in the context of an existing doctor-patient relationship, virtual consultations may also be given under limited circumstances, such as where a diagnosis can be accurately made with the patient's history and limited audiovisual observation.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

The Malaysian government has yet to exercise its right to issue compulsory licences in relation to COVID-19-related patents. Under Section 84(1) of the PA 1983, the Minister in charge may allow a government agency or third party to use the patented invention without the patent owner's consent on the following grounds:

- if there is a national emergency or where the public interest so requires, particularly nation-

al security, nutrition, health or the development of other vital sectors of the national economy as determined by the government; or
- where a judicial or relevant authority has determined that the manner of exploitation by the owner of the patent or their licensee is anti-competitive.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

No liability exemptions were issued to exclude civil liability from the use of COVID-19 vaccines or treatments.

11.9 Requisition or Conversion of Manufacturing Sites

Pursuant to the Emergency (Essential Powers) Ordinance 2021 (2021 Ordinance), the Yang di-Pertuan Agong or anyone authorised by him may take temporary possession of land, building, movable property or resources, and issue directions which appear necessary or expedient. A person who contravenes such orders is liable to a fine of up to MYR5 million or imprisonment for a period of not more than ten years, or both.

While the 2021 Ordinance allows the mandatory requisition of land and resources, there have been no documented cases of its use by authorities to acquire land, buildings, movable assets, or resources for the manufacturing of COVID-19 medicines and medical equipment.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

Typically, public procurement of supplies valued above MYR500,000 are done through an open tender process. To address the urgent need of access to vaccines, the government has implemented a system of public procurement specifically for the procurement of COVID-19 vaccines in Malaysia. Accordingly, a Special Committee for Ensuring Access to COVID-19 Vaccine Supply was set up to assist with the procurement process.

Malaysia also participated in global initiatives such as the COVAX Facility and entered into bilateral agreements with countries in an effort to secure the public procurement of vaccines.

MEXICO

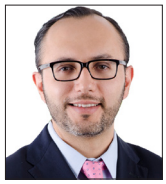
Law and Practice

Contributed by:
Christian López Silva, Marina Hurtado Cruz, Carla Calderón and José Hoyos-Robles
Baker McKenzie

Contents

Baker McKenzie has a healthcare and life sciences industry group that is active in matters throughout the whole life cycle of products, from research and development to manufacturing and commercialisation. It provides industry-focused and integrated advice in the fields of regulatory, data privacy, IP, transactional and M&A, foreign trade, antitrust, compliance, tax and litigation. The firm acts for leading industry players, including local and multinational companies, in key sectors such as medicines, medical devices, health services, dietary supplements, cosmetics, food and beverages, cleaning products, seeds, biocides, fertilisers, biofuels, alcohol and tobacco. Lawyers are also actively involved in legal and trade associations that have a life sciences focus or working groups.

Authors



Christian López Silva is head of Baker McKenzie's healthcare and life sciences group in Mexico. He has more than 20 years' experience in the regulation of life sciences, pharmaceutical law and biotechnology matters, and is a member of the Latin American and North American healthcare steering committees. Christian advises on regulatory, transactional and IP matters in the registration, manufacturing, import, distribution, advertising, labelling, commercialisation and post-market vigilance of medicines, medical devices, food and beverages, cosmetics, seeds, veterinary products, chemicals, alcohol and tobacco. He is a member of the Healthcare and Life Sciences Committee of the IBA and the co-ordinator of the Health Regulation Committee of the Mexican Association of In-House Lawyers (ANADE).

Marina Hurtado Cruz is a partner and head of the patent practice at Baker McKenzie in Mexico. She has more than a decade of experience in handling sophisticated IP matters and advises on a broad range of areas, including the prosecution, licensing and litigation of patents, utility models, industrial designs and trade marks. Marina also has extensive experience in the areas of health, advertising and consumer laws. In October 2019, she was appointed by the Ministry of Foreign Affairs as ad honorem external adviser on IP issues in order to collaborate in the development of IP public policies in Mexico.

Contributed by: Christian López Silva, Marina Hurtado Cruz, Carla Calderón and José Hoyos-Robles, **Baker McKenzie**

Carla Calderón is a senior associate in the healthcare and life sciences group at Baker McKenzie in Mexico, and is experienced in the regulation of life sciences, pharmaceutical law and biotechnology matters. She regularly advises on matters at the intersection of health regulation, data privacy and IP for the manufacturing, import, distribution, advertising, labelling, commercialisation and post-market vigilance of medicines, medical devices, food and beverages, cosmetics, seeds, cannabis, veterinary products, chemicals, alcohol and tobacco. Carla also has experience in consultancy, government relations, administrative proceedings, product registration, regulatory litigation and contractual work.

José Hoyos-Robles has been a partner of the foreign trade practice group at Baker McKenzie since 2000. He is experienced in foreign trade and customs matters, free trade agreements (FTAs), regulatory matters, consumer protection, export controls, sanctions and the implementation of forced labour bans. José has contributed to several publications related to foreign trade and customs matters, and is a professor of international trade law at the Universidad Panamericana. His practice focuses on trade matters such as tariff classification of goods, rules of origin, customs valuations, FTAs (including origin verifications), labelling, tariff and non-tariff regulations, and restrictions such as Mexican official standards, export controls, health regulations and other regulatory issues.

Baker McKenzie

Edificio Virreyes
Pedregal 24
Floor 12th
Colonia Lomas Virreyes
CP 11040
Mexico City
Mexico

Tel: +52 55 4335 6419
Fax: +52 52 79 2999
Email: Adrian.Rodriguez-Montfort@bakermckenzie.com
Web: www.bakermckenzie.com

Contributed by: Christian López Silva, Marina Hurtado Cruz, Carla Calderón and José Hoyos-Robles, Baker McKenzie

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The legal framework regulating pharmaceuticals and medical devices is largely federal in Mexico, and includes the following laws and regulations:

- the General Health Law (GHL);
- the Health Supplies Secondary Regulations (*Reglamento de Insumos para la Salud*, or RIS);
- the Health Services Secondary Regulations;
- the Health Advertisement Secondary Regulations;
- the Clinical Research Secondary Regulations (CRSR); and
- several official Mexican standards on specific technical aspects (eg, good manufacturing practices, labelling and stability).

In Mexico, the legal and administrative nature of the Federal Commission for the Protection against Sanitary Risks (*Comisión Federal para la Protección contra Riesgos Sanitarios*, or COFEPRIS) is that of an autonomous agency, under the administrative structure of the Ministry of Health (MoH). The GHL created COFEPRIS and gave it administrative, technical and operational autonomy. However, that autonomy was placed under pressure after a ministerial decree was issued in 2020, changing its ascription from the Minister directly to a Vice-Minister.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Decisions of the regulatory bodies that apply and enforce pharmaceutical and medical device regulations may be challenged through the following optional appeal proceedings:

- an initial administrative review, decided by the same authority that issued the original administrative decision;
- an annulment trial, decided by the Federal Administrative Tribunal; and
- an *amparo* trial, decided by a judicial body, a judge or a court (depending on the nature of the decision being challenged).

The formal requirements for challenging a decision vary depending on the nature of the decision being challenged, but generally the appeal lawsuit will include:

- identification of the affected party;
- identification of the challenged decision;
- identification of the authority that issued the decision;
- a description of the facts; and
- the available evidence.

However, the most important element for successfully litigating regulatory decisions is to have an interdisciplinary team of lawyers and pharmaceutical chemists, so that the science and the law can be properly understood and argued in each case.

Strangely, there is still a general impression within companies that there has been no significant litigation relating to decisions taken by health regulators. However, this is not an accurate perception, as litigation has always existed in this area – particularly in relation to sanctions. There is now a lot of litigation in relation to the system of authorisations and the interpretation of technical regulations. As the regulatory system has evolved into a more complete set of legal rules, and as regulatory work is now being undertaken not only by pharmaceutical chemists but also by lawyers, companies have better understood their rights and have felt increasingly confident in

challenging regulatory decisions that affect their interests.

For a whole decade following the creation of COFEPRIS in 2000, regulatory work was highly technical and was mainly handled by pharmaceutical chemists, both in companies and in regulatory agencies. The health law and regulation did not evolve as quickly as the science and the market. The government's regulatory decisions were frequently taken based not on existing legal rules but exclusively upon technical criteria, which led to a highly discretionary system. Although decisions were always legally vulnerable, the concern of companies was that legally challenging a decision on one product would affect other decisions pending over other products. At the same time, public affairs actions were rather successful in achieving results without the need to litigate.

Two COFEPRIS administrations (2010–18) then brought the legal framework up to date, bringing in lawyers to key positions and modernising the administrative system. This helped to trigger a trend for in-house lawyers and external counsel specialising in the field. At the same time, compliance controls tightened, forcing companies to evaluate, enforce and defend their rights and obligations on the one hand and to put pressure on the area of public affairs on the other.

Finally, the actions of the two most recent COFEPRIS administrations (2018–20 and 2020–23) deliberately isolated the agency from the industry by replacing experienced examiners and reducing the number of available examiners, leading to a huge backlog that disrupted commercial operations. This created strong incentives for companies to litigate all kind of pending approval applications.

All of that combined has resulted in a significant and sustained increase in litigation, year after year, for the past decade. This led to the creation of a Specialised Chamber for Regulatory Matters within the Federal Administrative Tribunal, which heard 300 cases against COFEPRIS in 2020. Now there is significant litigation against a lack of response on renewals, modifications, rejections and inspection procedures, in addition to litigating sanction decisions. In 2022, the total number of all types of litigation cases against COFEPRIS skyrocketed to 12,000.

Since 2023, the current administration has partially restarted communication with the regulated industries via the Commissioner for Health Promotion, through technical sessions and goodwill meetings. Both schemes are confidential, non-binding and not regulated by applicable regulations. Nonetheless, these represent an alternative means for the industry to understand COFEPRIS' interpretation of regulations and requirements.

1.3 Different Categories of Pharmaceuticals and Medical Devices

The GHL contains many relevant classifications for medicines, including reference and generic/biocomparable drugs, prescribed and non-prescribed drugs, standard and controlled drugs, and so on.

Medical devices are divided into three classes, according to the risk they represent to human health, as follows:

- Class I – those that are recognised in medical practice, whose safety and efficacy have been proved, and that generally are not introduced into the human body;
- Class II – those that are recognised in medical practice, that can vary in the way they are

manufactured or in their concentration, and that are regularly introduced into the human body (remaining there for less than 30 days}; and
- Class III – new products or those recently accepted by medical practice, or those that are introduced into the human body and remain there for more than 30 days.

2. Clinical Trials

2.1 Regulation of Clinical Trials

The regulation of clinical trials includes the following key instruments:

- the GHL;
- the CRSR;
- Technical Standard NOM-012-2012-SSA3;
- the Guidelines for Good Clinical Practice published by COFEPRIS; and
- the Decree for the Operation of Ethics Committees, co-ordinated by the National Bioethics Commission.

In general, clinical trials (Phases I–IV) must be:

- preceded and supported by pre-clinical data;
- conducted in accordance with scientific and ethical principles;
- performed with the informed consent of the participating human subjects;
- executed under a research protocol;
- overseen by a principal investigator; and
- performed in licensed health institutions.

In addition, they must obtain the relevant approvals from a health institution, an ethics committee and COFEPRIS.

Historically, the operation of ethics committees was largely self-regulated and based on international best practice. There was also a lack of co-ordination between COFEPRIS and the National Bioethics Commission (ConBioetica). However, the Decree for the Operation of Ethics Committees (2012) provides a clearer legal framework for ethics committees, establishing their structure, their objectives, the role of their members and the requirement to be registered with ConBioetica and COFEPRIS. Unfortunately, ConBioetica has accumulated enormous regulatory delays, forcing serious consideration of litigating the lack of response.

Notably, the Guidelines for Good Clinical Practice (2012) make clear reference to international best practice, including standards developed by the International Conference on Harmonisation. These good clinical practices will be the basis to move towards a certification system, for which COFEPRIS has already started to conduct inspections of research sites.

The operation of contract research organisations (CROs) is not fully regulated, with references only found in the guidelines, but there are ongoing initiatives to address this.

Other regulatory measures have been introduced to promote Mexico as a place for conducting clinical research, including the following.

- An important amendment to the RIS – Article 170 of the RIS originally required a certificate of free sale of the country of origin to be submitted as part of an application for obtaining a marketing authorisation (MA) of a drug produced abroad, which therefore made it impossible to have Mexico as the first country of registration. In 2012, however, this was changed to make it possible to submit a clinical trial report instead, provided that the Mexican population was included in the trial.

- The creation of third authorised parties for clinical research – COFEPRIS has authorised several public hospitals with extensive experience in clinical research to conduct a pre-evaluation of research protocols. If their report is positive, approval times at COFEPRIS are reduced significantly.

The same rules regulate medical devices and pharmaceuticals.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

The procedure for securing authorisation to undertake a clinical trial of a pharmaceutical or a medical device is comprised of three basic steps, which are sequential and cannot be applied for in parallel, as follows:

- favourable opinion of the research protocol by the ethics committee of the health institution where the trial is to be conducted, which – according to the Decree for the Operation of Ethics Committees – must take place within 30 business days of filing;
- authorisation of the research protocol by the director of the health institution where the trial is to be conducted, which must take place under its relevant internal rules; and
- approval of the research protocol from COFEPRIS, which – according to the Federal Law on Administrative Proceedings – must take place within three months of filing.

2.3 Public Availability of the Conduct of a Clinical Trial

After their protocols have been authorised by COFEPRIS, most trials are currently recorded in the National Registry of Clinical Trials (*Registro Nacional de Ensayos Clínicos*, or RNEC). The information contained in the RNEC is collected by COFEPRIS in collaboration with those responsible for conducting the clinical trial (ie, sponsor, CRO or healthcare institution). The RNEC publishes an electronic database that includes only general information about the clinical trials. Although limited, this shows significant progress, as until very recently almost no local information was made publicly available. Confidential information is not included in the RNEC, nor is the health information of patients, which will be regarded as sensitive personal information under data protection laws and will be protected accordingly.

On the other hand, there is no binding provision to disclose or publish the results of clinical trials, but the CETIFARMA (the Council of Ethics and Transparency of the Pharmaceutical Industry)'s Code of Ethics does contain a specific obligation for sponsors to disseminate the positive and negative results of trials, particularly the adverse events.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no specific restrictions regarding online clinical trial platforms. However, it would be important for the platform to comply with the regulations regarding the recruitment of and interaction with patients enrolled in a clinical trial if those functionalities are included in the platform. Additionally, this platform could involve other regulatory implications, such as the advertising of health inputs, services and privacy protection, so it is important for its content to be reviewed on a case-by-case basis.

The data resulting from the clinical trial would be considered personal if the patients enrolled in the clinical study are identified. If the results of the clinical trial are presented without providing information or images that could lead to the

identification of the patients, those results would not be considered personal data.

2.5 Use of Data Resulting From Clinical Trials

It is permitted to transfer the data resulting from the clinical trial to a third party or an affiliate, as long as the privacy notice reveals that a transfer will occur and identifies a justifiable purpose for that transfer. When sensitive personal data is involved, the data controller must obtain express written consent for processing, through a signature, an electronic signature or any authentication mechanism established for that purpose.

2.6 Databases Containing Personal or Sensitive Data

The creation of databases that contain sensitive personal data must be justified and must follow legitimate and concrete purposes that correspond to the activities and explicit objectives of the data controller. These kinds of databases are not subject to authorisation before operations commence.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The GHL provides a general definition for pharmaceuticals. In this respect, any product that falls into such definition should be considered a pharmaceutical. According to the GHL, a medicine is any substance or mixture of substances of natural or synthetic origin that has any therapeutic, preventative or rehabilitative properties, which is presented in any pharmaceutical form and is identified as such for its pharmacological activity and physical, chemical and biological characteristics.

On the other hand, the new definition of medical device contained in Section 3.41 of Standard NOM-241-SSA1-2021 (NOM-241) is broader: "Medical device, instrument, apparatus, utensil, machine, software, implantable product or material, diagnostic agent, material, substance or similar product, to be used, alone or in combination, directly or indirectly in human beings; with any of the following purposes of use:

(i) diagnosis, prevention, surveillance or monitoring, and/or aid in the treatment of diseases;
(ii) diagnosis, surveillance or monitoring, treatment, protection, absorption, drainage, or aid in the healing of an injury;
(iii) substitution, modification or support of the anatomy or of a physiological process;
(iv) life support;
(v) control of conception;
(vi) disinfection of medical devices;
(vii) disinfectant substances;
(viii) provision of information through an in vitro examination of samples taken from the human body, for diagnostic purposes;
(ix) devices incorporating tissues of animal and/or human origin, and/or
(x) devices used in in vitro fertilisation and assisted reproductive technologies,

as well as those whose main purpose of use is not through pharmacological, immunological or metabolic mechanisms; however, they can be assisted by these means to achieve their function. Medical devices include supplies for health in the following categories: medical equipment, prostheses, orthoses, functional aids, diagnostic agents, supplies for dental use, surgical and healing materials, and hygienic products."

Initially, any product that falls into this definition should be considered a medical device.

It is also important to remember the List of Products That Due to Their Nature, Characteristics and Uses Are Not Considered Medical Devices. Products included on this list will be excluded from the regulation of medical devices.

There are other categories that are recognised in practice (eg, combination products), but these are not formally regulated through mandatory instruments.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

In general, there is only one type of MA for pharmaceuticals for human health and for medical devices, which is granted by COFEPRIS. The same requirements of quality, safety and efficacy apply, regardless of whether the product is allopathic, homeopathic, herbal or a vitamin pharmaceutical.

However, there is a significant difference between the extent and scope of safety and efficacy data that would be required for an innovator product and that which would be required for a subsequent product, and the specific requirement for releasing biologic products after importation. Biotech drugs are also subject to a pre-submission regulatory meeting with the COFEPRIS' New Molecules Committee.

Please note also that a new class of approvals was introduced during the COVID-19 pandemic (albeit without a legal basis for doing so): emergency authorisations. These would have to expire once the health emergency is declared to be over.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

The period of validity of any MA for pharmaceuticals and medical devices is five years. After this period, MAs may be renewed every five years. In contrast, a Recognition Letter for Orphan Drugs (the equivalent of an MA) lasts for two years only.

Also, any authorisation may be revoked by COFEPRIS at any time – for instance, when a new risk to human health is found, if an infringer repeatedly disregards safety measures, or if false information is submitted. During the pandemic, MAs were cancelled for companies that failed to submit renewal application on time.

A recent change to the RIS means that the second and subsequent renewals of MAs – both for medicines and for medical devices – will only be subject to a notification, not to an authorisation.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

In general, the procedure for obtaining an MA for pharmaceuticals includes filing the MA application form at COFEPRIS, along with evidence of the following:

- the payment of governmental fees;
- a manufacturing licence or equivalent;
- notice of appointment of a qualified sanitary officer;
- draft labels;
- the information to prescribe;
- certificates of good manufacturing practices for the finished product, its active ingredients and its additives;
- the draft distinctive name;
- the quantitative and qualitative formula;
- quality information; and

- pre-clinical studies, including pharmacodynamics, pharmacokinetic and toxicology studies.

For products manufactured abroad, it is also necessary to file a representation letter granted to the holder.

The application to obtain an MA for medical devices must be submitted with the following:

- the payment of governmental fees;
- the technical and scientific information that proves the security and efficacy standards;
- draft labels;
- instructions;
- a general description of the manufacturing process;
- a description of the structure, materials, parts and functions;
- certificates of good manufacturing practices for the finished product;
- laboratory tests; and
- bibliographic references, if such are required.

For products manufactured abroad, it is also necessary to file the following:

- a free sale certificate;
- a representation letter issued by the manufacturer of the product;
- a certification of analysis;
- sanitary notification of the distribution warehouse; and
- notification of the sanitary official of the distribution warehouse.

Approval times are as follows:

- for pharmaceuticals that include active and therapeutic indications already registered in Mexico, the decision must be granted within 180 days;
- for pharmaceuticals whose active ingredients are not registered in Mexico but are registered and sold freely in their country of origin, a decision shall be taken within 240 days;
- for new molecules, after a prior technical meeting between applicants and the New Molecules Committee of COFEPRIS, the decision shall be taken within 180 days;
- for homeopathic, herbal and vitamin pharmaceuticals, decisions shall be taken within 45 days; and
- for biotechnological drugs, applications must be resolved within 180 days.

These approval times can be extended if COFEPRIS requires additional information.

For Class I medical devices, the decision must be granted within 30 days; for Class II, the decision shall be taken within 35 days; and for Class III, the decision shall be taken within 60 days.

As with pharmaceuticals, these approval times can be extended if COFEPRIS requires additional information.

There is no mandatory requirement to conduct clinical trials in a paediatric population nor to obtain a waiver from this requirement in relation to individual pharmaceuticals; this is completely optional and subject to stricter requirements.

The variation of MAs can be classified as administrative or technical. Technical modifications are those relating to changes in the formulation, indication or manufacturing process. Administrative modifications include variations such as changes to the corporate name or address of the holder, or changes to the information to prescribe. An assignment of an MA is regarded

as an administrative modification. Each application to modify an MA must contain the technical and legal documentation supporting the relevant change.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

There are a limited number of cases where an unauthorised product can be imported into the country and be supplied to patients, including low-prevalence diseases, donations (eg, in natural disasters), personal use, experimental products for clinical research, and medical use.

In addition, if the relevant product is included in the List of Products That Due to Their Nature, Characteristics and Uses Are Not Considered Medical Devices, it would not be considered as a medical device and consequently would not require an MA.

The MoH published two decrees, on 28 January 2020 and 22 June 2021, creating the option to import medicines and medical devices that do not have an MA in Mexico and to place them on the public market, provided they have an MA from certain recognised jurisdictions. For that, a number of steps must first be taken, including obtaining a prior declaration of necessity issued by multiple authorities. These decrees have also become a source of litigation.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

Holders of MAs must comply with good manufacturing practices and stability, pharmacovigilance or technovigilance and labelling standards and regulations; they must also comply with the advertising regulations that apply to pharmaceuticals or medical devices. Product recall obligations have also became relevant of late.

In general, pharmaceuticals and medical devices are subject to post-approval vigilance. These obligations are developed in technical standards, which generally specify the rights and obligations for holders of MAs, distributors, research sites, health institutions, physicians and patients to monitor adverse events or incidents, and to investigate and report them. It is also necessary to have a pharmacovigilance or technovigilance unit, someone responsible for pharmacovigilance and someone responsible for technovigilance, and a pharmacovigilance or technovigilance manual.

However, Phase IV data is only required for more complex products (eg, complex biologics or biotech drugs), as decided by the New Molecules Committee.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

COFEPRIS has periodically published lists of applications and lists of granted or rejected MAs. However, these lists are not updated regularly, and frequently contain limited information that excludes confidential information. Full access to individual files is only granted to the applicant.

Although third parties have long been able to file public information requests in relation to any file held by COFEPRIS under the mechanisms overseen by the National Institute for Access to Public Information and Data Protection (INAI), COFEPRIS historically resisted providing access to most of the files of MAs, which it regarded as being confidential in their entirety. Nevertheless, through several INAI decisions, an increasing number of data elements can now be accessed.

Fortunately, COFEPRIS has now begun to populate a public database on its website that displays key data contained in the MAs for pharmaceuticals.

Confidential information is protected by several special laws, including those related to privacy, IP and administrative procedures, and labour and criminal law.

3.8 Rules Against Illegal Medicines and/or Medical Devices

Relevant legislation includes the GHL, the Federal Consumer Protection Law, and the Federal Criminal Code. These legislative bills provide jurisdiction to multiple government agencies to undertake enforcement actions upon the notice of existence of falsified or illegal goods that could affect healthcare. The action that can be triggered will depend on the facts of the case and the illicit goods involved, as it could be within the legal authority of any of the above-mentioned laws.

In essence, the bills provide a legal framework to file and start complaints, through a potential infringement of the Consumer Protection Law or the GHL. These investigations will be based on a human health risk or a consumer protection liability, rather than IP infringement. Please note that other actions – such as a damages claim for unlawful conduct that affects a company or damages its prestige and reputation – could be explored in a subsequent stage, provided that an infringement is found to have existed and depending on the direct liability of the offender.

The actions available under these bills are not in the title-holder's control; instead, they are under the control of the relevant agency, such as COFEPRIS, the Federal Attorney General Office, the Federal Consumer Protection Agency or the federal police. In this regard, the title-holder/manufacturer is entitled to present a complaint for the relevant agency to start an investigation, which could be a joint investigation with law enforcement agencies, depending on the facts of the case. The agency will be in control of the investigation, while the title-holder/manufacturer can assist with the investigation and provide relevant information that will help build the case, although they will not be in control of the investigation and its outcome.

As a result, depending on the investigation's outcome, there can be injunctive relief such as seizure of illicit goods, or temporary closure of the factory or retail store. These options will be taken by the administrative agencies or the law enforcement agencies ex officio, as the title-holder is not part of the case. For these situations, it is important for the title-holder to follow the official investigation closely to ensure that the administrative agencies or law enforcement agencies liaise in due course.

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

A combination of provisions found in international free trade agreements, the Mexican Industrial Property Law and Customs Law provide for the possibility of filing border measures against counterfeited pharmaceuticals and medical devices – provided a recognised IP right is at risk, which includes trade marks, patents and industrial designs. The system is operated through detection technology and databases that are built or fed by title-holders, who will be alerted to suspected goods.

4. Manufacturing of Pharmaceuticals and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

A pharmaceutical manufacturing plant is subject to a licence, and a medical device manufacturing plant is subject to submitting a notice of operation. COFEPRIS is the authority responsible for granting the manufacturing licence and receiving the notice of operation.

To obtain the manufacturing licence, a certificate of Good Manufacturing Practices (GMP) must be obtained. For that, a COFEPRIS inspection visit to the manufacturing plant must first be requested, to review whether the plant complies with Technical Standard NOM-059-SSA1-2015 on GMP for pharmaceuticals. If COFEPRIS determines in the inspection visit that the facility is in compliance, it will grant a certificate, which must be included in the manufacturing licence application. Once the application is submitted, COFEPRIS will take no more than 60 business days to grant the manufacturing licence. The activities typically approved by the manufacturing licence are the manufacture and warehousing of pharmaceuticals in the same facility. The operation licence does not have an expiry date.

The notice of operation for a medical device manufacturing plant needs only to be submitted to COFEPRIS, and becomes valid the moment it is filed. The notice of operation requires the appointment of a sanitary officer, who shall be in charge of the facility. The typical activities covered by the notice of operation are the manufacture and warehousing of medical devices in the same facility. The notice of operation does not have an expiry date. With the recent issuance of the new NOM-241 on GMP for medical devices, a GMP certificate must be obtained. This new version of NOM-241 has been a source of controversy, as it also applies to manufacturing sites dedicated exclusively to exporting, which are covered by the IMMEX (Manufacturing Industry, Maquiladora, and Export Service) programme.

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

As a general rule, establishments involved in the wholesale of pharmaceuticals and/or medical devices are only required to submit a notice of operation to COFEPRIS. The notice of operation enters into effect at the moment of filing and does not have an expiry date.

The exception to the general rule is warehouses dedicated to the wholesale of controlled pharmaceuticals (eg, psychotropic and narcotics) and/or biological products for human use, which are subject to a licence.

5.2 Different Classifications Applicable to Pharmaceuticals

Pharmaceuticals are divided into the following six sections in relation to their prescription status:

- Section I – prescription pharmaceuticals that can only be acquired by a special prescription or permit issued by the regulatory authority (eg, controlled substances);
- Section II – prescription pharmaceuticals that require a prescription to be collected and retained in the pharmacy as well as being registered in the pharmacy control books;

- Section III – pharmaceuticals that can only be purchased with a prescription that may not be supplied more than three times and that must be recorded in the control book and retained in the pharmacy after the third supply;
- Section IV – pharmaceuticals that require a prescription, but which can be supplied as many times as directed by the physician (eg, antibiotics);
- Section V – non-prescription pharmaceuticals, authorised for sale only in pharmacies; and
- Section VI – pharmaceuticals that do not require a prescription and can be supplied in any establishments other than pharmacies (eg, OTC products).

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

A vast body of law, including secondary regulations, technical standards and administrative decrees, controls the area of foreign trade and customs law. These are not necessarily co-ordinated with the health regulation, creating frequent issues for companies in the pharma and medical devices sectors.

By way of example, product classifications can differ to the extent that a product may be classified from a customs perspective as a cosmetic for importing purposes and as a medical device from a regulatory perspective for commercialisation purposes. This in turn can have a tax impact on the applicable rate of Value Added Tax.

Depending on the moment and the type of regulation to which the goods are subject, the following authorities could be involved:

- the Tax Administration Service;
- the National Customs Agency of Mexico;
- the MoH, through COFEPRIS;
- the Ministry of Economy, mainly through the General Direction of Standards and the Federal Consumer's Protection Agency (PROFECO); and
- the Attorney General's Office.

Depending on the type of good, enforcement may also be in the remit of the Ministry of Agriculture, Livestock and Natural Resources, the Ministry of Defence, the Federal Commission of Telecommunications, etc.

6.2 Importer of Record of Pharmaceuticals and Medical Devices

Imports must be carried out by an individual or legal entity that is registered in the Importers' Registry, which is administered by the Tax Administration Service.

Depending on their tariff classifications, certain goods – including certain chemical products, radioactive goods, chemical precursors and essential chemical products – may be subject to registration in the Specific Sectors of the Importers' Registry. This registration is subject to additional requirements, which depend on the sector in which the importer is to be registered.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Imports of all pharmaceuticals and some medical devices are subject to the obligation of securing specific import permits.

While such imports are normally administered by the MoH through COFEPRIS, depending on the type of product they may also be subject to other types of import or export permits, including those imposed by the Ministry of Economy, the Ministry of Agriculture, Livestock and Natural Resources, the Ministry of Defence, and the Federal Commission of Telecommunications.

Among others, the following exceptions to the obligation to secure an import or export permit may apply, but only for non-commercialisation purposes:

- importing for personal use;
- importing for donations;
- importing for experimental use; or
- importing for low-prevalence diseases.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

In Mexico, non-tariff regulations and restrictions – such as import permits and licences – are imposed based on the tariff classification (Harmonised Tariff Schedule (HTS) code) and the description of the goods to be imported or exported.

Pursuant to the Mexican Constitution, the executive power may regulate or restrict the importation or exportation of products, provided that Congress grants it such authority. The use of that authority needs to be approved by Congress at the end of each year.

Under the Foreign Trade Law, Congress grants this authority to the executive power, with the condition that – in order for a non-tariff regulation or restriction to be imposed – the corresponding decree or administrative regulation must be published in the Federal Official Gazette and the goods subject to such regulation or restriction must be listed by tariff classification and description.

6.5 Trade Blocs and Free Trade Agreements

Mexico has entered into 14 free trade agreements with more than 50 different countries.

Mexico is an active party to the Pacific Alliance (along with Chile, Colombia and Peru). The Pacific Alliance and its framework agreement have specific provisions on regulatory co-operation and product-specific annexes, covering cosmetics, medical devices, dietary supplements and cleaning products. This has started a very promising regulatory harmonisation/convergence process in the region.

Mexico is also party to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (the revised Trans-Pacific Partnership Agreement), which contains promising provisions on the regulatory co-operation side, as well as product-specific annexes.

The United States–Mexico–Canada Agreement (USMCA) entered into force in July 2020 and contains several regulatory annexes for pharmaceuticals, medical devices, chemical substances, cosmetic products and food products.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

In Mexico, the private and public markets for medical products have separate rules depending on whether the products are patented. However, this mainly applies to pharmaceuticals and has changed during the new federal administration.

The very general legislative bases of the dual system are contained in two laws: the GHL (Article 31) and the Federal Economic Competition Law (Article 9). However, the rest of the rules are largely contained in separate regulatory instruments of lower hierarchy, including the Addendum to the Agreement for Drug Pricing Co-ordination signed in 2004 between the Ministry of Economy and the National Chamber of the Pharmaceutical Industry, and the technical standard for the labelling of drugs (NOM-072-SSA1-2012).

Private Market

Patented drugs for the private market are subject to a hybrid system that is largely self-regulated and voluntary. Under this system, companies compile their own information about their prices in other jurisdictions and submit that to the authority, which monitors the accuracy of the data.

The manufacturer is required to stamp the price on the label of the product at the end of the manufacturing process. PROFECO verifies that the prices at the point of sale (ie, at pharmacies) do not exceed that price.

Generic drugs, off-patent products and medical devices in general are not part of this pricing regulation, being subject to direct price competition in the market. Newly launched products are initially exempted, as explained here.

Public Market

Until very recently, patented pharmaceuticals for the public market were subject to a different process of annual negotiation. For ten years, such negotiations were held with the Co-ordinating Commission for Negotiating the Price of Medicines and other Health Inputs (*Comisión Coordinadora para la Negociación de Precios de Medicamentos y otros Insumos para la Salud*, or CCPNM), which was created in 2008 and gathered all major public institutions buying drugs in Mexico, as well as the Ministries of Public Administration, Finance, Economy and Health. However, the new federal administration that took office on 1 December 2018 introduced two major changes.

First, it eliminated the CCPNM, transferring the whole pricing process to the public procurement system. That change eliminated the prior distinction between pricing and acquisition, which are now defined in the same process for patented medicines.

The estimated price for generic and off-patent products was initially defined by those public institutions co-ordinating the public procurement exercise, based on their market research. However, the price would also be influenced by the discounts offered by the participating bidders and would ultimately be determined in the acquisition award and contract.

The administration then changed the rules again, by means of issuing a new version of the Secondary Regulations for the National Compendium, which creates a National Formulary from which public health institutions must – in principle – acquire the medical products they need. The new version incorporated new provisions under which a company must provide a maximum price as part of process to add products; if the addition is approved, that maximum price will become the basis for any public acquisition mechanism.

7.2 Price Levels of Pharmaceuticals or Medical Devices

Newly launched pharmaceuticals for the private market are initially exempted from the maximum

retail price (MRP) system – given that, in principle, they would not have a comparator. The manufacturer can initially set the price, subject to a re-evaluation three months after the product launch. The review is conducted to verify whether the product exists in the international market. If this is confirmed, an MRP will be estimated. If this occurs, the price of newly launched products will be influenced by prices for the same product in other countries, but not based on a health technology assessment. The price regulations for medicines do not apply to medical devices.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

The Mexican system operates not through a model of reimbursement, but through a model of public procurement of drugs and medical devices.

There is a comprehensive legal regime for public procurement in Mexico, overseen by the Ministry of Public Administration in co-ordination with the purchasing entity. However, this may change during the new federal administration. In general, public procurement operates through three mechanisms:

- public bidding, with a national or international scope;
- invitation to at least three persons; and
- direct awards.

Whereas public bidding is the general rule, purchasing by invitation or direct award is allowed under certain circumstances, which are listed in the Federal Law for Procurement, Leases and Services of the Public Sector. One of the exemptions refers to cases where there are no substitute products, there is only one possible supplier or the required product is patent protected.

Accessing the public market for pharmaceuticals does not begin directly with public procurement. Other key regulatory steps must first be met, given that public procurement works through product codes granted by other health authorities, in relation to a Basic Formulary and several Institutional Formularies. The process for incorporating a product to the Basic Formulary and then to Institutional Formularies takes two to four years. The decision is based largely on economic evaluation. A product can only become part of a public procurement exercise once it has been allocated a code, which – in the case of medicines – is assigned per active ingredient.

On 8 November 2022, the General Health Council (GHC) published a Decree that created a new Commission for the National Compendium for Medical Products, replacing the Inter-Ministerial Commission for the Basic Formulary. A new set of International Regulations for the National Compendium was then issued on 22 November 2022, bringing several changes to the system – including one that has been a source of controversy and litigation, relating to the introduction of a new requirement. The new rules now state that an application to add a product must first obtain and submit a sponsoring letter from one of the public payors, representing an access barrier.

In 2022, after the results achieved through the collaboration agreement signed by the National Health Institute for Wellness (*Instituto de Salud para el Bienestar*, or INSABI) and the United Nations Office for Project Services (UNOPS), it was decided that the mechanism would no longer be used as the main route to acquire medical products. Instead, a new decentralised body was created (*Instituto de Seguridad Social para*

el Bienestar, or IMSS-Bienestar), which – together with INSABI – is expected to co-ordinate public acquisitions of medical products.

A lot of uncertainty continues to exist and many stakeholders expect the public procurement system to go back to normal once this federal administration finishes its term in 2024.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Previously, the methodology was quite clear and included cost-benefit analyses. Now it is not clear. It is also not currently clear whether the new administration will be open to exploring value-based proposals.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

The regulatory framework links the rules of prescription and dispensing with those of substitution at the point of sale. There are two scenarios for the private and public markets.

- For the private market, the first rule is that prescribing by the active ingredient or generic name is mandatory, and that the use of the distinctive name or trade mark of the product is optional for the health professional. The second and perhaps most important rule is that if the prescription contains only the generic name, pharmacists are allowed to substitute the product. Conversely, if the product was prescribed by its distinctive name, then substitution at the point of sale is forbidden.
- For the public market, although the basic rule structure is the same, there is no reference to the option of prescribing by trade mark – meaning that substitution is always allowed. At the same time, it has also become a long-held practice in the public sector to prescribe using the product code allocated in the Basic Formulary or National Compendium, which is based on the active ingredient as well. There are provisions allowing prescriptions to be made under different conditions, but the respective institution would need to authorise such decisions, which is not common.

8. Digital Healthcare

8.1 Rules for Medical Apps

Until December 2021, there were no specific regulations for medical apps. However, this changed with the new version of NOM-241 and there are now specific provisions for software with health-related functionalities, including a definition of software as a medical device (SaMD). NOM-241 entered into force on 20 June 2023.

In addition, a new version of the Supplement on Medical Devices was published. The Supplement on Medical Devices is the more detailed legal instrument for the regulation of digital health applications, including medical apps. These new rules a cover classification of risk level, quality system, and clinical evaluation of both SaMD and medical apps. SaMD as a concept was introduced by the International Medical Device Regulators Forum.

8.2 Rules for Telemedicine

There are no special rules for telemedicine as yet; a technical regulation was drafted at one point but it was withdrawn. That failed attempt did not fully address the physician-to-patient private market interaction,covering only a clinic-to-clinic scenario, mainly to address an urban-to-rural public institution vision.

The absence of special new rules for telemedicine means that the existing rules and requirements for the provision of health services and the exercise of medicine are applicable, including the existence of a physical consulting room from which the health service is supposedly provided, and the need to be licensed in Mexico in order to practise medicine. Several draft initiatives on digital health have been submitted to the Federal Congress, all of which proposed a prior approval system for telemedicine platforms.

8.3 Promoting and/or Advertising on an Online Platform

The same legal instruments that are applicable to printed regulated advertising material apply to online content. However, additional guidance documents have been produced by the regulator, including provisions that refer to digital advertising, advertising on social networks, and permits for online portals.

8.4 Electronic Prescriptions

There is still a contradiction between two key regulatory instruments. Whereas the Secondary Regulation for Medical Services was amended in 2018 to allow the prescription of medicines by electronic means, the Secondary Regulations for Medical Products still refers to a handwritten signature. The problem is that the first instrument applies to physicians and the second one applies to pharmacies. The contradiction has made pharmacies hesitate, as they are primarily bound by the unchanged instrument. However, in 2020, the Supplement for Establishments of the Mexican Pharmacopeia was amended to allow for an e-signature. The problem was that it imposed an additional authentication measure that was not previously required and it excluded certain groups of products from its scope. Several draft initiatives have been submitted to the Federal Congress that would align this at the law level. One of these draft initiatives was approved by the lower chamber on 27 March 2023.

8.5 Online Sales of Medicines and Medical Devices

The online sale of medicines and medical devices is closely linked to the issue of whether the retail of a product category is restricted to a particular point of sale.

In that context, there would essentially be three groups of medicines:

- those that require a prescription and can only be sold in pharmacies;
- those that do not require a prescription but have to be sold in pharmacies; and
- those that do not require a prescription and can be sold elsewhere.

In contrast, there would be two groups for medical devices:

- those that are restricted to specialised shops (ie, orthopaedic devices); and
- those that can be sold elsewhere, including pharmacies.

From there, it is important to note that there is not yet any regulation addressing the online sale of medicines; the existing rules applicable to physical pharmacies would apply. Thus, the regulatory set-up to support the online sale of products would have to take into account the existence of a retail control for the relevant medical product and the existing rules for certain specialised retail shops.

8.6 Electronic Health Records

There are multiple legal instruments to consider, including Technical Standard NOM-004-SSA3-2012 on health records and NOM-024-

SSA3-2012 on the electronic health record. However, there are still gaps in the regulation, including more flexible mechanisms to account for the electronic signature of such records.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices

Patents are regulated by the new Federal Law for the Protection of Industrial Property (FLPIP), which entered into force on 5 November 2020, and are granted by the Mexican Institute of Industrial Property (*Instituto Mexicano de la Propiedad Industrial*, or IMPI).

In Mexico, the issues most frequently encountered by companies when trying to apply for patents include the intention of some examiners to limit the scope of protection of the subject matter as exemplified in the specification of the invention. Understanding the law and the science behind the invention is required to overcome this, which calls for in-house technical expertise.

9.2 Second and Subsequent Medical Uses

One of the critical issues with regard to pharmaceutical patents is the need to obtain patent protection for second and subsequent medical uses. Despite the fact that second uses have been accepted in Mexico, there had been no legal bases for their protection. The new FLPIP provides legal certainty for such protection and expressly states that new uses of known compounds shall be patented as long as they comply with the other requirements established in the law.

Any activity conducted in relation to the protected second use without proper consent will constitute an infringement.

9.3 Patent Term Extension for Pharmaceuticals

Under the new FLPIP, it is now possible to adjust the validity of patents through supplementary certificates for patent applications filed as of 5 November 2020. These supplementary certificates must be requested by the patent applicant to compensate for unreasonable delays from the IMPI, provided that the granting of the patent took more than five years from the date of its presentation in Mexico. The term of validity of the supplementary certificates may not exceed five years, and the validity will be one day for every two days of unreasonable delay attributable to the IMPI.

Unreasonable delays will be counted from the date on which the IMPI notifies the patent owner of the official action informing that the formal examination has been concluded. The periods attributable to actions or omissions of the applicant (such as delays in answering requests or extending the deadlines to respond to them) will not be taken into account when accounting for the unreasonable delay, nor will periods that are not attributable to the IMPI (such as the procedure being suspended owing to litigation or by acts of force majeure).

Supplementary certificates that were granted in violation of the law could be objected to by third parties.

9.4 Pharmaceutical or Medical Device Patent Infringement

The following activities constitute patent administrative infringements:

- giving the appearance that a product is patented when it is not – if the patent has lapsed or been declared invalid, the infringement will begin one year after the date of the lapse or, where applicable, the date on which a declaration of invalidity became effective;
- manufacturing or producing products that are protected by a patent without the consent of the owner of the patent, without the appropriate licence;
- offering for sale or distributing products that are protected by patent knowing that they were manufactured or produced without the consent of the patent owner or without the appropriate licence;
- using patented processes without the consent of the patent owner or without the appropriate licence; and
- offering for sale or distributing products that are the result of the use of patented processes, knowing that these have been used without the consent of the patent owner.

It is worth noting that, in Mexico, only actual infringement is actionable; the threat of infringement is not considered by the FLPIP.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

The Bolar Exemption was initially incorporated into the health regime. The RIS grant this protection to an application of a generic drug that is submitted during the last three years of a patent over an active ingredient, and to an application of a biosimilar drug that is submitted during the last eight years of a patent over the active ingredient.

The new FLPIP included a new provision that the right conferred by a patent will not produce any effect against a third party that uses, manufactures, offers for sale or imports a product with a valid patent exclusively to generate tests, information and experimental production necessary to obtain an MA for drugs for human health.

This is different to the Research Exemption found in the former industrial property regulation and maintained in the new FLPIP, which stipulates that a patent shall not have effect against any third party who – in the private or academic field, and not for commercial purposes – engages in scientific or technological research for purely experimental, testing or teaching reasons.

Under the Mexican IP regime, compulsory and emergency licences are available.

Compulsory Licences

With regard to compulsory licences, the FLPIP provides that – three years after the date of the grant of the patent or four years from the filing of the application (whichever happens first) – any person may apply for the grant of a compulsory licence to use the invention when it has not been used, unless there are justified reasons for the invention not having been used. The importation of the patented product is considered to be use.

However, prior to granting the first compulsory licence, the IMPI shall give the patent owner the opportunity to exploit the patent within a period of one year, counted from the date the compulsory licence request was notified. If the patent is not exploited after that year, there will be a hearing, and the IMPI will decide whether to grant the compulsory licence. If it decides to do so, the IMPI shall specify its duration, terms and scope, as well as the royalties payable to the patent holder.

Emergency Licences

As regards emergency licences, the FLPIP provides that – for emergency reasons or national security and for as long as the relevant situation continues (including serious diseases designated as such by the GHC) – the IMPI shall publish a declaration in the Federal Official Gazette, whereby certain patents can be exploited by means of granting a public use licence. This is for cases where the production, supply or distribution of the patented product would be prevented, hindered or made more expensive for the public if such a declaration is not made.

In the case of an emergency caused by serious diseases that may harm national security, the GHC will make a declaration of priority treatment. Once the declaration is published in the federal Official Gazette, pharmaceutical companies may request from the IMPI the right to exploit the corresponding patent. The IMPI would then have 90 days to decide whether to grant the emergency licence, after hearing the parties and evaluating the circumstances.

The MoH shall establish the conditions applicable to the production, quality, duration and scope of the emergency licences, and the qualification of the technical capacity of the applicant, as well as a reasonable amount for the royalties to be paid to the patent owner.

9.6 Proceedings for Patent Infringement

The following points are worth noting in relation to important procedural considerations:

- any patentee or licensee can submit a suit against a third party for infringement (unless it is expressly forbidden from doing so in its licence agreement);
- an important available remedy is the option to obtain provisional injunctions; and
- another essential available remedy is to claim damages before a civil court or before the IMPI under the new FLPIP, but this can only be initiated after the administrative infringement has been declared by the IMPI.

The patent infringement procedure is essentially composed of two stages. First, an infringement declaration is obtained through an administrative proceeding before the IMPI. Then, damages must be obtained directly with the IMPI or before a civil court.

An invalidity defence is available in the Mexican IP regime if the patent being enforced was:

- granted in violation of the provisions on requirements and conditions for the grant of patents;
- granted in violation of the provisions of the law in force at the time the patent was granted;
- abandoned as an application during its prosecution; or
- granted by error or to someone who was not entitled to it.

In practice, invalidity is invoked by the defendant when answering the infringement complaint.

9.7 Procedures Available to a Generic Entrant

In Mexico, there are no pre-launch declaratory actions, requirements to notify a patent holder, or requirements to clear the way.

Patent linkage was introduced in Mexico in 2003 through a parallel amendment of the RIS and the Secondary Regulation of the Industrial Property Law (SRIPL).

The amendment to the RIS introduced a patent linkage that excludes process patents and explicitly includes only product patents over the active ingredient. However, through litigation, protection has been extended to patents over formulation, doses and use.

The amendment to the SRIPL created a Special Edition of the Intellectual Property Gazette, issued by the IMPI, in which all relevant and valid patents for active ingredients are listed.

The trigger for protection is the inclusion of a relevant patent in the Special Gazette. The extended protection mentioned was achieved through litigation aimed at the inclusion of patents over formulation, dosing and use in the Special Gazette.

At the same time, the amendment to the RIS mandates all applicants for an MA of a drug to submit full information on the status of patent protection relating to its product. Applicants must demonstrate that they are the owner or the licensee of the relevant patent, if any. For this, applicants must produce and sign a sworn oath that they do not infringe patent rights. Then, when receiving an application for a drug approval, COFEPRIS is obliged to make an internal consultation to the IMPI in relation to the patents that may be directly relevant to that product.

However, the provisions are not very clear, and the ambiguities have created a system that has led to much litigation and to a situation where the burden of proof is essentially carried by users. Patent holders have to litigate inclusions and, if successful, they have to inform COFEPRIS of the results in order to have an impact on the drug approval system.

At the end of 2020, the IMPI implemented electronic tools to make it easier to consult information on patents, with the aim of improving transparency. Through these tools, it is possible to consult:

- the list of patents that will expire in the next ten years;
- a search tool for patents associated with allopathic drugs; and
- the IMPI's responses to COFEPRIS on patent linkage issues.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Assuming that a patent infringement action has already been initiated, there are a couple of additional measures that can be taken to obtain extra protection against the counterfeit of protected pharmaceuticals and/or medical devices. One of these measures is the seizure of the infringing goods, both in actual commerce and in customs. Alternatively, the confiscation of packaging, stationery, advertisements and similar objects that might be used to infringe the protected rights is also possible, as well as the seizure of instruments used for the manufacture and commercialisation of those infringing products, according to the Mexican IP Law.

Criminal procedures can be triggered against the following:

- the reoccurrence of a patent infringement;
- the intentional falsification of a protected trade mark;
- the production, storage, transportation, importation, distribution or commercialisa-

tion of goods that bear a counterfeited trade mark; or
- the intentional supply of raw materials used for the manufacture of the previously mentioned goods.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Once the trade mark registration has been obtained from the IMPI, no direct restrictions can be actioned against the use of those rights, unless a prior annulment declaration has been issued by the proper authority. However, limitations on the use of a trade mark can be caused by infringement actions against unfair competition practices or trade dress violations. In addition, parallel importation restrictions could affect the use of brands, but only when the owner of the trade mark abroad is not the same as the one in Mexico or when both parties do not belong to the same corporate structure. Given that prior use rights are recognised under the Mexican IP Law, restrictions on the exclusive use of a protected trade mark could be updated as well, as prior users are not regarded as infringers.

Antitrust, consumer welfare and sanitary restrictions could also affect the use of trade marks, although they do not jeopardise the validity of the IP registration. By way of example, the name of a pharmaceutical product could first be protected by a registered trade mark, but eventually not be allowed by COFEPRIS to be used as the distinctive name for the approved medicine, owing to the different approval criteria (eg, the health law regime forbids names that contain the same three letters in a word or generally any reference to organs and diseases on the respective product's name).

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

Under the new FLPIP, trade dress (plurality of operative elements, image elements (including size, colour, design, packaging) or any other elements that distinguish products or services) can be protected in Mexico as a trade mark. In addition, trade dress had been protected in the former law and continues to be protected by the FLPIP through infringement actions against any individual who uses signs, operative elements and image combinations that are employed to identify goods or services that are confusingly similar to previously registered ones – given that such usage deceives consumers, making them believe a commercial relation exists between the owner of the rights and the unauthorised user.

Protection for the design of pharmaceuticals and medical devices, as well as their packaging, can be achieved through the registration of a trade mark (design, 3D or trade dress), copyrights, unfair competition and/or an industrial design (ornamentation arrangements in 2D and 3D).

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

According to the Mexican IP Law, data exclusivity for pharmaceuticals (only) is protected under the terms of the international treaties to which Mexico is a party (eg, the USMCA). The protection is granted for at least five years from the date of the approval, but the regulator – as a matter of policy – has only recognised such protection for new chemical entities, excluding orphan drugs, biologics and biotech drugs. However, the protection for these can be obtained through litigation.

Although the first USMCA text adopted in 2018 contained stronger provisions on data exclusivi-

ty, the final amended protocol of 2019 eliminated them, leaving the protection essentially as it was before.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

The federal government did not generally seek to facilitate the import and commercialisation of any medicine or medical device required in the private sector to combat COVID-19, focusing only on public acquisitions of medicines and medical devices. On 27 March 2020, the government issued a decree in which it exempted medicines and medical devices acquired by the federal government from public tenders and import permits.

Instead of facilitating existing procedures, it created new authorisations and emergency approvals, which did not exist before and still lack any legal bases.

11.2 Special Measures Relating to Clinical Trials

COFEPRIS did not issue any measure to facilitate the continuation of clinical trials. Instead, it issued a communication on 21 April 2020 whereby it reiterated that any change to the approved conditions described in a research protocol would require the approval of an ethics committee and COFEPRIS.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

Although emergency authorisations do not exist in the regulatory framework in Mexico, the federal government issued many of these during the pandemic, including for:

- diagnostic tests performed at labs;
- ventilators;
- sanitisation services;
- vaccines; and
- medicines.

The scope of these authorisations is largely unknown, as there is no transparency or publicly known database in this regard.

Apparently, certain restrictions have been incorporated in some of these emergency authorisations – for example, in the authorisation of the medicine Remdesivir, the indication for which was apparently limited to "use in specialised hospitals". However, as this form of authorisation does not exist in the legal framework, any restriction could be challenged.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

COFEPRIS published an informal announcement on its website on 8 July 2020, in which it indicated that GMP certificates could be extended for six months under certain conditions. The extension would apply if the product had not been subject to:

- complaints in Mexico;
- sanitary alerts issued abroad; or
- safety measures in Mexico (eg, suspension of activities).

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

On 27 March 2020, a presidential decree was issued in relation to any medicine or medical device related to COVID-19, allowing for:

- its public acquisition without public tenders; and

- its importing without any administrative requirement.

11.6 Drivers for Digital Health Innovation Due to COVID-19

No specific regulation was issued to facilitate telemedicine, although some local governments created limited programmes for remotely monitoring the conditions of patients. However, no new instrument was issued to clarify any of the pending issues, such as the existence of contradictory secondary regulations in relation to e-prescriptions.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

The federal government did not announce any intention to issue compulsory licences for products related to COVID-19. However, during a formal visit to Mexico in February 2021, the President of Argentina announced Argentina's intention to request G20 countries to declare COVID-19 vaccines as "global goods", which the Mexican President endorsed. Nevertheless, no further legal step was taken in this regard.

If the federal government decides to pursue that avenue, it would have to comply with Article 153 of the FLPIP, which establishes the conditions for issuing a compulsory licence in the event of emergencies when not doing so would impede, hinder or make more expensive the availability of medicines.

The aforementioned provision creates a procedure where the GHC first issues a declaration of serious disease for priority attention. Interested companies can then apply for licences to the IMPI, which will make a decision in no later than 90 days, after receiving the opinion of the GHC. The MoH will then define the manufacturing and quality requirements for the product, as well as the scope, timeframe and royalties for the compulsory licence, which shall be non-exclusive and non-transferable.

The federal government has declared that, since March 2020, COVID-19 constituted a serious disease for priority attention. However, this was a verbatim replication of the similar declaration made regarding the 2009 AH1N1 pandemic, rather than an announcement of its intention to issue compulsory licences.

On May 2023, the federal government declared the end of the emergency health measures to prevent and control COVID-19, formally putting an end to the pandemic.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

No special provisions were introduced over product liability of COVID-19 vaccines.

11.9 Requisition or Conversion of Manufacturing Sites

In contrast to health services, where there was indeed an official programme to convert public hospitals into COVID-19 care facilities, there was no equivalent intention in relation to the manufacturing of pharmaceuticals or medical devices.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

There have been profound changes to the system for public procurement of medicines and medical devices since the new federal administration took office in 2018, including changes to large centralised purchases, which for many years had been managed by the Mexican Institute of Social Security. The administration first transferred the responsibility to the Ministry of Finance; when that failed, it signed a collabora-

tion agreement and transferred it to the United Nations Office for Project Services (UNOPS), which so far has also failed. However, those changes pre-dated the pandemic.

Trends and Developments

Contributed by:
Juan Luis Serrano-Leets
Sánchez DeVanny

Sánchez DeVanny is a Mexican legal consulting firm with international expertise, specialising in providing holistic and innovative solutions to resolve clients' needs, understanding their industries from the inside out. The firm practises law with social responsibility, exercising legal practice with transparency, ethics and inclusion. Sánchez Devanny forms lasting relationships with its clients that go beyond a simple contract for temporary services, with some clients having been with the firm since its foundation in 1996. The team unites experience and creativity in the creation of solutions for clients, because it is easier to innovate successfully when there is an understanding of how to do things correctly.

Author

Juan Luis Serrano-Leets leads the intellectual property and data privacy practice groups at Sánchez Devanny, and co-heads the life sciences industry group. He is a councillor of the Mexican Health Foundation and a board member of the Association of Pharmaceutical Industry Physicians and Professionals and of the Commission of Legal Affairs of the National Chamber of the Pharmaceutical Industry. He is also a professor of Sanitary Law in the Escuela Libre de Derecho and the Universidad Panamericana. Juan Luis was previously legal director of the Mexican affiliate of a multinational pharmaceutical company, and worked in law firms specialising in IP.

Sánchez Devanny

Av. Paseo de las Palmas 525 P6
Col. Lomas de Chapultepec
11000 Miguel Hidalgo
Ciudad de México
Mexico

Tel: +52 5550 2985 00
Email: jlserrano@sanchezdevanny.com
Web: www.sanchezdevanny.com

Life Sciences in Mexico: an Introduction

BIRMEX appointed as the government office in charge of purchasing all drugs/devices for the public sector

Through a communication published in the Official Gazette of the Federation on 22 December 2023, *Laboratorios de Biológicos y Reactivos de México* (Birmex) was designated as the government body in charge of purchasing health supplies for the public sector. This is a new attempt to improve procurement efforts by the current administration, as several problems arose with prior models, such as the hiring of the United Nations Office for Project Services (UNOPS), leading to shortages in key supplies and acquisitions at higher prices than expected.

At the time of writing, the acquisition process is ongoing. Prior acquisitions have been subject to judicial challenges, based on claims of inobservance of regulatory standards, breach or abuse of IP rights, and wrongful awards based on pricing.

Strategy for regulatory certainty – biosimilars guideline

Issued by the Federal Commission for Protection against Health Risk (COFEPRIS) in January 2024, this guideline has two objectives:

- to provide a regulatory framework that strengthens the biopharmaceutical sector in Mexico, with a focus on biosimilars; and
- to move the country towards sanitary self-sufficiency.

It refers to regulatory certainty as clarity for the user in requisites, evaluation criteria, response times and harmonisation with international standards. It also refers to a guarantee for interactions between the regulator and regulated companies, which has been a point of pain for companies throughout the current administration.

The measures to be implemented under this guideline include:

- the establishment of a Good Regulatory Practices Committee, focused on guaranteeing that regulatory changes are coherent and viable, aimed at regulatory improvement;
- the creation of a specialised unit of biosimilar products as an internal office at COFEPRIS, focused on efficiencies for the evaluation of products; and
- the creation of the Pharmaceutical Development Committee for Biosimilar Products, focused on incentivising the development of national biosimilars.

The regulatory goals set forth by the guideline include:

- updating regulations applicable to Good Manufacturing Practices;
- restructuring the New Molecules Committee;
- exhaustive pharmacovigilance;
- clarification of the scope of the Bolar exemption to eliminate the time limit – there is a discrepancy between the Mexican IP Law, which clearly states that patents will not be enforceable against third parties seeking to obtain a regulatory approval, and the relevant regulations, which establish a three-year timeline for the Bolar exemption to apply on small molecules and eight years on biologics; and
- modification of Mexico's linkage system, which has prevented the grant of marketing authorisations in violation of patent rights since 2003, leading to several litigation actions by both innovators and generic/biosimilar manufacturers. It is likely that any

change deriving from the guidelines will also be contested.

Strategy for regulatory certainty – medical devices guidelines

These guidelines were issued by COFEPRIS in October 2023 and seek to provide regulatory certainty to companies in the medical devices space, and guarantee access to innovations in medical technology.

They refer to several actions to be taken by COFEPRIS, including:

- the establishment of a Good Regulatory Practice Committee;
- approvals of medical devices based on recognition of approval by recognised agencies (such as the US FDA, Health Canada, or PMDA in Japan);
- regulatory harmonisation;
- the reclassification of devices – Mexico's current three levels of risk for devices, ranging from those that are generally not introduced to the body (Class I) to those that remain in the body for more than 30 days (Class III), will be harmonised with international recommendation, going to a four-level classification, ranging from low to high risk; and
- the digitalisation and automatic approval of regulatory proceedings.

Judicial challenges against labelling prohibitions still pending study by the Supreme Court

On 27 March 2020, a modification to Official Norm NOM-051-SCFI/SSA1-2010 was published in the official gazette, ordering companies selling food and drinks to adhere to a front labelling system including highly visible warnings against products considered to be high in sugar, salt or calories, or containing caffeine/sweeteners. These modifications also banned the use of cartoons or famous athletes in the labelling or promotion of relevant products. This prompted judicial challenges by several companies, which separately claimed that the general imposition of the labelling system and the specific prohibition against advertising activities were unconstitutional.

The initial challenges have been decided, with the Court concluding that the overall labelling system does not go against the Mexican Constitution. What is pending – and should be decided this year – is the constitutionality of the ban on advertising activities.

The decision by the Court is not a simple one, as the ban effectively limits the scope and usage of IP rights associated with fictional characters or the image of famous persons, thus pitting two constitutional rights against each other.

Federal government proposal to elevate ban against e-cigarettes to Constitutional level

In March 2022, the President's office issued a decree forbidding the circulation and sales in the Republic of electronic systems to administer nicotine, similar systems without nicotine, alternative systems for nicotine consumption, electronic cigarettes and vaping devices with similar uses, as well as the solutions and mixtures used in said systems. This decree has created a windfall of legal challenges, from companies that had challenged prior prohibitions and now had to re-file said challenges, and from companies seeking to enter the market for the first time.

The main arguments in these challenges are usually violations of the Mexican Constitution's rights to work and self-determination. The combination of companies filing these challenges and those deciding to sell at risk of sanction-

means that, in practice, e-cigarettes are easily available to Mexican consumers, without regulatory oversight.

In the latest development in this case, the President proposed a reform to Article 4 of the Mexican Constitution in January 2024, to elevate the ban to a constitutional level, thus preventing legal challenges and avoiding any interpretation to the contrary by the Supreme Court. Constitutional changes require the vote of two thirds of congress, so support from opposition parties will be required to pass this reform.

New linkage rules regarding analysis of patent rights before issuing marketing authorisations still pending

The Federal Law for the Protection of Industrial Property established in a transitory article that the Mexican Institute of Industrial Property (IMPI) and COFEPRIS would issue new rules to co-ordinate linkage review. Under the current system, a review is conducted between the agencies, without allowing either party to provide input, and the applicant is then informed if the product is considered to infringe a patent in force.

These new rules might adopt some aspects of the US Orange Book system, such as:

- a linkage gazette tied to approved products (as opposed to containing any patent covering a pharmaceutical product);
- a system allowing for claims of invalidity, and a specific timeframe for the suspension of study of a marketing authorisation if infringement is claimed; and
- first generic market exclusivity.

NETHERLANDS

Trends and Developments

Contributed by:
Judith Krens and Stefan van Kolfschooten
Pinsent Masons Amsterdam

Pinsent Masons Amsterdam is a solutions-driven life sciences team that brings together experts in the field to provide clients with solutions to unprecedented legal challenges. Working in 20 EMEA offices, the team comprises more than 120 sector-focused lawyers, who understand the technical as well as legal issues – with many having scientific backgrounds, in-house industry experience and strong relationships with industry bodies. Pinsent Masons' team acts for some of the most innovative life sciences companies in the world, including pharmaceuticals, generic and biosimilar, biotech and medtech companies. The work aligns with the firm's purpose, leading on precedent-setting litigation and market-leading transactions that make a real difference in the world. Pinsent Masons offers businesses a holistic approach, with transactional, tax, competition, IP, medicines regulatory, dispute resolution, employment, product liability, cyber and data, public policy and compliance professionals working seamlessly together to support life sciences companies that push the boundaries of science and law.

Authors

Judith Krens leads Pinsent Masons' life sciences team in Netherlands. She has two decades of experience working for top-tier law firms in both Amsterdam and New York, as well as working in-house for a US multinational technology consultancy. Judith has extensive experience of cross-border patent and SPC litigation in the field of pharmaceuticals, biotech and medical devices. As a life sciences specialist, she assists clients with complicated matters in pharmaceutical and medical device regulatory law. On top of that, Judith's experience working in the M&A and private equity team of Debevoise & Plimpton in New York gave her a top-class education in negotiating IP licences and transfer agreements.

Stefan van Kolfschooten is an associate in Pinsent Masons' Amsterdam office, with a particular focus on life sciences. Owing to hands-on experience in medical imaging, nuclear medicine, and radiotherapy, as well as specialising in patent law during his Master's in Information Law (cum laude) at the University of Amsterdam, Stefan has expertise in patent litigation and advising on regulatory matters. He is also an active member of the International Association for the Protection of Intellectual Property (AIPPI), Young EPLaw and the Amsterdam Bar Association.

Pinsent Masons Amsterdam

Gelrestraat 42
44 1079 MZ
Amsterdam
The Netherlands

Tel: +3120 797 7700
Email: Wouter.seinen@pinsentmasons.com
Web: The Netherlands (pinsentmasons.com)

Introduction

The global life sciences landscape has rapidly evolved during the past couple of years, thanks to developments in advanced healthcare technologies. Given that these developments are hardly limited to the Dutch life sciences landscape, and as it goes beyond the scope of this contribution to provide an exhaustive list of these advancements, a few of these will be touched upon here by way of an introduction.

However, two buzzwords that cannot be left out are machine learning and AI. The evolution and application of AI technology has led to some significant advancements in all kinds of medical fields. While developments can be seen in the application of AI in imaging techniques for radiology and pathology, the use AI has already reached even the consulting room of the general practitioner.

Another hot topic and a driving force of progress in healthcare is the field of molecular diagnostics. A recent development in this area concerns a method of analysing non-cellular DNA to look for genomic variants associated with hereditary or genetic disorders. These advancements provide attractive opportunities for early diagnosis, assessment of treatment response, and minimally invasive disease monitoring.

Although not necessarily new technologies, there has been a clear acceleration in the adoption of the use of telemedicine and remote monitoring technologies. Technologies such as blood pressure monitors and electrocardiogram (ECG) devices with remote monitoring capabilities enable patients to monitor their health from the comfort of their own homes while staying in contact with their healthcare providers. It is believed that the COVID-19 pandemic has greatly accelerated the adoption of these technologies. The same can be said for wearable devices with medical advantages (eg, smart watches and continuous glucose monitors). These devices provide users with real-time data on their health, as well as the option to share this data with their clinicians without even needing to visit the hospital.

Furthermore, the EU patent litigation landscape saw the greatest change in more than 50 years in 2023. This refers, of course, to the opening of the Unified Patent Court on 1 June 2023 and the option to acquire a unitary patent – thereby creating a single approach to patent registration and litigation currently across 17 participating EU member states. Parties with patents in the life sciences space were eager to kick things off, leading the way in filing cases in the early weeks of the new court's operation.

Now, following this brief introduction to trends that have affected the Netherlands to a more general extent, it is time to take a closer look at the specific developments in the Dutch life sciences sector: what is going well, what could be better, and in which direction it may be heading.

The Netherlands' Position Within the EU Clinical Trials Ecosystem

Conducting clinical trials is an essential step in assessing the safety and efficacy of potential new drugs and vaccines. As such, clinical trials are a crucial link between research being done in the lab and the actual advantages it may bring to the patient. It is estimated that around 2,800 clinical trials are authorised each year in the EU/European Economic Area (EEA). So, how is the Netherlands performing in this field?

A recent report has shown that clinical research in the Netherlands is ranked at the top within the EU clinical trials ecosystem. The research was performed by a company called Citeline and focused on – among other things – the amount of clinical trials being performed per country, the quality and areas of research, and the robustness of its logistics.

The report shows that the Netherlands excels in clinical research in oncology, autoimmune diseases, rare diseases and nervous system disorders. Additionally, a relatively large amount of research in the Netherlands is conducted in the field of cardiology when compared with the surrounding countries – the difference being 10% versus 7%. Moreover, the report demonstrates that the Dutch ecosystem harbours innovative leadership and robust infrastructure and logistics.

Besides harbouring a good healthcare system, the Netherlands has a ratio of 41 doctors per 10,000 people. Combined with a relatively large number of hospitals and a high population density, performing clinical research is relatively easier from a logistical standpoint in comparison with other countries. On top of that, the researchers working on clinical trials in the Netherlands are among the most cited scientists in the world (ie, third in Europe and seventh worldwide in 2022).

Naturally, there are areas in which the Dutch clinical trials system can improve. The report states that the Netherlands should more actively engage at international conferences, invest in skilled talent, streamline approval processes, improve key metric reporting and foster better academic-industry collaboration. The Dutch Clinical Research Foundation has already stated work on a plan to implement these findings, which is scheduled to be published in April 2024.

M&A and Investments

The deals space in the Dutch healthcare sector has not been quiet. More activity was, however, expected as a result of the removal of certain thresholds for the approval of M&A in the healthcare sector. Such deals in many cases require prior approval from the supervising Dutch Healthcare Authority (DHA). In short, the test applied by the DHA verifies whether the intended merger or acquisition could have an adverse effect on the Dutch market – be it for competition or the provision of care in general.

From 2018, specific lower turnover thresholds were in force for companies in the healthcare sector, with the effect that healthcare providers were more likely to meet the criteria of needing to seek regulatory approval before proceeding with a deal. As of 1 January 2023, the lower turnover thresholds were removed – as a result of which, the generic higher turnover thresholds applied to healthcare providers, as they also

apply in other economic sectors. This meant that, from that date onwards, considerably fewer M&A within the healthcare sector require regulatory approval.

Despite this change, there has not been an increase in the number of M&A within the Dutch healthcare sector. In the first half of 2023, 95 M&A took place, whereas a total of 170 deals took place in the same period of 2022. It is still unclear what has led to this noticeable difference. As in earlier years, most M&A occurred in the oral healthcare sector.

Private equity

What has increased is the influx of private equity in the Dutch healthcare sector. In 2019, about 50% of the investments in large healthcare institutions were done by private equity. By 2022, however, this percentage had increased to about 60% in total. Private equity has thus become a dominant force for transactions in the Dutch healthcare sector.

The desirability of this development is highly debated. Critics believe that providing care and making a return on investments do not go hand in hand and that healthcare can or may not be seen as a revenue-generating model. Proponents, however, believe that investors' capital can actually be used to invest in improving healthcare, as private equity frequently also brings networks and knowledge to the market.

As a result of these discussions, research is currently being conducted to determine the effects of private equity on the Dutch healthcare landscape. The results of this research are expected to be presented by the end of the first quarter of 2024 and hopefully provide insights into the desirability of this development.

Dutch Inventors and the Patent Litigation Landscape

For such a small country, the Netherlands continues to make a name for itself when it comes to being a hub for innovation – at least based on the number of patents filed by Dutch companies. In 2023, Dutch companies and inventors filed 7,033 EU patent applications, which is an increase of 3.5% compared to 2022. This increase also supersedes the average EU-wide increase of 1.5%. Patents in the medical technology field dominate among Dutch inventors – although the chemical and biotechnology sectors also show significant growth.

Dutch patent litigators were, moreover, kept aptly entertained with regard to one specific topic in the past year. At conferences, in articles and in case law reviews, one topic was invariably on the agenda: the test of plausibility. In short, this test plays a role in patents where the issue is whether the patent makes sufficiently clear what the technical contribution of the invention is to the state of the art. After much litigation and uncertainty concerning the interpretation of this test, debate still persists among scholars and professionals. Naturally, the authors are following the developments on this topic closely.

However, the impression should not be given that there was a lack of attention on other patent cases at the Dutch courts. In fact, the number of patent cases that are being handled by the courts in The Hague shows a rising trend. After a record low of only 116 cases handled in 2021, presumably due to the COVID-19 pandemic, plaintiffs filed 149 new patent cases in 2022. Although not as high as the numbers in 2017, which rose to 172 cases in total, the trend upwards is a good sign of the value and persisting appreciation of the Dutch patent litigation system.

Kinks in the Supply Chain and the Option of Circularity

In the past two years, the Dutch pharmaceutical landscape has seen more issues with the availability of pharmaceuticals. In 2023, as a short-term solution to the shortages, the Dutch Medicines Evaluation Board (*College ter Beoordeling van Geneesmiddelen*, or CBG) and the Health and Youth Care Inspectorate (*Inspectie Gezondheidszorg en Jeugd*, or IGJ) granted permissions to pharmacists, manufacturers and wholesalers to import alternative products on a total of 140 occasions for 46 different drugs. In 2022, such permissions were granted in 132 instances for a total of 54 drugs.

In those two years, delay in production or release of end products caused more than half of all delivery problems. For long-term shortages, manufacturers reported that the problems were mainly due to a shortage of raw materials or long-term production issues. Specific to the global shortage of Ozempic was its off-label use as a weight-loss drug and the media attention this received. Recent articles (such as "*CBG en IGJ: Beperkte Alternatieven Antibiotica voor Kinderen Beschikbaar*" (CBG and IGJ: Limited Antibiotic Alternatives Available for Children), which was published in *Pharmaceutisch Weekblad*) have further stressed that there were limited supplies of alternatives to antibiotics for the treatment of children available, owing to shortages of liquid antibiotics.

As a result of these issues, Dutch Minister for Medical Care Pia Dijkstra has stated that she wants to lead the way in the debate on drug shortages with her position in the EU. In her announcement, Dijkstra has stressed that the Netherlands is a small country dependent on other countries for the supply of raw materials. Specifically with regard to the shortage of antibiotics for children, Dijkstra has called on Dutch producers of antibiotics to come forward to provide short-term relief for the shortages. In the long term, a team consisting of suppliers, pharmacists, wholesalers, health insurers and the Dutch Medicines Evaluation Board has been enacted to investigate how antibiotics should be distributed in the future.

Reissuance of drugs

Nonetheless, drug shortages could possibly be resolved via other methods. One of the suggested methods is to reissue unused drugs. In theory, it is possible to reissue drugs. In practice, however, drug reissuance is only allowed for use in scientific studies at the present time. Several obstacles, such as laws and regulations and the lack of a sustainable reimbursement system for reissuance, currently stand in the way. Various parties in the pharmaceutical supply chain are therefore exploring how these obstacles could be removed.

By way of example, a roundtable discussion was held, to which all parties in the chain – from manufacturers to patients – were invited. The conclusion was that there appeared to be a great incentive to join forces. As such, Dutch demissionary Minister for Health, Welfare and Sport Ernst Kuipers has sent a letter to the EC, pleading for EU law to be amended so that reissuance might be possible in the future.

In his letter, Kuipers drew particular attention to the Falsified Medicines Directive (FMD). Even though the FMD has proven effective in the fight against falsified drugs and is important to ensure the safe use of drugs in the European Union, he believes it is necessary to re-examine this EU Directive, given the current unprecedented drug shortages and the desire to combat the waste of drugs. Kuipers stressed that he does not want

to tamper with the core of the FMD, nor does he advocate a large-scale reissue of all returned drugs. His main focus is the examination of the conditions under which reissuance is a safe and beneficial option. According to Kuipers, a sustainable approach to the pharmaceutical supply chain is indispensable in securing the future resilience of the Dutch healthcare system.

Prevention, Prevention, Prevention

Another notable trend in the Dutch healthcare landscape is the increasing move towards preventative care, rather than retrospective cure. The focus on prevention is an important means of keeping healthcare accessible and affordable. Earlier in 2024, two motions on medical prevention were adopted in the House of Representatives. These motions require the government to:

- propose ways in which budgets for new vaccines can better reflect positive opinions from the Dutch Health Council confirming the effect of the vaccine; and
- develop a set of tools that can quantify the broad costs and benefits of prevention in the short, medium and long term.

With these adoptions, the majority of the MPs have spoken out in favour of structural attention to the social benefits of (medical) prevention.

The same call to move towards prevention is being heard from the Dutch Hospital Association (*Nederlandse Vereniging van Ziekenhuizen*, or NVZ). Earlier in 2024, the NVZ handed over a consultation document entitled "Open Hospitals" to Pia Dijkstra. In this document, the NVZ identified pre-conditions that it believes are crucial to continue in order to enable accessible and quality care, such as:

- the recruitment and retention of sufficient healthcare professionals;
- appropriate funding;
- the realisation of good data exchange; and
- the removal of competition rules that hinder or delay co-operation.

Digitalisation is also frequently mentioned in the document as one of the solution-based approaches. As touched upon in the introduction to this article, the provision of hybrid or digital care will play an ever-increasing role in and is an important way of delivering care at home, be it via home monitoring or remotely – thereby partly overcoming the issue of shortages of staff.

Beyond the political aspects of moving towards prevention, a new project involved in the development of antiviral drugs commenced in March 2024 at the Dutch Leiden University Medical Center. The aim of this new project, called Pan-ViPrep, is to be able to better protect Europe in case of any following. The combined knowledge of the experts involved in the project cover the areas of virology, protein chemistry, medicinal chemistry, pharmacology and AI systems. The research project focuses on antivirals, as they can be developed with a broader possible effect than that of vaccines.

Forthcoming Developments

In the Netherlands, most drugs are reimbursed through the basic health insurance scheme. In recent years, there has been an uptick of very expensive drugs on the market and those that are intended to enter the Dutch market may temporarily be placed in the so-called lock system. Once there, the Dutch National Health Care Institute assesses whether the new and expensive drug is effective, complies with the standards of science and practice, and has a proportionately reasonable price. Following the assessment, the

Health Care Institute advises the Minister for Medical Care whether or not to admit the drug to the insured package under certain conditions. The Minister for Medical Care may then decide to negotiate the price with the manufacturer and decide whether to reimburse the drug though the national insurance scheme.

Duing the next two years, the number of drugs being placed in the lock is expected to rise sharply. Besides autonomous growth in the number of "locked" drugs, the proposed adjustment of the lock criteria – to essentially lower the price threshold for a drug to be in scope for placement in the lock – is seen as a reason why pressure on the lock system might be increased in the coming years. However, it has been shown that the lock system does have an overall positive effect on the Dutch national healthcare system.

Duration reimbursement process

To provide insights regarding the status of drugs that are put in the lock system, the Ministry of Health, Welfare and Sport launched the *Dashboard Doorlooptijden Geneesmiddelen* ("the Dashboard"). The Dashboard provides patients, prescribers and drug manufacturers insight into which stage of the reimbursement process (submission, review or negotiation) expensive new drugs are at.

Horizon Scan

Further insights with regard to the pharmaceutical landscape have been provided by the publishing of the new Horizon Scan by the National Health Care Institute in late 2023. The Horizon Scan maps the potential impact of new drugs on patient treatment and healthcare costs. In addition, the Horizon Scan monitors indication extensions for existing drugs. This provides patients, practitioners, hospitals, health insurers and government bodies with early information on developments in the field of these drugs.

The Horizon Scan shows that, before the end of 2025, 104 indication extensions and 83 new drugs are expected to enter the market for various cancers (mostly lung and breast cancers). It is also notable that more than 10% of the drugs expected to receive European Medicines Agency approval in the next two years will be gene, cell and tissue therapies.

Long-Term Outlook

In conclusion, it is worth looking a bit further ahead to what is expected to happen in the Dutch life sciences landscape.

Vision for first-line care

Dutch Minister for Health, Welfare and Sport Conny Helder has presented the Primary Care Vision 2030 to the House of Representatives. The aim of the Primary Care Vision 2030 is to strengthen the organisation of primary care, assuring that care will always accessible to everyone who needs it. In addition to contributions from the Patient Federation Netherlands, the Royal Dutch Pharmacists Association (*Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie*, or KNMP), the Netherlands Society of General Practitioners, the Federation of Medical Specialists, Health Insurers Netherlands and Social Work Netherlands (among others), the input from citizens' platforms proved very helpful in shaping the Primary Care Vision 2030 document.

The main aims of the Primary Care Vision 2030 document can be summarised as follows.

- The co-operating parties will work together in the coming years to reduce the unwanted

pressure on primary care and better prepare and guide patients to primary care.
- Capacity within primary care should also be better utilised by organising tasks differently where necessary.
- There will be a point of contact for primary care in the region and a 24/7 infrastructure for crisis situations.
- Healthcare professionals want more sustainable co-operation within primary care, both between primary care and other domains and between primary care and its financiers. The focus here will be less on competition – co-operation and contracting should be based more on continuity and mutual trust.

A total amount of EUR104 million has been made available for the programme to be implemented according to what the parties have set out in the Primary Care Vision 2030 document before 2026. It has been agreed that a number of concrete scenarios for the bolstering of primary care will be worked out before the summer of 2024.

Vision for future-proof long-term care

In addition to plans for primary care, plans are also being made to ensure a sustainable system for long-term care. Demand for this type of care is high and continues to grow under the pressure of an ageing population. For this purpose, the Dutch Care Assessment Centre (*Centrum Indicatiestelling Zorg*, or CIZ), the National Health Care Institute, the DHA and the Dutch Central Administration Office set out – in a joint work agenda – to tackle the steps needed to keep long-term care available in the future. The four areas in which the stakeholders believe the system of care and welfare should be adjusted can be summarised as follows.

- A patients' social network currently does not play a role in the Long-Term Care Act (*Wet langdurige zorg*, or Wlz). This should be incorporated.
- The Wlz should remain available for the most vulnerable – meaning that, if appropriate care and support for others can be well established in other domains, this should be possible and preferably encouraged.
- In several regions of the county, the availability of healthcare is already constrained – for example, owing to a greater presence of elderly patients in that region. The agenda sets out to think of solutions to help with distribution issues in regions with scarcity.
- Lastly, the agenda sets out to explore how to reduce complexity in the care/system with the Ministry of Health, Welfare and Sport.

These four themes will be fleshed out in the coming period.

NIGERIA

Law and Practice

Contributed by:
Chinyere Okorocha, Toyosi Odunmbaku, Yeye Nwidaa and Oloruntobi Opawoye
Jackson, Etti & Edu

Contents

Jackson, Etti & Edu (JEE) is a leading full-service, sector-focused commercial law firm. With more than 25 years' experience and several awards for excellence, JEE consistently renders legal services to Nigerian, pan-African and international clients from diverse jurisdictions – as evidenced by the firm's presence in Lagos, Abuja, Accra, Harare and Yaoundé. JEE's lawyers have extensive expertise in advising clients on a wide range of matters pertaining to the healthcare sector, including financing, business regulatory compliance, ethics for health professionals, debt recovery, litigation, arbitration and ADR, as well as health law advocacy and reviews of laws in this sector. The firm consists of 14 partners, 60 fee earners and more than 50 paralegals and support staff. The size of JEE's dedicated commercial team is indicative of the firm's rich human resource base and its capacity to effectively and efficiently help clients achieve their goals.

Authors

Chinyere Okorocha is a partner at Jackson, Etti & Edu, where she co-heads the health and pharmaceuticals team. She has more than 30 years' experience and expertise in the medicolegal sector, couple with a great grasp of the technical implementation of legal strategy. Chinyere sits on the advisory boards of several medical organisations and companies, and is also a member of the World Association for Medical Law. She has accumulated hands-on experience in business leadership, strategic thinking, vision setting and problem solving of clients' diverse needs. She is currently the President of the Nigerian Bar Association's Women Forum.

Toyosi Odunmbaku is a partner at Jackson, Etti & Edu, where he co-heads the health and pharmaceuticals team. He advises on a wide range of health and pharmaceutical projects in Nigeria, including the procurement, importation and distribution of pharmaceutical products and medical devices. He is a specialist in IP litigation and has acted in trade mark, design and patent litigation involving pharmaceutical manufacturers and brand owners. Toyosi is also responsible for co-ordinating enforcement actions against counterfeiters, which is at the very heart of ensuring medical and pharmaceutical products are safe for use.

Contributed by: Chinyere Okorocha, Toyosi Odunmbaku, Yeye Nwidaa and Oloruntobi Opawoye,
Jackson, Etti & Edu

Yeye Nwidaa is a partner at Jackson, Etti & Edu and is a chartered secretary, a governance specialist and a member of the Chartered Governance Institute of the United Kingdom (ICSA). She heads JEE's business regulatory, compliance and governance practice, where she provides legal advisory services to foreign investors and local companies with regard to founding and running businesses in Nigeria. Yeye has been offered company secretary roles in several pharmaceutical companies in Nigeria. Her experience includes international commercial arbitration, IP rights enforcement, commercial litigation, payroll management and general commercial legal advisory.

Oloruntobi Opawoye is a senior associate at Jackson, Etti & Edu and deputy head of the health and pharmaceuticals team. She combines in-depth knowledge of the law with diplomatic skills so that disputes reach a swift and respectful conclusion. She advises a wide range of health and pharmaceutical organisations on various aspects of their businesses, including ethics, debt recovery, arbitration and IP protection, as well as enforcement, regulation and compliance. Oloruntobi is a member of the Nigerian Bar Association and the Chartered Institute of Arbitrators (UK), and provides advice to the Medical Ethics Board of a hospital chain.

Jackson, Etti & Edu

RCO Court
3–5 Sinari Daranijo Street
Off Ajose Adeogun
Victoria Island
Lagos
Nigeria

Tel: +234 1 2806989
Fax: +234 1 2716889
Email: jee@jee.africa
Web: www.jee.africa

Contributed by: Chinyere Okorocha, Toyosi Odunmbaku, Yeye Nwidaa and Oloruntobi Opawoye,
Jackson, Etti & Edu

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The key legislation and regulations that govern pharmaceuticals are:

- the Food and Drugs Act (Chapter F32) LFN 2010;
- the National Agency for Food and Drug Administration and Control Act Chapter (N1) LFN 2010;
- the Food, Drugs and Related Products (Registration) Act (Chapter F.33) 2010; and
- the Pharmacy Council of Nigeria (Establishment) Act 2022.

The Food and Drugs Act and the Food, Drugs and Related Products (Registration) Act regulate the manufacture, sale, advertisement and distribution of drugs in Nigeria. The National Agency for Food and Drug Administration and Control Act establishes the main regulatory agency (ie, NAFDAC) responsible for issuing marketing authorisations and product registrations for the sale and distribution of imported and locally manufactured pharmaceuticals in Nigeria.

However, the Pharmacy Council of Nigeria (Establishment) Act 2022 regulates the sale and distribution of pharmaceutical products in Nigeria. It seeks to control the supply chain of pharmaceuticals and ensure the registration and regulation of premises where pharmaceuticals are sold and distributed, whether such sales are on a large-scale basis or for retail. The Act also establishes the Pharmacy Council of Nigeria (PCN), which is the regulatory agency responsible for the control and supervision of pharmacists and the premises used for the manufacture, distribution and sale of pharmaceutical products in Nigeria.

To reinforce their regulatory oversight, both the PCN and NAFDAC have issued guidelines and regulations on the distribution, advertisement and importation of pharmaceutical products, including:

- Guidelines for Pre-Production Inspection of Pharmaceutical Manufacturing Facilities in Nigeria;
- Guidelines for Pre-Registration Inspection of Pharmaceutical Manufacturing Facilities in Nigeria;
- Good Distribution Practice for Pharmaceutical Products Regulations 2021;
- NAFDAC Guidelines for Contract Manufacturing of Finished Pharmaceutical Products in Nigeria;
- Drug and Related Products Labelling Regulations 2021; and
- Online Pharmacy Regulations 2020.

The legislation governing pharmaceuticals also governs medical devices, so the PCN and NAFDAC are also the major regulators of medical devices. However, he Standards Organisation of Nigeria (SON), the Federal Competition and Consumer Protection Commission and the Nigerian Nuclear Regulatory Authority (NNRA) have also been set up under the Standards Organisations of Nigeria Act 2015, the Federal Competition and Consumer Protection Act 2018 and the Nuclear Safety and Radiation Protection Act 1995, respectively.

Although the SON is responsible for regulating the standards of medical devices, the Federal Competition and Consumer Protection Act 2018 seeks to protect the consumer from exposures from manufacturers. The NNRA regulates the

use, installation and operation of medical devices that have radiation, including x-ray machines and MRI machines.

However, it is crucial to note that NAFDAC remains the main regulatory authority for medical devices. To this end, it has issued regulations and guidelines to control the distribution, sale and distribution of medical devices, including:

- Drug and Related Products Advertisement Regulations 2021;
- Guidelines for Registration of Medical Devices Made in Nigeria;
- NAFDAC Guidelines for Registration of Imported Medical Devices in Nigeria;
- NAFDAC Guidelines for the Renewal of Certificate of Registration Licence for Imported Medical Devices; and
- Guidelines for Advertisement of NAFDAC Regulated Products.

The following regulatory bodies enforce pharmaceuticals and medical devices laws and regulations:

- NAFDAC is the statutory body that administers the NAFDAC Act and enforces its objectives – it regulates and controls the importation, exportation, manufacture, advertisement, distribution, sale and use of drugs, medical devices, pharmaceuticals and chemicals;
- the PCN is the statutory entity responsible for the control and supervision of pharmacists and the premises used for the manufacture, distribution and sale of pharmaceutical products in Nigeria; and
- the SON is the statutory body responsible for standardising and regulating the quality of products in Nigeria, including medical products – it also oversees the standard of goods imported and distributed in Nigeria.

The SON, the PCN and NAFDAC are all semi-autonomous regulatory entities, supervised by the Nigerian federal government through the Federal Ministry of Health and the Federal Ministry of Trade and Investment.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Filing a Complaint

A party that is dissatisfied with the decision of a regulatory body is entitled to request a review of said decision. It is not unusual for decisions of the major regulatory bodies that enforce pharmaceutical and medical device regulation (especially the PCN and NADFAC) to be contested or challenged, generally through the following procedure.

Petition or appeal to the regulatory body

First, an attempt should be made to seek a reconsideration of the regulatory body's decision, outlining the grounds for such petition or appeal. There is a statutory time limit of three months for challenging decisions of regulatory bodies; therefore, this petition or letter must be issued to the regulatory body within this timeline in order to avoid the party's right to challenge an unfavourable decision being limited and exhausted by operation of law.

Pre-action notice to the relevant regulatory body

Most regulatory bodies that enforce pharmaceutical and medical devices regulations require a party challenging their decision to issue a pre-action notice as a precondition to the commencement of a court action or to seek judicial review. One such example can be found in the

NAFDAC Act, which provides that a pre-action notice (or a written notice of intention to commence a suit) must be issued one month prior to the commencement of the suit. A pre-action notice must be submitted within one month if a PCN decision is to be challenged.

Court action for judicial review

After taking these steps, a party is entitled to proceed to court in order to challenge the decision of the regulatory body. It is crucial to note that the court action must be filed within three months of the date of the decision of the regulatory body, or else the matter will be considered statute-barred.

1.3 Different Categories of Pharmaceuticals and Medical Devices

There are different categories for medical devices and pharmaceuticals, as reflected in the laws and regulations in force.

Pharmaceuticals

Pharmaceuticals are not specifically categorised in Nigeria. Although NAFDAC regulates all types of drugs, the NAFDAC Drug and Related Products Advertisement Regulation makes separate provisions for the labelling and advertising of prescription medication, which differ from those for OTC medication.

Medical Devices

NAFDAC has adopted the guidelines of the Global Harmonization Task Force (GHTF) for the international classification of medical devices, known as the Principles of Medical Devices Classification. These classes include:

- Class A for low risk (eg, cholesterol, uric acid test system, surgical instruments, bandages, surgical cameras);
- Class B for low-to-moderate risk (eg, surgical lamp, surgical mask, electric hospital bed);
- Class C for moderate-to-high risk (eg, condom, x-ray unit, syringe, contact lens); and
- Class D for high risk (eg, pacemaker, defibrillator, HIV blood donor screening, stent, intraocular lens).

The higher the risk, the more stringent the regulatory requirements for such class will be.

2. Clinical Trials

2.1 Regulation of Clinical Trials

In Nigeria, clinical trials for pharmaceutical products and medical devices are regulated under the Clinical Trial Regulations 2021. NAFDAC is the supervising agency and is empowered to review protocols and grant authorisation of clinical trials before they are conducted.

However, the National Health Research Ethics Committee (NHREC) and the Institutional Review Board (IRB) are statutorily expected to provide an ethical opinion, which is a precondition for the grant of NAFDAC's approval of a clinical trial.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

The procedure for securing authorisation to conduct clinical trials for pharmaceutical products and medical devices is governed by Clinical Trial Regulations 2021, the Good Clinical Practice Guidelines 2020 and the Guidelines for Clinical Investigation for Medicinal Products in the Paediatric Population.

The requirements for applying for approval to undertake a clinical trial are as follows.

- Application form – every organisation that wishes to undertake a clinical trial must fill out and submit an application form, along with supporting documents and a completed checklist, containing details of the study, the organisation conducting the trial and the technical details of the pharmaceutical or medical device being tested, as well as other relevant details.
- Protocol – certain protocols are required under the regulation, including investigation of approved trial sites and facilities used for clinical trial, processing of data of trial participants (patient information leaflet), signed declaration by the sponsor or principal investigator and co-investigators and persons of interest, informed consent of participants, and proof of indemnity or insurance certificate.
- Ethics Committee approval – after observing protocol measures, the Ethics Committee is set up only for specific matters that ensure the risks to the participants are equally managed. It operates under a valid certificate issued by the NHREC, and members of the Ethics Committee must not have any interest in the trial.
- Registration – upon completion of the application form, submission of other supporting documents and observance of protocol measures, the applicant for clinical trial will then be registered with the Nigerian Clinical Trial Registry (NCTR) or the Pan-African Clinical Trial Registry, and the evidence must be submitted to NAFDAC.

2.3 Public Availability of the Conduct of a Clinical Trial

Information on clinical trials is accessible to the public, so their status is ascertainable.

Clinical trial applications filed in Nigeria for pharmaceuticals and medical devices can be accessed through NAFDAC's Electronic Clinical Trial Application Platform. Along with the NHREC and the Federal Ministry of Health, NAFDAC also maintains the NCTR, which is accessible to the public and provides information on ongoing and completed trials.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There is currently no restriction on using online tools to support clinical trials. However, in practice, NAFDAC and the NHREC have associated online platforms used as a database for clinical trials, which they update with new information on the investigations and upload information particular to the trial.

2.5 Use of Data Resulting From Clinical Trials

Data resulting from clinical trials may not be considered as personal data under Nigerian law.

Section 5(10) of the Clinical Trial Regulations 2021 protect the rights of the participant to physical and mental integrity, privacy and personal data. The protection of the participant's data is at the frontier of the clinical trial, such that the resulting data and other information made publicly available do not contain any information concerning participants that may be considered personal data.

Where the resulting data includes details that might identify the participants, it is classed as personal data and can only be published if the participant has provided informed consent to use their personal data.

Transference of Data to a Third Party

In the same vein, such resulting data may be transferred to a third party or affiliate in accordance with the laws that protect such data.

Pursuant to Section 7(6) of the Clinical Trial Regulations 2021, any transfer of ownership of the content of the clinical trial must be documented, and the new owner is to assume the responsibilities set out in the regulations. Likewise, Article 3.1(7)(f) of the Nigeria Data Protection Regulation (NDPR) 2019 provides that – prior to collecting personal data from a data subject (in this case, from the participant in the trial) – the data controller (in this case, the person/organisation that is running the study) must inform the data subject of:

- the fact that the data controller intends to transfer personal data to a third party, another country or an international organisation; and
- the existence or absence of an adequacy decision by the National Information Technology Development Agency (NITDA), which indicates whether another country satisfactorily protects personal data.

Data resulting from clinical trials containing sensitive data may not be shared on the associated platform with third parties unless the participant consented to the use and transfer of their personal data.

2.6 Databases Containing Personal or Sensitive Data

By law, the creation of a database containing personal or sensitive data is subject to further protective requirements. Such a database must comply with the Clinical Trial Regulations 2021 and with the provisions of the NDPR aimed at the protection of sensitive data collected on a database.

For instance, Article 2.1(1)(l) of the NDPR requires that personal data (applicable to the participant's information used in the trial) is collected and processed where consented to by the data subject, provided that further processing may be done for archiving, scientific research or statistical purposes for public interest. Therefore, participants are required to consent to their personal data being uploaded onto a public database. Section 3 (9) of the Clinical Trial Regulations specifies that the confidentiality of records that could identify subjects must be protected in order to respect their privacy.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

In the determination and classification of pharmaceuticals and medical devices, the NAFDAC Act prescribes a number of specific requirements or criteria. It defines a "drug" as any substance of vegetable, animal or mineral origin (or any preparation or admixture thereof) that is manufactured, sold or advertised for use in:

- the diagnosis, treatment, mitigation or prevention of any disease, disorder or abnormal physical state (or the symptom thereof) in humans or animals;
- restoring, correcting or modifying organic functions in humans or animals;
- disinfection or the control of vermin, insects or pests; and
- contraception.

A medical device is defined as "any instrument, apparatus or contrivance (including components, parts and accessories thereof) manufac-

tured, sold or advertised for internal or external use in the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof" in humans or animals.

Therefore, products that fall within the scope of these definitions would be assessed and placed in such categories, if considered to be either pharmaceuticals or medical devices.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

In Nigeria there are no specific obligations provided for the granting of marketing licences for biologic medicinal products; the general obligations under the Guidelines apply.

However, the National Control Laboratory for Vaccines and Other Biologics (NCLVB) is a specially constituted NAFDAC unit responsible for confirming the quality, safety, efficacy and fitness for use of vaccines, biological products and medical diagnostic devices after analysis/evaluation. This unit may recommend restrictions on the marketing of specific biologics based on the review thereof.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

The NAFDAC Drug and Related Products Registration Regulations 2019 provide that the registration of a drug with NAFDAC will be valid for five years.

Renewal of Marketing Authorisation

The NAFDAC Drug and Related Products Registration Regulations 2019 state that marketing authorisations may be renewed. NAFDAC has published further Guidelines for Renewal of Certificate of Registration for Locally Manufactured Drug Products in Nigeria, in addition to Guidelines for Renewal of Certificate of Registration for Imported Drug Products in Nigeria. These guidelines set out the mode of renewal and cover the nature of the application and the supporting documents required – eg, annual licence/premises registration, trade mark registration, Certificate of Pharmaceutical Product (COPP–WHO Format) and notarised declaration. Similar provisions are found in the Guidelines for Renewal of Certificate of Registration for Medical Devices Made in Nigeria and the Guidelines for Renewal of Certificate of Registration for Imported Medical Devices in Nigeria.

All the above-mentioned guidelines provide that an application for renewal must be initiated no later than 30 calendar days before the date the current/valid licence is due to expire. Successful renewal applications for drugs and medical devices, whether locally manufactured or imported, will result in the issuance of a Certificate of Registration with a validity period of five years.

Revocation or Withdrawal of Marketing Authorisations

Pursuant to Section 7 of the Drug and Related Products Registration Regulations 2019, marketing authorisations may be revoked or withdrawn by competent authorities if:

- the ground of registration happens to be false;
- the conditions of registering the drug product have been breached;
- the standard of quality in the paperwork of the registration has been contravened;
- the product is ineffective for its primary purpose;
- the premises where the drug product or part thereof is manufactured – or kept on behalf

of the Certificate of Registration Holder ("the Holder") – contravene the provisions of current Good Manufacturing Practice (cGMP);
- the Holder has given notice to NAFDAC in writing of any intentions to suspend product registration for a period not exceeding the validity of the certificate of registration; and
- the registration is inchoate based on the information supplied.

The regulations further provide that, where the registration of a drug product is suspended or cancelled, NAFDAC must then withdraw the drug product and cancel it from circulation.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

In practice, there is a standard procedure for obtaining a marketing authorisation for drugs and all regulated products. Pursuant to the Drugs and Related Products (Registration) Regulations 2019, a drug cannot be imported, distributed or sold without being registered by NAFDAC.

According to the regulations, a marketing authorisation may be granted through a single application process, as follows.

- The applicant must submit an application form, along with relevant documents as prescribed by NAFDAC, including a clear description of the product and all technical and administrative information relating to the product. The applicant must pay the fees prescribed by NAFDAC, which may be done at any time in the course of applying for registration.
- NAFDAC may ask the applicant for further information in order to reach a decision about the application if deemed necessary. Once satisfied, NAFDAC issues a Certificate of Registration, which subsists for five years until renewal.
- NAFDAC then publishes the list of registered products on its official website, thereby notifying the registration status.

According to the Guidelines for Registration of Drug Products Made in Nigeria, the procedure for obtaining authorisation entails the following steps.

- Dossier application – the applicant must submit a dossier of the drug product for screening as a prerequisite for registration.
- Application letter – this allows the applicant to submit an application for the registration of the products, which is processed on the NAFDAC Automated Product Administration and Monitoring System (NAPAMS) portal. A separate application must be made for each product and addressed to the Director General of NAFDAC. Other documents are attached and the original copies will be made available on request. These documents include:
  (a) the Certificate of Incorporation or any evidence of registration of the business of the applicant in Nigeria;
  (b) a legal manufacturing agreement/contract;
  (c) any evidence showing that the trade mark or brand name of a drug has been registered under Class 5 in the name of the trade mark owner at the Trademarks, Patents and Designs Registry;
  (d) a copy of the superintendent pharmacist's valid annual licence to practise;
  (e) a copy of the valid Premises Retention Licence for the facility;
  (f) a certificate issued by GMP or any evidence of a successful inspection by any regulatory authority; and
  (g) an artwork or product label that complies

with the Drug and Related Products Labelling Regulations.
- Product approval meeting – the Food and Drug Registration Committee then holds an approval meeting to determine whether the drug or product has satisfied the requirements.
- Issuance of Certificate of Registration – upon approval of the product, an electronic Certificate of Product Registration is issued to the applicant and subsists for a period of five years unless renewed.

Procedure to Vary a Marketing Authorisation

There is a standing procedure to vary a marketing authorisation previously granted by NAFDAC. According to the Drugs and Related Products (Registration) Regulations 2019, such variation can only be made where the product has been previously authorised.

The procedure begins with the applicant submitting a variation application to NAFDAC with details of the changes to be carried out. This is accompanied by the prescribed fees per the request of NAFDAC. The further requirements depend on the type of change requested.

Such change may be made by:

- annual notification;
- immediate notification;
- minor variation; or
- major variation.

The applicant who is deemed to hold the Certificate of Registration must not distribute the product until the variation to the authorisation has been assessed and approved by NAFDAC and the product label reflects the change, where necessary. However, changes that do not adversely affect the quality of the drug may be made prior to approval by NAFDAC.

Pursuant to Section 6 of the Regulations, the applicant must seek a new application where the variations to be made fall under the following categories:

- change of the Active Pharmaceutical Ingredient (API);
- inclusion of an additional API in a multi-component product;
- removal of one API from a multi-component product;
- change in the strength of one or more APIs;
- change from an immediate-release product to an extended or delayed-release dosage form or vice versa;
- change from a liquid to a powder for reconstitution or vice versa; and
- changes in the route of administration or other changes as prescribed by NAFDAC.

Transference of Marketing Authorisation

The position of the law on the transference of a marketing authorisation is outlined in the relevant NAFDAC laws and regulations. Pursuant to Section 2(3) of the Drugs and Related Products (Registration) Regulations 2019, once issued, a certificate of registration cannot be transferred, disposed of, hired or sold to a third party unless approved by NAFDAC.

Although the guidelines do not recommend any appropriate procedure, in practice it may be achievable by applying to NAFDAC with supporting documents.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

Section 2 of the Drugs and Related Products (Registration) Regulations 2019 expressly prohibits the sale and distribution of regulated products that are not registered with NAFDAC. This implies that a product must have a Certificate of Registration before it can be distributed in Nigeria.

However, Section 2(2) of the Regulations allows exceptions and provides that NAFDAC may issue the permits to allow the supply or entry/importation of drugs for the purpose of registration (limited quantity). The exception would also be applicable for the conduct of a clinical trial or a service drug scheme, and for any use in emergency situations resulting from epidemics or disease pandemics, donation for humanitarian interventions, etc. This exception was explored during the COVID-19 period, during which vaccines were allowed entry for humanitarian reasons owing to the pandemic.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

Pharmacovigilance of Pharmaceuticals and Obligations Imposed on the Marketing Authorisation Holder (MAH)

In regulating and assessing the quality of products, NAFDAC has paved the way for post-marketing surveillance/pharmacovigilance that imposes certain obligations on a MAH.

For pharmaceutical products, the NAFDAC Good Distribution Practices Guidelines for Pharmaceutical Products outline the recommendations and principles guiding the distribution of pharmaceutical products in Nigeria, highlighting the responsibilities of the distributor as endowed by the NAFDAC authorisation.

As imposed by the guidelines, distributors or their agents can only supply pharmaceutical products to those who are authorised to sell or distribute such products to patients. Such authorisation must be approved and valid before the MAH distributes accordingly. Likewise, the guidelines make provisions for a quality management system so that the activities carried out by the distributors and MAHs are compliant with GMP principles.

In the same vein, a MAH may be subject to post-marketing obligations to ensure that quality goods are distributed accordingly – hence pharmacovigilance of medical devices, pharmaceuticals and regulated products.

Through the Guidelines for Post-Marketing Surveillance in Nigeria, NAFDAC has made express provision for pharmacovigilance of pharmaceutical products and the necessary steps and considerations to be taken.

Under the guidelines, post-marketing surveillance (PMS) planning involves international organisations, procurement organisations, NGOs, MAHs or other persons involved in the distribution of products, which must all be adequately trained in the requirements of PMS prior to commencing PMS tasks. As a prerequisite, the training must be based on written standard operating procedures (SOPs). This is mandatory, given that MAHs are obliged to comply with such post-monitoring activities.

During the PMS planning stage, the quality of the products must be considered among other things. Likewise, the system of distributing and supplying the target medicine is sorted

and reviewed to reflect the quality desired. The patient's exposure to the products and the effects thereof are also considered, as is the mode of carrying out the pharmacovigilance.

Pharmacovigilance of Medical Devices and Obligations Imposed on the MAH

On the other hand, pharmacovigilance of medical devices is much more straightforward. The holder may be required to carry out passive and active pharmacovigilance. Passive surveillance calls for manufacturers or MAHs to submit reports to the National Pharmacovigilance Centre (NPC) on adverse events that may occur in carrying out post-monitoring activities.

Active surveillance or pharmacovigilance uses proactive measures to detect and report on adverse events resulting from medical devices authorised for distribution – for example, active follow-up of patients who subsequently used such medical devices, recording of medical events or occurrences, and so on. It may be done prospectively or retrospectively.

Circumstances in Which Obligations May Be Imposed on MAHs

There is no express provision in the guidelines regulating pharmaceutical products that allow for specific circumstances in which such obligations are imposed when granting marketing authorisations. However, MAHs and importers and distributors of medical devices are mandated to report to the NPC if:

- the marketed devices may have caused death or serious injury; or
- a malfunction of the marketed device may cause death or serious injury should it recur.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

The status of third-party access to applications for market authorisation under NAFDAC laws is not apparent.

However, in reality, NAFDAC has executed agreements with each of its staff on the issue of confidentiality. Such agreements are contained in the NAFDAC Confidentiality, No Conflict of Interest, Code of Conduct Agreement Form, which stipulates that information obtained and treated in the course of their duties is to be treated as confidential. The agreement also mandates that "clients" of NAFDAC shall be notified ahead of any disclosure of such confidential information.

This is also mirrored in practice, where access to the records of registration and application are treated as being confidential and are not easily accessible by the public.

3.8 Rules Against Illegal Medicines and/or Medical Devices

The legislation and procedures against falsified and illegally distributed medical devices are as follows.

First, Section (1)1 of the Food, Drugs and Related Products (Registration, etc) Act proscribes the import, export, advertisement, sale or distribution in Nigeria of unregistered drugs and devices. Section 6 of the Act imposes a fine of NGN50,000 or imprisonment for up to two years (or both) where an individual violates this provision. However, where the offence is committed by a company, the fine is NGN100,000 and the key persons in such organisations would also be individually liable.

Furthermore, by virtue of Section 25 of the NAFDAC Act, any person who contravenes the provisions of the Act would be guilty of an offence and liable on conviction to the penalties specified in the regulations.

The NAFDAC Drug and Related Products Advertisement Regulations 2021 provide that a manufacturer may be liable to sanctions if a regulated product is advertised without authorisation. If such advertisements are made with the knowledge of an officer of the manufacturing company or any person acting in that capacity, such individuals may be severally and jointly liable on conviction to a fine of NGN100,000. The Advertising Regulatory Council of Nigeria Act creates further penalties for the broadcasting of unauthorised adverts.

The Guidelines for Procurement and the Management of the Mobile Authentication Service (MAS) Scheme in Nigeria 2018 were put in place to combat falsified medical products.

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

A number of measures to tackle counterfeit pharmaceuticals and medical devices are worth noting.

Primarily, the Counterfeit and Fake Drugs (Miscellaneous Provisions) Act prohibits any counterfeit or fake drugs from being distributed, imported, manufactured or sold within Nigeria. A similar provision is also found under the Food, Drugs and Related Products (Registration) Act.

In addition, NAFDAC has introduced hand-held devices for on-the-spot detection of counterfeit medicines, allowing law enforcement agents to conduct screening on site to identify counterfeits.

In reality, there is significant collaboration between the Nigerian Customs Service and NAFDAC in the implementation of border measures to combat fake and unregistered regulated products.

4. Manufacturing of Pharmaceuticals and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

The NAFDAC Guidelines for Pre-Production Inspection of Pharmaceutical Manufacturing Facilities in Nigeria provide that manufacturing facilities must be inspected and comply with GMP, and must have received NAFDAC authorisation to manufacture pharmaceutical products.

NAFDAC approves the manufacture of medicines and related products before consumer use. The Good Manufacturing Practice Guidelines for Pharmaceutical Products 2016 regulate the manufacture of these products, and the NAFDAC Guidelines for Pre-Production Inspection of Pharmaceutical Manufacturing Facilities in Nigeria grant authorisation.

Furthermore, the SON has a general mandate to regulate local manufacturing in Nigeria; manufacturers of pharmaceutical products are to be authorised by this agency.

Procedure for Obtaining Authorisation of Manufacturing Plants

The NAFDAC Guidelines for Pre-Production Inspection of Pharmaceutical Manufactur-

ing Facilities in Nigeria prescribe the following authorisation procedure for manufacturing plants.

- Application for inspection – an application for Pre-Production Inspection should be made and submitted on the company's letterhead to the director of the Drug Evaluation and Research (DER) Directorate, along with supporting documents.
- Payment for inspection – a payment invoice for the inspection is collected from the DER Directorate. The applicant may visit www.remita.net to generate a Remita invoice before printing out a copy of the invoice and paying at the nearest bank. An official receipt is issued by the Finance and Accounts Section.
- Schedule of inspection – the facility is scheduled for inspection at a convenient date, with the following documents provided during the inspection:
  (a) the site master file;
  (b) the current annual licence to practise of the superintendent and production pharmacists issued by the PCN;
  (c) letters of appointment and acceptance of key officers;
  (d) credentials of the key officers (minimum qualification should be first degree in the relevant disciplines);
  (e) job descriptions for key personnel;
  (f) validation master plan for the facility;
  (g) documentary evidence showing the qualification of production and laboratory equipment;
  (h) documentary evidence showing the analytical method validation/verification;
  (i) documentary evidence showing the water system validation (where applicable);
  (j) a list of production and quality control equipment and their identification numbers; and
  (k) any other relevant documents.

In addition, self-inspection is included in NAFDAC's Guidelines on Good Manufacturing Practice, to monitor whether the manufacturers are compliant with the principle in GMP and to make necessary corrections.

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

For medical devices in Nigeria, wholesalers are held accountable for activities that relate to wholesale. Only co-ordinated wholesale centres (CWC) granted authorisation by NAFDAC may sell and distribute their products.

In the same vein, wholesalers of pharmaceuticals are restricted from selling and distributing their products in wholesale centres unless approved or granted an authorisation by the PCN, which regulates and controls pharmacies and the movement of pharmaceutical products.

Procedure for Obtaining Authorisation for Medical Devices

Wholesale centres may be granted authorisation to engage in wholesale activities in Nigeria by the guidelines and regulations on wholesale. Since the regulations are non-specific about obtaining authorisation for wholesale distributors of medical devices, the due process for granting a marketing authorisation follows suit.

Procedure for Obtaining Authorisation for Pharmaceuticals

However, the guidelines for pharmaceutical products posit that CWC may be granted a permit to sell products by applying to NAFDAC.

According to the procedure stipulated, the applicant may apply for the premises of the wholesale centres to be granted an authorisation by a PCN application form for registration of premises (Form B). Such application must contain the number of premises (not less than 200 centres) and prohibit street trading within the centres.

The application is submitted to the registrar of the PCN with other supporting documents/information as prescribed by the PCN, including:

- a photocopy of the annual licence to practise/application for retention of name on the Pharmaceutical Register (Form J);
- any evidence of the payment of inspection and registration fees as prescribed by the PCN;
- a contract of agreement between the superintendent pharmacist and employer;
- the company's Certificate of Incorporation;
- a certified true copy of the Articles and Memorandum of Association;
- a certified true copy of particulars of directors issued by the Corporate Affairs Commission (CAC);
- a letter of undertaking by the superintendent pharmacist;
- a letter of undertaking by the managing director of the company handling the management of pharmaceuticals to the superintendent pharmacist; and
- evidence that the board of directors includes a registered and licensed pharmacist on the board of directors.

Activities Approved by the Authorisation

The activities approved by the authorisation of medical devices are such that, where granted, pharmaceuticals and medical devices may be sold within or to a country or territory.

For pharmaceuticals, the authorisation enables wholesale centres to sell medicines. However, other provisions may extend the authorisation to food vendors and banks.

Period of Validity of Marketing Authorisation for Wholesalers

The regulations do not provide for a standing validity period applicable to wholesalers. However, a marketing authorisation is valid for five years and may be renewed upon expiration.

5.2 Different Classifications Applicable to Pharmaceuticals

Although the NAFDAC Act is unclear on the classification of pharmaceuticals, some guidelines (including the Drug and Related Products Advertisement Regulations 2021) distinguish between prescription medication and OTC products.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

Medical Devices

In Nigeria, the Guidelines for Registration of Imported Devices in Nigeria provide for the measures to be taken when importing medical devices. The application will pass through the following five stages.

- Submission of the application – a written application for the registration of imported medical devices should be made on the company's letterhead paper to the Director-General of NAFDAC. It must indicate the name of the brand and associated product and be submitted with a separate application form for each product.
- Import permit – after the documents are screened, an import permit is issued while the products are submitted for vetting.
- Submission of products for laboratory analysis – laboratory samples are submitted with payment evidence, certificate of analysis and evidence of submission for vetting.
- Product approval meeting – after they have been reviewed and deemed to satisfy the requirements of GMP for the production facility and laboratory analysis of product, the requested documents are presented for approval. Product labels that do not comply with the restrictions will be re-sent with the compliant artwork, along with a commitment letter from the manufacturer undertaking to ensure compliance.
- Issuance of notification – the approved products are issued a Notification of Registration or Listing, which is valid for a period of five years, while those yet to be approved receive compliance directions.

Pharmaceuticals

A registered pharmacist may apply to import pharmaceuticals once they have completed the National Youth Service Corps (NYSC) programme and presented a discharge certificate to that effect.

The registration is done through a single application process. The applicant must submit an application form (Form B) to the registrar of the PCN through the Director of Pharmaceutical Services in the state where the pharmacy is to be operated.

The following documents must be submitted alongside the application letter:

- a photocopy of the annual licence to practise/application for retention of name on the pharmaceutical register (Form J);
- inspection and registration fees as prescribed by the PCN;
- the legal agreement between the superintendent pharmacist and the employer;
- the company's Certificate of Incorporation or evidence of registration of business for a pharmacist-owned retail premises;
- a certified true copy of the Articles and Memorandum of Association;
- a certified true copy of the particulars of directors issued by the CAC;
- a photocopy of the NYSC discharge or exemption certificate;
- a letter of undertaking by the superintendent pharmacist;
- a letter of undertaking by the managing director handling the management of pharmaceuticals to the superintendent pharmacist;
- a pharmacists' inter-state movement form (where applicable); and
- the current annual licence of the pharmacist director.

Governmental Agencies Enforcing Import Rules

The governmental agencies responsible for enforcing import rules in Nigeria include:

- NAFDAC – the key regulatory authority for drugs and medical products in Nigeria, as well as the import thereof;
- the SON – through the use of Harmonised Systems (HS) Codes for the examination of

goods at the nation's entry points, the SON has been in line with international best practices aimed at reducing conflicts to the bare minimum; and
- the Nigerian Customs Service – by statute, Customs are empowered to enforce custom rules, including rules of importation and any prohibition thereof through officers allocated in different units.

6.2 Importer of Record of Pharmaceuticals and Medical Devices

Only a company duly registered in Nigeria is permitted to import pharmaceutical products into Nigeria. A foreign company seeking to import drugs must either set up a Nigerian entity for this purpose or appoint a pharmaceutical company incorporated in Nigeria as its agent for the importation. The pharmaceutical company must also comply with the Pharmacy Council of Nigeria (Establishment) Act 2022.

Importer of Record

A company must fulfil a number of requirements before it can be authorised to import pharmaceutical products, including:

- providing evidence of business incorporation with the CAC, showing that the company is registered in Nigeria;
- complying with the provisions of the Pharmacy Council of Nigeria (Establishment) Act 2022; and
- disclosing a suitable warehouse or storage facility where such drugs can be kept, bearing in mind the storage method prescribed for such drug.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

The importation of pharmaceuticals and medical devices is subject to prior authorisation, according to the Drug and Related Products Registration Regulation. The application process is specified under the Guidelines for Registration of Imported Drug Products in Nigeria (Human and Veterinary Drugs) and the Guidelines for Registration of Imported Drugs, as well as the Guidelines for Registration of Imported Medical Devices into Nigeria.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Non-tariff restrictions are imposed on the importation of goods in Nigeria. However, existing non-tariff measures are not specific to medical devices and pharmaceuticals. The issuance of import permits has been made a prerequisite for food, drugs and other products to be imported into Nigeria so that neither manufacturers nor distributors can import their products without such authorisation. This applies to all entities – foreign and local – regardless of origin.

Certain requirements must be met before an import permit is issued, which may be peculiar to the type of product. In order to import pharmaceuticals into Nigeria, one must follow the application procedure provided under the Pharmacy Council of Nigeria (Establishment) Act 2022, which requires the applicant to submit an application form to the registrar with related information as prescribed by the PCN. Upon satisfying these requirements, the PCN then issues an import permit that will allow the premises to import goods.

Likewise, NAFDAC issues import permits for regulated products in Nigeria. The due process

is outlined in the Guideline for Approval to Import Products by Government Agencies, International Bodies and Multinational Organisations (including documents needed for the application). Once approved, the permit subsists until December 31st every year and may be renewed on January 1st of the following year.

The Guidelines for Issuance of Permit to Import Laboratory and Industrial Chemicals prescribe the requirements and supporting documents involved in applying to NAFDAC for an import permit for laboratory and industrial chemicals.

Import permits are also issued by the SON. Under the Nigeria Conformity Assessment Programme introduced by the SON, certain imported products must meet the requirements before importation into Nigeria. The SON may issue a SON Conformity Assessment Programme (SONCAP) certificate for goods to be imported, forming a prerequisite for the entry and clearance of imported goods. However, this does not extend to food, drugs, medicine and medical devices, as the SON has other regulations that cater to those products.

Import Prohibition List

Goods are also prohibited from being imported if they are on the import prohibition list, which makes provisions for the different classes of goods and products that are not granted entry to Nigeria, thereby alerting distributors and manufacturers in this respect.

The list includes medicaments under Headings 3003 and 3004, which specify the kind of drug products prohibited (eg, penicillin/gentamycin ointments, aspirin tablets, levamisole tablets and syrups). It also separates some goods based on HS Codes. This is a standardised method used in identifying the traded products – for instance, under the list, live or dead frozen poultry has HS Codes 0105.1100-0105.9900, 0106.3100-0106.3900, 0207.1100-0207.3600 and 0210.9900.

Some variation of a product may be exempted – eg, bird eggs are prohibited from importation, with the exception of hatching eggs.

Laws and Regulations Prohibiting Importation

The Customs and Excise Management Act (CEMA) provides for an import prohibition list banning the import of different product categories, with the aim of promoting local industries and the health and safety of Nigerians. The CEMA regulates the goods imported and exported in Nigeria and enforces rules and regulations to this effect.

Besides the import prohibition list, the CEMA further restricts other goods from being imported permanently under Schedule 4 of the Act, such that Customs may enforce its authority as granted under the Act to prevent any activity inconsistent with the provisions as instilled. Goods that are absolutely prohibited include air pistols, counterfeit or pirated materials, indecent articles or paintings, cowries and second hand clothing.

6.5 Trade Blocs and Free Trade Agreements

Nigeria is a member of the African Continental Free Trade Area (AfCFTA), as created by the African Continental Free Trade Area Agreement on Trade Facilitation, so benefits from the trade facilitation provisions therein. The AfCFTA is focused on customs and trade facilitation, and aims to ensure free movement of labour, goods and services. It helps to increase profit and contributes to the development of the manufacturing sector.

Nigeria's involvement is predicted to promote business collaborations with other African countries. The Central Bank of Nigeria is heavily involved in the AfCFTA as a stakeholder, unifying the vision for the trade agreement across all sectors.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

Nigerian law does not expressly permit the regulation of pricing for pharmaceutical and medical devices. However, the Federal Competition and Consumer Protection Act 2018 prohibits the fixing of a minimum price for resale of goods and services, except in cases of a patent licence.

7.2 Price Levels of Pharmaceuticals or Medical Devices

There are no standing provisions inferring that the price level of pharmaceuticals and medical devices is dependent on the price in foreign countries.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

In order to mitigate cost and facilitate the accessibility of expensive pharmaceuticals and medical devices in Nigeria, the government has deployed public funds as a means of reimbursing such cost as envisaged in its laws. For instance, the National Health Insurance Authority Act 2022 (the "NHIA Act") addresses healthcare services for Nigerians by mitigating health expenditure for children, pregnant women, physically and mentally challenged Nigerians, or other indigents under the Vulnerable Persons Scheme. Specifically, Section 11 of the NHIA Act covers healthcare services for indigent and poor persons by the Basic Health Care Provision Fund, which is funded by the consolidated revenue fund of the federal government. This is particular to indigenes who fit the category under the Basic Health Care Provision Fund.

The NHIA Act also makes provisions for states in Nigeria to establish a contributory scheme to maintain health insurance for its citizens. It may be inferred from this law that the cost of medical or pharmaceutical devices incurred by a citizen will be reimbursed through the funds in the scheme. The NHIA Act was passed recently and, as such, its applicability can only be determined after a period of time.

However, the bearing of cost by the government is not exclusive to these circumstances, as it may apply:

- where the patient makes contributions to the National Health Insurance Scheme; and
- through other health insurance schemes organised by the State – eg, Health Maintenance Organisations.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Cost-benefit analysis has yet to be applied when determining the price for medical devices and pharmaceuticals in Nigeria. This is because, notwithstanding the overall legal framework in place, Nigeria is yet to make laws and legislation concerning the pricing of medical devices and pharmaceuticals.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

The Code of Ethics for Pharmacists mandates that dispensing pharmacists must refrain from dispensing drugs that may endanger the patient.

A pharmacist should also not dispense drugs to a patient if they believe it is not necessary for the patient to use the drug. The code is enforced by the Pharmaceutical Society of Nigeria.

8. Digital Healthcare

8.1 Rules for Medical Apps

There are specific rules for medical apps. The PCN's Online Pharmacy Regulations 2020 govern medical applications, and cover the extent to which medical apps are accessed via the internet.

They do not define "medical devices" and "medical apps", but medical devices cover a wide range of medical equipment, whether used online or offline, so medical apps may be considered as medical devices. However, not all medical devices are medical apps, as not all medical devices can be accessed online.

Medical devices have been defined as any instrument that is produced or sold for the diagnosis or treatment of a disease in humans or animals, whether internally or externally. Therefore, a medical app may be considered a medical device if it is used for any such means.

8.2 Rules for Telemedicine

According to the Rules of Professional Conduct for Medical and Dental Practitioners in Nigeria, telemedicine is recognised in professional practice in Nigeria and is seen as an opportunity to include computer and telecommunication technology in the medical profession. Telemedicine aids the process of requesting and practising medicine at a distance.

As a result of telemedicine, physicians and those who provide medical attention may do so electronically and manage patient care effectively. This is not restricted, as there is room for specialist consultation and any form of medical attention sought out through the web across various industries and fields of medicine and dentistry.

In addition, specific conditions and criteria are deemed necessary to improve telemedicine in Nigeria. Section 22 of the Code of Medical Ethics expressly provides that – in order to avoid legal action – registered practitioners bear full responsibility for ensuring they act in compliance with rules on the following matters:

- confidentiality;
- professional competence;
- legal and registration status of the specialist being consulted;
- reliability of the equipment used;
- patient management; and
- referral of patients timeously.

In the same vein, the Code of Medical Ethics emphasises specific rules to be followed when processing data electronically. Practitioners must ensure that personal information is secure, including any information/data stored on a database and sent or received by fax, computer, email or other electronic means. Likewise, the security of the information must be ensured before connecting to a network.

The regulations also provide that practitioners must ensure that data sent is not accessible to any party other than the intended recipient. They should also be informed about the likelihood of their emails being intercepted by internet hackers.

The same is envisaged in the NDPR, which provides for the electronic processing of patients' data to be carried out only with the consent of

the patient. Article 1.3 of the NDPR sheds light on consent of the data subject (the patient in this instance) as an indication that the patient agrees to the processing of their personal data. Personal data in this context includes health-related information of the patient, which must be stored and sent with their informed consent.

Likewise, Article 2.6 of the NDPR states that extra security measures must be taken in the electronic space to protect personal data of the patient – eg, setting up firewalls, restricting access to authorised persons only, data encryption and other measures for handling patients' data.

8.3 Promoting and/or Advertising on an Online Platform

There are special rules guiding the advertisement of medical devices on online platforms: the NAFDAC Drug and Related Products Advertisement Regulations 2021 and the PCN's Online Pharmacy Regulations 2020.

The Drug and Related Products Advertisement Regulations 2021 provide that, after obtaining the Certificate of Registration, an application for advertisement approval must be submitted to NAFDAC. Both regulations provide that only medicine that can be bought without a prescription can be advertised publicly, meaning that only OTC should be advertised online publicly (see **8.5 Online Sales of Medicines and Medical Devices**).

For adverts on online portals, the applicant may be required to submit the script, artwork and storyboard used in the advertisement. The same applies for any publication on radio, print, by SMS or pre-recorded messages.

The Online Pharmacy Regulations 2020 make regulations for pharmaceutical service providers who are based online, covering all registration requirements but making specific provisions for granting licences. According to the regulations, online pharmaceutical service providers must be registered with the PCN.

Pursuant to Section 2, such licence is applied for by submitting an application letter to the registrar of the PCN through the superintendent pharmacist in charge of online pharmaceutical services. The application is submitted with the documents/related information prescribed by the PCN, which include:

- the current annual licence of the superintendent pharmacist;
- a photocopy of the registration licence of the current premises;
- evidence of the payment of fees as prescribed by the PCN;
- the letter of appointment of the superintendent pharmacist;
- the legal agreement between the superintendent pharmacist and the employer;
- the Certificate of Incorporation of the company or evidence of business name registration for pharmacist-owned retail premises;
- certified true copies of the Articles and Memorandum of Association;
- certified true copies of CAC documents showing the names and particulars of directors;
- the NYSC discharge or exemption certificate;
- an undertaking by the superintendent pharmacist;
- an undertaking by the managing director of the online company handling management of the business for the superintendent pharmacist; and

- policy documents including procedures and processes for all operations of the internet services.

Once granted, the licence may subsist for a year such that it expires on December 31st every year and may be renewed on January 1st the following year.

8.4 Electronic Prescriptions

Electronic prescriptions are allowed and regulated in Nigeria, with Section 11 of the PCN's Online Pharmacy Regulations 2020 providing that pharmaceutical service providers may dispense prescription-only medicines (among others) electronically. Such pharmaceutical service providers are internet-based and must dispense within the confines and provisions of the regulations and subsidiary legislation.

According to the regulations, a system must be put in place to ensure that the prescription orders for drugs are legitimate. Likewise, there must be a system to regulate the validity of the prescription from a professional before it is dispensed.

The regulations also restrict the prescription of drugs based on telephone or online medical consultations as it may be difficult to authenticate their validity. This extends to restricting the quantity of prescribed drugs that can be ordered or sold online.

8.5 Online Sales of Medicines and Medical Devices

Online sales of medicines and medical devices are permitted in Nigeria, subject to the provisions of the law. The PCN's Online Pharmacy Regulations 2020 provide that the following requirements must be complied with in the online sale of medicines:

- policies must be in place to guarantee the legitimacy of the drugs;
- such drugs must not be sold without confirming that they were prescribed by a licensed officer;
- telephone or electronic medical consultation should be reduced; and
- the quantity of medicines to be sold or prescribed online must be reduced.

The law also makes a distinction between prescription and non-prescription drugs, providing that only non-prescription drugs should be sold or prescribed online.

As mentioned in **8.3 Promoting and/or Advertising on an Online Platform**, pursuant to Section 12(2) of the Drug and Related Products Advertisement Regulations 2021, prescription drugs are prohibited from being advertised through television, radio or any online media. They are only advertised in scientific journals, health newsletters strictly accessed by professionals, and other means as approved by NAFDAC.

8.6 Electronic Health Records

There are no express electronic health laws in Nigeria, but there are other relevant provisions that address the subject matter. Health records, like any other records of personal or sensitive data, are regulated under the NDPR.

Of course, medical personnel utilising electronic health records continue to be bound by a duty of confidentiality and a duty to secure medical records under the Medical and Dental Practitioners Act and the Code of Medical Ethics in Nigeria (Rules of Professional Conduct for Medical and Dental Practitioners).

Regulation of Health-Related Information as Sensitive Data

This depends on the importance of the data. The NDPR defines sensitive personal data as any data relating to religious or other beliefs, health, race or ethnic background, sexual orientation and political views. Thus, health-related information is classed as sensitive data in Nigeria.

The National Health Act 2014 provides that health records must be kept safe by the holder in order to prevent any authorised access, implying that health records are considered sensitive. Thus, health-related information that reveals personal data will be classed as sensitive.

Stricter Regulations

Health-related information is often subject to stricter regulations, as it qualifies as sensitive personal data. Such stricter regulations may include the need to conduct a Data Protection Impact Assessment (DPIA). According to NITDA regulations, the holder of such health-related information may request the submission of such DPIA or mandate the appointment of a Data Protection Officer (DPO).

Cloud Platforms

There are currently no special laws on the transfer and storage of sensitive data of patients on cloud platforms.

However, the NDPR considers sensitive personal data to be of a critical nature and therefore special requirements apply. Before such personal sensitive data can be transmitted to a cloud, the cloud platform must comply with the requirements for handling personal sensitive data as outlined in the NDPR (eg, collection of data, using the data for the purpose for which it was obtained, and appointment of a DPO).

Transfer and Storage of Sensitive Data on Cloud Platforms

There are currently no special laws on the transfer and storage of sensitive data of patients on cloud platforms. Nevertheless, under the NDPR Regulations 2020, the data controller must ensure that the sensitive data of patients is transferred to cloud platforms and stored in line with the NDPR.

The Draft National Cloud Computing Implementation Strategy is an indication that a proper legal framework specifically designed for cloud computing will soon be established.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices

Patent protection in the pharmaceutical and healthcare industry is duly regulated and managed in Nigeria. The Patents and Designs Act 1971 is the legal framework for patent-related matters such as registration, procedural steps for application, etc.

The National Office for Technology Acquisition and Promotion Act assists in the filing of patents and innovations applicable only to government-funded research, as well as in the private sector.

Nigerian legislation on patents has some shortcomings in terms of pharmaceuticals and medical devices:

- there are no provisions on the infringement of second and subsequent use patents for pharmaceutical products;

- there is no provision for term extensions for pharmaceuticals;
- there is no specific means of applying for a patent term extension for pharmaceuticals in Nigeria; and
- there is no requirement for pre-launch action to "clear the way" in market entry.

There are also no specific requirements for patents for pharmaceutical and medical devices in Nigeria.

9.2 Second and Subsequent Medical Uses

In Nigeria, second and subsequent medical uses of a known product are generally unpatentable in respect of product patents, as such patent would not be considered novel; patents are granted for either inventive activities or improvements in either products or processes. Under the Patents and Designs Act 1971, an invention results from inventive activity "if it does not obviously follow from the state of the art, either as to the method, the application, the combination of methods, or the product that it concerns, or as to the industrial result it produces". This is clearly not the case with second and subsequent medical uses of a known product.

Nonetheless, this may apply where a known product is used in respect of a "novel process". Processes are also the subject matter of patents and, as such, the patentability of second medical uses of a known product may be explorable under this regime. This is yet to be tested, however.

As regards the infringement of second and subsequent patents of pharmaceutical products, there is no express provision on second patentability of drugs.

9.3 Patent Term Extension for Pharmaceuticals

Nigerian patent laws do not currently provide for term extension for pharmaceuticals. The 20-year lifespan of a patent is sacrosanct, subject of course to the payment of an annuity.

9.4 Pharmaceutical or Medical Device Patent Infringement

Pharmaceutical or medical device patent infringement entails the reproduction and exploitation of the subject matter of the patent. This would include making, importing, selling or using a product or stocking the pharmaceutical or medical device for sale or use without the approval, assignment or consent of the owner of the patent right.

Seeking a marketing authorisation does not strictly amount to patent infringement. However, the plaintiff may be entitled to explore a quia timet action through a patent infringement action in order to prevent the issuance of such authorisation that would result in infringement.

Although the Patent and Design Act 1971 does not make specific requirements for a threat of infringement in the case of imminent infringement, a party may fall back on the equitable relief of a quia timet injunction. To be entitled to such a relief, a party must prove that:

- there is a threat of serious infringement;
- potential harm will be caused if the injunction is refused;
- irreparable harm will be caused if the injunction is not granted; and
- it will suffer more injury if the injunction is not granted.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

There are no specific defences to patent infringement of medical devices and pharmaceuticals. However, under the law, general defences are available to a party that has allegedly infringed a patent right, including:

- lack of novelty of the subject matter of the patent;
- prior publication of the subject matter of the patent;
- defence of previous use;
- the subject matter of the patent is not patentable;
- ambiguity of the claims;
- insufficiency of the claim;
- inability to work the subject matter of the patent; and
- the description of the invention or claim does not conform with the provisions of the Patent and Designs Act 1971.

Compulsory Licences

There is a compulsory licensing regime under the Patent and Designs Act 1971, which allows a party to seek the compulsory licensing of patents that have not been worked to the benefit of the economy.

The Patent and Designs Act 1971 provides the requirements for the issuance of compulsory licences either by the court or by an order of the Minister in the Federal Gazette. Where leave to obtain a compulsory licence is made through the court, the Patent and Designs Act 1971 provides that the applicant must show the court that:

- they have approached the patentee for a licence and were unable to secure one within a reasonable time;
- there is a deficiency in the invention and, as such, assure the court that they will rectify the deficiency;
- the patent has not been worked on as required;
- if it has been worked on, the extent of the work is not reasonable considering the nature of the product;
- the patented article has hindered the operations of patented inventions in Nigeria; and
- the refusal by the licensee has hindered industrial commercial activities in Nigeria.

Where the request for compulsory licences is made to the Minister, it is expected that the Minister will have issued a declaration stating patented products and processes that may be the subject of compulsory licences and the Minister may permit the importation or exploitation of the subject matter of such products.

9.6 Proceedings for Patent Infringement

Under the Patent and Designs Act 1971, the patentee may bring proceedings for patent infringement. Likewise, a patent licensee may do so in circumstances where:

- the licensee notifies the patentee of the infringement;
- the patentee refuses to act on the infringement; and
- the licensee files a copy of the notice to the patentee with the registrar.

Remedies

Under patent law in Nigeria, the following remedies are available to the plaintiff:

- injunctions restraining the other party from further infringement of the patent right;
- damages to compensate the owner or inventor of the patent right;

- declaration of the patent of a plaintiff as valid where such relief is sought by the plaintiff;
- account of profits made from infringement; and
- delivery up of infringed products.

Procedure for Patent Infringement Actions

The action for infringement typically goes to trial after the service of documents and processes, with the following steps.

- The claimant files a writ of summons at the Registry of the Federal High Court accompanied by a statement of claim, list of witnesses, copies of document to be relied on at the trial, list of exhibits, and written statements made under oath by witnesses.
- The defendant files a statement of defence in response to the plaintiff within 30 days, along with a list of its witnesses and written testimonies, and the documents to be relied on. The defendant may also file a counterclaim.
- The plaintiff may file a reply upon receipt of the defendant's filing within 14 days.
- After service of all processes, parties may explore discoveries and interrogatories in order to obtain relevant evidence and admissions from either party.
- Upon the close of pleadings and interrogatories, the matter is scheduled for trial. Parties to the action give evidence and file final addresses, which are later adopted.
- Upon adoption, the court enters a judgment within three months.

Patent Invalidity as a Defence

The invalidity of a patent may be raised as a defence by a defendant to an action for patent infringement. Such defendant is entitled to raise it in the Statement of Defence and file a separate petition for nullification of such patent. Said petition may be consolidated within the action for infringement to the extent that, if the court finds that the patent was invalid, the court action for infringement will be dismissed.

9.7 Procedures Available to a Generic Entrant

A generic product to be launched and potentially distributed would be allowed market entry in accordance with the NAFDAC Guideline on Registration Requirements to Establish Interchangeability of Generic Pharmaceutical Products. However, based on the current case law, there is no requirement for pre-launch action to "clear the way".

There is a procedure in place for obtaining marketing authorisations in Nigeria under the guidelines. However, unlike the requirement for confirmation of trade mark ownership, the rules do not require a similar confirmation that the applicant is the patent holder or duly licensed.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Other than IP laws, there are regulations and laws in place that may be utilised to combat the counterfeiting of pharmaceuticals and medical devices in Nigeria, including:

- the National Agency for Food and Drug Administration and Control Act 2004;
- the Food, Drugs and Related Products (Registration) Act 1993;
- the Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act 2004 (Chapter 34);
- the Customs and Excise Management Act 2004 (Chapter 45);

- the Standards Organisation of Nigeria Act 2015; and
- the Merchandise Marks Act.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Under Nigerian law, the general restrictions that apply to other products may apply to medical devices and pharmaceuticals, including:

- only distinctive trade marks are registrable;
- a mark that is deceptive or scandalous, contrary to law or morality, or in any way disentitled to protection is not registrable; and
- a mark that contains prohibited words and/or symbols (such as names of chemical substances), use of the Coat of Arms of Nigeria or use of any emblem or title such as President or Governor without the appropriate authority is restricted.

Specifically, Section 12 of the Trade Mark Act proscribes the registration of a single chemical element or single chemical compound as a chemical or preparation.

Restrictions on Importation of Pharmaceuticals or Medical Devices

Nigerian trade mark laws do not expressly prohibit parallel importation. However, it has been noted that parallel importers often violate trade mark laws with regard to disclosures as to country of origin, labelling, etc. Parallel imports are therefore dealt with for violation of such laws.

Furthermore, when a drug is to be imported into Nigeria, one of the requirements for the processing of NAFDAC registration is that an importer obtains power of attorney from the manufacturer. By requiring such power of attorney before registration for the purposes of importation, NAFDAC whittles down the likelihood of parallel importation.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

The Business Facilitation and Miscellaneous Provisions Act 2022 provides that the trade dress (packaging), shape and design of a trade mark are protected. The Patent and Designs Act 1971 also protects the trade dress or trade design of a product, which may extend to a medical or pharmaceutical device.

The trade mark or patent of a pharmaceutical and medical device covers its trade dress (shape, colour and commercial look) to the extent that, once such device has been registered, it will enjoy all the trade mark protection guaranteed under the Trade Mark Act and the Patent and Designs Act.

This protection is also available under the common law of passing off, which is a tort that prevents a manufacturer from misrepresenting goods or services as those of another. This avails a party even where the trade mark is not registered.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Data exclusivity is essential to legal practice as well as the protection of medical devices and pharmaceuticals.

Although there is no specific provision for protecting data gathered for pharmaceuticals and medical devices in Nigeria, Section 3 of the Food, Drugs and Related Products (Registration) Act provides that information disclosed while applying to NAFDAC for registration cannot be shared without the written consent of the

person who supplied the information or unless instructed by NAFDAC or for the purpose of a proceeding. This applies to both medical devices and pharmaceuticals in Nigeria.

Difference Between Chemical Drugs and Biologics

There is a notable difference between chemical products and biologics. Under Section 18 of the Chemical and Chemical Products Regulations 2020, "chemical products" refers to a substance formed by a chemical reaction to yield one or more products such as cleaning chemicals, paint, adhesives, wood preservatives and polishers, and agrochemicals. In contrast, although the NAFDAC Act does not define biologics, it refers to products derived from living cells or animal tissues, thereby differentiating them from chemical products, which are formed from chemical solutions.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

The commercialisation and distribution of medicines were handled differently throughout the COVID-19 pandemic, with the following special regulations or guidelines being issued in response to the crisis.

- In 2020, NAFDAC released a newsletter (Vol 3, No 2) that discouraged the use of falsified chloroquine. NAFDAC also discouraged the commercialisation or distribution of unregistered hand sanitisers.
- There were cautionary notices with regard to various drugs claimed to be used to treat COVID-19.
- The Presidential Task Force on COVID-19 issued guidelines covering various areas, including:
  (a) expedited/emergency approvals for products;
  (b) limited GMP inspections for local facilities;
  (c) alternatives to GMP for foreign facilities when inspections could not be undertaken owing to the pandemic travel restrictions;
  (d) applications for the registration of products deemed to have urgent public health impact to be processed and given conditional and limited approvals; and
  (e) encouraging the use of email and other electronic platforms when interacting with NAFDAC.

The applicability and enforcement of rules on the commercialisation and distribution of medicines in Nigeria were not relaxed, and continued to be overseen by the responsible agencies of the Nigerian federal government.

11.2 Special Measures Relating to Clinical Trials

Special measures were employed to regulate clinical trials in Nigeria. NAFDAC issued the Clinical Trial Regulations 2021 to provide clarity and purposeful measures in relation to ongoing clinical trials. With regard to specific matters, Section 3(16) made provision for investigations by NAFDAC into the trial sites and facilities to be used in order to ensure they meet the standard required under the regulations.

The regulations also catered to the rights of the participants in the trial. Section 5 provides that the investigator must inform the participant of all due processes and aspects of the trial to be conducted (including the review of the participant by

the Ethics Committee), prior to the participant's involvement in the trial.

Special Regulations

NAFDAC issued special regulations in relation to COVID-19 treatments, including Guidance on Regulatory Preparedness for Licensing or Access to COVID-19 Vaccines 2020. This included a requirement for external review of the marketing authorisations granted to manufacturing plants – a deliberate provision that caters to COVID-19 vaccine applications. NAFDAC also released guidance notes to sponsors of clinical trials during the COVID-19 pandemic as part of the procedure.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

Certain protocols were updated following the emergence of COVID-19, and other regulations were set in order to facilitate emergency approvals for the necessary medical devices and pharmaceuticals.

On record, NAFDAC allowed emergency approvals of pharmaceutical and medical devices via a circular dated 9 April 2020. This regulatory pathway was created specifically for COVID-19 and provides that such emergency approval must meet the following criteria:

- previous registration and approval by the relevant regulatory authorities (eg, the European Medicine Agency);
- registration by the regulatory authority in the country of production;
- declaration of conformity; and
- validation/performance evaluation/clinical evaluation report.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

There were no specific instances where NAFDAC was flexible in granting certifications to manufacturers owing to the COVID-19 pandemic. However, NAFDAC granted the emergency conditional use of COVID-19 vaccines through Emergency Use Authorisations, which cleared the bottlenecks for authorising vaccines needed to prevent COVID-19 in people over the age of 18.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

Some import restrictions were put in place for medical devices following the COVID-19 pandemic. On 24 March 2020, the federal government of Nigeria introduced an import duty waiver on medical equipment, medicines, personal protection equipment and other medical necessities required for the treatment and management of COVID-19 in Nigeria, effective from 1 March 2020 until 31 December 2020.

There were import restrictions in relation to medicines and medical devices during the COVID-19 as a result of the national and global lockdown. Nigeria could not produce medicines for export, even though most of the drugs were imported.

11.6 Drivers for Digital Health Innovation Due to COVID-19

Digital healthcare forms an integral part of the healthcare industry and was made more practical as a result of the COVID-19 pandemic. However, the Nigerian authorities appear not to have adopted any measures to facilitate digital health innovation or digital transformation.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

Notwithstanding the measures taken to adapt to the COVID-19 pandemic, the Nigerian government has not announced any intention to issue compulsory licences for COVID-19-related treatments or vaccines. However, the Nigerian Patent and Designs Act 1971 allows the Minister to issue compulsory licences for patented products declared to be important for public health. A compulsory licence may also be granted by a court upon application by an interested party/entity.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

Liability exemptions regarding COVID-19 vaccines were not adopted in Nigeria.

11.9 Requisition or Conversion of Manufacturing Sites

The existing provisions for granting authorisation to manufacturing sites were adapted in response to the COVID-19 pandemic. However, no clear provisions appear to have been introduced with regard to manufacturing sites as a result of COVID-19.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

Following the emergence of COVID-19, changes were made to the system of public procurement of medicines and medical devices in Nigeria.

The Bureau of Public Procurement (BPP) introduced the Guidelines on the Conduct of Public Procurement Activities, according to which an emergency procurement plan must be prepared for all projects specific to the COVID-19 pandemic and uploaded into the Nigeria Open Contracting Portal (NOCOPO), where it will be accessed by the BPP in order to qualify for funding from the federal government.

In another notable change, instead of the previous rigorous process of placing advertisements in two national dailies and the Federal Tenders Journal, as was standard practice, emergency procurement plans were only required to be uploaded directly to the website.

In addition, the standard “No Objection” requirement required prior to the emergency procurement plan was no longer mandated as a result of the COVID-19 pandemic. Instead, procuring entities were allowed to respond and act on the emergencies at hand before providing a detailed report to the BPP later.

Trends and Developments

Contributed by:
Chinyere Okorocha, Toyosi Odunmbaku, Yeye Nwidaa and Oloruntobi Opawoye
Jackson, Etti & Edu

Jackson, Etti & Edu (JEE) is a leading full-service, sector-focused commercial law firm. With more than 25 years' experience and several awards for excellence, JEE consistently renders legal services to Nigerian, pan-African and international clients from diverse jurisdictions – as evidenced by the firm's presence in Lagos, Abuja, Accra, Harare and Yaoundé. JEE's lawyers have extensive expertise in advising clients on a wide range of matters pertaining to the healthcare sector, including financing, business regulatory compliance, ethics for health professionals, debt recovery, litigation, arbitration and ADR, as well as health law advocacy and reviews of laws in this sector. The firm consists of 14 partners, 60 fee earners and more than 50 paralegals and support staff. The size of JEE's dedicated commercial team is indicative of the firm's rich human resource base and its capacity to effectively and efficiently help clients achieve their goals.

Authors

Chinyere Okorocha is a partner at Jackson, Etti & Edu, where she co-heads the health and pharmaceuticals team. She has more than 30 years' experience and expertise in the medicolegal sector, couple with a great grasp of the technical implementation of legal strategy. Chinyere sits on the advisory boards of several medical organisations and companies, and is also a member of the World Association for Medical Law. She has accumulated hands-on experience in business leadership, strategic thinking, vision setting and problem solving of clients' diverse needs. She is currently the President of the Nigerian Bar Association's Women Forum.

Toyosi Odunmbaku is a partner at Jackson, Etti & Edu, where he co-heads the health and pharmaceuticals team. He advises on a wide range of health and pharmaceutical projects in Nigeria, including the procurement, importation and distribution of pharmaceutical products and medical devices. He is a specialist in IP litigation and has acted in trade mark, design and patent litigation involving pharmaceutical manufacturers and brand owners. Toyosi is also responsible for co-ordinating enforcement actions against counterfeiters, which is at the very heart of ensuring medical and pharmaceutical products are safe for use.

Contributed by: Chinyere Okorocha, Toyosi Odunmbaku, Yeye Nwidaa and Oloruntobi Opawoye,
Jackson, Etti & Edu

Yeye Nwidaa is a partner at Jackson, Etti & Edu and is a chartered secretary, a governance specialist and a member of the Chartered Governance Institute of the United Kingdom (ICSA). She heads JEE's business regulatory, compliance and governance practice, where she provides legal advisory services to foreign investors and local companies with regard to founding and running businesses in Nigeria. Yeye has been offered company secretary roles in several pharmaceutical companies in Nigeria. Her experience includes international commercial arbitration, IP rights enforcement, commercial litigation, payroll management and general commercial legal advisory.

Oloruntobi Opawoye is a senior associate at Jackson, Etti & Edu and deputy head of the health and pharmaceuticals team. She combines in-depth knowledge of the law with diplomatic skills so that disputes reach a swift and respectful conclusion. She advises a wide range of health and pharmaceutical organisations on various aspects of their businesses, including ethics, debt recovery, arbitration and IP protection, as well as enforcement, regulation and compliance. Oloruntobi is a member of the Nigerian Bar Association and the Chartered Institute of Arbitrators (UK), and provides advice to the Medical Ethics Board of a hospital chain.

Jackson, Etti & Edu

RCO Court
3–5 Sinari Daranijo Street
Off Ajose Adeogun
Victoria Island
Lagos
Nigeria

Tel: +234 1 2806989
Fax: +234 1 2716889
Email: jee@jee.africa
Web: www.jee.africa

Contributed by: Chinyere Okorocha, Toyosi Odunmbaku, Yeye Nwidaa and Oloruntobi Opawoye, **Jackson, Etti & Edu**

Life Sciences in Nigeria: An Introduction

Workforce emigration in Nigeria

There has been a notable increase in the emigration of healthcare professionals from Nigeria to more developed countries or to the Western world, seeking better-paying work, improved working conditions and access to superior facilities for their practice. This emigration trend has had a detrimental impact on the Nigerian health sector, resulting in brain drain and severely affecting the delivery of standard healthcare services in many health centres in the major cities, with the rural areas being even worse affected.

The reduction in the number of available doctors, nurses, laboratory scientists and other healthcare professionals has exacerbated the situation, leaving healthcare facilities struggling to meet the needs of their patients or the increased remuneration demands of the available healthcare professionals.

The emigration of healthcare professionals has also adversely affected medical education in the country. With fewer healthcare professionals available to train medical students, the quality of education and practical experience has suffered. Despite these obvious deficiencies in the medical and healthcare education system, the government urged the university to increase its admission quota by 100% in December 2023, in an attempt to combat the emigration.

In March 2024, the federal government announced a new policy prohibiting healthcare workers from taking leaves of absence with the intention of travelling abroad for work. This policy targets a subset of healthcare workers who take recurrent (sometimes unpaid) extended leave to work abroad. While this mid-line seems better than an outright emigration, the positions often cannot be filled by a more permanent alternative, leaving the healthcare facilities unattended to for an extended period in a year.

Digitisation of the healthcare sector

The healthcare sector in Nigeria has undergone a remarkable evolution in recent times, propelled by a steady shift towards digitisation and somewhat necessitated by the dearth of available professionals. This shift, once considered implausible, has gained momentum, primarily catalysed by the exigencies of the COVID-19 pandemic and the widespread penetration of internet connectivity and mobile technology across the country.

As a result of this digitisation drive, patients now have unprecedented avenues for engaging with healthcare professionals. They can (as much as possible) communicate their symptoms through simple text messages, facilitating remote consultations and even enabling the delivery of prescriptions and medications to their doorsteps. There has also been a proliferation of online pharmaceutical platforms specialising in deciphering prescriptions, fulfilling medication orders and offering doorstep delivery services, providing unparalleled convenience to patients.

However, amidst these advancements, significant challenges persist, including the absence of robust regulatory frameworks governing the digital health landscape. The lack of clear regulations poses potential risks in terms of patient safety and the quality of healthcare services delivered through digital platforms. Nonetheless, stakeholders are working towards developing and implementing comprehensive regulatory frameworks to safeguard the integrity and efficacy of digital health services in Nigeria.

Growth of local pharmaceutical companies

According to a recent report from the National Agency for Food and Drug Administration and Control (NAFDAC), there has been a notable surge in the number of indigenous pharmaceutical companies emerging in Nigeria, coinciding with the departure of multinational pharmaceutical corporations from the market. NAFDAC reported that a total of 105 applications for the construction of drug manufacturing facilities have been greenlit nationwide, with 35% of these applications having completed construction and progressing through various registration stages mandated by NAFDAC.

Moreover, NAFDAC emphasised that more than 20 of these newly established local manufacturers have joined forces, collectively investing upwards of USD20 billion to establish WHO-compliant facilities dedicated to producing standardised medicines for the country. This collaborative effort underscores a strategic initiative aimed at addressing the perennial issue of drug shortages in Nigeria and reducing the nation's heavy reliance on pharmaceutical imports.

The emergence of these local pharmaceutical manufacturers represents a significant step towards achieving greater self-sufficiency in drug production, bolstering Nigeria's healthcare infrastructure and fostering economic growth within the pharmaceutical sector.

Exit of multinational pharmaceutical companies

The country has witnessed the closure of several multinational pharmaceutical companies, leading to the termination of their distribution and sales agreements. These multinational firms were responsible for producing a significant portion of medicines, so their departure poses a grave threat to the nation's healthcare landscape, but also a great opportunity for other businesses to fill in the vacuum – particularly with an understanding of the factors that affected such multinationals. Several factors contributed to their exit from the country, including unfavourable foreign exchange rates, high import duties and stringent regulatory processes imposed by the government.

These companies also faced challenges such as multiple taxation, leading to increased operational costs that outweigh their profits. In addition, the inadequate healthcare infrastructure exacerbated their predicament, as large-scale production without proper distribution facilities resulted in financial losses.

The departure of these multinational pharmaceutical companies has some consequences that are both a threat as well as an opportunity, including increased dependence on imports, a justifiable increase in medication costs and the scarcity of essential drugs. These developments underscore the urgent need for regulatory reforms and infrastructure improvements to sustain the pharmaceutical sector and safeguard public health.

Request for intervention funds for local manufacturing

The Federation of Nigerian Pharmaceutical Industry Associations (FeNPIA) has made a significant appeal for special priority in accessing foreign exchange at rates conducive to moderating and subsidising the final costs of medicines and other healthcare commodities. This initiative aims to ensure equitable access to essential healthcare provisions for all segments of society.

Furthermore, FeNPIA has advocated for the creation of a substantial pharmaceutical manufacturing development fund by the federal govern-

ment, amounting to USD600 billion. Proposed at a favourable interest rate of 5% over a minimum tenure of five to ten years, this fund is intended to bolster the local production of Active Pharmaceutical Ingredients (APIs) and vaccines, and to facilitate essential research initiatives. By supporting local production, the Association aims to strengthen domestic pharmaceutical companies, thereby mitigating the high costs of drugs and ensuring their accessibility and affordability for all Nigerians.

FeNPIA has proposed measures to stimulate the growth of local manufacturing firms, including a request for a 0% duty rate on pharmaceutical machinery, equipment and accessories. It is also seeking VAT exemption on raw materials to alleviate production costs and subsequently reduce the final prices of pharmaceutical products.

In response to these critical requests, the Minister of Health and Social Welfare has assured FeNPIA that comprehensive measures will be implemented to address its concerns and support the growth and development of the pharmaceutical industry in Nigeria. The expected reforms are yet to be ascertained.

Investment in the health sector

At the event unveiling Nigeria's Health Sector Renewal Investment Initiative and the signing of the Health Renewal Compact, the Nigerian President promised improvements in the country's healthcare strategy. Notably, there has been an increase in the allocation for the health and social welfare sectors in the proposed 2024 budget, signalling efforts to achieve Universal Health Coverage (UHC) and elevate the overall health status of Nigerians.

The federal government appears to show some commitment to promoting and enhancing the nation's health sector through investments in health infrastructure, the expansion of health insurance coverage and the provision of essential commodities for the sector. Of particular note is the allocation of approximately USD2.5 million towards improving the primary health system, which forms the backbone of accessible healthcare delivery in the country.

Recognising the persistent challenge of high healthcare costs, the government has outlined plans to redesign the Basic Health Care Provision fund to facilitate greater access to crucial health services and facilities for all Nigerians. Initiatives are also underway to revamp health infrastructure and equipment while prioritising the retraining of frontline health workers.

Depreciation of the Nigerian currency

The Nigerian currency has depreciated more than 7% against the US dollar in the past year. While the effects of this are not limited to the healthcare sector, this sector is amongst the worst hit due to significant reliance on imports of both finished products as well as excipients and raw materials for pharmaceutical products, and reliance on foreign loans and finance for costly health infrastructure, amongst others. The impact of the devaluation of the Naira also affects the general cost of leaving for health professionals, who feel more compelled to emigrate to more profitable climes. Furthermore, the unwillingness and incapacity of the public to access increasingly expensive healthcare becomes more apparent – unwillingness in view of competing needs and incapacity due to the widespread financial difficulties experienced by the populate.

However, due to the essential nature of much medical care, many healthcare facilities continue

to see steady patronage, despite the increased fees for service delivery.

India increases investment in pharmaceutical manufacturing in Nigeria

The Indian Consul General has underscored India's commitment to filling the void left by the departure of major multinational pharmaceutical companies from Nigeria. This commitment was exemplified during the inauguration of a pharmaceutical facility by Artemis Laboratories Limited, an Indian company. NAFDAC's confirmation of approval for Indian investors to inject approximately NGN25 million into the Nigerian economy is also indicative of India's interest in collaboration.

Beyond healthcare, such endeavours are expected to bolster Nigeria's economy by creating employment opportunities, fostering skill development and facilitating technology transfer. However, the weight of the impact would be evaluated in the coming years. Beyond financial investments, Indian investors, like all other investors, have been advocating for a more conducive regulatory environment to spur innovation and investment in Nigeria's health and pharmaceutical sector.

United Kingdom commits to strengthening health workforce in Nigeria

The WHO has embraced a commitment from the UK's Department of Health and Social Care aimed at bolstering Nigeria's healthcare workforce and advancing UHC. This commitment entails a pledge of GBP2 million from the UK to Nigeria, intended to enhance the quality, performance and impact of the healthcare workforce while fostering resilience against global health challenges.

Moreover, the commitment seeks to provide support at both national and sub-national levels, aiding regulatory bodies, professional associations and other key stakeholders in developing transformative strategies. These strategies will focus on scaling up the quantity and quality of health workers, with initiatives such as competency-based curriculum development and reviews.

The implementation of this commitment will draw upon the technical expertise of the WHO. It is slated to be rolled out in six states across Nigeria: Cross River, Enugu, Jigawa, Kaduna, Kano and Lagos. By leveraging this partnership and targeted interventions, Nigeria aims to fortify its healthcare system and make significant strides towards achieving comprehensive health coverage for all its citizens.

Increasing prioritisation of mental well-being

There is a growing focus on mental health in Nigeria, in line with the global trend, reflecting a broader societal recognition of the prevalence and repercussions of mental health disorders. This has also resulted in the enactment of the Mental Health Act in 2023, repealing the Lunacy Act of 1958, which included significant penal punishments for involuntary admission, discrimination against persons for mental ill health and violations of fundamental rights of persons with mental ill health, as well as entrenching other statutory protections for the mentally disabled.

Efforts led by the government, NGOs and healthcare providers aim to combat stigma, enhance access to mental health services and integrate mental healthcare into primary care settings. This trend underscores the imperative of prioritising mental health within the framework of comprehensive healthcare delivery. It emphasises the need to foster mental well-being across all

segments of society, from healthcare facilities to workplaces, schools and communities.

As awareness about mental health grows, advocacy initiatives are gaining momentum, prompting policy reforms and resource allocation towards mental health services. Moreover, there is an increasing emphasis on destigmatising mental illness and promoting mental wellness through education, awareness campaigns and community support networks.

By mainstreaming mental health into broader healthcare agendas and societal discourse, Nigeria is taking strides towards ensuring that mental health concerns are addressed with the same urgency and importance as physical health issues, ultimately fostering a healthier and more resilient population.

Expansion of health insurance coverage

Efforts to broaden health insurance coverage in Nigeria are gathering significant momentum, propelled by a combination of government policies and private sector initiatives. The National Health Insurance Scheme (NHIS) and several private health insurance schemes are actively engaged in enhancing access to high-quality healthcare services and offering financial safeguarding against medical expenses. This trend is anticipated to enhance the affordability of healthcare services and foster the realisation of UHC throughout the nation. However, the programmes implemented have faced a number of teething problems, including issues around capitation payment, increases in minimum share capital for insurance companies, quarterly remittance of contributions to the NHIA, and mandatory fixed deposits,. Stakeholder engagement continues on these issues.

Despite the challenges, the ongoing expansion of health insurance coverage represents a critical step towards mitigating the financial burden associated with healthcare expenses, particularly for vulnerable populations. By extending insurance coverage to a larger segment of the population, Nigeria aims to ensure that individuals and families can access essential medical services without facing undue financial hardship. In addition, the emphasis on health insurance underscores the government's interest in improving overall health outcomes and promoting equity in healthcare access. As these initiatives continue to evolve, Nigeria moves closer towards achieving comprehensive health coverage and enhancing the well-being of its citizens.

Research and development (R&D) collaboration

In the Nigerian health and pharmaceutical sector, there is a notable increase in collaboration among academia, industry players and government agencies to drive R&D initiatives. These partnerships are aimed at accelerating drug discovery, vaccine development and medical innovations, thus fostering a culture of innovation, knowledge exchange and scientific excellence.

Recent data reveals a significant rise in collaborative R&D projects across various domains of healthcare, including infectious diseases, maternal and child health, and non-communicable diseases. Academic institutions such as universities and research centres are teaming up with pharmaceutical companies and government research agencies to pool resources, expertise and infrastructure for impactful research endeavours.

These collaborative efforts are vital for building local research capacity and fostering technology transfer within the Nigerian health sector. By lev-

eraging shared resources and expertise, stakeholders are better equipped to address public health challenges unique to Nigeria, such as endemic diseases, inadequate healthcare infrastructure and access barriers.Through strategic partnerships and joint initiatives, Nigeria aims to strengthen its position as a hub for healthcare innovation, ultimately improving health outcomes and quality of life for its citizens.

POLAND

Law and Practice

Contributed by:
Marcin Tomasik, Tomasz Jaworski, Agnieszka Herman and Filip Gołba
Tomasik Jaworski Law Firm Sp. p.

Contents

Contributed by: Marcin Tomasik, Tomasz Jaworski, Agnieszka Herman and Filip Gołba,
Tomasik Jaworski Law Firm Sp. p.

Tomasik Jaworski Law Firm Sp. p. is an independent law firm founded by lawyers with almost 20 years' experience in advising the pharmaceutical and medical devices industries in Poland. It offers comprehensive advice to entities operating in the pharmaceutical and medical devices market, including both local businesses and multinational companies, representing innovative and generic industry. The team provides legal assistance on all aspects of day-to-day operations, as well as strategic issues. Over the years, it has been especially active advising on regulatory matters, contracts, compliance, product liability, intellectual property, data privacy, competition law, public tenders and commercial litigation, in addition to providing training for executives and other staff of pharmaceutical companies. The firm's lawyers are often retained as experts by industry organisations in regulatory dialogue and legislative processes.

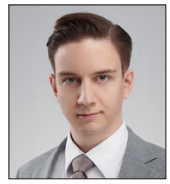
Authors

Marcin Tomasik advises businesses and organisations in regulated industries. He also specialises in compliance and unfair competition, and in administrative and criminal proceedings. Marcin is a member of the District Bar Association in Warsaw and a graduate of the Faculty of Law at the University of Warsaw and the Center for English and European Law organised in co-operation with Cambridge University. He is a lecturer in post-graduate studies on Compliance and Risk Management at the Warsaw School of Economics.

Tomasz Jaworski is an attorney-at-law whose areas of expertise include pharmaceutical law, medical device law, public procurement law, litigation and administrative proceedings. He is the co-author of a commentary on the law on so-called class actions (CH Beck, 2010) and the concept of reforming the Ukrainian drug registration system (within the framework of the EBRD project). Tomasz has also written numerous publications in the legal press and legal reports on the pharmacy market, laboratory diagnostics and spa communities.

Contributed by: Marcin Tomasik, Tomasz Jaworski, Agnieszka Herman and Filip Gołba,
Tomasik Jaworski Law Firm Sp. p.

Agnieszka Herman provides ongoing corporate services to entrepreneurs, advises on public procurement law and supports investors in administrative and administrative court proceedings. She has received multiple scholarships from the Rector of UMCS University in Lublin for the best students. Agnieszka is the co-author of a monograph on family law (2017). She is a member of the District Chamber of Legal Advisers in Lublin, and a graduate of the Maria Curie-Skłodowska University in Lublin.



Filip Gołba advises regulated industries, primarily in the pharmaceutical, medical devices and pharmacy sectors. He represents clients before administrative courts and regulatory bodies, including the European Commission, advises on legislation, and helps to align businesses with European and national regulations. Filip previously worked in academia, teaching at the Jagiellonian University, participating in research projects funded by the National Science Center at the Departments of Legal Theory and of Constitutional Law, and authoring academic articles and chapters in commentary. He worked on reforming the Ukrainian Pharmaceutical Law (EBRD project), and has represented in proceedings concluding with key judgments shaping the Polish pharmacy market. He is a member of Bar Association in Warsaw.

Tomasik Jaworski Law Firm Sp. p.

Al. Ujazdowskie 39/4
00-540
Warsaw
Poland

Tel: +22 625 10 81
Email: kancelaria@tjsp.pl
Web: www.tomasikjaworski.com

Contributed by: Marcin Tomasik, Tomasz Jaworski, Agnieszka Herman and Filip Gołba,
Tomasik Jaworski Law Firm Sp. p.

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Polish legislation regarding pharmaceuticals and medical devices is heavily influenced by EU legislation.

The manufacturing, registration, distribution, marketing and advertising of pharmaceuticals are regulated by the Pharmaceutical Law Act of 6 September 2001 and its executive regulations. Since 2022, clinical trials of pharmaceuticals have been regulated by the Clinical Trials of Medicinal Products for Human Use Act of 9 March 2023, which adjusted Polish law to Regulation 536/2014. The Medical Devices Act of 7 April 2022 and its executive regulations deal with the regulation of medical devices, including safety and quality. Polish legislation has been adjusted to comply with the following EU Regulations relating to medical devices:

- the Medical Device Regulation (MDR); and
- the In Vitro Diagnostic Device Regulation (IVDR).

The Act on Reimbursement of Medicines, Food Products Intended for Particular Nutritional Uses and Medical Devices of 12 May 2011 regulates reimbursement from public funds. A major amendment of this statute entered into force in November 2023.

The key regulatory authority for medicinal products is the Pharmaceutical Inspection, which is led by the Chief Pharmaceutical Inspector and supervises the quality, manufacture, import, distribution, transport and storage of pharmaceuticals, among other matters. The Inspection is also responsible for overseeing the advertising of those products, and for controlling the operations of pharmacies and wholesalers.

The Pharmaceutical Inspection is also comprised of regional pharmaceutical inspectors, but these are formally subordinate to *voivodes* (regional governors in charge of governmental administration) rather than to the Chief Pharmaceutical Inspector. The Pharmaceutical Law was due to be amended in 2023 so that regional inspectors would report to the Chief Pharmaceutical Inspector instead, but this amendment has not yet been made.

The Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL) is the regulatory body responsible for the registration and approval of pharmaceuticals and medical devices. It is also responsible for issuing decisions regarding medical devices in relation to their classification, safety, advertising, marketing and use. For a brief period of time, the Minister of Health and the Chief Sanitary Inspector supervised the advertising of business or professional activity in which a medical device is used to provide a service, but this competence has been moved to the URPL and henceforth the latter has sole charge over the enforcement of medical devices advertising regulation.

The Ministry of Health decides on the reimbursement of pharmaceuticals and medical devices.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

The procedure for challenging administrative decisions is generally similar for all regulated products, since all of the proceedings are at least partially regulated by the Administrative

Procedure Code of 14 June 1960. As a rule, there is always a legal remedy.

Decisions made by local branches of the authorities can be challenged by appealing to the main authority (eg, a decision of the Regional Pharmaceutical Inspector can be appealed to the Chief Pharmaceutical Inspector), and the final decision is subject to judicial review by the Administrative Courts. In general, the administrative appeal is free of charge and not subject to any specific formal requirements other than the explicit disagreement of the party. The judicial review is subject to a fee, which differs depending on the type of decision that is being questioned.

It is not possible to appeal against decisions made by the central authorities, such as the Chief Pharmaceutical Inspector. The party may file a motion for the decision to be reconsidered, or proceed directly to a judicial review by the Administrative Courts.

1.3 Different Categories of Pharmaceuticals and Medical Devices

In principle, the regulations of the legislation mentioned in **1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices** apply to all categories of medicines.

Medical devices and in vitro diagnostic medical devices are regulated separately at the level of EU law, but in national law they are regulated by a single statute.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials of pharmaceuticals and medical devices are subject to similar regulations, in accordance with the relevant European regulations. Clinical trials of pharmaceuticals are regulated by the Clinical Trials of Medicinal Products for Human Use Act of 9 March 2023, while clinical investigations/performance studies relating to medical devices and in vitro diagnostic medical devices are regulated by the Medical Devices Act (Articles 31 to 47). The Act of 9 March 2023 adjusted the local legal landscape to Regulation No 536/2014.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

The provisions of the Clinical Trials of Medicinal Products for Human Use Act clarify the rules of procedure for issuing a clinical trial authorisation set forth in Regulation 536/2014.

A clinical trial can be started after a decision from the President of the URPL to issue a clinical trial permit (subject to the possibility of "so-called" implied consent in cases specified by Regulation No 536/2014) has been obtained and a bioethical committee has issued a positive opinion on the study. The application for permission is submitted through the Clinical Trials Information System. As a rule, it is possible to submit documentation in English or Polish (with the exception of certain elements which the law provides must be in Polish).

The rules for the payment of the application fee are determined in Article 58 of the Act. The amount of the fee depends on the phase of the clinical trial. In the case of a commercial phase I-III clinical trial, the fee is PLN30,000 (circa EUR7,000) when Poland acts as rapporteur and PLN 5,000 (circa EUR5,800) when Poland does not act as rapporteur.

Clinical trials for medical devices are required for higher-risk devices. The provisions of the Medical Devices Act detail the rules set by the

MDR for applying for a clinical trial permit and the rules set by the IVDR for applying for a performance study permit.

2.3 Public Availability of the Conduct of a Clinical Trial

In Polish law, there is no legal requirement for a compulsory, publicly available database of ongoing clinical trials and their results. The Employers' Association of Innovative Pharmaceutical Companies (INFARMA – member of EFPIA) represents pharmaceutical companies engaged in research and development activities in Poland, and has voluntarily established a publicly available database of ongoing clinical trials conducted by its members (ie, pharmaceutical manufacturers).

2.4 Restriction on Using Online Tools to Support Clinical Trials

There is no specific restriction against using online tools to support clinical trials. The processing of personal data connected with clinical trials is subject to the general provisions of the Personal Data Protection Act. Sponsors and clinical investigators have to ensure that any online tools used to recruit or monitor study participants comply with the Personal Data Protection Act and other relevant data protection regulations.

2.5 Use of Data Resulting From Clinical Trials

Data obtained from the conduct of a non-commercial clinical trial may not be used for marketing purposes nor for the purpose of obtaining a marketing authorisation for a medicinal product or making changes to the granted authorisation, except for changes to the marketing authorisation for a medicinal product with respect to the safety of the medicinal product's use.

The use of clinical trial data may be either primary or secondary. All processing operations related to a specific clinical trial protocol throughout the period covered by the protocol – from the start of the trial to the deletion of the data after the end of the archiving period – are to be understood as primary uses of clinical trial data.

Secondary use occurs if the sponsor processes the clinical trial participant's data outside the clinical trial protocol, for scientific purposes.

2.6 Databases Containing Personal or Sensitive Data

The provisions of the Clinical Trials of Medicinal Products for Human Use Act do not specify additional technical obligations for the maintenance of databases obtained in the course of a clinical trial. The provisions of Regulation No 536/2014 and the GDPR apply. In practice, entities conducting clinical trials in Poland usually maintain at least three databases:

- a database of clinical trial participants;
- a database of research team members; and
- a database of persons reporting adverse events.

It is the responsibility of these entities to implement technical and organisational measures to protect the processed information and personal data from unauthorised or unlawful access, disclosure, dissemination, alteration, destruction or accidental loss, especially in the case of processing involving transmission over a network.

Contributed by: Marcin Tomasik, Tomasz Jaworski, Agnieszka Herman and Filip Gołba,
Tomasik Jaworski Law Firm Sp. p.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The provisions of the Pharmaceutical Law Act shall apply to a product that simultaneously meets the criteria of a medicinal product and the criteria of another type of product, in particular a dietary supplement, a cosmetic product or a medical device, as defined by separate regulations.

Product qualification is carried out by the manufacturer, in accordance with the statutory definitions of a medical device and pharmaceutical. Competent authorities have the opportunity to react if there is a misclassification. However, the competences of authorities in this respect are not clearly defined or demarcated, which sometimes leads to delays in decisions.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Marketing authorisations for biologic medicines are granted in accordance with Regulation 726/2004; therefore, they are not granted by the President of the URPL.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

The marketing authorisation is issued for five years and may be renewed indefinitely, at the request of the marketing authorisation holder. An application for an extension should be made at least nine months before the expiry date of the authorisation.

The President of the URPL is obliged to revoke a marketing authorisation if any of the circumstances described in Article 33 of the Pharmaceutical Law occur, including:

- an unexpected serious adverse reaction;
- the pharmaceutical does not have the declared therapeutic efficacy; or
- the risk of using it is found to be disproportionate to its therapeutic effect.

The President of the URPL can suspend a marketing authorisation when the circumstances described above do not pose a direct threat to public health.

The marketing authorisation expires if the marketing authorisation holder does not actually place the medicinal product on the market within three years of receiving the authorisation.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

The national procedure for obtaining marketing authorisation is as follows.

- The applicant should submit an application for a marketing authorisation for the medicinal product to the President of the URPL.
- The President of the URPL formally verifies the application and attached documentation.
- If formal deficiencies are found, the President of the URPL calls for the application to be supplemented within at least seven days, under pain of leaving the application unprocessed.
- If there are substantive comments on the submitted documentation, the President of the URPL calls on the applicant to submit supplements and clarifications.
- Proceedings for the issuance of a marketing authorisation for a medicinal product should

be completed within no more than 210 days of the application being submitted.
- If it is necessary to supplement the documents or to submit explanations, the President of the URPL shall issue a decision to suspend the deadline.

The costs for obtaining a marketing authorisation depend on the nature of the medicinal product, and can be up to PLN84,000 (circa EUR19,500).

The procedure for a variation of a market authorisation is governed by Commission Regulation No 1234/2008 of 24 November 2008 and the Pharmaceutical Law Act (Article 31). The change procedure depends on the type of change. Changes are made by the President of the URPL at the request of the marketing authorisation holder.

If there is a change of marketing authorisation holder, the President of the Office shall issue a new authorisation on the basis of the application of the person assuming the rights and obligations of the existing marketing authorisation holder. The decision issued in favour of the new marketing authorisation holder shall come into force no later than six months after it is issued. The new permit shall be issued no later than 30 days after the application is made.

The requirements that have to be satisfied before medical devices can be placed on the market are contained primarily in the MDR and the IVDR.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

The following products are approved for sale without a marketing authorisation:

- magistral formulas;
- official formulas;
- radiopharmaceutical products prepared at the time of use in authorised medical entities, from authorised generators, kits, radionuclides and precursors, in accordance with the manufacturer's instructions, and radionuclides in the form of sealed radiation sources;
- blood and plasma in full composition or blood cells of human or animal origin, excluding plasma processed by an industrial process;
- pharmaceutical raw materials not intended for the preparation of prescription and pharmacy pharmaceuticals;
- immunological veterinary medicinal products made from pathogens or antigens derived from animals on a farm and intended for the treatment of animals on that farm; and
- advanced therapy medicinal products (hospital exceptions).

There are no Polish regulations relating directly to compassionate use programmes. Any medicinal products imported from abroad are allowed to be marketed without the need for authorisation if their use is necessary to save the life or health of a patient, provided that the medicinal product is authorised in the country from which it is imported and has a current marketing authorisation.

In accordance with Article 59(1) of the MDR, the competent authority (ie, the President of the URPL in Poland) may, upon receiving a duly justified request, allow the placing on the market or putting into service in the territory of the member state concerned of a specific device for which the relevant procedures referred to in the relevant provisions of the MDR have not been carried out, but the use of which is in the interest of public health or the safety or health of patients.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

The following obligations may be imposed in the marketing authorisation:

- to take measures, within the framework of the risk management system for the use of the medicinal product, to ensure the safe use of the medicinal product;
- to conduct post-authorisation safety studies;
- to record or report adverse reactions;
- to use an appropriate system for the supervision of the safe use of medicinal products;
- to conduct post-authorisation efficacy studies where doubts have arisen regarding certain aspects of this medicinal product's efficacy that can only be clarified after it is placed on the market; and
- to provide information on the safety and efficacy of the medicinal product in question resulting from scientific and technical progress and the expansion of knowledge about that medicinal product.

With regard to medical devices, each manufacturer analyses all the complaints about the device, as well as cases of errors in use and misuse. The analysis depends on risk management, ergonomics, design validation, and corrective and preventative actions. The manufacturer shall make the results of the analysis available at the request of the President of the URPL and the notified body involved in the conformity assessment of the device. The manufacturer assesses the risks associated with the devices affected by the medical incident and, based on the assessment of the risk analysis, decides whether corrective actions are necessary and to what extent. The manufacturer shall describe the corrective action in the Field Safety Corrective Action Report. The corrective action must be communicated to customers via a Field Safety Notice.

The manufacturer initiates an investigation into the reported medical incident and decides whether said incident meets the criteria for reporting to the President of the URPL.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

Third parties have access only to information on medicinal product authorisation published by the URPL (ie, the authorisation itself, the Summary of Product Characteristics, the Patient Information Leaflet and a summary of the Risk Management Plan). Other documents are available on request but only to entities that can substantiate their legal interest (eg, violation of rights), and subject to the protection of proprietary information. There are no specific regulations allowing disclosure of the process of applying for the marketing authorisation.

In the case of medical devices, it is possible to obtain public information on information contained in safety notes and certificates of conformity, and on the issuance, amendment, supplementation, suspension and withdrawal of certificates of conformity.

3.8 Rules Against Illegal Medicines and/or Medical Devices

The Pharmaceutical Law imposes an obligation on manufacturers, importers and wholesalers to notify the Chief Pharmaceutical Inspector, the President of the URPL and the relevant marketing authorisation holder of any suspected falsification of a medicinal product. If a medicinal product is suspected or found to be counterfeit, pharmaceutical inspection authorities are authorised to withhold it from the market,

prohibit its introduction or withdraw it. In addition, the Pharmaceutical Law states that a fine, restriction of liberty or imprisonment of up to five years can be imposed for the manufacturing, supplying or making available of a falsified medicinal product.

The Medical Devices Law states that fines can be imposed for the distribution of medical devices in violation of regulations.

In addition, the National Organisation for Drug Verification (KOWAL) was established in July 2017 to create a drug verification system and to co-operate with the European Medicines Verification Organisation. The Integrated System for Monitoring the Circulation of Medicinal Products (ZSMOPL) operates in Poland independent of EU regulations.

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

The Customs Service is responsible for preventing the import or release of counterfeit products. It is entitled to inspect and review imported goods, and may suspend the release of the goods or detain them for a period of three working days if it has sufficient grounds to suspect that goods are counterfeit products.

In order to counter the threat of counterfeit medicinal products, the Minister of Health has established a Team for Counterfeiting and Illegal Trade in Medicinal Products and Other Counterfeit Products Meeting the Criteria for a Medicinal Product. This team includes the Chief of the Customs Service.

4. Manufacturing of Pharmaceuticals and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

Undertaking the business of manufacturing pharmaceuticals requires a manufacturer's licence, issued by the Chief Pharmaceutical Inspector. The manufacturing of a medicinal product is any activity leading to the creation of a medicinal product, including the purchase and receipt at the manufacturing site by the manufacturer of materials used for production and their release for subsequent manufacturing stages, including packaging or repackaging and storage and distribution of manufactured medicinal products covered by the application for a manufacturing authorisation, as well as control activities related to these activities.

An applicant for a manufacturer's licence should submit an application containing, among other things, the type and pharmaceutical form of the medicinal product, the place of manufacture of the medicinal product, and a determination of the scope of manufacture of the medicinal product.

The model application is specified in the Regulation of the Minister of Health of 29 April 2019 on the model application for a change in the authorisation to manufacture or import medicinal products.

The permit is issued for an indefinite period of time.

The manufacture of active pharmaceutical ingredients is subject to registration in the National

Register of Manufacturers, Importers and Distributors of Active Pharmaceutical Ingredients.

The manufacture of medical devices does not require a special licence. The President of the URPL controls medical device manufacturers.

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

Undertaking the business of operating a pharmaceutical wholesaler requires a licence from the Chief Pharmaceutical Inspector. Wholesale is any activity involving the acquisition, possession, supply or export of pharmaceuticals or veterinary drugs by holders of a marketing authorisation.

An applicant for a licence should submit an application that includes:

- a definition of the scope of the wholesale business;
- the date on which the intended activity is to be undertaken;
- the name of the person responsible for the operation of the wholesale business; and
- the number of the professional licence for those who are pharmacists, or the PESEL number in the case of other individuals (PESEL is the Polish acronym for "Universal Electronic System for Registration of the Population").

The following items should be submitted with the application:

- relevant declarations, including a declaration from the responsible person that they undertake this function as of the date the wholesale business started;
- an opinion of the competent district pharmacy chamber regarding the responsible person, if they are a member of the pharmacy chamber;
- a description of the procedures for effective withholding or withdrawal of the medicinal product or veterinary medicinal product from the market and from distributors;
- a document confirming the legal title to the premises intended for the business;
- a technical description including illustrations concerning the premises intended for the business, prepared by an authorised person; and
- an opinion on the suitability of the premises.

The model of the application is specified in the Regulation of the Minister of Health dated 29 April 2019 on the model of the application for a licence to operate a pharmaceutical wholesaler.

A wholesaler engaged in the wholesale distribution of medicines must:

- have adequate facilities to carry out this activity;
- employ a qualified person;
- have a description of the procedure for the effective cessation of distribution or withdrawal of a drug from the market; and
- comply with the more specific obligations set forth in the Pharmaceutical Law.

A wholesale licence is issued for an indefinite period of time, unless the applicant has applied for a fixed-term licence. The fee for granting a licence to operate a pharmaceutical wholesaler is PLN6,756 (approximately EUR1,440).

The distribution of medical devices does not require any special licence. The President of the URPL controls distributors of medical devices and, as of 2023, keeps a record of distributors of devices with headquarters in Poland.

5.2 Different Classifications Applicable to Pharmaceuticals

The Pharmaceutical Law Act divides pharmaceuticals into the following categories:

- available without prescription (OTC);
- available on prescription only (Rp);
- available on prescription only, for restricted use (Rpz);
- available on prescription only, containing narcotic drugs or psychotropic substances specified in separate regulations (Rpw); and
- for hospital use only (Lz).

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

In accordance with the Pharmaceutical Law, the import of medicinal products takes place only if such products are brought in from a territory outside the European Economic Area (EEA). If a medicinal product is delivered to Poland from another country within the EEA, such delivery is deemed to be wholesale of medicinal products, rather than being qualified as an import. Export and parallel import are also classified as instances of wholesale.

Similarly, the Medical Devices Act defines an importer by reference to the MDR and the IVDR, under which the importer is an entity that places a medical device from a third country on the EU market.

Articles 38 to 51a of the Pharmaceutical Law govern the import of medicinal products. The import of medical devices is regulated primarily in the MDR and the IVDR, although important provisions might be found in the Medical Devices Act as well. The main obligations for an importer are contained in Articles 13 and 16 of these two Regulations.

The Chief Pharmaceutical Inspector is a central organ of the Polish administration, which issues licences for the import of medicinal products. Importers of medical devices have to register with the President of the URPL.

6.2 Importer of Record of Pharmaceuticals and Medical Devices

Any person, natural or legal, can act as an importer of record of pharmaceuticals. However, an importer of pharmaceuticals cannot apply for a licence to run a pharmacy.

Any person, natural or legal, whose place of residence or headquarters, respectively, is in the EU can act as an importer of record of medical devices.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

The importation of medicines requires a licence from the Chief Pharmaceutical Inspector. Obtaining such a licence is compulsory even if the pharmaceuticals are only intended to be imported for the purpose of further exporting them outside the EEA. It is likewise compulsory for the import of investigational medicinal products, for example.

An application for a licence should specify which medicinal products are going to be imported. An importer can only import medicines that are covered by a licence. The Pharmaceutical Law also allows imports on the basis of an agreement with another importer.

Information on importers is publicly available in the Register of Manufacturers and Importers of Medicinal Products provided by the Chief Pharmaceutical Inspector.

Licensed importers of a medicinal product are not exempt from civil or criminal liability in relation to the use of the medicinal product.

The import of medical devices will require registration with the European Database on Medical Devices (EUDAMED) prior to a device being placed on the market. After filing with the register, the importer should apply to the President of the URPL for a single registration number. The obligation to register will not apply to custom-made devices.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Parallel import is allowed (it is an instance of wholesale trade) as required by EU law, especially the standards related to the single market. However, this requires obtaining a licence for a particular medicinal product from the President of the URPL. The licence is valid for five years, although it is possible to extend it for a further five years.

In order for the parallel import of the medicinal product to be allowed, the medicines in question have to have:

- the same active substances;
- at least the same indications up to level 3 of the Anatomical Therapeutic Chemical (ATC) code;
- the same strength;
- the same route of administration; and
- the same form or a similar form that does not result in therapeutic differences.

The medicinal product subject to parallel import has to be properly repackaged in order to satisfy all the demands of the Pharmaceutical Law. Generally, if such repackaging is necessary, it is a legal requirement and the trade mark holder cannot object to it.

6.5 Trade Blocs and Free Trade Agreements

Poland is a member state of the EU and thereby is part of the European single market comprised of all EU member states and three countries of the European Free Trade Association (EFTA) that chose to be part of the EEA: Iceland, Liechtenstein and Norway. Poland is also a member of the EU Customs Union. The EU itself is a party to an array of free trade agreements with third countries, which thus have an impact on Poland.

Poland is also a member of the World Trade Organization (WTO) and the Organisation for Economic Co-operation and Development (OECD).

Following the aggression of the Russian Federation against Ukraine in 2022, sanctions have been imposed on the import and export of certain goods to and from Russia and Belarus. Poland applies EU sanctions and has also adopted a national law that allows the application of further sanctions on Polish entities and their related companies that deal with Russian/Belarussian entities that support the aggression. The trading of pharmaceuticals and medical

devices has not been expressly excluded from these national regulations.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

Generally, only the prices for publicly reimbursed medicinal products or medical devices are regulated. Key pieces of legislation in this respect are the Act of 12 May 2011 on the Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Uses and Medical Devices and the Act of 27 August 2004 on the Financing of Health Services by the State Fund. In accordance with the former, the following products may be publicly reimbursed:

- medicinal products, medical devices and foodstuffs intended for particular nutritional uses that have to prescribed;
- medicinal products and foodstuffs intended for particular nutritional uses available within a drug programme;
- medicinal products available within chemotherapy; and
- medicinal products, medical devices and foodstuffs intended for particular nutritional uses available for use within the provision of publicly funded services other than those listed above.

Until recently, OTC medicines could not be publicly reimbursed, so their prices could not be regulated. However, the recent amendment of the Reimbursement Act opens the possibility to reimburse OTC drugs from public funds, although no such cases have yet arisen.

If a product is reimbursed, its price is fixed unless it is procured by an entity providing publicly funded health services, in which case the net disposal price serves as the maximum price at which the product may be bought by said entity. Net disposal prices are uniform nationwide and so are the margins: the wholesale margin is 6% (not more than PLN150), while the retail margin depends upon the gross price of the medicinal product, medical device or foodstuffs intended for particular nutritional uses that is the limit basis for the given limit group.

For a product to be publicly reimbursed, the marketing authorisation holder has to apply for inclusion in the public reimbursement system.

The recent amendment of the Reimbursement Act envisages special incentives for products manufactured in Poland. Available preferences include expedited processing of the application, exemption from price negotiations with the Economic Commission or prolonged term of reimbursement. Net selling prices are set by the Minister of Health. The negotiations with the Economic Commission, which is an institution within the Ministry, are a key element here. The resulting prices are put on the reimbursement list, which is published on a three-monthly basis.

Medicinal products, medical devices or foodstuffs intended for particular nutritional uses are assigned to reimbursement limit groups (internal reference pricing). Medicines with the same international name or with a different international name but similar therapeutic effects and similar mechanisms of action should be classified in a single group. Medical devices or foodstuffs intended for particular nutritional uses are classified in a single group if they have the same or similar reimbursement indications or uses and similar efficacy.

The net disposal price of the first equivalent on the list may not be higher than 75% of the net selling price of the presentation with the lowest cost per defined daily dose (DDD), calculated according to the net selling price of the only counterpart reimbursed in a given indication. In the case of subsequent counterparts, the net disposal price may not be higher than the price of the counterpart determining the basis of the financing limit or the cheapest counterpart if the basis for the limit in the limit group is a drug that is not equivalent to the subject of the application.

After the market exclusivity expires, the new net disposal price cannot be higher than 75% of the product's price during the market exclusivity period.

7.2 Price Levels of Pharmaceuticals or Medical Devices

The prices in other countries are legally relevant for the Minister of Health when pricing medicinal products and foodstuffs intended for particular nutritional uses that are not classified as any of the following categories of reimbursement availability:

- available in pharmacies on prescription;
- available within a drug programme; or
- available within chemotherapy.

Therefore, this broad category of reimbursement availability encompasses medicines, medical devices and foodstuffs intended for particular nutritional uses used within the provision of publicly funded services, including services provided in hospitals, in outpatient clinics and as part of dental treatment or therapeutic rehabilitation.

The criteria that are to be taken into account by the Minister of Health when setting the net disposal price of such products include the minimum net selling price of those products within the publicly funded system of reimbursement of particular member states of the EU or EFTA. If a given product is not publicly funded in some of these countries, then the market prices are taken into account.

Moreover, in the course of the negotiations, the Economic Commission is obliged to take into account the minimum and maximum net selling price of the product that is the subject of negotiations within the publicly funded system of reimbursement of particular member states of the EU or EFTA. If a given product is not publicly funded in some of these countries, then the market prices are taken into account. The Economic Commission can also consider rebates, discounts or price agreements in these countries.

Usually, it is expected that the price will be among the lowest in the EEA member states. An applicant must provide the prices of a product, together with information on the reimbursement status of the product (level of reimbursement, conditions, restrictions, existence of risk-sharing schemes, for which indications it is reimbursed) in all EEA member states.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Polish public health funding includes reimbursement of medicinal products, medical devices and foodstuffs intended for particular nutritional uses that are provided to patients in publicly funded establishments and purchased by them in pharmacies and pharmacy outlets.

The levels of reimbursement are as follows:

- 100% reimbursement (free of charge) – products with proven efficacy in the treatment of malignant cancer, psychotic disorders, mental disability and development disorders, or contagious diseases posing a special epidemic risk for the population, or products administered in drug programmes;
- lump sum (PLN3.20):
  (a) products that must be administered for more than 30 days and whose monthly administration cost for the service recipient would, in the case of a payment level of 30% of the financing limit, exceed 5% of the minimum wage; and
  (b) products that must be administered for no more than 30 days and whose cost for the service recipient would, in the case of a payment level of 50% of the financing limit, exceed 30% of the minimum wage for work;
- partial reimbursement – 50% of the financing limit, for products that must be administered for not more than 30 days; and
- partial reimbursement – 70% of the financing limit, for other products.

The abovementioned patient payment amounts are reduced by 10% if the medicine is made in Poland or if an active substance made in Poland was used in its manufacture. If both of these conditions are met, the payment is reduced by 15%.

Medical devices are publicly funded in several ways.

- Prescribed medical devices available in pharmacies are covered by the Minister of Health's reimbursement decisions and published in its reimbursement list. This category consists of devices that do not require personalisation for every patient – eg, diagnostic strips for blood glucose monitoring and special types of dressings. The pricing of this device group is regulated as for pharmaceuticals.
- Medical devices supplied on the instructions of an authorised healthcare professional are included in the Minister of Health's regulation, which indicates, for example, the device's public fund financing limit, the patient's own share in the limit and the criteria on which devices are granted. There are no negotiation procedures; conditions apply to every device and are set formally. This group consists of devices that require personalisation (eg, infusion sets for a personal insulin pump, lenses, prostheses, adult diapers and wheelchairs).
- Medical devices provided in an inpatient setting are financed from the public fund as part of the medical procedure and are supplied to patients free of charge. These devices are procured by hospitals and clinics in public procurements.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

During the reimbursement procedure, a health technology assessment (HTA) is provided for originators with no reimbursement equivalents. The reimbursement decision has to be made on the basis of scientific evidence. The applicant marketing authorisation holder has to prove the product's cost-effectiveness compared to the alternative therapeutic substance that is already reimbursed from public funds. The Agency for Health Technology Assessment and its advisory body, the Transparency Council, play a crucial role in the assessment process.

The Minister of Health issues an individual administrative decision on the reimbursement of a product, taking into account other medical procedures that may be applied for a given

clinical condition and that may be replaced with the medicine, foodstuffs for particular nutritional uses, or medical device covered by the application. The following are also taken into account:

- the stance of the Economic Commission;
- the recommendations of the President of the Agency for Health Technology Assessment and Tariff System (AOTMiT);
- the significance of the clinical condition to which the reimbursement application relates;
- clinical and practical efficacy;
- safety;
- the relationship between health benefits and administration risk;
- the cost to health effects ratio of the previously reimbursed products compared to that covered by the application;
- price competitiveness;
- the impact on the expenses of the entity obliged to finance healthcare services from public funds and on service recipients;
- the existence of an alternative medical technology and its clinical efficacy and safety;
- the map of health needs developed by the Minister to identify priority health needs and challenges for the organisation of the healthcare system and to ensure sustainable and co-ordinated spending of public funds;
- the threshold cost of gaining an additional quality-adjusted life year; and
- commitment to continuity of supply.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

While dispensing reimbursed medicinal products, medical devices or foodstuffs intended for particular nutritional uses, pharmacy staff (pharmacists and pharmacy technicians) should inform a patient about the availability of an affordable and publicly reimbursed equivalent whose retail price does not exceed the price of the prescribed product and the financing limit. In the case of medicines, the equivalent has to share its international name, dosage and indication with the prescribed product, and must have a pharmaceutical form that cannot give rise to therapeutic differences. The pharmacy is obliged to display this information on its premises.

Pharmacy staff are also obliged to issue an equivalent to patients who make such requests. This obligation also extends to equivalents with the same or even higher price and to equivalents that are not publicly reimbursed. In the latter case, the cost is fully payable by the patient.

These rules also apply to pharmacy outlets.

8. Digital Healthcare

8.1 Rules for Medical Apps

Apps can be classified as medical devices. There are no regulations specific to apps in Poland: EU regulations apply. The criteria for qualifying an app as a medical device are that it fulfils the definition of a medical device from the MDR/IVDR and that it has a medical purpose. An app can be independent or can be connected with another medical device.

To consider an app as a medical device, it is crucial that the manufacturer indicates its specific medical purpose. All implementing rules in Annex VIII of Regulation (EU) 2017/745 or Annex VIII of Regulation (EU) 2017/746 shall be considered.

The Polish Ministry of Health announced the start of the certification process for medical apps in the first quarter of 2023.

8.2 Rules for Telemedicine

According to the Medical Activity Act of 15 April 2011, health services may be provided via telemedicine systems. Telemedicine advice constitutes a health service that is equal to medical advice given in a traditional manner. When providing telemedicine services, it is important to remember the basic duties of a doctor: to act in accordance with the indications of current medical knowledge, available methods and means of prevention in the diagnosis and treatment of diseases, in accordance with the principles of professional ethics and with due diligence.

In addition, the Regulation of the Minister of Health of 12 August 2020 on the organisational standard of teleportation in primary healthcare sets out the doctor's information duties and the rules for providing online consultations.

In 2021, the public payer (National Health Fund) announced that it would be entitled to cancel contracts for primary care if a clinic switches to operating mainly as telemedicine.

There are restrictions on prescriptions for medicines containing certain categories of narcotic drugs, psychotropic substances or precursors. Such prescriptions are issued after verification through the system or after ascertaining through an interview with the patient that the amount and type of pharmaceuticals prescribed to the patient in prescriptions issued and filled are not sufficient for the proper conduct of pharmacotherapy.

A prescription for the above preparations necessary for the continuation of treatment, if it is justified by the patient's health condition reflected in the medical records, may be issued without examining the patient if no more than three months have passed since the last examination of the patient.

The above does not apply to primary care doctors.

8.3 Promoting and/or Advertising on an Online Platform

Regulations on advertising to the public are applicable. In addition to the general rules for the advertising of medicines and medical devices, further restrictions are imposed on advertising directed to the public – eg, it may not include images of medical professionals or celebrities, it may not contain forbidden suggestive content, and it may not contain anything that encourages children to purchase medical devices.

The advertising of prescription-only medicines that contain narcotics and psychotropic substances and are included in the lists of reimbursable pharmaceuticals is not allowed.

Access to online platforms for healthcare professionals must be effectively protected from general public access.

Online promotion is hindered by a strict ban on pharmacy advertising. The European Commission filed a complaint against the ban with the CJEU in 2023.

8.4 Electronic Prescriptions

Electronic prescriptions are allowed in Poland. Paper prescriptions are issued exceptionally, in strictly defined cases. The rules for issuing e-prescriptions derive from the Pharmaceutical Law and the Regulation of the Minister of Health of 23 December 2020 on prescriptions.

8.5 Online Sales of Medicines and Medical Devices

Online sales of medical devices and non-prescription medicines are allowed, except for medicines for which dispensing is limited by the age of the patient. The terms and conditions for online sales of medicines are set forth in the Regulation of the Minister of Health of 26 March 2015 on the mail-order sale of medicinal products.

8.6 Electronic Health Records

The rules for maintaining electronic medical records are contained in the Health Care Information System Act of 28 April 2011. The Regulation of the Minister of Health of 6 April 2020 on the types, scope and models of medical records and the manner of their processing is also in force, and introduced the principle of keeping medical records in electronic form.

Health-related data is considered sensitive and is protected in accordance with the GDPR and the Data Protection Act of 10 May 2018. The use of cloud platforms is permitted, and there are no specific obligations for cloud platforms. The operation system should comply with the provisions of the GDPR and provide the required level of security.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices

Patents and other key types of intellectual property (excluding copyright), such as trade marks, utility models and industrial designs, are regulated by the Industrial Property Law of 30 June 2000. In accordance with Article 24 of this statute, an invention must be new, have an inventive step and be suitable for industrial application in order to be patentable.

Generally, provisions regarding patents apply to pharmaceuticals and medical devices on a general basis. However, although only new inventions are generally patentable, there is an exception in Article 25.4 of the Industrial Property Law for inventions relating to substances or mixtures that are used for diagnosis and treatment. Even if such substances or mixtures are not new, applying said mixtures or substances for diagnosis or treatment purposes might be patentable if this application itself is new. Likewise, if their particular diagnostic or therapeutic application is not new, another diagnostic or therapeutic application might be new and thereby patentable.

Although products used in diagnostics or treatment (in particular, substances or mixtures) can be patented, the treatment of humans and animals by surgical or therapeutic methods and methods of diagnostics applied on humans or animals cannot.

Most disputes regarding patents revolve around the expiry of the patent for the original medicinal product and the placement of a generic product on the market by the generic manufacturer.

9.2 Second and Subsequent Medical Uses

New dosage regimes and new patient populations can justify additional patent protection under the new medical use rule established in Article 25.4 of the Industrial Property Law. Pursuant to this provision, a patent might be granted for a new (or specific) use of a substance or mixture in the methods of treatment or diagnosis if such use does not constitute the current state of the art.

Any actions regarding the use of the product for the patented use, such as manufacturing, placement on the market or offering of the product, would be considered an infringement of second and subsequent medical uses.

9.3 Patent Term Extension for Pharmaceuticals

As a rule, patents are granted for a period of 20 years. The patent term cannot generally be extended, except for pharmaceuticals, where the term can be extended by up to another five years by obtaining a supplementary protection certificate (SPC). An application for an SPC must be made within six months of the marketing authorisation being issued.

The decision to grant the SPC will be declared to have expired by the Polish Patent Office if the basic patent has expired before the end of the term for which it was granted, or if, during the term of the basic patent, the market authorisation for the product has been withdrawn or the right-holder has surrendered their supplementary protection right.

The SPC can be revoked on the following grounds:

- if it has been granted in contravention of the conditions required to obtain it; or
- if the basic patent was invalidated insofar as it was the basis for the existence of a supplementary protection right.

If the basic patent is invalidated in its entirety, the granted SPC becomes null and void by virtue of law.

9.4 Pharmaceutical or Medical Device Patent Infringement

A patent confers the exclusive right to exploit the invention, for profit or for professional purposes, throughout the territory of the Republic of Poland. Exploiting a patent holder's invention without the holder's consent for profit or for professional purposes in the following ways is considered an infringement of the patent:

- making, using, offering or putting on the market a product that is the subject matter of the invention, or importing the product for such purposes; or
- employing a process that is the subject matter of the invention, as well as using, offering, putting on the market or importing for such purposes the product directly obtained by that process.

However, the Bolar exemption is expressly set out in Article 69.1.4 of the Industrial Property Law. By virtue of this provision, one does not infringe a patent if one uses the invention by making, applying, storing, depositing, offering, placing on the market, exporting or importing in order to conduct acts which, under the law, are required for obtaining registration or authorisation, also by a third party, as a condition for allowing the marketing of certain products, including medicines, in the territory of the EEA or of another country.

The threat of infringement is actionable under Polish law. According to Article 285 of the Industrial Property Law, the holder of a patent, an SPC, a right of protection or a right in registration, or another entitled person, may demand the ceasing of infringing activities. According to the case law and doctrinal writings, the threat of infringement should be real and actual (plausible), and not merely hypothetical. The plausibil-

ity of the threat can be indicated by the nature of the actions taken (for instance, preparatory steps to produce products that violate exclusive rights).

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

The following actions are not considered as patent infringements:

- using an invention for national purposes, to a necessary extent, without the exclusive right, where it is indispensable to prevent or eliminate a state of emergency relating to the vital interests of the State, particularly security or public order;
- the employing of an invention for search and experimental purposes, for the evaluation thereof, analysis or teaching;
- the use of the invention by making, applying, storing, depositing, offering, placing on the market, exporting or importing in order to conduct acts which, under the law, are required for obtaining registration or authorisation, also by a third party, as a condition for allowing the marketing of certain products, including medicines, in the territory of the EEA or of another country (the Bolar exemption); and
- the extemporaneous preparation of a medicine in a pharmacy on a physician's prescription (the Galenic exemption).

According to Article 82 of the Industrial Property Act, a compulsory licence may be granted under the following circumstances:

- if it is necessary to prevent or eliminate a state of national emergency, particularly in the fields of defence, public order, the protection of human life and health, and the protection of the natural environment;
- if it has been established that the patent has been abused; or
- if it has been established that the patent holder enjoying the right of priority of an earlier application (the earlier patent) refuses to conclude a licence contract and thereby prevents the meeting of home market demands through the exploitation of the patented invention (the dependent patent), whose exploitation would encroach upon the earlier patent; in such case, the holder of the earlier patent may demand to receive an authorisation for the exploitation of the invention that is the subject matter of the dependent patent (a cross-licence).

A compulsory licence may be granted if the applying party is able to prove that it has previously made efforts to obtain a licence, in good faith. This requirement may be waived in the case of a compulsory licence granted for the purpose of preventing or eliminating a state of national emergency.

9.6 Proceedings for Patent Infringement

Any person holding a patent or rights stemming from a patent (such as a licence holder) can bring proceedings for patent infringement after the patent has been granted. The remedies include:

- cessation of the infringement;
- the handing over of unlawfully obtained profits; and
- compensation for damages (under general provisions of the Civil Code, including lost profits, or the equivalent of the licence fee or other relevant remuneration for the use of the invention).

Furthermore, the judgment can be made public (in a manner specified by the court) and the infringer can be ordered to publish a statement in the press. Upon a court order, any unlawfully manufactured or marketed products and materials used to produce them can be disposed of (destroyed or withdrawn from the market).

At the infringer's request, if the infringer was not culpable and the order to cease the infringement would be disproportionately harsh for the infringer, the court may order the payment of an appropriate sum of money (but only if it is also in the interest of the entitled person).

The invalidity of the patent can be used as an indirect defence that would require a motion to be filed at the Patent Office. Such a motion is possible and will be successful if a person with a legitimate interest is able to prove that the requirements for the granting of the patent were not met.

The procedural rules for granting interim injunctions in IP cases were altered in 2023. Until recently, injunctions were granted in ex parte proceedings, but the court is now obliged to hear the opposite party before deciding whether to grant an injunction against it. A deadline has also been introduced for seeking interim injunctions against infringements of IP rights, which is only possible within six months from the date the IP right holder became aware of the infringement.

9.7 Procedures Available to a Generic Entrant

There are no specific requirements in the area of patent law for generic market entry, but also no specific procedures available to "clear the way" for generic entry. It is theoretically possible to file a declaratory action but, in practice, it would last too long to be effective. A generic entrant can perform all the necessary actions in order to obtain market authorisation while the patent is still binding. However, even if the marketing authorisation is granted, the product cannot be marketed until the patent has expired.

There is no patent linkage in Poland, and patent protection is not considered possible grounds for the refusal of a marketing authorisation under the Polish Pharmaceutical Law. The market authorisation holder (not the registration authority) is responsible for any patent infringement stemming from manufacturing or marketing the product.

However, even though the Pharmaceutical Law perceives patents as being irrelevant to the procedure of marketing authorisations, it does include data and market exclusivity rules, established in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001. After the market authorisation has been granted, the beneficiary can withhold access to the results of clinical and non-clinical studies from other entities (including generic entrants) for a period of eight years from the date the first (initial) marketing authorisation was granted in an EU or EFTA member state (data exclusivity). In addition, the generic of the referenced pharmaceutical product cannot be released onto the market until ten years have passed since the date of the initial marketing authorisation in an EU or EFTA member state (market exclusivity).

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Depending on the type and scope of the counterfeit infringement, the infringer can be held responsible on the following grounds:

- general civil responsibility for torts regulated in the Civil Code;
- violation of the Industrial Property Law (trade marks, designs);
- violation of the Act on Copyright and Related Rights;
- violation of the Unfair Competition Act; or
- violation of Regulation 608/2013 of 12 June 2013 concerning customs enforcement of IP rights.

The procedure and possible remedies differ significantly in each of these regimes.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

General rules regarding trade marks also apply to pharmaceuticals and medical devices. Any sign capable of being represented graphically can be a trade mark, as long as it possesses the attribute of distinctiveness (ie, it is capable of distinguishing the goods of one business from those of other businesses). A trade mark will not be granted for signs that:

- were filed in bad faith;
- are contrary to public order or good customs;
- consist of customary elements that are present in current business practices; or
- may mislead consumers, especially with respect to the safety or quality of the product.

The Pharmaceutical Law contains special rules regarding the name of medicinal products, which might be an invented name that is not liable to cause confusion with the common name, or a common or scientific name that bears the trade mark or the name of the marketing authorisation holder.

The URPL issues guidelines for naming pharmaceuticals used by human beings. The latest one, including the issue of umbrella branding, was published on 24 September 2019. Despite being a soft law regulation, the guidelines have a significant impact on the practice of the Pharmaceutical Inspection.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

The trade dress or design of pharmaceuticals and medical devices or their packaging can be protected as industrial designs or trade marks under the Industrial Property Law. Remedies are also available under general civil law rules and unfair competition regulations, and include cessation of the infringement, surrender of the unlawfully obtained profits and redress of the damage. In certain cases (violation of industrial property and fair competition), the judgment can be made public and the infringer can be obliged to publish a statement in the media.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Polish law follows the data and market exclusivity rules established in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. After the market authorisation has been granted, the beneficiary can withhold access to the results of clinical and non-clinical studies for a period of eight years from the date the first (initial) market-

ing authorisation was granted in an EU or EFTA member state (data exclusivity).

With regard to market exclusivity, irrespective of whether a marketing authorisation has been issued, the equivalent of a reference pharmaceutical product cannot be released onto the market by the marketing authorisation holder until ten years have passed since the date the initial marketing authorisation for the reference pharmaceutical was issued in an EU or EFTA member state.

If a decision is issued to add a new indication or indications that are held to bring significant clinical benefits, the ten-year period of market exclusivity can be extended by a maximum of 12 months during the first eight years after the marketing authorisation was issued for the reference pharmaceutical.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

Rules on pharmaceutical prescriptions have been made more flexible. Pharmacists can now issue prescriptions even if there is no life-threatening emergency; a mere threat to health suffices.

11.2 Special Measures Relating to Clinical Trials

Measures adopted in order to adjust ongoing clinical trials to the COVID-19 pandemic primarily consisted of soft law rules.

The European Commission issued Guidance on the management of clinical trials during the COVID-19 pandemic, prepared in co-operation with the Good Clinical Practice Inspectors Working Group, the Clinical Trials Facilitation and Coordination Group (a working group of the Heads of Medicines Agency), the Clinical Trials Expert Group and, especially, the European Medicines Agency. The document includes measures to be taken in relation to ongoing trials as well as initiating new ones.

In general, it urges sponsors of ongoing trials to make changes in clinical trials based on risk assessment and to consider adopting an array of measures in their risk assessment adequacy. Sponsors should seek the approval of investigators. The well-being and best interests of the trial participants take priority in these considerations. Changes should be balanced and proportionate, and the compliance with the trial protocol should be secured to a relevant degree. Such measures include:

- the postponement of trials;
- the extension of a trial's duration;
- the postponement, limiting or even cancelling of physical visits;
- the cancelling or slowing of the recruitment of new participants;
- moving participants to other safer sites; and
- the closing of sites.

Initiating new trials is to be critically assessed.

Five versions of this document were issued, with the version dated 10 February 2022 being the latest.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

The obvious key emergency approvals during the COVID-19 pandemic were for COVID-19 vaccines. Despite the extraordinary situation, the procedure used for that purpose was the

standard procedure for conditional marketing authorisation provided for in Regulation (EC) No 726/2004, Article 14-A of which includes requirements that have to be satisfied if conditional marketing authorisation is to be issued. Further relevant rules are provided for in Commission Regulation (EC) No 507/2006.

Such conditional marketing authorisation can be granted for a medicine in order to meet unmet medical needs of patients if this medicine is intended for the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases. In standard situations, it may be granted prior to the submission of comprehensive clinical data, provided that the benefit of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data is still required. However, in emergency situations even comprehensive pre-clinical or pharmaceutical data is not required.

Article 14-A specifies some further conditions and imposes certain obligations on marketing authorisation holders.

Conditional marketing authorisation is valid for one year and is renewable.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

The possibility of extraordinary flexibility in regulatory requirements for medicinal products introduced during the COVID-19 pandemic has been withdrawn. During the pandemic, on-site good manufacturing practice (GMP) and good distribution practice (GDP) inspections were postponed or conducted remotely, but these have now resumed. The GMP/GDP Inspectors Working Group has determined that the validity of GMP and GDP certificates will be extended until 2024 or until the conclusion of the next on-site inspection, whichever comes first, unless otherwise specified in the document's clarifying remarks.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

No new specific legislation has been adopted in this respect. However, Poland has numerous measures aimed at counteracting the illegal export of medicines and monitoring such trade.

11.6 Drivers for Digital Health Innovation Due to COVID-19

The digitalisation of healthcare in Poland began before the COVID-19 pandemic started. One of the most significant developments was the introduction of the electronic prescription as a default form of prescription, which took place not long before the implementation of the first lockdown measures in Poland. The process of digitalisation then continued, to a significant extent in response to challenges posed by COVID-19.

The development of telemedicine is one of the examples, as it became much more dynamic after the beginning of the pandemic, as regulations were adopted to facilitate that development (although telemedicine in principle was provided for beforehand).

The key legislative development happened at the very beginning of the pandemic, when the Minister of Health chose to use its right to issue subordinate legislation determining organisational standards of healthcare in selected fields of medicine and issued such standards for primary care. The Minister's ordinance regulated various technical issues.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

Under standard Polish patent regulations, the Patent Office may grant a compulsory licence. The Industrial Property Law of 30 June 2000 allows the granting of such licence if it is necessary to prevent or remove a threat to the security of the State, particularly in the fields of defence, public order, the protection of human life and health, and the protection of the environment.

However, the Polish authorities have made no publicly available declarations about a plan to use this clause or to introduce new regulations of compulsory licences tailored specifically to COVID-19-related treatments.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

Legislation aimed at counteracting COVID-19 introduced liability exemptions for persons providing healthcare services.

The regulation exempts criminal liability for a few unintentional offences: manslaughter, bodily harm and exposing a person to imminent danger of loss of life or grievous bodily harm. It provides that a healthcare professional who engages in conduct that would otherwise be classified as a criminal offence during the period of the declaration of an epidemic emergency or epidemic, while providing healthcare services in the prevention, diagnosis or treatment of COVID-19 and acting under special circumstances, does not commit a crime. The liability exemption does not apply if the effect caused by the perpetrator was the result of a grave failure to take due care, as required under the given circumstances.

However, the period of the declaration of an epidemic emergency ended on 30 June 2023, so the exemptions no longer apply.

11.9 Requisition or Conversion of Manufacturing Sites

The Act of 2 March 2020 on specific solutions related to the prevention, counteraction and eradication of COVID-19, other communicable diseases and emergencies caused by them introduced several legal measures enabling certain authorities to issue orders to other public bodies, as well as private entities (entrepreneurs).

These provisions are very generally worded and thus give authorities broad leeway as to the contents of orders that can be issued. Amongst other things, they can be used to convert manufacturing sites in a way deemed necessary by the authorities due to COVID-19.

The orders can be issued during a period when an epidemic emergency or an epidemic has been declared, and for up to three months after such emergency has ended. This period has already expired.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

Some COVID-19-related changes to the system of public procurement were enacted in order to make it more flexible – eg, new provisions excluded the application of the provisions regulating public procurement if procured goods or services are needed for counteracting COVID-19 and there is a high likelihood of rapid and uncontrolled spread of the disease, or if the protection of public health so requires.

PORTUGAL

Law and Practice

Contributed by:
Eduardo Nogueira Pinto, Hugo Monteiro de Queirós, Eliana Bernardo and Ricardo Rocha
PLMJ

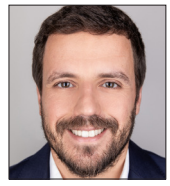
Contents

PLMJ is a law firm based in Portugal that combines a full service with bespoke legal craftsmanship. For more than 50 years, the firm has supported clients in all areas of the law, often with multidisciplinary teams, and always acting as a business partner in the most strategic decision-making processes. PLMJ has specialist lawyers that know the sectors and markets they work in well, and keep in close contact with the regulators for each sector. The firm created PLMJ Colab, a collaborative network of law firms spread across Portugal and other countries with which it has cultural and strategic ties. PLMJ Colab makes the best use of resources and provides a bespoke response to clients' international challenges. International co-operation is ensured through firms specialising in the legal systems and local cultures of Angola, Cabo Verde, China/Macau, Guinea-Bissau, Mozambique, São Tomé and Príncipe, and Timor-Leste.

The firm would like to thank Vasco Granate for his contribution to this chapter.

Authors

Eduardo Nogueira Pinto is a partner at PLMJ, where he heads the healthcare, life sciences and pharmaceuticals practice. He has 20 years' experience in advising Portuguese and foreign companies, and has worked on many projects in the areas of healthcare and pharmaceuticals. Eduardo focuses on regulatory matters, licensing, compliance, advertising, prices and reimbursements, contracts and market access. He has a law degree from the Faculty of Law of Universidade Católica Portuguesa.



Hugo Monteiro de Queirós is a partner at PLMJ and head of the intellectual property practice. He has more than 15 years' experience, and advises on patents, trade marks, designs, copyright and software licensing. Hugo also has a strong focus on IP litigation, with an emphasis on arbitration and court cases involving patent disputes and trade mark enforcement. He also drafts opinions and contracts in all areas of intellectual property. Hugo has been an Official Industrial Property Agent since 2012 and a European Trademark and Design Attorney since 2016. He is a frequent speaker at universities and at Portuguese and international congresses and seminars.

Eliana Bernardo is a senior counsel at PLMJ, in the healthcare, life sciences and pharmaceuticals practice, and has more than 15 years' experience in legal practice. She acts for Portuguese and multinational companies from various sectors, including the distribution and retail sale of medicines, medical devices, food supplements, cosmetics and personal hygiene products. Eliana assists her clients with licensing, prior medical assessments, the reimbursement and revision of medicine prices, compliance and controlled substances. She also has experience in administrative litigation.

Ricardo Rocha is a senior associate at PLMJ, in the healthcare, life sciences and pharmaceuticals practice, and has more than seven years' experience. He focuses on providing regulatory advice to Portuguese and international companies in the pharmaceutical industry. Ricardo assists his clients with all matters relating to the development and marketing of medicines, medical devices, food supplements and cosmetics.

PLMJ

Av. Fontes Pereira de Melo, 43
1050-119
Lisboa
Portugal

Tel: +351 213 197 300
Fax: +351 213 197 400
Email: plmjlaw@plmj.pt
Web: www.plmj.com/en

PLMJ
Transformative Legal Experts

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The rules on medicines for human use come from Decree-Law 176/2006 of 30 August 2006, while the rules on medical devices come from Decree-Law 145/2009 of 17 June 2009 and Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 and Decree-Law n 29/2024 of 5 April (the Medical Devices Regulation – MDR). There are also several sets of regulations implementing the decree-laws in different matters.

The regulatory body that applies and enforces pharmaceutical and medical device regulation is INFARMED (the National Authority of Medicines and Health Products, IP), which is part of the State's indirect administration and is endowed with administrative and financial autonomy. It is responsible for carrying out the responsibilities of the Ministry of Health under the supervision and guidance of the Minister of Health.

As a rule, decisions regarding expenditure on medicines and medical devices are taken by the Minister of Health, who may delegate these decisions to INFARMED.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

INFARMED's decisions regarding medicines and medical devices may be challenged through administrative and/or judicial channels, within a given period.

Individuals and entities who are affected by these decisions can react against them, mainly on the grounds of breach of the law. These means of reaction are common to decisions that affect other products (eg, food supplements and cosmetics), although there may be specific details.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Certain categories of medicines and medical devices are subject to specific regulation. For example:

- medicines containing psychotropic and narcotic substances are regulated by Decree-Law 15/93 of 22 January 2022, Decree-Regulation 61/94 of 12 October 1994, Law 33/2018 of 18 July 2018 and Decree-Law 8/2019 of 15 of January; and
- medical devices for in vitro diagnosis are regulated by Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 and Decree-Law 189/2000 of 12 August 2000.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials of medicines and clinical studies of medical devices are regulated by different pieces of legislation.

Medicines

Clinical trials of medicines are regulated by Regulation (EU) 536/2014 of the European Parliament and of the Council of 16 April 2014 ("Clinical Trials Regulation") and Law 21/2014 of 16 April 2014 ("Clinical Trials Law").

The entry into force of the Clinical Trials Regulation on 31 January 2022 involved the entry into force of the Clinical Trials Information System (CTIS), through which all clinical trial submission, assessment and supervision processes in

the EU are to be submitted. The Clinical Trials Regulation provides for a three-year transition period, with the following timeline:

- from 31 January 2022 to 31 January 2023, clinical trial sponsors were able to choose to submit their clinical trial applications under the Clinical Trials Directive or through the CTIS;
- from 31 January 2023, new applications for clinical trials in the EU and the European Economic Area must be submitted under the CTIS; and
- by 31 January 2025, all ongoing trials will have to be transferred to the CTIS under the Clinical Trials Regulation.

Medical Devices

The rules regarding clinical studies of medical devices are found in Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and in DL 24/2024, implementing MDR in Portugal.

In Vitro Medical Devices

The legal rules applicable to in vitro medical devices are established in Decree-Law 189/2000 of 12 August and Decree-Law 145/2009.

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (IVDR) has been applicable since 26 May 2022. In January 2023, the European Parliament and the Council adopted a staggered extension of its transitional period, ranging from 26 May 2025 for high-risk IVDs to 26 May 2027 for lower-risk IVDs, and to 26 May 2028 for certain provisions concerning devices manufactured and used in health institutions.

In January 2024, the European Commission published a proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 regarding a gradual roll-out of a European database on medical devices (EUDAMED), an information obligation in case of interruption of supply and transitional provisions for certain in vitro diagnostic medical devices.

The amending act must now go through the EU legislative process, starting with the public consultation.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Medicines

In the transition period up to 31 January 2023, authorisation to conduct a clinical trial of a medicine was obtained under the rules established in the Clinical Trials Law or through the CTIS, pursuant to the Clinical Trials Regulation.

Since 31 January 2023, new applications for clinical trials in the EU and the European Economic Area must be submitted under the CTIS, under the terms provided by Regulation (EU) 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials of medicinal products for human use. In this case, applications must be submitted through the CTIS and the sponsor should propose a reporting member state, which will be responsible for the analysis of the application.

Until 31 January 2023, if the sponsor opted for the Clinical Trials Law arrangements, the application for authorisation to conduct clinical trials had to be submitted to INFARMED through the National Clinical Trials Register, together with the relevant documentation.

INFARMED will decide on the application for authorisation within 30 days, and may ask the applicant for additional information once only.

Within the period granted, the sponsor may change the content of the application for authorisation, only once, and the period will be suspended until the change is made. If the sponsor does not change the application as requested, the clinical trial may not be conducted.

INFARMED may decide on the need to obtain express authorisation to conduct trials involving the following medicines:

- those that do not have a marketing authorisation (MA) and that are listed in Annex A to Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004; and
- those that have special characteristics – ie, whose active substance or substances are biological products of human or animal origin or contain biological components of human or animal origin, or whose production requires such components.

Clinical trials involving the following medicines will require express authorisation from INFARMED:

- those for gene therapy;
- those for somatic cell therapy;
- those containing genetically modified organisms; and
- those for xenogeneic cell therapy.

Medical Devices

Applications to conduct clinical investigations as defined in the MDR must be submitted by the sponsor to the member state(s) in which the clinical investigation is to be conducted. The application must be submitted through the electronic system referred to in the MDR, accompanied by the documents referred to in Chapter II of Annex XV of the MDR.

2.3 Public Availability of the Conduct of a Clinical Trial

Clinical trials of medicines and clinical studies of medical devices are available on the National Clinical Trials Register website at www.rnec.pt. The results of clinical trials and clinical studies of medical devices are not available in publicly accessible databases.

2.4 Restriction on Using Online Tools to Support Clinical Trials

The methods of recruitment for clinical trials of medicines and clinical studies of medical devices must follow the legally prescribed rules. In addition to physical advertising methods, digital means can be used for this purpose. These means may also be used for monitoring purposes, provided that they do not jeopardise the purpose and safety of the trial.

2.5 Use of Data Resulting From Clinical Trials

Data from clinical trials of medicines and clinical studies of medical devices may qualify as personal data in the sense of sensitive data. However, if the data is fully anonymised (and not merely pseudonymised), it is no longer personal data so does not fall within the category of sensitive data. Anonymisation implies that the identity of the data subject is unobtainable, in which case the data becomes anonymous.

If the resulting data is still personal data, it might be transferred to third parties or affiliates, provided such transfer complies with the requirements set out in the General Data Protection Regulation (GDPR), notably when it comes to consent and

information obligations, security of the processing issues, joint-controllership or sub-processing agreements, and international data transfers. If the resulting data is anonymised data, then those GDPR requirements do not apply.

2.6 Databases Containing Personal or Sensitive Data

The requirements under the GDPR regarding the processing of health data apply with regard to the grounds for the lawfulness of processing, transparency and security measures.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

Products are classified through the definition of medicine (function and/or presentation) and the definition of medical device provided in the applicable legal provisions. In the case of borderline products, the purpose intended by the manufacturer of the product in question and the mechanism through which the main desired effect is achieved are taken into consideration.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Medicines developed by means of one of the following biotechnological processes must be subjected to the centralised community procedure:

- recombinant DNA technology;
- controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells; and
- hybridoma and monoclonal antibody methods.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

Medicines

In the case of medicines, the MA is valid for five years; after the first renewal, it is valid indefinitely or, if considered necessary, for a second five-year period. The renewal of the MA is subject to a specific renewal procedure.

An MA may be revoked, suspended or amended whenever there is non-compliance with the applicable legal and regulatory provisions, or with the conditions of the MA in question. This includes when it is concluded that the risk-benefit balance is unfavourable, the medicine is harmful or the manufacturing process does not comply with the applicable good practices.

Medical Devices

No authorisation is required for placing medical devices on the market. The manufacturer must submit the medical device to a conformity assessment and notify the competent authority that the medical device has been made available on the market. INFARMED may withdraw a product from the market or may suspend, restrict or subject to certain conditions the placing on the market and putting into service of a device or group of medical devices under certain conditions – namely, when the use of medical devices could compromise the health and safety of patients or other persons, or for public health reasons.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

The marketing of a medicine may follow one of these procedures:

- a national procedure, if the medicine is intended to be approved only for placing on the Portuguese market;
- a mutual recognition procedure, in which an authorisation obtained in a member state is used to apply for authorisation in a new member state;
- a decentralised procedure, when the application is submitted in several member states simultaneously and when the medicine does not have an MA in any member state; and
- a centralised procedure, managed by the European Medicines Agency (EMA), leading to an MA that is valid in all member states.

Any change in the terms of an MA must be subject to an application for a variation of the MA, including changes to the summary of product characteristics and any conditions, obligations or restrictions affecting the MA, or changes to the labelling or package leaflet in connection with changes to the summary of product characteristics.

An MA may be transferred to a new holder through the submission of a transfer application by the MA holder.

The placement of a medical device on the market does not require authorisation (see **3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices**).

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

Medicines without an MA or without an MA that is valid in Portugal may be made available to patients through the exceptional use authorisation, under which they can be accessed by patients through early access programmes, which have a specific regulation issued by INFARMED.

Regarding medical devices, INFARMED may authorise the placing on the market or putting into service of a medical device for which no conformity assessment procedures have been carried out but the use of which is in the interest of public health or patient safety or health.

Compassionate use also takes place in the context of clinical trials.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

The MA for a medicine may be granted subject to the subsequent conduct of additional studies or compliance with special rules regarding safety and the reporting of all incidents associated with the use of the medicine and the measures to be taken, the conduct of a post-authorisation safety or efficacy study, or the fulfilment of other obligations established by INFARMED.

After the granting of an MA, INFARMED may require its holder to conduct a post-authorisation safety study if there are doubts about the risks of the authorised medicine or if knowledge about the disease or clinical methodology indicates that previous efficacy evaluations may need to be significantly revised.

The holder of an MA is obliged to comply with the obligations provided for by law – namely, to comply with pharmacovigilance obligations and to make this or other data proving that the benefit-risk relationship of the medicine remains favourable available to INFARMED.

Manufacturers of medical devices other than investigational devices must report any field

safety corrective action to INFARMED, as well as any serious incident or any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected to have undesirable side effects that could have a significant impact on the benefit-risk analysis, and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

INFARMED publishes information on the status of an MA application and its assessment report on its website. It suppresses any commercially confidential information and allows access to the summary of product characteristics and the package leaflet, as well as information on the medical devices placed on the market.

3.8 Rules Against Illegal Medicines and/or Medical Devices

Decree-Law 26/2018 of 24 April 2018 incorporated the European legislation on falsified medicines into Portuguese law. This legislation establishes the mandatory placement of safety devices on the packaging of certain medicines, which must be checked by all participants in the chain, to allow the detection of falsified or adulterated medicines in the circuit and the individual identification of packaging.

Under the regulatory framework, INFARMED must draw up an annual surveillance activity plan and perform appropriate checks on the conformity characteristics and performance of medical devices, including, where appropriate, a review of documentation and physical or laboratory checks based on adequate samples.

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

INFARMED established a protocol with the Tax and Customs Authority to inspect and intercept counterfeit medicines. The Legal Framework for Tax Infractions and Customs Crimes also provides for the existence of customs offences and crimes associated with the counterfeiting of goods, which may include counterfeit medicines and medical devices.

4. Manufacturing of Pharmaceuticals and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

The manufacture of medicines, experimental medicines and medical devices requires authorisation from INFARMED.

The manufacture of medicines requires the existence of facilities licensed for the purpose, and compliance with good manufacturing practices. The facilities are subject to periodic inspections by INFARMED, which certifies their compliance and issues a certificate of good manufacturing practices, which is valid for three years.

For medical devices, facilities must obtain an industrial activity licence in accordance with the applicable legislation and have an industrial activity code associated with the categories of medical devices produced in conjunction with the respective manufacturing activities performed.

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

Authorisation for the wholesale of medicines is issued by INFARMED and covers the activities of supplying, holding, storing or delivering medicines for processing, resale or use in medical services, healthcare facilities and pharmacies, excluding the supply to the public. It specifies the facilities from which distribution is carried out and is subject to the validity of the certificate of good distribution practices, which must be renewed every five years.

The wholesale of medical devices is subject to prior notification to INFARMED and covers the activities of supplying, holding, storing or supplying medical devices for resale or use in medical services, healthcare facilities, pharmacies and other points of sale to the public, excluding supply to the public.

5.2 Different Classifications Applicable to Pharmaceuticals

For dispensing to the public, medicines are classified into prescription-only medicines (MSRMs) and non-prescription medicines (MNSRMs). The former can also be classified as renewable, special or for restricted use in specialised monitored conditions, and the latter as MNSRMs for dispensing only in pharmacies.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The import and export of medicines is regulated by Decree-Law 176/2006 of 30 August 2006 and by related legislation on good practice in transportation and distribution. For medical devices, the MDR and Decree-Law 29/2024 are applicable.

INFARMED is the entity responsible for monitoring compliance with these regulations.

6.2 Importer of Record of Pharmaceuticals and Medical Devices

Any natural or legal person can be an importer of medicines and medical devices if they are duly authorised and licensed for that purpose by INFARMED.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

The import and export of medicines and medical devices require the economic operator to be licensed by INFARMED for that purpose. For personal use, medicines can be transported only for the necessary period, provided that they are accompanied by a medical prescription, when necessary. In the case of emergency situations or donations, INFARMED will assess each case individually.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

The following regulations are to be considered upon the importation of any products into the

Portuguese territory, which is part of the customs territory of the European Union:

- Regulation (EU) 952/2013 of the European Parliament and of the Council of 9 October 2013, which approves the Union Customs Code;
- Commission Delegated Regulation (EU) 2015/2446 of 28 July 2015; and
- Commission Implementing Regulation (EU) 2015/2447 of 24 November 2015.

6.5 Trade Blocs and Free Trade Agreements

Portugal is part of the EU and the single European market, and it applies the principle of free movement of goods and services; it also has harmonised regulatory rules for medicines and medical devices.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

Price Control for Medicines

Non-reimbursed medicines have free pricing arrangements, but all other medicines have their prices regulated and are subject to maximum price rules or notified price rules. They cannot be sold unless the MA holder obtains a retail price (RP).

The RP of the medicine is composed of:

- the ex-factory price (EFP), which is the maximum price at the stage of production or import and has fixed rules for its determination;
- the wholesalers' and retailers' selling margins, as fixed by ministerial order;
- the tax on the sale of medicines; and
- value-added tax (VAT).

The MSRMs intended to be dispensed and used in National Health Service (NHS) establishments are also subject to maximum price rules, and their final price is composed of the EFP, the sales tax and VAT.

The prices of medicines subject to the maximum price rules are reviewed annually. The pricing rules for medicines are set out in Decree-Law 97/2015 of 1 June 2015 and regulated by several Ministerial Orders (in particular Ministerial Order 195-C/2015 of 30 June 2015 and Ministerial Order 154/2016 of 27 May 2016).

Requests for price authorisation and price revision communications follow their own procedures and are submitted to INFARMED by the MA holder.

Price Control for Medical Devices

As a rule, medical devices financed by the State have fixed maximum prices. Medical devices not financed by the State have free pricing.

The pricing rules for medical devices are set out in Decree-Law 97/2015 of 1 June 2015, and there are Ministerial Orders that define the maximum prices applicable to certain devices or groups of medical devices, which usually include the marketing margins and VAT. In these cases, the RP proposed is indicated by the manufacturer at the time of the request for reimbursement to INFARMED, which follows its own procedure.

7.2 Price Levels of Pharmaceuticals or Medical Devices

Medicines

The price of medicines is generally set and reviewed on the basis of the prices in the refer-

ence countries with comparable GDP per capita or lowest price level, defined annually among EU countries.

Ministerial Order 39-C/2024 of 2 February has defined Spain, France, Italy and Slovenia as reference countries in 2024.

Medical Devices

The price of medical devices does not depend on the prices applied in other countries.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Public financing of medicines and medical devices depends on an application to INFARMED by the MA holder or the manufacturer, respectively. This public financing may be full or partial and differs according to various factors, such as pathologies or special groups of patients, therapeutic indications, prevalence of certain diseases in the population, etc; see **7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices**.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Medicines

As a rule, State funding of medicines is cumulatively subject to prior technical-scientific demonstration of therapeutic innovation or equivalence for the therapeutic indications claimed, as well as demonstration of the economic advantage of the medicine. These factors are not decisive in fixing the price of medicines, because these prices tend to be fixed taking into account the prices in the reference countries – see **7.1 Price Control for Pharmaceuticals and Medical Devices** and **7.2 Price Levels of Pharmaceuticals or Medical Devices**.

Medical Devices

A cost-benefit analysis is also carried out in the financing of medical devices by the State, considering the therapeutic innovation demonstrated for the clinical purposes claimed and the demonstration of an economic advantage – see **7.1 Price Control for Pharmaceuticals and Medical Devices**.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

In order to ensure the sustainability of the NHS, the prescribing of reimbursed medicines is made using the international non-proprietary name and may only include the commercial name of the medicines in the exceptional cases listed in the law. Pharmacies are obliged to inform the patient about the medicine that, in compliance with the prescription, has the lowest price. These rules apply to reimbursed medical devices, with the necessary adaptations.

8. Digital Healthcare

8.1 Rules for Medical Apps

As software, medical apps are considered active medical devices under the MDR, with lifestyle and well-being apps being expressly excluded from the scope of the MDR. The classification criteria are provided by the MDR and supporting documents are published for this purpose by the European Commission.

8.2 Rules for Telemedicine

The rules on telemedicine are laid down in the Code of Ethics of the Portuguese Medical Association, which establishes standards for the safety and quality of the means used.

8.3 Promoting and/or Advertising on an Online Platform

The advertising of medicines and medical devices is highly regulated and there are specific regulations for each of these product categories, which are also applicable to online portals, company webpages and social networks.

8.4 Electronic Prescriptions

Electronic prescribing is the rule and has been in place for several years. Non-electronic prescriptions are exceptions and are only allowed in specific cases.

8.5 Online Sales of Medicines and Medical Devices

Under certain circumstances, pharmacies and MNSRM outlets can perform home delivery of medicines, and such medicines can be ordered over the internet. Medicines cannot be delivered by post or courier.

It is possible to market medical devices online and deliver by post or courier. Admissibility must be assessed on a case-by-case basis and, in any case, the quality of the medical device must be guaranteed.

8.6 Electronic Health Records

Health-related records are regulated as health data under the GDPR, and health-related information is considered sensitive data under the GDPR. Moreover, Law 58/2019 of 8 August 2019, which ensures the implementation of the GDPR, contains specific obligations regarding professional secrecy. These obligations apply to all corporate bodies, employees and service providers of the controller, and to students and researchers in the field of health who have access to such data. The data subject must be notified of any access made to their personal data, and the controller must ensure that a traceability and notification mechanism is in place.

There are no special requirements for cloud platforms. Portugal does not restrict the processing of health data to its territory, so the general rules provided in Chapter V of the GDPR on international data transfers apply. It is permitted to store sensitive patient data on cloud platforms. However, in addition to the general requirements of the GDPR, most public bodies, including public hospitals, are obliged to comply with Council of Ministers Resolution 41/2018 regarding information security. This contains technical guidelines for the Public Administration on the security architecture of networks and information systems regarding personal data.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices

The Portuguese Industrial Property Code (IPC) contains the most relevant provisions for patents, including for patent prosecution and enforcement.

Special inhibitory actions relating to pharmaceutical patents and generic medicines are available under Law 62/2011 of 12 December 2011.

The most common issues encountered by pharmaceutical companies in Portugal relate to patent disputes between originator and generic companies under Law 62/2011. Other issues that usually arise relate to the validity of patents and supplementary protection certificates (SPCs).

There are no specific patentability requirements for medicines or medical devices per se. However, according to the IPC, processes for cloning human beings, processes for modifying the germinal genetic identity of the human being and uses of human embryos for industrial or commercial purposes are not patentable.

Methods of surgical or therapeutic treatment are also not patentable, but the products, substances or compositions used in any of these methods may be patented.

9.2 Second and Subsequent Medical Uses

Second and subsequent medical uses of a known substance or composition are regarded as patentable in Portugal, provided that any such use meets the general patentability requirements.

According to the Guidelines of the Portuguese Institute of Industrial Property, the term "use" may include new dosage regimes and new patient groups.

There is no clear guidance from the Portuguese courts as to what specific activities constitute infringement of second and subsequent patents of medicines. However, in a 2015 judgment, the Lisbon Second Instance Court decided that the patent-holder of a second medical use patent can only react against the applicant of an MA for the generic medicine if the active pharmaceutical ingredient is prepared and adopted for the specific therapeutic use that is patented. In the first instance decision of this case, the ad hoc arbitral tribunal considered that one cannot conclude that there has been an infringement of the second use patent if the generic medicine does not have the patented use as a therapeutic indication according to the granted MA.

9.3 Patent Term Extension for Pharmaceuticals

The patent-holder may obtain a patent term extension for medicines by applying for an SPC. The application for an SPC is regulated in the IPC and is governed by Regulation (EC) 469/2009 of the European Parliament and of the Council of 6 May 2009 ("SPC Regulation"). The SPC application must be filed with the Portuguese Industrial Property Office (INPI) in Portuguese, with a copy of the first MA of the product in Portugal.

If granted, the SPC can extend the protection conferred by the basic patent for the time that has passed between the filing of the patent application and the date of grant of the MA, minus five years. The validity of the SPC cannot exceed five years from the expiry of the basic patent, except when it concerns medicines for paediatric use, where a further six-month extension is available.

Patent term extensions via an SPC may be challenged by any interested party before the INPI if the date of the first MA indicated by the patent-holder in the SPC application is incorrect. The INPI can also amend the validity period of an SPC of its own motion when it verifies the existence of an error.

An action for the revocation of an SPC can be brought before the Portuguese Intellectual Property Court by any interested party, under the IPC.

9.4 Pharmaceutical or Medical Device Patent Infringement

Similarly to other patents, medicine or medical device patents give the patent-holder the right to prevent any third party from:

- manufacturing, offering, stocking, placing on the market or using a product that is the

subject matter of the patent, or importing or possessing it, for any of the purposes previously mentioned;
- using the process that is the subject matter of the patent or, if the third party knows or should have known that the use of the process is prohibited without the consent of the patent-holder, offering to use it; and
- offering, stocking, placing on the market or using, or importing or possessing for those purposes, products obtained directly by the process that is the subject matter of the patent.

Applying for an MA does not qualify as a patent infringement action in Portugal. However, the publication of an MA for a generic medicine by INFARMED enables the patent-holder to file a special inhibitory action under Law 62/2011 for invoking incompatible patent rights. The patent-holder can also request the IP Court (or an arbitral tribunal, if arbitration is agreed between the parties), in such action, to determine precautionary measures to prevent infringement of the patent in question.

The threat of infringement is actionable to inhibit any imminent infringement.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

Specific defences to patent infringement in relation to medicines and medical devices in Portugal include an experimental use exemption and, in particular, the Bolar exemption.

Compulsory licences on patents are provided for in the IPC in general terms, but there are no relevant precedents in Portugal with regard to the granting of compulsory licences. In any case, compulsory licences may be granted in Portugal in the following circumstances:

- lack or insufficient exploitation of the invention;
- dependency between patents;
- public interest;
- under EU and Portuguese Competition law; and
- under Regulation (EC) 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of medicines for export to countries with public health problems.

9.6 Proceedings for Patent Infringement

Patent infringement proceedings may be brought by the patent-holder or by the licensee. The licensee's right to bring an action depends on the specific terms of the corresponding licence agreement and on the record of the licence at the INPI.

Although patent infringement is a crime under Portuguese law, the typical procedure for patent infringement actions is a civil lawsuit at the IP Court. Special inhibitory actions relating to pharmaceutical patents and generic medicines are available under Law 62/2011 and must also be filed at the IP Court or, upon agreement of the parties, before an institutional or ad hoc arbitral tribunal.

Civil remedies include preliminary and permanent injunctions granting the patent-holder the right to prevent any imminent infringement or to prohibit the continuation of the infringement. There is also the possibility of requesting the IP Court to order the infringer to pay a periodic penalty for breach of the judgment, and to order the destruction, recall or definitive removal of

the infringing goods from the channels of commerce. Damages claims for infringement are also possible.

Invalidity is available as a defence in civil infringement proceedings on the merits, through the filing of a counterclaim for revocation of the patent or SPC.

9.7 Procedures Available to a Generic Entrant

In theory, under the Civil Procedure Code, pre-launch declaratory actions are possible for generic market entrants, although as far as is known there are no relevant precedents in Portugal in this regard. Nullity actions for the invalidation of patents or SPCs in advance of attempted market entry are also possible.

Law 62/2011 (see **9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices**) created a special action applicable to patent litigation involving generic medicines, whereby patent-holders can pursue an early assessment of prospective patent infringement, after publication of the MA applications for generic medicines. This law led to a large number of court cases and also to a large number of settlement agreements between patent-holders and generics.

Although the procedure provided for in Law 62/2011 is triggered by the publication of the MA, this procedure does not stay the grant of the MAs or their effect once granted, which means that no patent linkage effect exists.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Counterfeiting consists of the complete reproduction of a sign that is protected as a trade mark. The IPC provides that trade mark counterfeiting is a criminal offence, punishable with imprisonment for up to three years or a fine of up to 360 days. Civil liability also arises from trade mark counterfeiting.

Custom procedures against counterfeit medicines and medical devices are available under Regulation (EU) 608/2013 of the European Parliament and of the Council of 12 June 2013.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Besides the general requirements and impediments provided for in the IPC with respect to trade mark composition (that apply to all marks), Decree-Law 176/2006 further provides that the name of a medicine may comprise a trade mark, as long as that trade mark is not misleading with regard to the therapeutic properties and nature of the product.

The EU Regulations on medical devices also prohibit the use of misleading trade marks.

Under trade mark law, non-counterfeit genuine medicine or medical device products may suffer import restrictions if there is a prior registered trade mark in Portugal that prevents the use of the mark by the importer (eg, on the basis of likelihood of confusion).

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

IP protection for the trade dress or design of medicines and medical devices, or their packaging, is potentially available under design rights, copyright and trade mark rights, provided they meet the legal requirements for that protection.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

According to an a contrario interpretation of Decree-Law 176/2006, data exclusivity for medicines (chemical drugs and biologicals) will last for at least eight years from the date of the granting of the MA for the reference medicine.

Under the same Decree-Law, marketing exclusivity of the reference medicine lasts ten years from its first MA approval, or 11 years from its first MA approval if the originator obtained a new therapeutic indication that brings significant clinical benefit, within eight years of that date.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

During the COVID-19 pandemic, INFARMED issued guidelines to simplify the import and export of medicines, particularly regarding the import and export of medicines with controlled substances.

INFARMED also issued transitional guidelines to make the import, manufacture and distribution of medical devices faster and more efficient during the pandemic. In addition, it relaxed several rules that made it very time-consuming to obtain the necessary devices.

11.2 Special Measures Relating to Clinical Trials

Within the constraints imposed by the pandemic, INFARMED issued guidelines to mitigate the impact of the pandemic on clinical trials that were in progress or about to start. These measures do not specifically target clinical trials of medicines to treat COVID-19. INFARMED stressed the possibility of remote visits through technological means, ensuring the collection and recording of the information foreseen for the visit.

EMA also implemented exceptional measures regarding the approval and documentation of medicines to treat COVID-19.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

EMA has created a specific, expedited procedure for the approval of medicines, which is characterised by significantly shorter timeframes for the review and approval process.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

Within the context of the COVID-19 pandemic, INFARMED established special and temporary abbreviated procedures for the certification of medical devices that are essential to answer the needs caused by the pandemic – eg, the certification of medical devices such as surgical masks and ventilators for medical purposes.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

In the context of the outbreak of the pandemic, INFARMED and other authorities issued guidance on easing import requirements for medical devices needed to contain the spread of the virus.

11.6 Drivers for Digital Health Innovation Due to COVID-19

Telemedicine was already allowed in Portugal before the pandemic. These means were used more frequently during the pandemic period, considering the saturation of the NHS hospitals and health facilities.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

There is no intention to issue compulsory licences for COVID-19-related treatments or vaccines.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

No liability exemptions have been introduced in existing or new provisions regarding COVID-19 vaccines or treatments.

11.9 Requisition or Conversion of Manufacturing Sites

During the pandemic period, industries were turned over to the production of medical devices. Several textile industries temporarily converted their production to the production of medical devices (mainly surgical masks).

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

Measures to make public procurement more flexible were adopted to ensure the immediate availability of goods and services urgently needed to respond to the pandemic. In addition, an exceptional system of public procurement, expenditure authorisation and administrative authorisation was created. In this system, the creation of exceptional arrangements for simplified direct adjustment stands out, particularly for the acquisition of medicines and medical devices.

Trends and Developments

Contributed by:
Ana Rita Paínho, Mariana Costa Pinto and Leonor Ruano Silveira
Sérvulo & Associados

Sérvulo & Associados is a Portuguese full-service law firm with 25 years of operation. It has a highly competent multidisciplinary team of more than 100 lawyers who are trusted by a vast number of private and public entities, both domestic and international, in the Portuguese-speaking legal markets and in all the most significant economic sectors. The life sciences team has in-depth knowledge of the life cycles of drugs, medical devices and other health products, enabling it to provide specialised advice at all stages, including research and development of new products and their respective intellectual property issues, data protection, regulation and inherent litigation.

Authors

Ana Rita Paínho is a partner in the life sciences, intellectual property and TMT departments at Sérvulo & Associados. She has been at the forefront of advising pharmaceutical industry associations and large multinationals in the pharmaceutical sector on topics related to patents and associated litigation, and on all regulatory aspects relating to medicines, medical devices, cosmetics, health products and technologies. Ana has 25 years of experience in the area, having assisted several pharma companies in litigation proceedings on patents.

Mariana Costa Pinto has more than 18 years of experience as an expert in intellectual property matters, especially intellectual property litigation. She has strong experience in patent litigation cases in IP courts and arbitration proceedings, advising clients mainly in the pharmaceutical sector. Mariana monitors all matters and is an expert in defining the best strategy for patents and trade marks, considering the clients' core businesses. She plays an active role at the IP commission of JALP Association and is involved in disputes on patent law and some cases involving authorship rights disputes and national and European trade marks.

Contributed by: Ana Rita Paínho, Mariana Costa Pinto and Leonor Ruano Silveira, **Sérvulo & Associados**

Leonor Ruano Silveira specialises in life sciences, intellectual property and TMT. She concluded the Intellectual Property Law LLM at Queen Mary University, University of London, in 2023. She attended the V Postgraduate Course in Digital Services at CIDP – Lisbon University Law School, in 2022 and concluded the XII Postgraduate Course in Intellectual Property Law at the Portuguese Intellectual Property Association and Lisbon University Law School, in 2021. Leonor also completed the Fashion Law Course at Milano Fashion Institute in 2021, and graduated in Law from University of Lisbon Law School in the same year.

Sérvulo & Associados

Rua Garrett, n.º 64
1200-204
Lisboa
Portugal

Tel: +351 210 933 000
Fax: +351 210 933 001/2
Email: geral@servulo.com
Web: www.servulo.com/en

Sérvulo & Associados | Sociedade de Advogados, SP, RL

Contributed by: Ana Rita Paínho, Mariana Costa Pinto and Leonor Ruano Silveira, **Sérvulo & Associados**

Life Sciences in Portugal: An Introduction

Overview

The technology and life sciences sector is experiencing rapid growth and evolution in Portugal due to advancements in research, regulatory policies and the integration of innovative technologies.

Portugal is a significant player in clinical trials and has attracted substantial investments from pharmaceutical companies, resulting in economic development. The government has taken steps to enhance the capacity and autonomy of Clinical Research Centres, and the compliance with the EU Regulation on Clinical Trials is transforming the landscape of clinical research practices.

Pioneering institutions like the Institute for Medical Systems Biology and the Católica Biomedical Research Centre are driving innovation in biomedical and digital technologies in Portugal.

Healthcare delivery in Portugal is undergoing a revolution with the adoption of cloud-based technologies and artificial intelligence (AI). From digital symptom evaluators to AI-powered dermatological diagnoses, technology is enhancing efficiency, accuracy and accessibility in healthcare services.

The integration of the Unified Patent Court (UPC) and the implementation of the SPC Waiver Regulation are causing significant changes in intellectual property litigation in the life sciences sector.

Life Sciences and Technology

Research and investigation

The biomedical investigation industry has been growing rapidly and has attracted significant public and private investments, envisioning the prosperity and developments in the life sciences sector.

In line with this vision, the Institute for Medical Systems Biology (NIMSB) was developed in 2023 by Nova University of Lisbon, in partnership with the Max Delbrück Centre in Berlin. It presents itself as a new centre of excellence that aims to apply emerging biomedical and digital technologies and innovative health solutions, focusing on the understanding of human biology and physiopathology on a cellular and molecular level.

Moreover, in late 2023, the Faculty of Medicine of the Portuguese Catholic University opened a new research centre, the Católica Biomedical Research Centre, the main objective of which is to promote health through fundamental science. The centre is staffed by talented researchers who utilise innovative technologies to unify medicine, biology and engineering. They aim to understand complex systems and develop solutions to current and future social challenges related not only to human health but also to the planet's well-being.

The government has recently created a programme called *Saúde+Ciência* (Health+Science) to boost scientific research in the field of healthcare. The aim of the programme is to encourage research in public institutions that offer health services and care, to train and appreciate health professionals, and to enhance the implementation of health promotion and disease prevention activities. Thus, the goal is to improve the organisation and quality of healthcare and services.

Focusing on projects targeted at specific therapeutics, the Champalimaud Foundation has recently received funding to invest in clinical research for pancreatic cancer.

The use of AI in the health sector

The healthcare industry has been undergoing a significant transformation due to technological advancements, particularly in AI. These advancements address various issues, including escalating costs, limited access to healthcare and disparities in healthcare delivery. AI's capacity to process large datasets and emulate human cognitive abilities has resulted in the creation of autonomous systems, reshaping healthcare models fundamentally.

Artificial intelligence is on the path to becoming consensually recognised by the scientific and clinical communities as a tool that can help increase accuracy and avoid delays in treatment, potentially saving lives when it comes to preventing the development of diseases and diagnosing pathologies.

Examples of how technology is being used in healthcare in Portugal include the following.

- A digital symptom evaluator available on the CUF (a private Portuguese hospital) mobile app allows patients to answer a series of questions in order to receive a possible diagnosis or referral, serving as a preliminary assessment.
- In early 2024, the National Health Service (NHS) introduced a funding line for the implementation of AI tools in dermatological diagnoses. Given the difficulty of accessing answers in this area, the NHS believes that the adoption of AI tools, which are duly validated and supervised by dermatologists, can provide faster and more accurate diagnoses for NHS users. Through an app, individuals can take a picture of their skin condition and, if necessary, it will be sent to a dermatologist with high priority, reducing the demand for face-to-face consultations.
- The NHS has been investing in the use of robotics in medical interventions, which improves the quality of the procedure and patient recovery.
  (a) In January 2024, the first robotic thyroidectomy was performed, at the Curry Cabral Hospital (an NHS hospital). This will revolutionise the way this common procedure is usually performed, allowing for a faster recovery and, because it is less invasive and aggressive, less significant physical sequelae.
  (b) In February 2024, the first paediatric surgery with the use of a robotic arm was performed (before that, the robotic had only been used in adult surgeries).
- During clinical trials, the recruitment of individuals or patients who fulfil the predetermined criteria outlined in the medicine study is essential. AI-based technologies play a crucial role in expediting, standardising and simplifying this selection process efficiently. Thus, researchers are now implementing AI algorithms on anonymised datasets to pinpoint clinical research centres housing patients suitable for the drugs under study.

Cloud data transformation

Many life sciences companies are now adopting cloud-based technologies to store their critical data remotely. This approach allows employees to access data from any location, at any time, while maintaining high levels of security. By utilising cloud infrastructure, these organisations are achieving greater operational flexibility, enabling faster decision-making and increasing overall efficiency.

Scientists at the Champalimaud Foundation have been working on the development of a cloud-based infrastructure to store health data for research purposes. This is the first time

such a system has been created in Portugal. The goal of the project is to establish a standardised method of storing patient information in the cloud, with appropriate anonymisation, to allow secure access for researchers worldwide. Eventually, this system could also be used by clinicians and patients, who will be able to access the information online from anywhere in the world.

Clinical trials – complying with demand and recent EU regulation

In recent years, Portugal has experienced a significant increase in the number and scale of clinical trials conducted in various therapeutic areas. As a result, Portugal has been identified as one of the "core countries" for clinical trials.

This growth in clinical research has attracted major pharmaceutical companies to invest in Portugal, leading to the country's economic development. However, the size of the industry and the increase in research activities requires adjustments in regulatory policies.

In an effort to promote the expansion of clinical research, the government issued Order No 1739/2024 on 14 February 2024. The order outlines a series of measures aimed at enabling Clinical Research Centres within the NHS to operate with increased capacity and autonomy by adopting new organisational forms.

Clinical trials for medicinal products are regulated by the Clinical Investigation Law (Law 21/2014 of 16 April). As of 31 January 2022, these trials must comply with the newest EU Regulation on Clinical Trials, which introduced the Clinical Trials Information System (CTIS). This system will be used for submitting, examining and overseeing all clinical trials in the European Union.

Starting from 31 January 2023, new submissions for clinical trials in the EU and the European Economic Area must be submitted under the CTIS. By 31 January 2025, all ongoing trials must be transferred to the CTIS. INFARMED (the National Authority of Medicines and Health Products) has recently urged all ongoing clinical trial sponsors to transition to the CTIS as soon as possible, to ease the process and avoid any suspensions or trial interruptions.

Patient protection – information on the prices of medicines

A new law, Decree-Law 128/2023, was issued in December 2023, amending the Legal Regime of Medicines for Human Use (Decree-Law No 176/2006, of 30 August), bringing significant changes to the information about medicine prices. The primary objective of this decree-law is to enhance the information provided to users when dispensing medicines by eliminating the reference to the retail price (PVP) on the packaging, which has been found to be of little importance and challenging to comprehend.

According to the law's recitals, the PVP appearance on the packaging does not usually reflect the actual cost of the medicine to the citizens, as there are too many variables that influence the final price, such as reimbursement and its varied application criteria. For that reason, eliminating the PVP on the packaging is intended to avoid providing misleading information and to avoid outdated information resulting from price changes. Instead, the government encourages other methods of accessing the pricing information, such as it being given by the pharmacies to the patient at the time of dispensing the medicine and being available by consulting the medicine search functionality of the INFARMED database.

For that reason, medicine packs distributed to pharmacies after 2 January 2024 no longer need to mention the PVP.

Environmental, social and governance (ESG) in the life sciences sector

Life sciences companies, including those based in Portugal, are facing increased scrutiny regarding their ESG policies.

With regard to the upcoming legislative elections in Portugal (March 2024) and the pressing need for sustainable practices in the health industry, the Portuguese Council for Health and Environment expressed its concerns and proposals the political parties should include in their agendas, issuing a public Manifest in January 2024. Such proposals include the promotion of a national strategy for the implementation of good sustainability practices, particularly in terms of energy efficiency, the use of water and transport, and the waste of packaging and materials.

To that end, efforts have been made to promote sustainable practices in the life sciences industry. The Champalimaud Foundation signed a partnership with Philips to halve its CO2 emissions, and partnered up with the Greenvolt Group to achieve carbon neutrality. Using the energy generated by solar panels at the Champalimaud Centre and shared by other Greenvolt Communities, the foundation aims to be the first healthcare institution in the world to consume only clean energy within five years.

Intellectual Property Litigation and Life Sciences

Unified Patent Court (UPC)

In 2023, Europe entered a new chapter in patent litigation with the launch of the new unitary patent (UP) and the establishment of the UPC on 1 June. This milestone represents a pivotal moment aimed at simplifying patent disputes and fostering commercial certainty for businesses across various sectors. The life sciences sector has become a significant focal point of litigation and attention in these early months following the entry into force of the UPC.

One notable trend in the early stages of the UPC's operation is the heightened involvement of big life sciences companies in patent disputes brought before the court, namely between big pharma corporations Amgen and Sanofi. Despite some initial predictions that those players would stay out of the big field in the first stages, the prominence of the life sciences sector in the UPC litigation underscores the importance of intellectual property protection in pharmaceuticals, biotechnology and medical devices.

Another interesting trend involves the use of protective letters, a legal figure not found in Portuguese law but allowed in the UPC under Rule 207 of the UPC's Rules of Procedure. A protective letter is typically submitted when an individual or entity anticipates the possibility of facing an application for provisional measures as a defendant in the UPC. Essentially, it serves as a proactive defence statement filed in advance to mitigate potential legal risks. This proactive action allows parties to address concerns regarding imminent legal proceedings and assert their position before the court. The increasing use of protective letters indicates a proactive strategy by companies preparing for a potential rise in preliminary injunctions within the UPC.

This trend highlights the importance of protecting intellectual property rights and proactively addressing potential disputes in patent law's constantly changing landscape, particularly in the UPC arena, with all its implications.

Furthermore, during the seven-year transitional period following the entry into force of the UPC Agreement, parties have flexibility in choosing the jurisdiction for actions involving classical European patents (excluding those with unitary effect). Article 83(1) of the UPC Agreement allows parties to bring such actions before national courts or other competent national authorities. Consequently, some companies are opting to pursue actions in national courts to avoid the potentially high litigation fees associated with the UPC.

This strategic decision, which has been embraced by several pharmaceutical companies in Portugal, underscores a practical approach aimed at navigating the transitional period effectively, weighting cost factors and litigation strategies within the evolving landscape of patent enforcement.

Although no lawsuits have yet been filed in the Lisbon Local Division, the judicial officer is actively handling cases in all divisions of the UPC. This highlights the efficiency and cohesion of the UPC's organisational structure, which operates like a well-oiled machine. The UPC's judicial officers' involvement in different divisions allows for streamlined patent litigation services across Europe, highlighting the importance of the organisational structure.

The Supplementary Protection Certificate (SPC) waiver

The process of developing medications and plant protection products involves significant research and investment, which highlights the need for additional protection for the underlying patent. The SPC is a specific right established to fulfil this purpose. It prolongs the exclusivity period of the pharmaceutical or plant protection product covered by a patent to make up for the time required to obtain initial administrative marketing authorisation.

The SPC Waiver Regulation of 2019 (Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019) has been introduced as an attempt to balance the threat of unfair monopolies and access to the market with the compliance of intellectual property rights. The regulation has allowed other companies (as generics) to export and store protected products before the certificate's expiry, provided that they notify the Industrial Property Authority and the SPC holder.

The SPC waiver legislation allows manufacturers of generics and biosimilars who produce their products outside the EEA and launch them right after the expiry of SPC protection to establish supply chains within the EEA during the SPC period of validity in order to prepare for the immediate launch after expiry.

However, recent trends of compliance with the SPC waiver Regulation might be surpassing the initial purpose for which it was designed. A recent Review of the SPC Manufacturing Waiver was published by Medicines for Europe (which represents the European generic, biosimilar and valued added pharmaceutical industries) concerning the recent integration of the waiver system.

Many companies are now using SPC waivers, and more than half of them have submitted at least one notification since the legislation was introduced. However, some companies are hesitant to manufacture due to concerns about potential "frivolous and abusive" litigation from SPC holders.

The report highlights various tactics used by SPC holders, including:

- initiating litigation based on hypothetical patents in export markets like the US; and
- misusing confidential data obtained through the SPC waiver system.

These actions can deter legitimate manufacturing activity under the SPC waiver system because of the potential cost of litigation.

For those reasons, the Report calls for urgent action to address abusive tactics against companies that are using the SPC waiver system. Measures proposed in the report aim to inhibit SPC holders from discouraging legitimate manufacturing activity under the SPC waiver system. This could involve interventions by courts, the European Commission and national competition authorities to uphold fair competition and protect manufacturers against abusive litigation.

Conclusion

Portugal's life sciences industry has been rapidly evolving in recent years, driven by a combination of factors such as innovation, societal demands and regulatory changes. The country is increasingly establishing itself as a hub for biotechnological advancement and clinical research, with a growing number of companies and institutions conducting cutting-edge research in fields such as genetics and biomedicine.

However, despite the sector's growth, there are still several challenges that need to be addressed, such as regulatory compliance, as the industry must adhere to strict regulations and guidelines to ensure safety and efficacy.

Sustainability is becoming an increasingly pressing issue, as the industry seeks to balance economic growth with environmental and social responsibility. This requires not only the adoption of eco-friendly technologies and practices but also a commitment to transparency, inclusivity and social impact.

To overcome these challenges and sustain its growth, Portugal's life sciences sector has been incorporating technological innovations such as AI and cloud-based data storage, which have the potential to transform the industry by enabling faster, more accurate data analysis, and improving patient outcomes. However, it is crucial that these technologies are implemented in a way that prioritises ethical considerations, regulatory compliance and sustainability imperatives.

Ultimately, Portugal's life sciences sector has the potential to make significant contributions to global healthcare and scientific progress.

SERBIA

Law and Practice

Contributed by:
Bisera Andrijašević and Anja Gligorević
BDK Advokati

Contents

BDK Advokati is a full-service commercial law firm for corporate, institutional and high net worth clients with multiple specialisations and with offices in Serbia, Montenegro, and Bosnia and Herzegovina. The firm advises clients on deals, supports and represents them in contentious situations and provides legal advice in support of their business. The firm's focus is on prime expert work and complex cross-border deals, but it is also able to work on bread-and-butter matters in an efficient manner due to institutionalised know-how and organised processes. BDK Advokati's Life Sciences and Healthcare Group has assembled lawyers with different areas of expertise of relevance to these industry sectors, and has advised leading multinational companies on commercial, competition, data protection, disputes, employment, M&A and industry regulations. Present and former clients from the industry include Aspen Pharma, Biotest AG, GlaxoSmithKline, Hoffmann-La Roche, Mylan, Hemofarm and Farmalogist.

Authors

Bisera Andrijašević is a partner and head of BDK Advokati's life sciences and healthcare sector, with a focus on regulatory issues. She is based in the Montenegrin office, and participates in work across the firm's three jurisdictions. She also has extensive experience in competition law matters. Bisera is a member of the AmCham Healthcare Committee. She is a frequent contributor to BDK Advokati's Competition Law Blog. She obtained LLM degrees from the University of Hamburg and the Erasmus University in Rotterdam and an MA from the University of Bologna. Bisera also completed studies at the European Pharma Law Academy 2017 at Downing College, Cambridge. She is fluent in English, conversant in French and reads Italian.

Anja Gligorević is an associate in the intellectual property and data protection departments of BDK Advokati. She obtained her LLB from the University of Belgrade in 2019 and is currently pursuing an LLM in intellectual property law. Anja is fluent in English and possesses intermediate knowledge in German.

Contributed by: Bisera Andrijašević and Anja Gligorević, **BDK Advokati**

BDK Advokati

Bulevar kralja Aleksandra 28
11000
Belgrade
Serbia

Tel: +381 11 3284 212
Email: office@bdkadvokati.com
Web: www.bdkadvokati.com

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Applicable Legislation

Pharmaceutical products in Serbia are regulated in the Medicines and Medical Devices Act of 2010 (as amended) (Medicines Act). The sections of the Medicines Act regulating medical devices have ceased to apply and medical devices are now regulated separately in the Medical Devices Act of 2017. A considerable number of by-laws regulate in more detail different matters governed by the Medicines Act and Medical Devices Act.

Competent Bodies

Competences for implementation and enforcement of pharmaceutical and medical devices legislation are shared between three governmental bodies:

- the Agency for Medicines and Medical Devices (ALIMS), the regulatory body tasked with enforcement of pharmaceutical and medical devices legislation for pharmaceuticals for human and veterinary use. The ALIMS is an independent regulatory body established by law;
- the Ministry of Health has certain competences with respect to the area of pharmaceuticals and medical devices for human use, particularly with respect to licensing and administrative oversight; and
- the Ministry of Agriculture, Forestry and Water Management is competent for matters concerning the pharmaceutical products intended solely for veterinary use.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Right to Appeal

Decisions of the ALIMS can be challenged before the competent ministry – ie, the Ministry of Health with regard to medicines and medical devices for human use, and the Ministry of Agriculture, Forestry and Water Management with regard to medicines for veterinary use.

A party to the proceeding before the ALIMS, or any person whose rights, obligations or legal interest may be affected by the outcome of the proceedings, may submit an appeal. An appeal may also be submitted if the ALIMS fails to adopt a decision within the statutory deadline.

Appeal Procedure

A party may submit an appeal against the ALIMS's decision to the competent ministry through the ALIMS. The deadline for submitting an appeal is 15 days from adoption of the first-instance decision, or, in the case of failure to adopt a decision, within a year from the expiry of the statutory deadline. Decisions of the competent ministry upon appeal, as well as first-instance decisions of the ministries in the matters from their competence, are final and may be challenged only before the Administrative Court.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Classification of Pharmaceuticals

Pharmaceuticals are classified into pharmaceuticals for human use and those for veterinary use. Furthermore, pharmaceutical products are classified into (i) prescription-only, and (ii) over-the-counter (OTC) pharmaceuticals. The ALIMS carries out the classification in the process for issuing marketing authorisations. Prescription-only and OTC pharmaceuticals are subject to different regimes with respect to pricing, advertising, dispensing and sale.

Classification of Medical Devices

Medical devices are classified into (i) general medical devices, (ii) in vitro diagnostic medical devices, and (iii) active implantable medical devices.

General medical devices are classified according to the degree of risk for the users into:

- Class I – medical devices with a low degree of risk for the user;
- Class IIa – a low-to-medium degree of risk for the user;
- Class IIb – a medium-to-high degree of risk for the user; and
- Class III – medical devices with a high degree of risk for the user.

A notified body carries out the classification of medical devices. As an exception, the manufacturer classifies class I medical devices and others as in vitro medical devices.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical Trials for Pharmaceuticals

The Medicines Act is the principal piece of legislation regulating clinical trials of pharmaceuticals. Additionally, the Healthcare Act of 2019 and the Rulebook on Clinical Trials for Medicines for Human Use (2022, as amended), set out detailed rules related to ethics committee approval and performance of clinical trials. As of October 2023, phase I (I, Ia, and Ib) clinical trials in Serbia may only be conducted in public healthcare institutions.

Clinical trials of pharmaceuticals are conducted in accordance with the Ministry of Health's guidelines on Good Manufacturing Practice (2017), Good Laboratory Practice (2008), and Good Clinical Practice (2017).

Clinical Trials for Medical Devices

The Medical Devices Act and the Rulebook on Clinical Trials for Medical Devices of 2018 (as amended) regulate clinical trials for medical devices.

Clinical trials of medical devices are conducted in accordance with the guidelines of the Good Clinical Practice.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Clinical Trials Subject to Approval

Sponsors must request simultaneous authorisations for conducting a clinical trial from the ALIMS and the Ethics Committee of Serbia, a government-appointed expert body that takes care of the provision and implementation of healthcare at the national level, in the case of:

- clinical trials for medicines which do not have a marketing authorisation or for which a different use from the one prescribed in the approved summary of product characteristics is proposed, or medical devices for which a conformity assessment has not been carried out; and
- an interventional post-marketing clinical trial, where the medicinal product is applied in accordance with the conditions prescribed in the marketing authorisation, but requires additional diagnostic procedures, as well as the monitoring procedures defined by the clinical trial protocol, or where a medical device has been subject to conformity assessment, but the clinical trial is conducted for a purpose that is absent from the conformity assessment.

Clinical Trials Subject to Notification Only

Sponsors must only notify the commencement of a trial to the ALIMS if they wish to conduct a non-interventional post-marketing clinical trial of a pharmaceutical or a medical device in accordance with an approved summary of product characteristics of a pharmaceutical for which a marketing authorisation has already been issued, or a clinical trial of a medical device for which a conformity assessment has already been carried out.

2.3 Public Availability of the Conduct of a Clinical Trial

Clinical Trials Database

Basic information on all clinical trials conducted at a given moment in Serbia are publicly available within the database kept by the ALIMS on the e-government Portal. The information includes the date and number of the relevant decision on approval of the clinical trial, the protocol number, the names of the sponsor and the client, and the title of the trial, as well as its basic description.

Publication of Clinical Trial Results

Sponsors of clinical trials do not have an obligation to make the results of clinical trials publicly available. They must submit to the ALIMS, within one year of completion of the clinical trial, the report containing detailed results, both positive and negative, obtained through the trial.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no restrictions for using online tools to support clinical trials, either for recruiting or monitoring purposes. Sponsors must, however, undertake all adequate measures to provide information to, and secure the consent of, the subjects and to protect their personal data.

2.5 Use of Data Resulting From Clinical Trials

The Serbian Data Protection Commissioner has long held that data on a patient participating in a clinical trial is personal data, as long as a specific individual can be identified from such data. The same conclusion also applies under the new Data Protection Act (2018), which is an almost verbatim copy of the GDPR.

The Commissioner has yet to express its opinion on the legal basis for the data processing concerning the resulting data, including for dis-

closing the data – ie, transferring them to third parties or affiliates. The Commissioner might consider that reliance on consent as the legal basis for any type of processing of data in the context of clinical trials is unavailable because consent could not be considered as freely given. Therefore, one or more of the following legal grounds for the processing could be employed:

- processing is necessary for compliance with a legal obligation to which the controller is subject;
- processing is necessary for the performance of a task carried out in the public interest; or
- processing is necessary for the purposes of the legitimate interests pursued by the controller, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.

The resulting data may be transferred abroad, under the conditions similar to those from the GDPR Articles 44 et seq. Importantly, the Data Protection Act does not recognise the model clauses of the European Commission as a transfer tool eliminating the need to seek and obtain transfer authorisation. Instead, the law authorises (in Article 45(11)) the data protection authority to adopt controller-to-processor standard contractual clauses. The authority adopted these clauses in January 2020. Controller-to-controller standard contractual clauses are still missing in Serbia because the Data Protection Act in the current iteration does not authorise the data protection authority to adopt them.

2.6 Databases Containing Personal or Sensitive Data

Creation of a database with the resulting data from the clinical trials would require carrying out a data protection impact assessment, in line with the Decision of the Serbian Data Protection Commissioner on the list of categories of data processing activities for which a data protection impact assessment must be carried out.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

An assessment of whether a product should be classified as a pharmaceutical or as a medical device is carried out by the ALIMS in the process of issuing of a marketing authorisation for a pharmaceutical product or registration of a medical device. The Medicines Act and the Medical Devices Act contain the criteria for classification.

The main criterion for differentiating between pharmaceuticals and medical devices is the following: pharmaceuticals are applied to humans or animals with the intention to restore, improve or modify physiological function by pharmacological, immunological or metabolic action, or by setting up a medical diagnosis; however, medical devices do not fulfil their principal intended purpose in or on the human body by pharmacological, immunological or metabolic means, but the medical device may be assisted in its function by such means.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Biological medicinal products must meet the same quality, safety and efficacy criteria as other medicinal products to receive marketing authorisation. Biosimilars, however, may benefit from the short-form procedure for the granting

of marketing authorisation, equivalent to the one available to generic medicinal products.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

Validity and Renewal of Marketing Authorisation

Marketing authorisation is valid for five years. It may be renewed based on the reassessment of the risk/benefit ratio of the medicine. If, on the basis of the available pharmacovigilance data, the ALIMS determines that a pharmaceutical is safe, it grants a permanent marketing authorisation. In the event that the ALIMS determines that the pharmaceutical product is not safe, it will refuse to grant a permanent authorisation. Instead, the ALIMS will decide on whether to renew an authorisation for an additional period of five years. A marketing authorisation may be renewed for an additional period of five years only once. If the ALIMS still has justified doubts with respect to product safety, it will terminate the already issued marketing authorisation.

Revoking of a Marketing Authorisation

The ALIMS will revoke a marketing authorisation if it determines that the product is not safe for the life and health of humans and animals. The ALIMS will revoke the marketing authorisation if:

- the medicinal product is harmful under normal conditions of use;
- the medicinal product has no therapeutic efficacy;
- the risk-benefit ratio is not favourable under typical application conditions;
- the qualitative and quantitative medicinal product composition does not match the declared composition of the medicinal product;
- the marketing authorisation was issued on the basis of incomplete or false information, or if data is not amended in accordance with the law;
- the marketing authorisation-holder no longer meets the prescribed requirements; and/or
- the medicinal product was not marketed in Serbia for three years from the date of marketing authorisation issuance or was withdrawn from the market in Serbia for three consecutive years.

The ALIMS may vary, suspend, or revoke a marketing authorisation on the basis of data on adverse drug reactions collected within the scope of its pharmacovigilance activities.

Medical Devices

If the Ministry of Health determines that a medical device constitutes an unacceptable risk to public health and/or safety, or does not meet the statutory requirements, the Ministry may order the manufacturer or its authorised representative to take all appropriate and justified preventive or corrective measures. The Ministry may also prohibit or restrict the placing of a medical device on the market, set specific requirements for the placement of a medical device on the market, or order the withdrawal of a medical device from the market.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

Pharmaceuticals

The Medicines Act and a series of implementing by-laws govern the granting of a marketing authorisation. The ALIMS is the competent authority for issuing marketing authorisations. A medicinal product may be granted a marketing authorisation after undergoing pharmaceutical (pharmaceutical, chemical, and biological),

pharmaco-toxicological and clinical trials and provided that it has the required quality, safety and efficacy. The ALIMS conducts a formal review of an application for marketing authorisation within 30 days. The substantive review must be completed within 210 days. If the ALIMS requests additional documents from the applicant, the deadline is paused until submission of those documents. There is also an accelerated procedure for obtaining a marketing authorisation, for a medicinal product which obtained a marketing authorisation in accordance with the EU centralised procedure, and for medicines for human use of utmost importance for public healthcare. The accelerated procedure may last no longer than 150 days from receipt of a complete application.

Medical Devices

Medical devices are not subject to marketing authorisation. Medical devices may be placed on the market or in use if they comply with essential requirements set out in the Medical Devices Act regarding conformity assessment, labelling and supporting documents, if they are properly procured, installed and maintained, and used in accordance with their purpose. A manufacturer or its representative must submit the application for registration of a medical device to the ALIMS before placing it on the market or putting it to use. The Medicines Act contains a limited list of medical devices which do not need to be registered in order to be placed on the market or put to use (ie, medical devices for approved clinical trials or research and development, custom-made devices, devices for the personal use of a patient previously treated abroad, devices imported on a temporary basis for medical fairs, and those manufactured in medical institutions for in-house use).

Variations

A request for a variation is submitted to the ALIMS. Marketing authorisation-holders are obliged to:

- report IA-type variations within 12 months from the moment of application ("do and tell" procedure);
- report IAIN variations without delay following their application for the purpose of continuous monitoring of the medicinal product;
- request the ALIMS's approval for IB-type and type-II variations before their application ("tell, wait and do" procedure); and
- submit a new request for marketing authorisation for variations related to changes of the active ingredient or changes in strength, pharmaceutical form, or manner of application of the medicine, and for variations of veterinary medicines for animals used in human alimentation.

The ALIMS conducts a formal assessment of the application within 15 days from the day the application and the substantive review within 90 days from the day when the application is deemed complete. The pharmaceutical product must be marketed in accordance with the approved variation at the latest within 12 months from the delivery of the ALIMS's act on approval of the variation.

Transfer of a Marketing Authorisation

A marketing authorisation may be transferred to a new marketing authorisation-holder at the request of the existing one submitted to the ALIMS. The ALIMS will assess whether the prospective new holder meets the requirements prescribed by the law. The ALIMS conducts a formal assessment of the application within 15 days from the day of the application and the

substantive review within 60 days from the day when the application is deemed complete.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

General Conditions

An importer may submit to the ALIMS a request for importation of a pharmaceutical for which a marketing authorisation was not issued in Serbia if:

- there is no registered pharmaceutical of the same international non-proprietary name (INN), strength, pharmaceutical form, and packaging size on the market in Serbia;
- the pharmaceutical is intended for treatment of rare diseases in humans;
- it is necessary to ensure sufficient quantities and types of a pharmaceutical in the case of epidemics, natural disasters, or other emergency situations; or
- when the safe provision of healthcare is impeded, meaning when there are insufficient quantities and types of medicines on the market for which a marketing authorisation has been issued due to production or distribution problems, if in Serbia there are insufficient quantities of a medicine with the same INN, strength, pharmaceutical form, and packaging size as the medicine for which an import request has been submitted.

Compassionate Use Programme

In addition to the import of unregistered pharmaceuticals under the general conditions previously described, import is also permitted on the basis of a compassionate use programme. The purpose of such a programme is to treat specific patients or a group of patients who are afflicted by life-threatening diseases such as AIDS, cancer and other malignant or auto-immune diseases. Import is organised as a donation or humanitarian aid to a health institution, provided that such pharmaceuticals are not subject to clinical trial in Serbia at the moment of the submission of request for import, and provided that they:

- are undergoing an advanced stage (Phase III) of clinical trial procedure in an EU country or in a country with similar requirements as Serbia regarding issuance of a marketing authorisation;
- have completed a clinical trial procedure in that country;
- are currently subject to a centralised marketing authorisation procedure in the EU; or
- have received a marketing authorisation in the EU centralised procedure.

Exceptionally, a patient or a group of patients who are not eligible to participate in the ongoing clinical trial for that medicinal product in Serbia may receive a donation or humanitarian aid in the form of unregistered pharmaceuticals or registered pharmaceuticals for an unregistered indication, which are at that time subject to clinical trial in Serbia.

Import of Unregistered Medical Devices

The ALIMS may also authorise the import of a medical device not registered in Serbia. This is permissible if that import is intended for a particular patient or group of patients, or comes as a donation or humanitarian aid, or the subject-matter of the import is a medical instrument for scientific research or for emergency situations. In order to be imported, these medical devices must have undergone a conformity assessment.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

Pharmacovigilance of Medicinal Products

In the post-marketing phase, marketing authorisation-holders must ensure continuous monitoring of adverse drug reactions to a pharmaceutical product (pharmacovigilance), namely:

- the continued monitoring of adverse drug reactions (ADRs), and have a full-time employee with adequate qualifications responsible for pharmacovigilance;
- keep records on all suspected ADRs notified in Serbia, EU countries or any third country, and provide the ALIMS with electronic reports;
- keep records of all suspected serious ADRs reported by health or veterinary professionals, or records of ADRs that MAHs can reasonably be expected to be aware of, and to report this information promptly to the ALIMS, no later than 15 days following the receipt of information;
- submit to the ALIMS periodic drug-safety reports at six-month intervals if the marketing authorisation was conditional or under special circumstances; and
- submit periodic drug-safety reports every six months for a period of two years following the placing of the pharmaceutical on the market, then annual reports for another two years and finally submit reports at three-year intervals.

Vigilance of Medical Devices

A manufacturer of medical devices or its authorised representative must employ a person responsible for vigilance and continuously monitor the medical device on the market, with the aim of identifying any need for corrective or preventive measures.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

The Agency and the competent Ministries must treat as confidential all the data in the documentation enclosed within an application for the issuance of a marketing authorisation, variation or a renewal. This obligation applies in particular in relation to trade secrets – ie, when the following cumulative conditions are met:

- the data is confidential – ie, not generally known or easily available to persons usually dealing with that kind of information;
- the data has commercial value due to its confidentiality, during the period of confidentiality; and
- an applicant for a marketing authorisation, variation, and/or renewal, under the circumstances, takes reasonable measures to keep that data confidential.

Information from the documentation submitted during the procedure of obtaining a marketing authorisation, as well as in other procedures handled by the Agency and/or relevant Ministries, may only be disclosed to third parties with the consent of the applicant, or if the data is already available to the general or professional public for the purpose of providing information necessary for use or handling of a pharmaceutical or a medical device, or required for the protection of health in humans and animals.

3.8 Rules Against Illegal Medicines and/or Medical Devices

Pursuant to the Medicines Act and Medical Devices Act, it is prohibited to manufacture or sell counterfeit pharmaceuticals and medical devices. If any such products are detected on the market, the competent ministry will prohibit

their sale and order recall at the proposal of the ALIMS.

In 2019, Serbia signed the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME).

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

If certain goods are suspected of infringing intellectual property rights, customs authorities may, upon request or ex officio, suspend the release of goods or retain the goods. Customs authorities will request that the owner of the goods and the right-holder make a declaration about the potential infringement. The right-holder may initiate court proceedings against the alleged infringer, and in that case the goods will remain confiscated until the court renders a decision, or the right-holder may give permission to the customs authorities to destroy the goods, in which case the goods will be destroyed, provided that the owner of the goods consents to, or does not oppose, the destruction.

4. Manufacturing of Pharmaceuticals and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

Manufacturing of Pharmaceuticals

The manufacturing of pharmaceuticals is subject to a licence issued by the Ministry of Health to legal entities. The application for a manufacturing licence must contain information and documents regarding the location and premises of the manufacturing site, equipment, personnel, medicines to be produced, relevant procedures, as well as other information required by the law. The Ministry issues a licence for a particular manufacturing site and certain forms of pharmaceutical manufactured at that site. The licence may include an entire manufacturing process or only a part of the process. The licence is valid for an indefinite period.

Manufacturing of Medical Devices

Manufacturers of medical devices may be both legal entities and individuals. A manufacturing licence is necessary only for class I medical devices (other than Is and Im class), other in vitro diagnostic medical devices, medical devices for which no conformity assessment has been performed, those not covered by the sign of conformity, custom-made devices for a particular patient, and medical devices for clinical trials, as well as a system or a kit. The Ministry of Health issues a manufacturing licence for medical devices, which is valid for five years.

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

Wholesale of medicines and medical devices includes purchase, storage, distribution, imports and export. A wholesale licence is issued by the Ministry of Health for an indefinite period for pharmaceuticals, and for medical devices for a period of five years.

The exception from obtaining of a wholesale licence applies to (i) manufacturers of medicines for products from their production programme, (ii) manufacturers of medical devices with a registered seat in Serbia, who must obtain a manufacturing licence for medical devices from their

production programme, and (iii) entities performing only import or export activities on behalf of and for the account of a medicines wholesale licence-holder.

Applicants for a wholesale licence must provide information and documents regarding the legal entity, location and premises, supply territory, products for which the wholesale licence is sought, personnel, equipment, a plan for an urgent withdrawal of products from the market, as well as the other information of relevance for the issuance of the wholesale licence.

5.2 Different Classifications Applicable to Pharmaceuticals

See **1.3 Different Categories of Pharmaceuticals and Medical Devices** relating to different categories of pharmaceuticals.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The import and export of pharmaceutical and medical devices in Serbia are governed by the Medicines Act and the Medical Devices Act, respectively. Import and export constitute the wholesale of medicines and medical devices and as such are additionally regulated in the rule books governing the wholesale of medicines and medical devices.

Depending on whether the product is intended for human or veterinary use, the Ministry of Health or the Ministry of Agriculture issues a pharmaceutical wholesale licence. The ALIMS issues (i) opinions on the import of cell or tissue samples for clinical trials' procedures of medicinal products, (ii) approvals for the import of medicines for clinical trials, and (iii) approvals for the import of medicines without a marketing authorisation.

Customs officials check if all the conditions are met in each case.

6.2 Importer of Record of Pharmaceuticals and Medical Devices

An importer of record for pharmaceuticals or medical devices may be a legal person with a relevant wholesale licence.

Furthermore, a pharmaceutical or a medical device manufacturer may import products from its production programme, raw materials and substances for production, interim products, and semi-finished products, in accordance with the manufacturing licence, medicinal products marketing authorisation, or a subcontracting agreement.

Manufacturers of medical devices with a registered seat in Serbia who do not need a manufacturing licence must obtain a wholesale licence for medical devices from their production programme.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

The import and export of pharmaceuticals and medical devices is subject to a prior issuance of a medicinal product wholesale licence, subject to exceptions described under **6.2 Importer of Record of Pharmaceuticals and Medical Devices**.

A legal entity that performs only the activities of import and export may perform these activities without a medicinal product wholesale licence if it conducts the import and customs clearance activities on behalf of and for the account of a wholesale licence-holder to the site of the goods' free marketing, in accordance with the customs regulations.

Generally, only medicinal products with a valid marketing authorisation and medical devices registered in the ALIMS's registry of medical devices may be imported. Exceptionally, the ALIMS may approve import of medicinal products without a marketing authorisation in Serbia or unregistered medical devices under conditions prescribed for compassionate-use programmes, donation or humanitarian aid, or the emergency situations described in **3.5 Access to Pharmaceuticals and Medical Devices ?Without Marketing Authorisations**.

Persons entering or leaving Serbia may carry medicinal products in the amount not exceeding their six-month requirement within one calendar year, for their personal usage or for an animal travelling with them, depending on the type and length of the underlying illness. They have to provide to the Customs Authority the approval of a competent Serbian ministry for bringing in or carrying out medicinal products for personal use.

The transfer of medicinal products across the border in the amount not exceeding the 15-day requirement of an individual is not subject to any approval.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Although Serbia is not yet an EU member state, nor a member of the World Trade Organization (WTO), Serbia has, to a large extent, harmonised its legislation with the EU acquis and WTO agreements. Therefore, non-tariff restrictions are rare and imposed only in particularly justified situations, in line with the general principles of the EU and WTO to limit the use of non-tariff restrictions.

Non-tariff regulations and restrictions are imposed based on the Harmonized Tariff Schedule (HTS) Code. The products that are subject to those restrictions (usually quotas) are listed for example in specific international agreements which Serbia has concluded.

6.5 Trade Blocs and Free Trade Agreements

Serbia is a party to the Stabilisation and Association Agreement with the EU, the Central European Free Trade Agreement, and the Agreement with EFTA, as well as a number of bilateral free-trade agreements.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

The prices of pharmaceuticals are controlled by the government only with respect to prescription-only pharmaceuticals. The government determines the criteria for the pricing of pharmaceuticals, and calculates their maximum prices at the joint proposal of the ministries competent for health and trade. The Ministry of Health calculates the maximum wholesale price for prescription-only pharmaceuticals.

The pricing of prescription-only medicines is governed by the Medicines Act, the Decree on Criteria for Forming of Prices of Prescription-

Only Pharmaceuticals for Human Use, and the Decision on Maximum Prices of Prescription-Only Pharmaceuticals for Human Use. Prescription-only pharmaceuticals for which the government did not determine the maximum wholesale price may not be placed on the market.

Once the government decides on the maximum permitted wholesale price of the pharmaceutical, marketing authorisation-holders may apply to include the pharmaceutical into the positive reimbursement list of medicines ("Positive List"), to be prescribed and issued at the expense of the compulsory health insurance. Wholesalers of pharmaceuticals, as well as pharmacies, must align the prices of pharmaceuticals that they have in stock with the maximum prices determined by the government on the same day as the relevant decision on maximum prices enters into force.

However, marketing authorisation-holders are free to determine the prices of over-the-counter medicines and must only notify the Ministry before March 1st of the current year of the price for the previous year.

7.2 Price Levels of Pharmaceuticals or Medical Devices

The Ministry of Health calculates the maximum wholesale price for prescription-only pharmaceuticals based on a number of criteria. One of these criteria is price parity – ie, the comparable wholesale prices of pharmaceuticals in reference countries, namely, Slovenia, Greece and Italy, and the current wholesale price in Serbia, in addition to other applicable criteria.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

For the cost of a pharmaceutical to be reimbursed, the product must be included in the Positive List. The general criteria for adding a pharmaceutical to the List are, as follows:

- pharmaco-therapeutic justification of the pharmaceutical;
- pharmaco-economic justification of the pharmaceutical; and
- financial resources provided by the annual financial plan of the National Health Insurance Fund.

In cases when there are not sufficient resources to include in the Positive List all pharmaceuticals which comply with the general criteria, the National Health Insurance Fund further considers two special factors: (i) the existence, if any, of a managed entry agreement, and (ii) the priority for adding the pharmaceutical to the list according to the following criteria:

- the lack of a pharmaceutical from the same pharmaco-therapeutic group on the Positive List for a particular medical indication;
- the significance of a pharmaceutical for public health; and
- ethical aspects.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Within the scope of the process for inclusion of pharmaceuticals into the Positive List of pharmaceuticals to be reimbursed from the national health insurance, the Central Medicines Commission established by the National Health Insurance Fund conducts the health technology assessment of medicines when reviewing the

applications for inclusion of pharmaceuticals on the List.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Dispensing and sale of pharmaceuticals is regulated only with respect to prescription-only medicines. The ALIMS decides whether a medicine is to be dispensed only on prescription in a marketing authorisation procedure. Prescriptions and dispensing of pharmaceuticals are regulated in the Rulebook on Form and Content of Medical Prescription, Manner of Issuing and Prescription of Pharmaceuticals. Healthcare professionals are obliged to observe the recommendations from Good Practice in Prescribing of Pharmaceuticals.

A pharmacy may replace the prescribed brand-name medicine with its generic equivalent only if the patient consents after being adequately informed by the pharmacist, and under the condition that the physician did not prohibit replacement on the prescription.

8. Digital Healthcare

8.1 Rules for Medical Apps

There are no special rules governing medical apps in Serbia. Medical devices are defined in the Medical Devices Act as any instrument, apparatus, appliance, software, implant, reagent, material and other product used alone or in combination, including software provided by the manufacturer for diagnostic or therapeutic purposes and which is software support that is necessary for its proper use in people intended by the manufacturer, and is used for:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation or compensation of injury or disability;
- investigation, replacement or modification of the anatomy or physiological or pathological process and state;
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations;
- control or support of conception; and
- products intended for cleaning, disinfection or sterilisation of medical devices.

Therefore, a medical app may be classified as a medical device, depending on its intended use. The ALIMS has the authority to determine if a medical app is a medical device, on a case-by-case basis.

8.2 Rules for Telemedicine

Telemedicine is not regulated in Serbia. In the context of the COVID-19 health crisis, the Ministry of Health introduced an e-health portal, where patients can fill out a questionnaire with regard to their symptoms and receive instructions on the steps to take, and can enter their contact information to be contacted by a physician for an appointment.

Conditions for the introduction of a wider variety of telemedicine services should be fulfilled through the implementation of a proposed Programme of Digitalisation of the Health System of the Republic of Serbia for 2022-2026.

8.3 Promoting and/or Advertising on an Online Platform

There are no special rules applicable to online advertising. Advertising of medicines and medical devices is regulated in the Medicines Act and Medical Devices Act, respectively, while the relevant by-laws provide detailed rules.

In addition, in 2014, the Serbian Association of Manufacturers of Innovative Drugs (INOVIA) adopted the Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (the INOVIA Code).

8.4 Electronic Prescriptions

Electronic prescriptions in Serbia are regulated in the Rulebook on Form and Content of Medical Prescription, Manner of Issuing and Prescription of Pharmaceuticals. Prescription of medicines is conducted through an integrated health information system in electronic form, and prescriptions in paper form may still be issued exceptionally.

8.5 Online Sales of Medicines and Medical Devices

Online sales of medicines and medical devices are prohibited in Serbia.

8.6 Electronic Health Records

A new Health Documentation and Health Records Act (2023) (HDHRA) was adopted in October 2023, in line with Serbia's healthcare digitalisation strategy. HDHRA, among other issues, regulates establishment, organisation, management, and development of an integrated health information system – RIZIS, which will enable the keeping of electronic health documents and records by healthcare institutions, private practices, and other legal entities obliged to keep health records. The records must be kept in electronic form, and only exceptionally and temporarily in paper format when there is no possibility for keeping them in electronic form (such as technical difficulties, malfunctions, natural disasters, and the like).

Additionally, the HDHRA prescribes the keeping of a so-called electronic medical dossier (e-dossier). According to the law, the e-dossier is kept within the Integrated Health Information System of the Republic of Serbia and it contains the assembled data important for the patient's long-term health status which derives from the patient's health records and health insurance records kept in electronic format. Only competent healthcare professionals may access the dossier, immediately prior to the provision of healthcare services. Patients are entitled to access their data from the dossier.

The Serbian Data Protection Act considers health-related information as sensitive data (Article 17 of the Act). The processing of sensitive data is permissible if the data controller may rely on a legal basis for processing of any category of personal data, sensitive or not, and additionally on a statutory exception from the general prohibition of the processing of sensitive data.

It is permitted to transfer and store sensitive data of patients on cloud platforms. The Serbian Data Protection Commissioner would typically consider a cloud platform to be a data processor. Therefore, exporters of health-related sensitive data may use as the transfer instrument the controller-to-processor standard contractual clauses which the Data Protection Commissioner issued in January 2020.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices

In Serbia, the Patent Act (Official Gazette of the Republic of Serbia, No 99/2011, 113/2017 – other act, 95/2018, 66/2019 and 123/2021) (Patent Act) applies to all patents.

Under the Patent Act, the general patentability requirements of novelty, inventive step, and industrial application apply to all inventions, including pharmaceutical and medical device inventions.

However, there are certain exceptions to patentability of pharmaceutical inventions. A patent will not be granted in respect of methods for treatment by surgery or diagnostic methods or therapy practised directly on the human or animal body (Methods). This exception does not apply to products, in particular substances or compositions, for use in any of these methods.

9.2 Second and Subsequent Medical Uses

The Patent Act allows for the patentability of a second or subsequent medical use of a known substance or composition.

The patentability requirement of novelty does not exclude patentability of any substance or composition, comprised in the state of the art, for use in a Method, provided that its application in any Method is not comprised in the state of the art. The requirement of novelty also does not exclude patentability of that substance or composition, for any specific use in a Method, provided that such use is not comprised in the state of the art.

Provisions of the Patent Act that regulate the issue of second and subsequent medical uses are in line with the corresponding provisions of the European Patent Convention (EPC). The European Patent Office's (EPO) interpretation of these provisions is that they also apply to patent claims for treatments that draw their novelty from new dosage regimes, methods of administration, or new classes of patients (the interpretation expressed in the EPO Enlarged Board of Appeal's decision G2/08). Since the corresponding provisions of the Patent Act are modelled after the EPC, it can reasonably be expected that the Serbian Intellectual Property Office (IP Office) and courts would also allow patent claims in relation to new dosage regimes, methods of administration, or new classes of patients.

The activities that constitute infringement of second and subsequent patents of pharmaceutical products are described in **9.4 Pharmaceutical or Medical Device Patent Infringement**.

9.3 Patent Term Extension for Pharmaceuticals

The owner of a pharmaceutical patent can apply for a supplementary protection certificate (SPC).

A patent-owner can submit an SPC request to the IP Office within six months from obtaining marketing authorisation for the patented product. The SPC is valid for the period equal to the period from the date of submission of the patent application to the date of the first marketing authorisation, minus five years. The maximum duration of an SPC is five years. Once Serbia becomes a member of the European Union, it will be possible to extend the SPC for six additional months if all necessary tests are completed in the European Union in accordance with an approved paediatric research plan.

SPCs obtained as of 2 July 2022 will not confer protection against the acts of (i) making of a product protected by an SPC for the purpose of export, and (ii) making, no earlier than six months before the expiry of the SPC, of a product, for the purpose of storing the product in Serbia, in order to place that product on the Serbian market after the expiry of the SPC.

Third parties can request that the IP Office declare an SPC invalid under the same conditions prescribed for declaration of patent invalidity.

9.4 Pharmaceutical or Medical Device Patent Infringement

The following activities constitute patent infringement:

- manufacturing, offering, placing on the market, using, and importing or storing for those purposes, a patented product or a product directly obtained through a patented process;
- using or offering a patented process; and
- offering or supplying products that constitute essential elements of a protected invention to parties unauthorised to use the invention, provided that the products are offered or supplied in bad faith.

An applicant, owner, or licensor of a patent may submit a lawsuit to the competent court for patent infringement or a serious threat of infringement. Applying for marketing authorisation before a patent expires does not amount to patent infringement, since it falls within the scope of exemption mentioned in **9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices**.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

Defences to patent infringement include:

- use in personal and non-commercial purposes;
- research and development activities, including activities that are necessary for obtaining an authorisation for placing medicinal products on the market (a Bolar exemption); and
- direct, individual preparation of a medicine in a pharmacy in accordance with a prescription, and placement of that medicine on the market.

Compulsory licences are available on request.

Requirements for obtaining a compulsory licence depend on the grounds on which the licence is sought (eg, insufficient use of the protected invention, inability to use another invention commercially, etc). Usually, the following will apply:

- a request for a compulsory licence can be submitted after the expiry of a period of four years from the date of filing of the patent application, or three years from the grant of the patent, whichever period expires later;
- in order to obtain the licence, the requestor must prove that they have previously unsuccessfully attempted to conclude a licensing agreement with the patent-owner.

These requirements will not apply if a compulsory licence is being issued because of a public emergency (eg, in the fields of health, defence and ecology) which jeopardises the survival of the state or its citizens, or in cases of public non-commercial use.

9.6 Proceedings for Patent Infringement

An applicant, patent-owner, SPC-owner, and patent licensor may submit a lawsuit to the competent court for patent infringement or a serious threat of infringement.

Available remedies include, among others:

- determination of infringement or serious threat of infringement;
- prohibition of acts that constitute infringement or serious threat of infringement;

- compensation of damages; and
- seizure, removal from the market, or destruction of infringing products.

Infringement proceedings are initiated with a lawsuit. The defendant then submits a response to the lawsuit, after which the court schedules hearings. The defendant may at any time submit a request for determination of invalidity to the IP Office. The court would consider the invalidity proceedings a preliminary issue, and may decide to rule on this issue itself, or, more likely, to discontinue the court proceedings and wait for the IP Office's decision on invalidity.

Before, during or after the proceedings, the court may order provisional measures on request, provided that the requestor presents evidence reasonably supporting their claim that their rights have been infringed or are about to be infringed. Such provisional measures include, for example, seizure or removal from the market of infringing products, and prohibition of acts that represent infringement or serious threat of infringement.

9.7 Procedures Available to a Generic Entrant

A generic entrant has no obligation to "clear the way". However, by not "clearing the way", a generic entrant exposes itself to possible infringement proceedings, in the event that its activities amount to a serious threat of patent infringement.

The authorisation procedure for pharmaceuticals and medical devices does not take account of patent protection.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Intellectual property right-holders may initiate civil proceedings in the case of counterfeiting. Moreover, counterfeiting is a criminal offence. Anyone can submit a criminal complaint to a public prosecutor, based on which the public prosecutor will decide whether to conduct an investigation, file an indictment, or reject the criminal complaint. Counterfeiting may also trigger misdemeanour proceedings. Customs authorities may prevent counterfeited goods from entering Serbian territory, as explained in **3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices**.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

The IP Office will reject an application for a descriptive trade mark. According to the IP Office's Methodology in the Procedure for Trade Mark Registration and Procedures for Registered Trade Marks (Methodology), a mark used for pharmaceuticals will be considered descriptive if:

- the mark consists exclusively of the name of the chemical substance used for production of that pharmaceutical; or
- the mark slightly deviates from the generic name of the chemical substance.

According to the Methodology, the IP Office will consult the WHO's list of international non-proprietary names (INNs). In trade mark registration proceedings, the IP Office considers the WHO's recommendation that a verbal trade mark for a pharmaceutical should differ in at least three letters from the generic name.

The Trademark Act, enacted in 2020, lifted the prohibition on parallel imports. According to the Trademark Act, a trade mark proprietor who has placed, or consented to placing, on the market anywhere in the world goods protected by the trade mark, cannot prohibit further circulation of such goods. However, the Medicines Act and the implementing by-laws have not yet been aligned with the amendments to the Trademark Act and do not regulate parallel import. The government has announced the plan to adopt a new Medicines Act, although no draft has yet been made publicly available. It remains to be seen whether the new law will regulate parallel imports.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

It is possible to protect a 3D shape as a trade mark. Therefore, pharmaceuticals, medical devices and their packaging may be protected, provided that they meet the requirements for trade mark protection. However, if a mark consists exclusively of the shape or another characteristic which results from the nature of the goods, or is necessary to obtain a certain technical result, or gives substantial value to the goods, trade mark protection cannot be granted. This restriction may be especially significant when seeking protection for 3D trade marks that relate to medical devices, tablets, etc.

A shape can also be protected as industrial design if it meets the requirements of novelty and individual character. However, protection will not be granted if the design is determined solely by the function of the product in question.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Different rules on data exclusivity apply to manufacturers with and without a seat in Serbia. Originators without a seat in Serbia may benefit from a ten-year exclusivity period from the issuance of the marketing authorisation for the data submitted to obtain that marketing authorisation. Originators may not extend the exclusivity period on account of amendments to the marketing authorisation in terms of medicinal product strength, pharmaceutical form, methods of administration, packaging, or variations and claims for extension of the scope of the marketing authorisation.

Therefore, an applicant for a marketing authorisation issuance in a short-form procedure (for a generic medicinal product, generic hybrid medicinal product, or biologically similar medicinal product) may obtain a marketing authorisation after ten years from the date of issuance of the marketing authorisation for the reference product, but may apply for that marketing authorisation earlier, after at least eight years have elapsed from the date when the initial marketing authorisation had been issued in Serbia, in the European Union or in countries that have the same or similar requirements for the issuance of the authorisation.

If, during the eight years from the issuance of the marketing authorisation for the reference medicinal product, the marketing authorisation-holder for the reference medicinal product obtains a new marketing authorisation for one or more new indications that show a significant improvement in that reference medicinal product therapy, the period of ten years may be extended (cumulatively) for one more year.

Data Exclusivity for Manufacturers with a Seat in Serbia

These rules will also apply to manufacturers with a seat in Serbia from the moment of accession of Serbia in the European Union. Currently, the ten-

year protection period applies only to biotechnological medicines, while for the other medicinal products the protection period is six years from the date of receiving the first marketing authorisation for the reference pharmaceutical.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

In March 2020, the Customs Administration announced that legal entities, regardless of the business activity they perform, may import masks and gloves for their employees' personal protection. However, masks and gloves imported for these purposes may not be distributed – ie, sold – to third parties.

During March, April and May of 2020, the Regulation on Special Technical Requirements, Standards and Application of Medical Devices During the Emergency Condition Due to COVID-19 Disease Caused by SARS-CoV-2 (Regulation) was in force. The Regulation allowed the procurement, putting into use and application in treatment of medicines and medical devices that were not manufactured in accordance with all prescribed standards. This relaxation applied only during the state of emergency.

11.2 Special Measures Relating to Clinical Trials

On 24 March 2021, the ALIMS issued Instructions for Clinical Trial Sponsors During the COVID-19 Pandemic. The instructions cover, among others, the following topics:

- handling the medicine in a clinical trial;
- changes in visits/transfer of respondents from one centre to another;
- informed consent of the respondents; and
- revising the monitoring plan, etc.

No special measures were issued in relation to COVID-19 treatments or vaccines.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

In accordance with the provisions of the Medicines Act, pre-dating COVID-19, the ALIMS can issue a temporary marketing authorisation for the duration of an epidemic, natural disaster or state of emergency and only for a certain type and quantity of a medicine. On that basis, the government has adopted the Regulation on Temporary Marketing Authorisation for Medicine – Vaccine for Immunisation of the Population Against Infectious Disease COVID-19 (Official Gazette of the Republic of Serbia, Nos 17/2021 and 97/2021) (Regulation), providing that the ALIMS may issue a temporary marketing authorisation for a COVID-19 vaccine if one of the following applies:

- the vaccine is on the WHO's list of COVID-19 vaccines (in accordance with the WHO's Emergency Use Assessment and Listing mechanism);
- there is a bilateral agreement signed by Serbia, the applicant is a medicine manufacturer that has a manufacturing licence in Serbia, and the vaccine is not yet on the WHO's list of COVID-19 vaccines (but the listing procedure has been initiated); or
- the vaccine is registered in the country of origin, the EU, or in countries that have identical or similar requirements for the issuance of a marketing authorisation as in the countries of the EU.

Under the Regulation, the ALIMS may only issue a temporary marketing authorisation if an epi-

demic has been declared, the Ministry of Health has issued an order on emergency immunisation, and the relevant national bodies have determined that it is necessary to obtain a certain amount of COVID-19 vaccine urgently.

Other possible pathways applicable for emergency approvals of pharmaceuticals under the Medicines Act are for the ALIMS to issue:

- a marketing authorisation in an expedited procedure for a medicine of the greatest interest for protection of population health, primarily relating to innovation of treatment, as well as for a medicine that has already been approved by the European Medical Evaluation Agency;
- a provisional marketing authorisation for medicines used in an emergency, or for other medicines of a greater public health interest; in a state of emergency where public health is in jeopardy, the applicant can obtain a provisional marketing authorisation without providing to the ALIMS the clinical, pharmaceutical, biological, toxicological, and other types of data that are generally required; or
- a "marketing authorisation under special circumstances" for a medicine of a particular public health interest.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

No new measures were introduced due to COVID-19 to facilitate obtaining the manufacturing certifications.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

During March, April and May of 2020, the export and re-export of medicines was prohibited, except in the case where:

- medicines were manufactured in Serbia, but were not registered in Serbia – ie, the medicines were manufactured exclusively for foreign markets; and
- a foreign person shipped medicines in the transit procedure from the Serbian customs territory.

Exceptionally, the export and re-export of medicines was allowed upon the approval of the government.

11.6 Drivers for Digital Health Innovation Due to COVID-19

The ALIMS announced during the COVID-19 crisis that, as of 20 August 2020, its activities that were previously performed in direct contact with parties were to be performed exclusively by e-mail, registered mail, or telephone. The ALIMS provided dedicated e-portal and email addresses for communication with parties.

In the context of the coronavirus health crisis, the Ministry of Health introduced an e-health portal, where patients can fill out a questionnaire regarding their symptoms and receive instructions on the steps to take. The patients can enter their contact information to be contacted by a physician for an appointment.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

The government has not announced an intention to issue compulsory licences for COVID-19-related treatments or vaccines.

The general rules for issuing compulsory licences, described in **9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices**, would also be applicable to COVID-19-related patents.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

No liability exemptions were introduced regarding COVID-19 vaccines or treatments.

In accordance with the regular liability regime, the marketing authorisation-holder is responsible for the quality, safety and efficacy of the medicine.

The manufacturer of a medicine is responsible for the process of manufacturing. If that manufacturer places a product batch on the market, they are also responsible for the quality, safety and efficacy of the medicine.

11.9 Requisition or Conversion of Manufacturing Sites

Existing provisions of the Rulebook on the Conditions, Content of Documentation and Manner of Approval of Amendments to the Marketing Authorisation (2012, as amended) regulates requisition or conversion of manufacturing sites. The marketing authorisation-holder must notify the ALIMS of suspension on any manufacturing site ("Do and Tell" procedure). In the case of a modification of a manufacturing site of biological medicine active substance, the marketing authorisation-holder must apply for a new authorisation.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

No changes to the system of public procurement were introduced due to COVID-19.

SINGAPORE

Law and Practice

Contributed by:
Tony Yeo and Benjamin Gaw
Drew & Napier LLC

Contents

Drew & Napier LLC has been providing exceptional legal service since 1889 and is one of the largest full-service law firms in Singapore. The firm has three senior counsel and is pre-eminent in dispute resolution, international arbitration, competition and antitrust, corporate insolvency and restructuring, IP (patents and trade marks), tax, and telecommunications, media and technology, and has market-leading practices in M&A, banking and finance, and capital markets. Drew & Napier has represented Singapore's leaders, top government agencies and foreign governments in landmark, high-profile cases. It is also appointed by Fortune 500 companies, multinational corporations, and local organisations. The firm is experienced in international disputes before the Singapore International Commercial Court and covers the full range of commercial litigation matters, including building and construction, constitutional law, debt recovery, defamation, fraud and white-collar crime.

Authors

Tony Yeo is the managing director of Drew & Napier's intellectual property (IP) practice, and a director in its dispute resolution department. He also heads the firm's healthcare and life sciences practice. Tony's expertise lies in litigation; in particular, IP litigation and enforcement comprising patent, trade mark and copyright. He was one of the select few IP practitioners appointed by the Intellectual Property Office of Singapore (IPOS) as an IP Adjudicator to adjudicate disputes at IPOS for a two-year term from April 2019. Tony is also the President of the International Association for the Protection of Intellectual Property (AIPPI) – Singapore Group. He has contributed to numerous publications in the domains of IP and life sciences.

Benjamin Gaw is a director in Drew & Napier's corporate and M&A department. He also heads the healthcare and life sciences practice – corporate and regulatory and co-heads the employment practice. Benjamin is also a member of the firm's telecommunications, media and technology and information technology departments. In relation to his healthcare and life sciences competency, Benjamin advises on matters involving the biotechnology, medical devices, healthcare and pharmaceutical industries. He has been appointed as Asia Pacific Regional Forum Liaison Officer of the Healthcare and Life Sciences Law Committee of the International Bar Association. Benjamin is also the Vice Chairman of the National Arthritis Foundation Executive Committee. He authors publications on the subject of life sciences regularly.

Drew & Napier LLC

10 Collyer Quay
#10-01
Ocean Financial Centre
Singapore
049315

Tel: +65 6535 0733
Fax: +65 6535 4906
Email: mail@drewnapier.com
Web: www.drewnapier.com

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The Health Products Act 2007 (HPA) is the main legislation governing pharmaceuticals, which are referred to as "therapeutic products", and medical devices.

Therapeutic products and medical devices are also regulated under the following legislation and regulations:

- the Health Products (Advertisement of Specific Health Products) Regulations 2016;
- the Health Products (Medical Devices) Regulations 2010;
- the Health Products (Therapeutic Products) Regulations 2016;
- the Health Products (Clinical Research Materials) Regulations 2016;
- the Poisons Act 1938 and its subsidiary legislations; and
- the Sale of Drugs Act 1914 and its subsidiary legislations.

The Health Sciences Authority (HSA), a statutory body under the Ministry of Health (MOH), is the main regulatory body which administers, applies and enforces the aforementioned legislation and regulations. The HSA also publishes guidelines in its administration of the legislation and regulations. As a statutory body, the HSA has substantial independence and autonomy over its operations. Nevertheless, it generally operates in line with the policy directions set by the government.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

An appeal can be made in respect of any of the following decisions made by the HSA:

- refusal of the HSA to register a health product;
- attachment of any condition to the registration of a health product;
- decision to re-categorise or reclassify a health product;
- decision to suspend or cancel the registration of a health product;
- refusal of the HSA to issue or renew a licence or to grant any approval;
- attachment of any condition to a licence; and

- decision to suspend or revoke a licence or to cancel an approval.

Any person aggrieved by the aforementioned decisions can make an appeal in writing within the time specified in the decision notice to the Minister of Health, whose decision is final. The Minister may choose to refer the appeal to an Appeal Advisory Committee before making a decision and will have to take into consideration any report made to him or her by the Appeal Advisory Committee in making the decision.

This challenge procedure is specific to health products.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Therapeutic Products

Therapeutic products in Singapore are classified as Prescription Only Medicines, Pharmacy Only Medicines and General Sale List medicines. These categories of therapeutic products are regulated differently on the basis of the types of marketing authorisation required.

Medical Devices

The appropriate product registration requirements and evaluation route depends on the risk classification of the medical device.

Medical devices are classified into the following risk groups, based on guidance developed by the Global Harmonisation Task Force:

- Class A – low risk, (eg, wheelchairs and tongue-depressors);
- Class B – low to moderate risk (eg, hypodermic needles and suction equipment);
- Class C – moderate to high risk (eg, lung ventilators and bone-fixation plates); and
- Class D – high risk (eg, heart valves and implantable defibrillators).

In vitro diagnostic (IVD) medical devices are separately classified on the basis of their risk levels:

- Class A (IVD) – low individual risk and low public-health risk (eg, specimen receptacles);
- Class B (IVD) – moderate individual risk and/or low public-health risk (eg, vitamin B12 and pregnancy self-tests);
- Class C (IVD) – high individual risk and/or moderate public-health risk (eg, blood glucose self-tests and rubella tests); and
- Class D (IVD) – high individual risk and high public-health risk (eg, HIV blood-donor screening and HIV diagnostic kits).

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials of therapeutic products are specifically regulated by the HSA under the Health Products (Clinical Trials) Regulations 2016.

Clinical trials of medical devices are not regulated by the HSA. Where clinical trials of medical devices involve human biomedical research, such trials are required to comply with the requirements of the Human Biomedical Research Act 2015, which is administered by the MOH. Clinical trials of medical devices which do not involve human biomedical research are currently unregulated in Singapore.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Therapeutic Products

In order to undertake a clinical trial of a therapeutic product, regulatory approval from the

HSA and ethics approval from the relevant Institutional Review Board (IRB) must be obtained.

Applicants must first determine whether the clinical trial is subject to the requirements of a Clinical Trial Authorisation (CTA) or Clinical Trial Notification (CTN). CTAs are required for higher-risk clinical trials involving therapeutic products unregistered in Singapore or uses of registered therapeutic products which are unapproved. CTNs are required for low-risk clinical trials involving only registered therapeutic products used in accordance with their approved labels.

The clinical trial application, together with the relevant supporting documents, should be submitted by the sponsor to the HSA via its online platform, PRISM. The study may be initiated after the HSA accepts the notification of clinical trial or authorises the clinical trial.

Medical Devices

Authorisation is generally not required for clinical trials of medical devices. However, a notification must first be submitted to the Director of Medical Services before the commencement of any clinical trial of medical devices involving human biomedical research.

2.3 Public Availability of the Conduct of a Clinical Trial

Particulars of ongoing clinical trials are made publicly available online on the Clinical Trials Registry. All information in the Clinical Trials Register is maintained and updated by the local sponsors at least once every six months. The results of the trials are not made publicly available.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no restrictions for using online tools to support clinical trials, as long as the use complies with the requirements and guidelines set out in the International Council for Harmonisation (ICH) E6 (R3) Good Clinical Practice Guidelines.

2.5 Use of Data Resulting From Clinical Trials

Data from clinical trials is considered personal data under the Personal Data Protection Act 2012 (PDPA), Singapore's primary data protection legislation. While there is no express categorisation of sensitive data in Singapore, the Personal Data Protection Commission (PDPC), which administers the PDPA, has taken the position in several enforcement decisions that medical data is more sensitive in nature and requires a higher standard of protection.

Resulting data may be transferred to a third party or an affiliate if consent has been obtained from individuals involved in the clinical trials. Data transfers are required to comply with the requirements of the PDPA.

2.6 Databases Containing Personal or Sensitive Data

The creation of a database containing personal or sensitive data would not be subject to requirements beyond that which is already required in the PDPA.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The classification of the health product is assessed when an application for registration is screened to determine whether it should be accepted for evaluation.

Therapeutic Products

A therapeutic product is any substance that has certain active ingredients as a constituent, and is intended for use by and in humans for any of the following purposes:

- preventing, diagnosing, monitoring, treating, curing or alleviating any disease, disorder, ailment, injury, handicap or abnormal physical or mental state, or any symptom thereof;
- investigating, modifying or replacing any physiological process;
- influencing, controlling or preventing conception; or
- inducing anaesthesia,

has as a constituent any of the following active ingredients:

- any chemical or botanical element, naturally occurring chemical or botanical material, or chemical product obtained by chemical change or synthesis;
- any metabolite from a micro-organism;
- any macromolecule extracted from an organism; or
- any substance derived from a biological system,

and which exerts an inherent effect, either pharmacologically, chemically or by other physiological means, leading to its use for a therapeutic, preventive, palliative or diagnostic purpose.

Medical Device

A medical device is any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article that is intended by its manufacturer to be used, whether alone or in combination, for humans for one or more of the specific purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment or alleviation of, or compensation for, an injury;
- investigation, replacement, modification or support of the anatomy or of a physiological process, mainly for medical purposes;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices; or
- providing information by means of in vitro examination of specimens derived from the human body, for medical or diagnostic purpose,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Medical devices also include the following:

- any implant for the modification or fixation of any body part;
- any injectable dermal filler or mucous membrane filler; or
- any instrument, apparatus, implement, machine or appliance intended to be used for

the removal or degradation of fat by invasive means.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Biologic medicinal products are generally classified as therapeutic products and are not subject to any specific obligations in relation to the granting of a marketing authorisation.

Biosimilars are "follow-on" versions of biologic medicinal products. Biosimilars are required to be submitted under a new drug application, rather than a generic drug application. The registration of biosimilar products involves a comprehensive comparability exercise, where similarity to an existing biologic medicinal product registered in Singapore in terms of physicochemical characteristics, biological activity, safety and efficacy needs to be established.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

Registrations of therapeutic products and medical devices generally remain valid for a year and may be renewed by paying an annual retention fee, unless the registration is suspended by the HSA or cancelled by either the HSA or the product registrant. There is no requirement to market the health product once it is registered by the HSA. However, under the Singapore Association of Pharmaceutical Industries Code of Conduct, the first use of all promotional materials circulated to the market may not be more than two years from the date of approval. Materials used beyond this time period are required to be re-approved.

The registration of a health product may be suspended or cancelled by the HSA on the following grounds:

- the registration has been obtained by fraud or misrepresentation;
- the registrant of the health product has contravened or is contravening any provision of the HPA, any condition attached to the registration, or any other prescribed requirement;
- the formulation, composition, design specification, quality, safety or presentation of the health product has changed in such a way as to render it unsuitable to continue to be registered;
- the health product no longer complies with a prescribed requirement; or
- it is in the public interest to do so.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

Therapeutic Products

Registration procedure

Pre-submission: at the pre-submission stage, applicants may submit a pre-submission enquiry to the HSA for any clarification and may also request a pre-submission meeting with the HSA where necessary to address specific submission issues.

Application submission: submission of the application form online via the HSA's portal, PRISM, and submission of the technical dossier accompanying the application, within two working days of the PRISM application submission, must be made.

Application screening: the application is screened to ensure that the application type is correct, and the technical dossier is complete. Where any changes are required or where there are deficiencies in the application, the HSA will request that the applicant take the necessary action via an Input Request. In the case

of certain major deficiencies, applicants will be requested to withdraw the application.

Application evaluation: the evaluation stage begins when the application is accepted. Evaluation queries may be issued to the applicant if clarification or additional information is required. The evaluation route applicable depends on the type of therapeutic product and whether the therapeutic product has received reference agency approvals.

Regulatory decision: the HSA will notify the applicant of one of the following outcomes after the application has been evaluated: approval, approvable, non-approvable or rejection.

Where the applicant receives an approvable regulatory decision, the applicant will be informed of the conditions for approval and will receive a grant of a final approval if the conditions are fulfilled within a stipulated timeframe.

Where the applicant receives a non-approvable regulatory decision, the applicant will be informed of the deficiencies leading to the non-approvable decision. The applicant may address the specified deficiencies by furnishing a response based on the original data set submitted to the HSA within the stipulated timeframe to continue with the application.

Variation procedure

Variation applications of registered therapeutic products are split into major variation applications (MAV) and minor variation applications (MIV). Each application type may be subject to different evaluation routes and different variation procedures.

As a whole, the procedure to vary a therapeutic product registration is largely similar to the registration procedure.

- At the pre-submission stage, applicants may submit a pre-submission enquiry to the HSA for any clarification and also request a pre-submission meeting with the HSA where necessary to address specific submission issues.
- Only MAV applications will be screened to ensure the correctness of the application type and completeness of the technical dossier.
- During the evaluation stage, applicants who have incorrectly selected an application type or evaluation route will be requested to make the appropriate changes. In such cases, the applicant will be required to withdraw and resubmit the application if they intend to pursue the application.

Transfer procedure

A registrant for a registered therapeutic product may be changed from one company to another.

Before the submission of a transfer application, the existing registrant should conclude all pending variation applications and payment of the annual retention fee. To make a transfer application, the existing registrant first initiates the application via the HSA's portal. The new registrant will receive an email notice with a PRISM transaction number. The new registrant is then required to retrieve the draft application on the same website, using the transaction number, and submit the completed application in PRISM within 30 calendar days of receiving the email notice.

Medical Devices

Registration procedure

The registration requirements and evaluation route for medical devices depend on their risk

classification, whether they have received reference agency approvals, and their prior safe marketing history. Generally, medical devices which have not received prior reference agency approvals will have to undergo the full evaluation route.

Medical device registration applications are submitted online via the HSA's portal, MEDICS. For applications under the full or abridged evaluation routes, the application will first be verified for eligibility and completeness before it is accepted for evaluation. In the event that the application does not qualify for the selected evaluation route, it will be re-routed accordingly. A regulatory decision is made after the HSA's evaluation of the application. Only applications that satisfy the registration requirements will be registered and listed on the Singapore Medical Device Register (SMDR). For applications under the immediate evaluation route, the medical device is registered immediately and listed on the SMDR within an hour.

Variation procedure

Registrants may be required to submit a "Change Notification" application to the HSA upon changes to the medical device registrations. A Change Notification to the HSA can be categorised into Notification, Administrative, Technical and Review changes.

Some changes may not qualify for a Change Notification and will require the submission of a new registration. These include:

- a change to the intended purpose of the registered medical device;
- a change to the risk classification of a registered medical device;
- a change to the medicinal substance in a device that incorporates a medicinal product in an ancillary role;
- any addition of model(s) that do not fulfil the grouping criteria, including permissible variants, as per the GN-12 guidance documents on Grouping of Medical Devices for Product Registration; and
- any addition of medical devices with device proprietary names that are different from the registered devices into a device listing, unless permitted to be listed together under one SMDR listing based on the GN-12 guidance documents on Grouping of Medical Devices for Product Registration.

A Change Notification application is submitted to the HSA via MEDICS. The following changes must be evaluated by the HSA first, prior to implementation:

- all Technical changes;
- all Review changes; and
- Administrative changes involving changes to administrative documents and information submitted at the point of registration of the medical device.

Where the HSA determines that the Change Notification is approvable, the change to the registered device may be implemented.

All other applications (ie, all Notification changes and all other Administrative changes to device particulars which are published on the public SMDR listing) may be implemented immediately upon the receipt of the acknowledgement email from the HSA.

Transfer procedure

A transfer application can only be made to the HSA after the medical device is listed on the

SMDR and there are no pending applications in the HSA's system in relation to the device.

The new registrant is responsible for making the transfer application, by emailing the application form and required supporting documents to the HSA. The new and existing registrants will then be notified of the outcome of the application for the change in registrant.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

Unregistered therapeutic products may be imported and supplied for patient's use via the Special Access Route (SAR) under certain circumstances, including the following:

- a licensed hospital or medical clinic importing the drug for use by its own doctors or dentists on patients under their care;
- a licensed retail pharmacy acting on behalf of, and in accordance with, a valid prescription issued by a registered doctor or dentist; or
- a company acting on behalf of a licensed hospital or clinic.

However, any such use of unregistered therapeutic products should only be considered for life-saving therapies, and are to be done through either a named-patient application or a buffer stock application.

Note that if the therapeutic product consists of controlled drugs or psychotropic substances, then the respective licences will also have to be obtained in order to import the product.

Unregistered medical devices may be supplied via SAR under a number of exceptions, including the following:

- for non-clinical purposes;
- for export or re-export; or
- for patients' use by qualified practitioners or licensed healthcare facilities, subject to approval.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

In general, health products may be registered subject to post-approval commitments.

Therapeutic Products

Ongoing obligations of registrants of therapeutic products include:

- maintaining records of every receipt and supply of the therapeutic product;
- maintaining records of defects and adverse effects and reporting them to the HSA within certain timeframes;
- notifying the HSA before any intended recall;
- informing the HSA of any information that adversely affects the validity of any data furnished to the HSA;
- submitting benefit-risk evaluation reports periodically to the HSA;
- implementing risk-management plans; and
- informing HSA of any regulatory actions taken by other regulatory authorities, or actions taken by the company arising from significant safety issues of the therapeutic product.

The Regulatory Guidance on Post-Marketing Vigilance Requirements for Therapeutic Products and Cell, Tissue and Gene Therapy Products, revised by the HSA in March 2021, sets out further guidance relating to the submission of relevant safety information during the post-marketing phase.

Medical Devices

Ongoing obligations of registrants of medical devices include:

- ensuring and maintaining objective evidence to establish that the medical device complies with safety and performance requirements;
- maintaining records of every supply of the medical device;
- maintaining records of complaint reports and of actions taken in response to these reports;
- reporting defects in the medical device or adverse effects arising from the use thereof;
- reporting information that adversely affects the validity of any data furnished to the HSA relating to the quality, safety or efficacy of the medical device;
- notifying the HSA prior to any intended recall and furnishing a report of that recall; and
- notifying the HSA prior to carrying out any field-safety correction in relation to a medical device and furnishing a report thereof.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

The Health Products (Medical Devices) Regulations 2010 and Health Products (Therapeutic Products) Regulations 2016 allow the disclosure of information relating to applications for registration. Trade secrets and information of commercial value that would be, or would be likely to be, diminished by disclosure are excluded from any such disclosure.

The HSA makes publicly available, on an online database, information submitted to the HSA in support of health product registration applications for registered health products. Information relating to pending applications is currently not publicly available.

Confidentiality

Disclosure of any confidential information obtained in the administration or enforcement of the HPA is generally prohibited, except with the consent of the person from whom the information was obtained. However, the HSA may disclose any confidential information relating to the quality, safety or efficacy of a therapeutic product or medical device if the disclosure is, in the HSA's opinion, necessary to protect the health or safety of members of the public or the disclosure is to a government body.

Additionally, confidential supporting information given in relation to an innovative therapeutic product application is protected by the HSA for a period of five years after the application is received by the HSA, subject to exceptions. An innovative therapeutic product application is a therapeutic product registration application of a substance that is an ingredient in the manufacture or preparation of the therapeutic product to which the application relates and that has not been referred to as an ingredient in the manufacture or preparation of any other therapeutic product in any previous application.

3.8 Rules Against Illegal Medicines and/or Medical Devices

It is an offence under the HPA to manufacture, supply or import:

- an adulterated health product;
- a counterfeit health product;
- a health product that has been tampered with; or
- an unwholesome health product.

If found dealing with any adulterated, counterfeit or tampered health products, offenders may be subject to a fine not exceeding SGD100,000 and/or imprisonment for up to three years.

If found dealing with any unwholesome health products, offenders may be subject to a fine not exceeding SGD50,000 and/or imprisonment for up to two years.

The HSA has also compiled a non-exhaustive public database of detected and tested illegal health products in Singapore.

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

Border measures are available under intellectual property law for proprietors or licensees of registered trade marks. See **10.1 Counterfeit Pharmaceuticals and Medical Devices** for more information.

4. Manufacturing of Pharmaceuticals and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

Manufacturers of therapeutic products and medical devices are generally required to obtain a manufacturer's licence from the HSA. The manufacture of a health product means to make, fabricate, produce or process the health product, and includes:

- any process carried out in the course of so making, fabricating, producing or processing the health product; and
- the packaging and labelling of the health product before it is supplied.

Manufacture of Therapeutic Products

To obtain a manufacturer's licence, the HSA must be satisfied that the applicant is able to comply with the Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice (GMP) for Medicinal Products in relation to the manufacture of the therapeutic product in question. The HSA enforces these standards by conducting pre-approval and routine GMP audits to ensure conformance to the standards. The details of the audit process may be found in the Regulatory Guidance published by the HSA on Audit and Licensing of Pharmaceutical Manufacturers in December 2017.

If the therapeutic products contain controlled drugs or psychotropic substances, the respective licences will also have to be obtained.

Manufacture of Medical Devices

Applicants for a manufacturer's licence are required to provide information on their Quality Management System through the submission of an ISO 13485 certificate, the scope of which must include distribution of the categories of medical devices and the activities performed, or a declaration of conformity to a Quality Management System (for companies dealing with Class A medical devices only).

A manufacturer's licence is not required for certain activities, including:

- manufacture at the request of a qualified practitioner practising at the licensed healthcare institution intended for the use of a particular patient of the licensed healthcare institution;
- manufacture by way of fitting or adjusting the medical device to meet the requirements of the end user;
- manufacture to enable the continued used of the medical device by the end user;

- secondary assembly where the company holds an importer's licence or wholesaler's licence and is able to comply with the requirements of the Good Distribution Practice Standard for Medical Devices or ISO 13485;
- manufacture for use in clinical research;
- manufacture of laboratory-developed tests;
- manufacture of Class A medical devices for a charitable purpose; or
- manufacture of specified dental medical devices.

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

Establishments are generally required to obtain a wholesaler's licence from the HSA in order to engage in the wholesale of therapeutic products and medical devices. The wholesale of a health product includes the supply of the product:

- to a person who obtains the product for the purposes of supplying it to another person;
- to a person as a commercial sample in the normal course of a lawful trade;
- to the Singapore government where it is required for the purposes of public service or use in connection with the exercise of any statutory power;
- to a person or an institution concerned with scientific education or research requiring the health product for such a purpose;
- to a person who requires the health product for the purpose of complying with any written law with respect to the medical treatment of individuals employed by that person in any business or trade carried out;
- to a person who requires to use the health product, other than by way of administration to one or more individuals, for the purpose of business or trade; or
- by export to a party outside Singapore.

Wholesale of Therapeutic Products

To obtain a wholesaler's licence for therapeutic products, the establishment must first be audited to comply with the HSA's Good Distribution Practice standards, which are set out in the HSA's Guidance Notes on Good Distribution Practice, revised in December 2023.

Where the establishment intends to export codeine cough preparations or therapeutic products containing psychotropic substances, additional approval must first be obtained from the HSA.

Certain activities may not require a licence if the exceptions available in the Health Products (Therapeutic Products) Regulations 2016 apply.

Wholesale of Medical Devices

To be granted a wholesaler's licence for medical devices, the establishment is generally required to submit to the HSA any of the following:

- an ISO 13485 certificate, the scope of which must include distribution of the categories of medical devices and the activities performed at the facility, where applicable;
- a declaration of conformity to a Quality Management System (for companies dealing with Class A medical devices only); or
- a Good Distribution Practice Standard for Medical Devices certificate issued by a certification body accredited by the Singapore Accreditation Council or a declaration of exemption thereof.

A wholesaler's licence is not required if the wholesaling is for a clinical purpose in clinical research.

A wholesaler's licence is generally valid for 12 months from the date of licence approval. Renewals must be submitted and processed before the expiry of the licence.

5.2 Different Classifications Applicable to Pharmaceuticals

Therapeutic products in Singapore are classified as Prescription Only Medicines, Pharmacy Only Medicines and General Sale List Medicines. Prescription Only Medicines may only be supplied by a registered medical practitioner or pharmacist in accordance with a prescription. Pharmacy Only Medicines may be supplied by a pharmacist without a prescription and General Sale List Medicines can be freely obtained from any retailer.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The import and export of therapeutic products and medical devices are governed by the Health Products (Therapeutic Products) Regulations 2016 and the Health Products (Medical Devices) Regulations 2010 respectively. Additionally, all goods imported into Singapore are regulated under the Customs Act 1960, the Goods and Services Tax Act 1993 and the Regulation of Imports and Exports Act 1995.

The Singapore Customs applies and enforces import regulations at the point of entry and thereafter, the regulations are applied and enforced by the HSA.

6.2 Importer of Record of Pharmaceuticals and Medical Devices

A licensed importer or licensed wholesaler of therapeutic products has to appoint a responsible person that is able to implement and maintain the quality system to meet the Good Distribution Practice (GDP) Standard. For pharmacy-only medicines or prescription-only medicines for local use, or unregistered therapeutic products for patients' use, only a qualified pharmacist may act as the responsible person under an importer's licence. There are no specific requirements regarding the importer of record of medical devices.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

An importer's licence is required to import therapeutic products and medical devices. In general, only registered therapeutic products and medical devices may be imported.

Some exemptions from holding an importer's licence include the following:

- a healthcare institution may import an unregistered therapeutic product without a licence, on a named-patient basis with the prior approval of the HSA;
- a person may import a therapeutic product that does not contain psychotropic substances or amounts of codeine and dextromethorphan greater than that specified by the HSA without a licence for personal use with the prior approval of the HSA;

- a licensed manufacturer may import any therapeutic product or medical device if required for the purpose of carrying out the licensed manufacture of a therapeutic product or another medical device; and
- medical devices may be imported without a licence for personal use subject to conditions set out by the HSA or for use in a clinical purpose in any clinical research.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Harmonised System (HS) codes are required in Singapore in the permit declaration of goods. They are used to determine the tariffs, controls and rule of origin applicable to the relevant goods. The HS code of goods used in Singapore is an eight-digit code known as the ASEAN Harmonised Tariff Nomenclature code. The HS codes are listed in the Singapore Trade Classification, Customs and Excise Duties published by the Singapore Customs.

6.5 Trade Blocs and Free Trade Agreements

Singapore is part of the ASEAN trade bloc and is a party to Free Trade Agreements with numerous jurisdictions containing provisions on trade/regulatory facilitation, including the European Union, China and New Zealand.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

In general, prices for therapeutic products and medical devices are not regulated in Singapore. However, it should be noted that public healthcare institutions in Singapore procure medicinal products in bulk by way of tender contracts through Group Procurement Offices to achieve economies of scale.

7.2 Price Levels of Pharmaceuticals or Medical Devices

Price levels of therapeutic products and medical devices generally do not depend on the prices for the same product in other countries, as prices are generally not regulated in Singapore. However, this may be a factor considered in negotiations with drug companies.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

The Singapore government provides direct subsidies of up to 75% for subsidised medications at specialist outpatient clinics and polyclinics. Patients receive drug subsidies and assistance based on their subsidy and means-test status, and the scheme under which the drug is covered (eg, Standard Drug List, Medication Assistance Fund).

The Singapore government has also implemented the Seniors' Mobility and Enabling Fund, which provides subsidies to offset the costs of assistive devices and home healthcare items.

Additionally, the government provides multiple tiers of financing for Singapore citizens and permanent residents for their healthcare expenditure, which includes a basic health insurance plan and a medical endowment fund.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

The Agency for Care Effectiveness (ACE), under the purview of the MOH, is the national health technology assessment agency in Singapore. The ACE works to lower prices of health technologies, including drugs, medical devices and

medical services, by evaluating their clinical and cost-effectiveness and negotiating with companies based on their proven outcomes. The evaluations made by the ACE also guide policymakers in making subsidy decisions. Summaries of the rationale for subsidy decisions, as well as the key clinical and economic evidence supporting such recommendations, are published by the ACE to increase the level of transparency in decision-making.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

There are generally no regulations restricting pharmaceutical spending with regard to prescriptions by physicians and dispensing by pharmacies. However, medical practitioners are increasingly reminded to prescribe medications which are the most cost-effective for patients.

8. Digital Healthcare

8.1 Rules for Medical Apps

There is currently no specific legislation governing mobile medical applications in Singapore. Mobile medical applications may be classified as telehealth products, which includes any equipment (eg, instruments, apparatus, machines or software, including mobile phone applications) that is involved in the provision of healthcare services over physically separate environments via info-communication technologies (including mobile technology). The HSA has clarified under the Regulatory Guideline for Telehealth Products that, generally, telehealth products may be considered medical devices if they are intended to be used for medical purposes such as investigation, detection, diagnosis, monitoring, treatment or management of any medical condition, disease, anatomy or physiological process.

Telehealth products that are medical devices are subject to the following medical device regulatory controls:

- product registration;
- dealer's licence requirements; and
- post-market obligations.

Separately, there is an immediate registration pathway for Standalone Medical Mobile Applications (SaMD). SaMD refers to a software and/or mobile application that is intended to function by itself and is not intended to be used to control or affect the operation of other hardware medical devices. Where the SaMD has been approved by at least one of the HSA's reference agencies for the same intended use, the submission of a product registration application with the HSA grants it immediate market access.

On the other hand, where the application is for general wellness purposes, such as for fitness tracking, then it is not regulated as a medical device. However, owners of such applications should clearly state that the application is intended for use only for general wellbeing purposes or to encourage or maintain a healthy lifestyle, and is not intended to be used for any medical purpose.

8.2 Rules for Telemedicine

While there is no legislation governing telemedicine, the policy stance taken in Singapore is reflected in the National Telemedicine Guidelines issued by the MOH in January 2015 and the HSA Regulatory Guidelines for Telehealth Products, which were revised in April 2019.

Registered medical practitioners may provide medical attention through a mobile device in Singapore. Such services were previously regulated under the Licensing Experimentation and Adap-

tation Programme (LEAP), a regulatory sandbox initiative launched by the MOH in April 2018. The MOH has since closed the sandbox for telemedicine, in February 2021.

Under the new Healthcare Services Act 2020 (HCSA), independent doctors/dentists offering teleconsultations themselves or organisations which have set up clinical and operational governance for their doctors and/or dentists to provide teleconsultation will need to be licensed. As part of the transition to the licensing framework under the HCSA, the MOH had also introduced a voluntary listing of direct telemedicine service providers. With the HCSA and the requirement for the licensing for telemedicine providers taking effect from 26 June 2023, this voluntary listing has been discontinued and licensees' information providing telemedicine services are now listed on HealthHub.

8.3 Promoting and/or Advertising on an Online Platform

There are no special rules governing the promotion and advertisement of therapeutic products and medical devices online. The general rules regarding the advertisement of therapeutic products and medical devices apply.

8.4 Electronic Prescriptions

Electronic prescriptions are allowed and used in Singapore by both public and private healthcare providers. Electronic prescriptions are not specifically regulated and are subject to the general legislation governing the collection of personal data and medical records under the PDPA and various healthcare-related legislation.

8.5 Online Sales of Medicines and Medical Devices

General Sale List Medicines may be sold online, subject to certain regulatory requirements. They are set out in the Medicines (General Sale List) Order 2016.

On 5 May 2020, the HSA introduced the roll-out of the e-pharmacy service. HSA-licensed retail pharmacies and wholesalers in Singapore with a good track record in handling Prescription Only Medicines and Pharmacy Only Medicines may apply for a retail pharmacy licence, or include such services in their existing retail pharmacy licence if they intend to carry out e-pharmacy operations.

8.6 Electronic Health Records

The MOH seeks to introduce the HIB in 2024, which, if passed, will facilitate and regulate the proper collection, use and sharing of patient information via the National Electronic Health Record (NEHR). Under the HIB, all licensed healthcare providers would be required to contribute summary data of patient's key health information to NEHR. Licensees would also be required to comply with the HIB when sharing information with other care providers.

The HIB categorises certain types of health information as Sensitive Health Information (SHI), being information that subjects individuals to greater harm during a data breach. Examples of SHI include Human Immunodeficiency Virus infection status, substance abuse and addiction and abortion-related records. Additional and more stringent safeguards will be put in place when dealing with SHI.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices

In Singapore, patents are regulated under the Patents Act 1994 (Patents Act) and its subsidiary legislation, which includes the Patents Rules. Therapeutic products are commonly patented in Singapore and there are generally no patentability requirements specific to therapeutic products or medical devices.

Issues

The Court of Appeal in Warner-Lambert Company LLC v Novartis (Singapore) Pte Ltd [2017] SGCA 45 has recently raised the issue of whether Swiss-type claims are necessary in Singapore to frame second and subsequent medical-use claims, given that purpose-limited product claims may be sufficient to protect such claims. While the Intellectual Property Office of Singapore continues to take the approach that Swiss-type claims are valid, it is not certain if this approach will change in the future to reflect the Court of Appeal's views.

As software is not patentable under the Singapore patent regime, medical devices consisting exclusively of software may not receive patent protection.

9.2 Second and Subsequent Medical Uses

Second and subsequent medical uses of a known product are patentable in so far as they are claimed in the form of "Swiss-type" claims. Additionally, second medical-use claims can only derive novelty from their intended use where the use is a method of treatment of the human or animal body by surgery or therapy or a method of diagnosis practised on the human or animal body. It should be noted that the Singapore patents' registry practice for using the Swiss-type claim format differs from that of the United Kingdom and Europe, which are contracting members of the Europe Patent Convention 2000.

Patentability of Claims

Second medical-use claims are typically used to protect the use of a substance or composition in the treatment of a different disease.

They are also allowable for new dosage regimes, on the condition that the claimed dosage regime is novel and inventive. However, the patents' registry recognises that, in most cases, it is generally presumed that new dosage regimes lack inventiveness, unless there is a clear technical prejudice pointing away from the claimed dosage regime.

Depending on the factual scenario, second medical-use claims may rely solely on the patient population to be treated to fulfil the requirements of novelty and inventive step, despite known associations of the claimed product and the disease to be treated. For such claims to be patentable, the new patient group must consist of a distinctly different patient population from those treated in the prior art.

Infringement

It is uncertain how the Singapore courts will apply the legislation on infringement to second and subsequent patents as, at the time of writing, there are no cases in Singapore on the infringement of second and subsequent patents of pharmaceutical products.

9.3 Patent Term Extension for Pharmaceuticals

Under the Patents Act, the proprietor of a patent can make an application to the patents' registry to extend the terms of the patent on any of the following grounds:

- where there was an unreasonable delay by the patents' registry in granting the patent;
- where the patent was granted on the basis of any prescribed documents relating to a corresponding application or related national phase application, and there was an unreasonable delay in the issue of the corresponding patent or related national phase patent, and the patent office that granted the corresponding patent or related national phase patent has extended the term of the corresponding patent or related national phase patent on the basis of that delay; or
- where the subject of the patent includes any substance which is an active ingredient of any pharmaceutical product, and there was an unreasonable curtailment of the opportunity to exploit the patent, due to the process of obtaining marketing approval for the first pharmaceutical product, which uses the substance as an active ingredient, and the patent term has not previously been extended on this ground.

Further guidance on how the aforementioned grounds are applied is set out in the Patent Rules.

9.4 Pharmaceutical or Medical Device Patent Infringement

When a person carries out any of the following acts in Singapore in relation to the invention of a patent without the consent of the proprietor's consent, it will constitute a patent infringement:

- where the invention is a product, the person makes, disposes of, offers to dispose of, uses or imports the product, or keeps it, whether for disposal or otherwise;
- where the invention is a process, they use the process or offer it for use in Singapore when they know, or it is obvious to a reasonable person in the circumstances, that its use without the consent of the proprietor would be an infringement of the patent; and
- where the invention is a process, they dispose of, offer to dispose of, use or import any product obtained directly by means of that process or keep any such product, whether for disposal or otherwise.

An application for marketing authorisation, in itself, will not infringe a patent. However, the HSA may refuse the application if the doing of the act for which the marketing authorisation is sought will infringe on an existing patent.

Only actual infringement is actionable under the Patents Act and a person aggrieved by groundless threats of infringement proceedings may bring an action against the person making the threats.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

Relevant to pharmaceuticals and medical devices, it is a defence to patent infringement if the act:

- is done for experimental purposes relating to the subject-matter of the invention;
- consists of the extemporaneous preparation of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner or consists of dealing with a medicine so prepared;

- consists of the doing of any infringing act in relation to the subject-matter of the patent to support any application for marketing approval for a pharmaceutical product, provided that anything produced to support the application is not made, used or sold in Singapore or exported outside Singapore, other than for purposes related to meeting the requirements for marketing approval for that pharmaceutical product; or
- consists of the import, disposal or offer to dispose of a patented pharmaceutical product for use by or on a specific patient in Singapore, or the use of that product by or on that patient, where that product is required for use by or on that patient, the relevant authority has granted approval specifically for the import of that product for use by or on that patient, and that product was produced by or with the consent (conditional or otherwise) of the proprietor of the patent or any person licensed by them.

Compulsory Licence

An interested person may apply to the court for the grant of a licence under a patent on the ground that the grant of the licence is necessary to remedy an anti-competitive practice. The court may grant the licence if:

- there is a market for the patented invention in Singapore;
- that market is not being supplied on reasonable terms; and
- the court is of the view that the proprietor of the patent has no valid reason for failing to supply that market with the patented invention, whether directly or through a licensee, on reasonable terms.

9.6 Proceedings for Patent Infringement

The proprietor of the patent may bring proceedings for patent infringement in court and make a claim for any of the following remedies:

- an injunction restraining the defendant from any apprehended act of infringement;
- an order for the defendant to deliver up or destroy any patented product in relation to which the patent is infringed, or any article in which that product is inextricably comprised, or any material, and implement, the predominant use of which has been in the creation of the infringing product;
- damages in respect of the infringement;
- an account of the profits derived by the defendant from the infringement; and/or
- a declaration that the patent is valid and has been infringed by the defendant.

The procedure for regular court proceedings applies to a patent infringement action in court. Typically, the plaintiff commences an action by filing an originating claim and serving it on the defendant. Parties will then file their respective pleadings and exchange their affidavits before setting down for trial. Patent infringement actions are heard in the General Division of the High Court and any appeals are made directly to the Court of Appeal.

Invalidity is an available defence to patent infringement and can be invoked during the infringement proceedings at the pleadings stage.

9.7 Procedures Available to a Generic Entrant

In general, when processing applications for therapeutic product registration, the HSA will take into account patent protection.

Before making an application for a generic market entry, the applicant must first declare the existence of any patent in force in respect of the therapeutic product, and whether the applicant is the proprietor of the patent. Where a patent is in force in respect of the therapeutic product and the potential applicant is not the proprietor, the potential applicant should first obtain the consent of the patent proprietor to make the application.

Where an applicant takes the position that the patent is invalid or will not be infringed by the generic market entry, the HSA may require the applicant to serve on the proprietor a notice in the form specified by the HSA, declaring that the applicant has made an application in respect of the proprietor's patent. If the proprietor does not make a court application to restrain the generic market entry or seek a declaration that the patent is valid or will be infringed by the generic market entry within 45 days of receiving the notice, the HSA may proceed with the generic market entry application. If the proprietor is successful in its court application, a 30-month moratorium will be granted, during which the HSA will not grant marketing approval for the generic market entry.

Where the patent proprietor misses the deadline to make a court application and the applicant successfully registers the therapeutic product, the proprietor may still make an application to the HSA to cancel the registration if the proprietor has obtained a determination that:

- the doing of an act authorised by the registration infringes a patent; or
- the initial declaration made by the applicant contains a statement that is false or misleading in a material particular or omits to disclose any matter that is material to the application.

This was confirmed in the recent Court of Appeal case Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd [2019] SGCA 31.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

It is an offence under the Trade Marks Act 1998 to counterfeit a trade mark, falsely apply a registered trade mark to goods or services, or do any of the following in relation to goods to which a registered trade mark is falsely applied:

- import into Singapore for the purpose of trade or manufacture;
- sell or offer or expose for sale; or
- possess for the purposes of trade or manufacture.

Seizure of Infringing Goods

The proprietor or licensee of a registered trade mark in Singapore who expects infringing goods to be imported or exported may request the Singapore Customs to seize the goods by giving written notice and sufficient information to identify the goods, enable the Singapore Customs to ascertain when and where the goods are expected to be imported or exported, and satisfy the Singapore Customs that the goods are infringing goods. The requestor may also be required to provide security for the liability or expense of seizing the goods, and their subsequent storage and disposal.

At any time after the goods have been seized, the Singapore Customs may give the requestor the name and contact details of any person connected with the import or proposed export of the seized goods and permit the requestor to inspect the seized goods. The seized goods

will be released to the importer or exporter if the requestor has not instituted an infringement action in relation to the goods before the expiry of the retention period.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Trade marks used for therapeutic products and medical devices will not be registered if they contain or consist of their international non-proprietary name without being accompanied by any other distinctive matter due to their descriptiveness and lack of distinctive character. There are no restrictions under trade mark law to import and distribute non-counterfeit, genuine pharmaceutical or medical device products.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

While the concept of trade dress is not expressly recognised in Singapore, it is possible to register the design of therapeutic products and medical devices and their packaging, and any such registered designs can receive protection for up to 15 years. Registrable designs generally refer to the features of shape, configuration, colours, pattern or ornament applied to any article or non-physical product that give that article or non-physical product its appearance, but do not include methods or principles of construction and designs that are solely functional.

The design and packaging of therapeutic products and medical devices, including their three-dimensional shape, may also potentially be registered as trade marks or receive protection under the common law tort of passing off.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Safety and efficacy data generated in support of an innovative therapeutic product registration cannot be relied on by a subsequent similar therapeutic product to obtain registration for a period of five years after the date of the registration of the first therapeutic product. Chemical drugs and biologics are not treated differently.

There is no such registration exclusivity period for medical devices.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

Waiver of Import Licence Requirements for Masks, Thermometers, etc

On 31 January 2020, an exemption order was effected, following which the HSA waived the requirement for import licences for surgical masks, particulate respirators (eg, N95 masks), thermometers and protective gear for medical professionals, such as gloves. Commercial importers were still required to file online notifications. However, the 2020 exemption order has been revoked from 1 September 2022 and all standard regulatory controls are now back in force.

Provisional Authorisations for COVID-19 Diagnostic Tests

As a temporary measure for the timely detection of COVID-19, the HSA had previously set up an expedited provisional authorisation process for COVID-19 diagnostic tests. However, the HSA is no longer accepting any such applications. With effect from 1 July 2023, COVID-19 test kits must

undergo a fully fledged registration with the HSA in order to be supplied in Singapore.

Regulatory Flexibility in Relation to Respiratory Devices

On 1 April 2020, the HSA announced a position of regulatory flexibility towards respiratory devices in view of the COVID-19 pandemic. The regulatory measures had:

- allowed the safe use of HSA-registered anaesthesia machines and positive airway pressure devices as emergency ventilators without approval;
- allowed upgrades or modifications to HSA-registered ventilators without approval as long as the changes do not affect registered performance specifications, the devices continue to meet the safety and performance requirements and the changes are notified on a six-monthly basis; and
- advised companies seeking to supply unregistered ventilators to meet local clinical needs.

However, these regulatory measures have since been discontinued. All standard regulatory controls are now back in force.

Provisional Authorisations for Respirator Decontamination Devices

On 11 June 2020, the HSA announced a provisional authorisation pathway for medical devices intended for decontaminating used respirators, in view of the increasing demand for respirators and the global supply constraints during the COVID-19 situation. However, this regulatory measure has since been discontinued. All standard regulatory controls are now back in force.

11.2 Special Measures Relating to Clinical Trials

As of February 2024, the HSA has not issued any special regulations in relation to clinical trials of COVID-19 treatments and vaccines specifically.

HSA Guidance on the Conduct of Clinical Trials

On 27 March 2020, the HSA issued a guidance on the conduct of clinical trials in relation to the COVID-19 situation, which was subsequently revised on 29 July 2020. The potential contingency measures discussed include:

- remote study visits;
- direct-to-patient services for investigational product supply;
- obtaining informed consent remotely; and
- sponsor site-monitoring visits.

Recommendations include:

- ensuring proper documentation of reasons for implementing any contingency measure and performing an impact assessment of the implemented measures on trial-participant safety, data credibility and trial integrity;
- engaging in early consultations with sponsors, investigators, IRBs and the HSA; and
- including in the Clinical Study Report the impact of COVID-19 and contingency measures on the safety and efficacy data for the clinical trial.

The guidance was revised again on 26 August 2022. A notable change from this latest revision is that the HSA will now prioritise clinical trial applications that are made to address the needs of public health emergencies such as COVID-19. The HSA may also allow for a shortened review time where appropriate. In a similar vein, the HSA will also prioritise requests made by sponsors

and investigators for rapid scientific and regulatory advice on the regulatory requirements for the development of novel vaccines and therapeutics to address the public health emergency.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

New Pandemic Special Access Route (PSAR)

In 2020, the HSA introduced the PSAR, which facilitates early access to novel vaccines, medicines and medical devices which the government designates as being required for a pandemic by granting such products an interim authorisation, exempting them from the registration and licensing requirements.

The HSA will consider interim authorisation if there is reasonable quality, safety and efficacy (QSE) data suggesting that the potential benefits outweigh the known risks and there is continuing QSE data generated from ongoing studies to support the eventual transition of the interim authorisation to full registration. The HSA may cancel an interim authorisation if the evolving data suggests that the benefits no longer outweigh the risks, or if the emergency ceases.

The PSAR allows vaccines, medicines and medical devices to be evaluated based on data submitted on a rolling basis instead of full data sets, giving the HSA more time to review submitted data while companies continue with clinical trials and development. Companies will be required to file an application to transition the status of the health product from PSAR interim authorisation to full registration, once sufficient data is available for full registration.

However, HSA is no longer receiving applications for therapeutic products under the PSAR, but applications for medical devices remain open.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

Other than the measures targeted at medical devices (such as diagnostic tests) for addressing COVID-19 specifically (discussed in **11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices**), no other simplifications or flexibilities in certification requirements were formally introduced by the HSA as a result of COVID-19.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

Waivers were granted for import licences on masks, respirators, thermometers and protective gear, although they are now discontinued (discussed in **11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices**).

The PSAR (discussed in **11.3 Emergency Approvals of Pharmaceuticals and Medical Devices**) allows, subject to conditions, the interim authorisation of vaccines, medicines and medical devices designated by the government to be exempt from the prohibition against importation without the required importer's licences and product registrations.

11.6 Drivers for Digital Health Innovation Due to COVID-19

Financial Support for Telemedicine

On 3 April 2020, to support the safe-distancing measures to minimise activities and to reduce the risk of local transmission of COVID-19, the Ministry of Health introduced a time-limited initiative to allow the tapping of funds from the Community Health Assist Scheme (a government scheme which provides subsidies for medical care at general practitioner clinics) and Medisave accounts (the national savings scheme which sets aside part of a person's income for

medical expenses) for follow-up video consultations by approved healthcare institutions for certain chronic conditions. The list of eligible chronic conditions was subsequently expanded from seven to 20.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

Power to Issue Compulsory Licences

There have been no announcements by the government regarding the compulsory licensing of COVID-19 treatments or vaccines. To the best of the available knowledge, the government has never exercised these powers.

Under the Patents Act, the government (and any authorised party) may do anything in relation to a patented invention for a public non-commercial purpose or, for or during a national emergency or other circumstances of extreme urgency, without amounting to an infringement of the patent.

In particular, the government may import any health product and do anything in relation to any imported health product that is patented, upon giving the Council for the Agreement on Trade-Related Aspects of Intellectual Property Rights the required notification.

Restrictions and Obligations of the Power to Issue a Compulsory Licence

The government can only issue licences which are non-exclusive and non-assignable (except where the assignment is in connection with the goodwill of the business in which the patented invention is used).

The government's right to use a patented invention is similarly non-exclusive, non-assignable and limited to the supply of the patented invention, predominantly in Singapore.

The government must inform the patentee promptly of its use of the patented invention and must pay the remuneration that has been agreed, or in default of agreement, remuneration as determined by the Singapore courts. There is no requirement to pay remuneration if the patentee has already received or will receive some other remuneration.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

As far as is known, no information is publicly available as to whether liability exemptions or indemnities are applicable for COVID-19 vaccines or treatments.

Notably, the government has introduced the Vaccine Injury Financial Assistance Programme to provide a one-time goodwill financial assistance to persons who experience serious side effects from the COVID-19 vaccines. To be eligible, the individual must have received their COVID-19 vaccine under the National Vaccination Programme and the side effect experienced must be assessed by a doctor to be related to the individual's COVID-19 vaccination.

11.9 Requisition or Conversion of Manufacturing Sites

As far as is known, no manufacturing sites were requisitioned or converted due to COVID-19.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

No systemic changes were made to the system of public procurement of medicines and medical devices due to COVID-19. However, according to a statement released by the Second Minister for Finance, emergency procurement procedures were invoked at the early stages of the pandemic to allow the government to source

and secure essential medical supplies quickly. Instead of open sourcing, the government contracted directly with suppliers with the necessary expertise and resources and who were best able to meet the requirements within the shortest timeframe possible.

The Minister signalled that, as the situation improves and the urgency to secure supplies abates, a larger proportion of procurement will be done through the default process of open sourcing.

SOUTH AFRICA

Law and Practice

Contributed by:
Tyron Grant, Dirk Hanekom, Chyreene Truluck, Jarred West and Patrick O'Brien
Spoor & Fisher

Contents

Contributed by: Tyron Grant, Dirk Hanekom, Chyreene Truluck, Jarred West and Patrick O'Brien,
Spoor & Fisher

Spoor & Fisher is a leading intellectual property firm that specialises in intellectual property (IP) law. The firm was established in 1920 and has since grown to become one of the largest and most respected IP firms in Africa. It provides a comprehensive range of legal services related to patents, trade marks, copyright, IP litigation, commercial IP transactions and IP portfolio management. The firm has a team of experienced attorneys, patent agents and technical specialists who serve clients in various industries, including pharmaceuticals, biotechnology, telecommunications and consumer goods. Spoor & Fisher has a strong reputation for excellence in the IP field and is consistently ranked among the top IP firms in South Africa and Africa as a whole. The firm has also been recognised internationally for its work in IP, receiving numerous awards and accolades over the years.

Authors

Tyron Grant is a partner at Spoor & Fisher and a registered South African patent attorney, with extensive experience in domestic and international patent matters, particularly in the field of biotechnology and life sciences. He specialises in the drafting, preparation and prosecution of patent applications. Tyron also assists with litigation matters related to biotechnological inventions and providing advice in respect of the Genetically Modified Organisms Act, Plant Breeders' Rights Act and National Environmental Management: Biodiversity Act.

Dirk Hanekom is a partner at Spoor & Fisher and a registered South African patent attorney. With his background in chemistry, he focuses on the prosecution of domestic and foreign patent applications relating to all areas of pharmaceutical science. He also advises his clients on regulatory matters relating to several industries including medicines, complimentary medicines, medical devices, and agricultural products.

Contributed by: Tyron Grant, Dirk Hanekom, Chyreene Truluck, Jarred West and Patrick O'Brien,
Spoor & Fisher

Chyreene Truluck is a partner at Spoor & Fisher and a registered South African patent attorney. She specialises in domestic and international patent and regulatory matters, particularly in the field of biotechnology and life sciences. Chyreene also has experience in commercial IP matters, life sciences regulatory matters and plant breeders' rights matters. She is a fellow of the South African Institute of Intellectual Property Law (SAIIPL) and a board member of the Licensing Executives Society of South Africa (LES).

Patrick O'Brien is a senior associate at Spoor & Fisher and a registered patent attorney with over seven years' experience in patent and design litigation across a broad spectrum of fields, including the mechanical, mining, metallurgical, electrical, chemical and pharmaceutical fields. He holds a BEng (Hons) (Chem) degree from the University of Pretoria and an LLB from the University of South Africa. Patrick is an attorney of the High Court of South Africa.

Jarred West is a partner at Spoor & Fisher with ten years of experience in anti-counterfeiting, with a specific focus on marketplace enforcement. He has presented numerous seminars on the topics of anti-counterfeiting and brand protection to officials from the Department of Customs and Excise and members of the South African Police Services. He is a South African trade mark practitioner and has a BCom (Hons) (Tourism Management) and an LLB. Jarred is also an attorney of the High Court of South Africa.

Spoor & Fisher

11 Byls Bridge Boulevard
Building No 14
Highveld Ext 73
Centurion
Pretoria 0157
South Africa

Tel: +27 12 676 1111
Fax: +27 12 676 1100
Email: info@spoor.com
Web: www.spoor.com

spoor • fisher

patents • trade marks • copyright

Contributed by: Tyron Grant, Dirk Hanekom, Chyreene Truluck, Jarred West and Patrick O'Brien,
Spoor & Fisher

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Regulation of the South African Pharmaceutical sector is primarily governed by The Medicines and Related Substances Act 101 of 1965 ("Medicines Act"), and the published Regulations thereto. These include the General Regulations to the Medicines and Related Substances Act, published under Government Notice 859 in Government Gazette 41064 of 25 August 2017 ("General Regulations"), which deal with general issues such as the registration and supply of medicines and requirements for permits and authorisations, including for conducting clinical trials. Regulations dealing with specific issues include, for example: (i) Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances, published under Government Notice R1102 in Government Gazette 28214 of 11 November 2005 ("Transparent Pricing Regulations"); (ii) Regulations Relating to Medical Devices and In Vitro Diagnostic Medical Devices (IVDs), published under Government Notice 1515 in Government Gazette 40480 of 9 December 2016 ("Medical Devices Regulations"); and (iii) Regulations Relating to the Period and Manner of Appeal Against Decisions of the Medicines Control Council, published under Government Notice R906 in Government Gazette 14826 of 28 May 1993 ("Appeal Regulations").

In addition, the Minister of Health is enabled to publish Notices in the Government Gazette relating to administrative aspects in terms of the Medicines Act and several such Notices have been published.

The regulatory body charged with administering the Medicines Act is the South African Health Products Regulatory Authority (SAHPRA), which took over administration of the Medicines Act from its predecessor, the Medicines Control Council (MCC). Both the MCC and the SAHPRA have issued several guidelines relating to various aspects of registration of medicines.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Administrative and Judicial Review

Under generally applicable administrative review provisions, an administrative action (a decision or omission in making a decision by a person exercising a public power or function) is subject to review under certain circumstances. The grounds for review include:

- the administrator was not authorised;
- a compulsory and material requirement was not complied with;
- the action was procedurally unfair;
- the action was materially influenced by an error in law;
- the action was taken for an ulterior purpose; or
- the action was unlawful or unconstitutional.

Challenging Pharmaceutical and Medical Device Regulators

A decision by the Director-General under the Medicines Act may be challenged by an aggrieved person by making written representations to the Minister within 30 days.

Any decision by the SAHPRA may be appealed on notice to the CEO of the SAHPRA within 30 days. The CEO must attempt to resolve the matter, failing which an appeal committee will be

formed. Any decision by the appeal committee is subject to judicial review.

1.3 Different Categories of Pharmaceuticals and Medical Devices

The Medicines Act provides for the regulation of health products intended for human and animal use including medicines, medical devices and IVDs, radiation-emitting devices and radioactive nuclides, complementary medicines and veterinary medicines. In terms of the General Regulations, medicines, including veterinary and complementary medicines, are classified as Category A, B, C or D medicines. Medical devices are similarly classified as Class A, B, C or D devices based on an assessment of the manufacturer's or distributor's intended use, the level of risk to users, the degree of invasiveness, and the duration of use and exposure. Although differing levels of supporting data will be required, each of the above-mentioned categories is regulated, in terms of the Medicines Act, by the SAHPRA. The SAHPRA has issued guideline documents for each category that detail the approach to be followed and the information required in the registration process. The Medicines Act and regulations do not make special provision for biologics, but separate guideline documents have been issued by the SAHPRA.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Non-clinical studies and clinical trials are provided for under the provisions relating to access to unregistered medicines in the Medicines Act. In terms of these provisions, the SAHPRA may authorise the sale of an unregistered medicine to a specific person or institution for the purpose of conducting clinical trials. The General Regulations to the Medicines Act set out the specific requirements for conducting clinical trials and investigations for medicines. In terms of these requirements, anyone wishing to initiate or conduct clinical trials must apply to the SAHPRA for authorisation to conduct such a trial by submitting the required fee, together with the stipulated information.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

In terms of the requirements set out in the Medicines Act and the General Regulations, anyone wishing to initiate or conduct clinical trials must apply to the SAHPRA for authorisation to conduct such a trial by submitting the required fee and stipulated information. There are set dates approximately every six weeks for submission of clinical trial applications to the SAHPRA, with the deadline published on its website. Once the clinical trial application is received it is screened and allocated to an evaluator within two weeks of the submission date and either rejected for being deficient or accepted for review, whereupon the evaluator reviews the study and submits its report to the clinical trials committee. Approximately six to eight weeks after the submission date, the clinical trials committee meets to discuss the report and provide its recommendation. Thereafter, the recommendation is communicated to the applicant, within ten weeks of the submission due date. In cases where the investigational product is unfamiliar, the submission may be referred to external reviewers or other committees of the SAHPRA for input, and the turnaround time may be prolonged.

2.3 Public Availability of the Conduct of a Clinical Trial

It is a requirement that all new clinical trials conducted in South Africa be registered in the South African National Clinical Trials Register (SANCTR), an official registry and member of

the World Health Organisation (WHO) Network of Primary Registers. The SANCTR provides a publicly searchable database including updated information on clinical trials on human participants conducted in South Africa. This information includes the purpose of the trial, details of who can participate, where the trial is located, and contact details.

The database ensures that the WHO-stipulated minimum dataset for registered trials is publicly and freely available to all users of the registry. It includes information on the questions being investigated, findings of studies, locations, funders, funding and research institutions involved. Further, principal investigators are obliged to ensure the reporting of the trial and its findings.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no restrictions on using online tools to support clinical trials, including for recruiting or monitoring purposes, provided that the data integrity and accuracy is maintained at all times.

2.5 Use of Data Resulting From Clinical Trials

The Protection of Personal Information Act, No 4 of 2013 (POPIA) commenced on 1 July 2020, with a one-year grace period to comply. POPIA was enacted to promote the protection of personal information processed by public and private bodies and to establish minimum requirements for the processing of personal information. The Academy of Science of South Africa has published a draft POPIA Code of Conduct for Research (POPIA Research Code) for public comment. However, POPIA and the POPIA Research Code only apply to identifiable personal information, and data is not considered personal data if it has been permanently de-identified or anonymised. Thus, clinical trial data is not considered personal, provided it is permanently anonymised and can be transferred.

2.6 Databases Containing Personal or Sensitive Data

Any database containing personal or sensitive data, that is data that is not permanently anonymised, would be subject to the requirements of POPIA. In terms of POPIA, such data may only be processed in a fair and lawful manner and only with the consent of the data subject. Such data may only be processed for specific, explicitly defined and legitimate reasons and may not be processed for a secondary purpose unless that processing is compatible with the original purpose and with the consent of the subject.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The assessment process and the related criteria for determining whether or not a product should be classified as a pharmaceutical or as a medical device should start with the definitions of "medicine", "medical device", and "IVD", provided in the Act. Where a reagent is used in vitro, alone or in combination, the product will be classified as a device. The regulations also deal with a "combination device" which is a device that incorporates a substance, which if used separately, would be considered a medicine. An application for registration of a medical device must provide the particulars of the scheduled substance or biological substances contained therein, which substances will require a separate registration as a medicine. Application may also be made to

transfer information pertaining to a medicine to the register for medical devices or IVDs.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

For biologic medicinal products, there are specific obligations that must be fulfilled in South Africa for granting a marketing authorisation. The SAHPRA has set out specific guidelines and requirements to ensure that biologic medicinal products are safe, effective and of high quality. These obligations include:

- conducting clinical trials;
- providing scientific data to demonstrate safety and efficacy;
- providing information on the manufacturing process and quality control measures;
- conducting post-market surveillance;
- complying with labelling and packaging requirements;
- providing updates to the SAHPRA regarding any changes to the manufacturing process; and
- complying with all relevant regulations and guidelines.

It is worth noting that the authorisation process for biologic medicinal products may be more complex and time-consuming than for other medicinal products due to the nature of these products and the need for extensive data on their safety and efficacy.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

The period of validity of marketing authorisation for pharmaceuticals and medical devices varies depending on the product and its characteristics. The initial period of validity for a marketing authorisation is ordinarily five years, but this period can be shorter or longer depending on the specific product and its intended use.

Marketing authorisation can be renewed for a further period of five years if the product continues to meet the necessary requirements for safety, efficacy and quality.

The SAHPRA can revoke a marketing authorisation:

- if the product is found to be unsafe, ineffective or of poor quality;
- if the holder of the authorisation fails to comply with the conditions of the authorisation; or
- if it fails to place the product on the market within a certain time frame.

The SAHPRA can also vary, suspend or withdraw a marketing authorisation under certain circumstances, such as if new safety concerns arise or if the product is found to be in violation of any regulatory requirements. The procedures for varying, suspending or withdrawing a marketing authorisation are outlined in the Medicines and Related Substances Act (Act 101 of 1965) and its associated guidelines.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

The procedure for obtaining a marketing authorisation for pharmaceuticals and medical devices in South Africa involves submitting an application to the SAHPRA.

The application must include:

- particulars of the applicant and the prospective holder of the certificate of registration;
- data on the safety, efficacy and quality of the product;

- a copy of the manufacturing licence;
- a copy of the current GMP certificate from the regulatory authority in the country where the product is manufactured; and
- details of the labelling and packaging.

The application is evaluated by the SAHPRA, and if all requirements are met, the marketing authorisation is granted.

The procedure for variation of a marketing authorisation involves submitting a variation application to the SAHPRA. The variation application should include all relevant data and information related to the proposed changes, such as changes in the therapeutic indication, formulation, posology, patient population, packaging and/or labelling. The SAHPRA will evaluate the variation application and determine if the changes are acceptable and whether the marketing authorisation can be amended.

It is permissible to transfer a marketing authorisation from one marketing authorisation holder to another. The transfer process involves submitting a variation application to the SAHPRA. The new marketing authorisation holder must meet all the requirements and obligations set out in the original marketing authorisation.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

In terms of Section 21 of the Medicines Act, the SAHPRA may authorise anyone to sell a specified quantity of an unregistered medicine, medical device or in vitro diagnostic to a specified person or institution for a specified period. Such approval may be withdrawn at any time by the SAHPRA. This section governs both clinical trials, as well as named-patient or compassionate use programmes.

Such application must be made online by a treating medical practitioner, who must provide details of the pharmaceutical or medical device, evidence of compliance with good manufacturing standards and reasons why a registered medicine cannot be used, together with the prescribed fee. Authorisation granted under Section 21 typically lasts for six months, following which re-authorisation must be requested.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

The holder of a marketing authorisation for a pharmaceutical or medical device is required to comply with ongoing obligations, including pharmacovigilance and technovigilance activities. These obligations entail monitoring, detection, assessment, understanding and prevention of adverse effects or incidents associated with the use of the product.

The holder of the marketing authorisation is required to report any suspected adverse reactions or incidents to the SAHPRA as per the prescribed requirements. The SAHPRA may also impose post-marketing obligations, including Phase IV trials, as part of the marketing authorisation, based on the evaluation of the risk-benefit profile of the product.

The holder must comply with these obligations and submit the required data to the SAHPRA within the specified timelines. Failure to comply with these obligations may result in sanctions, including revocation of the marketing authorisation.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

Third parties can access limited information regarding pending applications for marketing authorisation for pharmaceuticals and medical devices through the SAHPRA website. The information available includes the name of the product, the applicant's name, and the date the application was received. However, detailed information, such as clinical trial data or proprietary information, is not publicly available during the application process.

Once a marketing authorisation has been granted or refused, the decision and the reasons for it are made public on the SAHPRA website. Third parties can also request access to non-confidential portions of the marketing authorisation application through a formal request to the SAHPRA.

Commercially confidential information and personal information are protected under South African law. The SAHPRA may redact or withhold information that is considered commercially confidential or sensitive personal information, such as patient data or trade secrets, from the publicly available information. However, the SAHPRA is required to balance the public interest in accessing information against the protection of commercial or personal information.

3.8 Rules Against Illegal Medicines and/or Medical Devices

The Medicines Act and National Health Act provide for measures against contraventions in respect of medicines and medical devices. Inspectors under the Medicines Act may enter a premises relating to medicines or medical devices at reasonable times, and may inspect or seize such medicines or devices as evidence of contravention, or take samples necessary for further testing. Officials under the National Health Act may similarly enter health establishments to ensure compliance and obtain evidence of non-compliance, including search and seizure with a warrant. Various sanctions for contravention are available under the two Acts, including:

- fines;
- imprisonment;
- written warnings;
- revocation of compliance certificates; or
- referral to the National Prosecuting Authority.

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

Counterfeit goods, especially in relation to pharmaceutical and medical devices, represent a dire societal epidemic considering that their utility, as substandard goods, bears a strong possibility of adversely impacting the health and quality of healthcare treatment received by the general population. In terms of the counterfeit pharmaceuticals, most of these contain inter alia no active/substandard/illegal ingredients or incorrect dosages and their ingestion – especially where necessary for the management of life-threatening diseases – can prove fatal to the end-user. In relation to medical devices, the same concerns apply: the lower quality of equipment that is used when handling someone's life is of great concern because medical devices, in their ordinary sense, will not work as intended or cost someone their life due to inadequate use/functionality. Whilst they have gained popularity for their low cost amongst the less affluent groups, it nonetheless poses a danger to enable these goods to enter the South African channels of commerce.

One of the main purposes of the Counterfeit Goods Act is to prevent the release of counterfeit goods into the channels of commerce in South Africa. The Department of Customs and Excise ("Customs") is primarily responsible for monitoring the country's borders, including its ports of entry. To enable Customs to detain and seize any suspected counterfeit goods that are imported into South Africa, it is necessary for the owner of trade marks and/or copyright to file an application with the Commissioner for the South African Revenue Service (the "Commissioner") requesting such detention and seizure. This is governed by Section 15 of the Counterfeit Goods Act and the application filed is commonly referred to as "the Section 15 application".

In order to improve the success rate of counterfeit goods identification, sufficient training is required on how to identify them. Training of customs officials to maintain up-to-date knowledge of how counterfeiters are counterfeiting medical devices and pharmaceuticals is crucial. To promote this, brand awareness seminars and training sessions are necessary and, in conjunction with the experts from the brand owners, Customs officials can understand the intricacies of the goods and differentiate between that which is genuine and that which is not. Through this, Customs officials are given a basis of knowledge in what to immediately hone in on and look for when examining cargo.

4. Manufacturing of Pharmaceuticals and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

Manufacturing plants of pharmaceutical products and medical devices require a licence in terms of Section 22(C)(1)(b) of the Act. The application for registration as a manufacturer is made to the SAHPRA on the relevant Form, supported by the documentary proof specified in the General Regulations. A licensed manufacturer may validly conduct all operations including purchasing, processing, production, packaging, releasing, and storage and shipment. An annual renewal fee is payable and the licence is valid for a period of five years from the date of issue. In addition to the SAHPRA manufacturer's licence, an application will also require a site licence from the Department of Health and registration as a manufacturing pharmacy with the South African Pharmacy Council.

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

Establishments engaged in wholesale of pharmaceutical and medical devices also require a licence in terms of Section 22(C)(1)(b) of the Medicines Act. As with the manufacturer's licence, application for registration as a wholesaler is made to the SAHPRA on the relevant form, supported by the documentary proof specified in the General Regulations. In terms of the Regulations, a "wholesaler" is a person or entity that holds, stores, delivers or purchases medicines or scheduled substances from a

manufacturer and sells into the retail sector or to any person that may lawfully possess such substances. The licence is valid for a period of five years provided annual renewal fees are paid.

5.2 Different Classifications Applicable to Pharmaceuticals

Pharmaceutical products are scheduled as one of Schedule 0–8 for the purposes of sale, possession or manufacture. A consolidated list of the scheduled substances is available from the SAHPRA.

Schedule 0 substances may be sold in an open shop. Schedule 1 substances may only be sold without a prescription by a certain list of qualified individuals, and may not be sold to persons under the age of 12 years except where certain requirements are met. Schedule 2 substances may be sold without a prescription. The sale of Schedule 2, 3, or 4 substances may be repeated if indicated on the prescription, but not for longer than six months. Schedule 5 substances may only be prescribed for longer than six months if certain conditions are met. The sale of Schedule 6 substances may only be repeated on a new prescription and may only be sold for a course of not more than 30 days. Schedule 5 and 6 substances may be sold for use for a period of 48 hours in emergency situations on a verbal instruction, provided a written prescription is issued with 72 hours.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The importation and exportation of pharmaceuticals and medical devices in South Africa are governed by various laws and regulations, including the Medicines and Related Substances Act, the Customs and Excise Act, and the International Trade Administration Act.

The SAHPRA is the authority responsible for regulating the importation of pharmaceuticals and medical devices into South Africa. The SAHPRA applies import regulations at the point of entry to ensure that imported products comply with South African regulatory requirements.

Other entities that are involved in enforcing import regulations in South Africa include the South African Revenue Service (SARS), which is responsible for collecting customs duties, and the Department of Health, which has the power to prohibit the importation of certain pharmaceuticals and medical devices that do not meet South African regulatory requirements.

In addition to these entities, the National Regulator for Compulsory Specifications (NRCS) is responsible for enforcing technical regulations relating to the safety, health and environmental protection of products imported into South Africa, including medical devices. The NRCS ensures that imported products comply with relevant South African technical regulations and standards.

6.2 Importer of Record of Pharmaceuticals and Medical Devices

Any person who is a resident of South Africa, or who has a physical presence in the country, may act as the importer of record for pharmaceuticals and medical devices.

There are, however, specific requirements that must be met by the importer of record. The importer must be registered with the South African Revenue Service (SARS) as an importer and must hold a valid import licence issued by the Department of Health. The importer must also comply with all applicable regulations, including those related to labelling, packaging and storage of the products.

In addition, the importer must be able to demonstrate that the products being imported comply with all applicable regulations, including those related to safety, efficacy and quality.

It is important to note that the importer of record is responsible for ensuring that the products being imported comply with all applicable regulations and for any costs or liabilities associated with non-compliance.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Importation of pharmaceuticals and medical devices into South Africa is subject to prior authorisation, and the importer must hold a valid import permit issued by the SAHPRA. Without this permit, the importation of pharmaceuticals and medical devices is prohibited.

There are however certain exemptions available in terms of the Medicines and Related Substances Act (Act 101 of 1965) and the Medical Device Regulations of 2017, which provide relief from the requirement for prior authorisation for the importation of pharmaceuticals and medical devices.

Some of these exemptions include:

- personal use exemptions;
- emergency use exemptions;
- special use exemptions;
- low-risk medical device exemptions; and
- in vitro diagnostic medical device exemptions.

It is important to note that each exemption has its own specific criteria, and the importer must comply with all applicable requirements to qualify for the exemption.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

In South Africa, non-tariff regulations and restrictions (NTRs) on the importation of pharmaceuticals and medical devices are imposed by the Department of Health (DOH) and the SAHPRA under the authority of the Medicines and Related Substances Act, 1965 (Act No 101 of 1965). The NTRs are mainly based on the regulatory category of the products and are aimed at ensuring that imported pharmaceuticals and medical devices comply with the applicable standards, specifications and regulations.

Import permits and licences are generally required for the importation of pharmaceuticals and medical devices, depending on their regulatory category. The specific types of products subject to NTRs upon importation are listed in the Schedules to the Medicines and Related Substances Act, 1965, which include the Schedules of Medicines, Scheduled Substances, and Scheduled Devices. The Schedules categorise products according to their regulatory require-

ments, including registration, notification or exemption, and the importation requirements for each category are set out in the relevant regulations.

6.5 Trade Blocs and Free Trade Agreements

South Africa is a member of several trade bloc or free trade agreements that include provisions relating to the trade in pharmaceuticals and medical devices, and/or touch on regulatory standards or include statements in support of harmonisation. Examples include the Treaty of the South African Development Community (SADC Treaty), Agreement Establishing the African Continental Free Trade Area (AfCFTA), and the SADC-EU EPA (Economic Partnership Agreement (EPA) between the SADC EPA States, of the one Part and the European Union and its Member States, of the other Part). In addition, the SAHPRA provides for, and encourages, the use of reliance-based evaluations of products registered with a recognised regulatory authority (RRA). The RRAs include the European Medicines Agency Centralised Procedure (EMA CP); European Medicines Agency Decentralised Procedure (EMA DCP); Health Canada; the EU's Mutual Recognition Procedure (MRP); EU National Procedures; Medicines and Health Products Regulatory Agency; UK (MHRA); Ministry of Health, Labour and Welfare (MHLW), Japan; Swiss Agency for Therapeutic Products (Swissmedic); Therapeutic Goods Administration, Australia (TGA); the Unites States Food and Drug Administration (US FDA); and WHO listed Authorities (WLA).

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

The Medicines Act provides for a transparent pricing system and establishes a Pricing Committee tasked with overseeing the pricing of medicines and scheduled substances. The relevant regulations that govern pricing of medicines are the Regulations Relating To A Transparent Pricing System For Medicines And Scheduled Substances published under Government Notice R1102 in Government Gazette 28214 of 11 November 2005 (Pricing Regulations), as amended.

The Pricing Regulations establish a single exit price for each pharmaceutical. In terms of the Medicines Act and Pricing Regulations, no pharmacist, wholesaler, distributor or anyone permitted to sell medication may sell a medicine to anyone other than the State at a price higher than the single exit price. The Pricing Regulations provide for the charging of a dispensing fee by pharmacies; however, this is also strictly regulated.

The single exit price is made up of:

- the price determined by the manufacturer or importer;
- a logistics fee; and
- VAT.

In terms of the Pricing Regulations, the manufacturer or wholesaler must publish a schedule specifying the single exit price of a medicine or scheduled substance, as well as the logistics fee. The logistics fee is determined by agreement between a logistic services provider and the manufacturer or importer, which must be less

than the maximum logistics fee set by the Pricing Committee.

The single exit price may only be increased by the Minister of Health, on the recommendation of the Pricing Committee and taking into account several factors mentioned in the Pricing Regulations, including international pricing information, changes in foreign exchange rates and the need to ensure the availability, affordability and quality of medicines.

7.2 Price Levels of Pharmaceuticals or Medical Devices

The single exit price is determined by the Pricing Committee according to a methodology that conforms with international benchmarks, taking into account the price, and factors that influence price, at which the medicine or an equivalent thereof is sold in other countries in which the prices of medicines are regulated and published.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

The WHO advocates that procurement of medicines should take place against a list of essential medicines. In South Africa, there is a distinction between the procurement and pricing reimbursement of pharmaceuticals in the public sector versus the private sector.

In the public healthcare sector, the national selection of medicines available for procurement is provided for by the National Essential Medicines List Committee (NEMLC) and on a local level by the provincial and facility-based Pharmacy and Therapeutics Committees (PTCs). The State, through the National Department of Health, prepares, advertises, adjudicates, awards and manages the national medicines tenders. In terms of the tender process, pricing is evaluated critically on the basis of global trends in active pharmaceutical ingredient (API) price increases and formulation costs.

In the private healthcare sector, there is no reimbursement from public funds and clinical decisions regarding the selection of medicines are made within each medical scheme, as implemented by medical scheme administrators. The selection of medicines for private sector schemes is dependent on the type or class of medicine. For high-volume, low-cost medicines the selection is generally based on price. Where high-cost medicines are considered for selection, these are subject to a more thorough evaluation, which includes clinical efficacy and effectiveness, cost-effectiveness and budget impact on the medical scheme.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

In the private health sector, each medical scheme is allowed to use a selection process to create its own prescribed minimum benefit formulary on the basis of principles of evidence-based medicine, cost-effectiveness and affordability.

In the public health sector, the selection and pricing of medicines is subject to a tender process, the review of which includes a pharmacoeconomic analysis. However, this analysis merely informs whether a particular pharmaceutical will be procured and not necessarily the price at which it will be reimbursed.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

The Pricing Regulations specify the dispensing fee that may be charged with respect to the sale of any medicine. The maximum dispensing fee is calculated as a base amount plus a percentage of the single exit price of the medicine. Four cat-

egories are provided for, where the percentage of the single exit price for dispensing low-cost medicines is higher and the percentage of the single exit price for dispensing higher cost medicines is lower. The dispensing fee is reviewed annually by the Minister of Health.

8. Digital Healthcare

8.1 Rules for Medical Apps

Medical apps may be considered medical devices depending on their intended use and how they work. Medical apps that provide medical services for humans or animals relating to diagnosis, prevention, monitoring or treatment of diseases or injuries, or even relating to control of conception, fall within the legislative definition of a medical device in the Medicines Act. Accordingly, such medical apps are subject to the same rules and prescripts for medical devices.

8.2 Rules for Telemedicine

Regulation of Physicians and Telemedicine

Telemedicine is governed by the Health Professions Council of South Africa (HPCSA), as well as by legislation, including the Health Professions Act and National Health Act. Physicians may provide medical attention through mobile devices. Any telemedicine providers, including cross-border providers, must be registered in terms of the Health Professions Act and are subject to the ethical rules of conduct of the HPCSA. Cross-border telemedicine providers serving South African patients must be registered with the regulatory bodies in their respective countries, in addition to with the HPCSA.

Telemedicine Guidelines

The HPCSA guidelines provide that "Telehealth should preferably be practised in circumstances where there is an already-established practitioner-patient relationship. Where such a relationship does not exist, practitioners may still consult using Telehealth provided that such consultations are done in the best clinical interest of patients".

8.3 Promoting and/or Advertising on an Online Platform

Promotion or advertisement of medicines or medical devices on online media, including web pages or social media, is governed by the same regulations for any other form of promoting or advertising of such health products. Further, electronic promotion is not permitted unless, on first contact with a person, an option to opt out of further electronic communication is provided clearly and the decision in respect thereof is subsequently respected by the promoter. A comprehensive set of rules is applicable to advertising of medicines and medical devices, and is not set out here in detail. However, some of the provisions include that:

- scheduled medicines may only be advertised if registered;
- advertisements must be complete, clear and accurate, and not misleading in any form;
- advertisements may not disparage competitor products; and
- advertisements may not be set out in a manner relating to trade marks or otherwise that leads to the deception or confusion of consumers or practitioners as to the origin of the products.

8.4 Electronic Prescriptions

Electronic prescriptions are allowed in South Africa. A prescription prepared electronically must be in compliance with the Electronic Communications and Transactions Act, and if signed electronically, must be signed with an advanced electronic signature. The HPCSA guidelines pro-

vide that prescriptions must be issued under a practitioner's personal and original signature, which includes electronic signatures that meet the prescribed requirements. For Schedule 1 to 4 medicines the prescriptions may be computer generated, but for Schedule 5 to 8 medicines the prescriptions may be handwritten only and accordingly cannot be issued electronically.

The guidelines of the Digital Healthcare Association require that electronic scripts must be sent directly a patient's pharmacy of choice, and not to the patient to forward to the pharmacy.

Lastly, it is not an acceptable standard of care for prescriptions issued via telemedical services to be based solely on an online questionnaire.

8.5 Online Sales of Medicines and Medical Devices

The online sales of medicines and medical devices is generally governed by the same regulations for other forms of sale. There are no provisions prohibiting the online sale of medicines and medical devices, and accordingly such sale is permitted.

8.6 Electronic Health Records

Electronic Records and Health-Related Information

Electronic records are regulated generally by the Electronic Communications and Transactions Act (ECTA), and therefore include electronic health records. The National Health Act provides specifically that controls measures must be set up to prevent unauthorised access to health records.

Health-related information specifically is included in the definition of "personal information", which is governed in terms of the POPIA, in terms of which strict provisions are made for the lawful processing of personal information. Health-related information may strictly not be processed except by healthcare professionals or institutions, including insurance companies and medical schemes, as well as various other bodies under specific circumstances. The POPIA provides for the strict integrity, security and confidentiality of personal information.

The HPCSA guidelines also provide that arrangements must be made for proper security of electronic health records, including storage and transmission thereof, using internationally accepted standards. Passwords must be required for the access of health records in electronic format.

Cloud Platforms

There are not provisions in healthcare legislation specific to cloud platforms. Notwithstanding this, subject to the provisions of the ECTA and POPIA, and other measures put in place such as those of the HPCSA, regarding personal information, confidentiality and security, it would be permissible to transfer and store health-related data of patients on cloud platforms. Should a cloud platform be hosted outside of South Africa, the transfer of health-related information to a foreign country must be authorised, either by legislation or by the relevant regulatory body.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices

The South African Patents Act governs patents in South Africa. Under the Act, a patent provides the patent holder with the exclusive right to prevent others from making, using, exercising, dis-

posing of, or offering to dispose of the invention within South Africa, without their consent.

In practice, one common issue faced by pharmaceutical and medical device products under the Act is the question of whether a particular invention is patentable subject matter. Section 25(2) of the Act sets out certain exclusions from patentability, such as methods of treatment of the human or animal body by surgery or therapy, and diagnostic methods.

Another issue that may arise is the question of whether an invention is new and inventive. To be patentable, an invention must be new and inventive, which means it must not have been previously disclosed or made available to the public and must not be obvious to a person skilled in the art.

In addition to the general requirements for patentability, pharmaceuticals and medical devices may also be subject to specific patentability requirements. For example, Section 27(1) of the Act requires that an invention in the pharmaceutical field must involve a new chemical entity or a new use of a known chemical compound, and that the invention must be capable of being used in trade or industry.

9.2 Second and Subsequent Medical Uses

In South Africa, second and subsequent medical uses of a known product may be regarded as patentable subject matter. The South African Patents Act does not explicitly exclude second and subsequent medical uses from patentability. Therefore, claims directed to such uses may be patentable, provided that the relevant patentability criteria are met, including novelty, inventive step and industrial applicability. Additionally, in terms of decided South African case law, a claim directed to a first medical use should be drafted in the "for use type" claim format and a claim directed to a second medical use should be drafted in the "Swiss-type" claim format.

In relation to new dosage regimes and new or selected patient populations, such inventions may also be patentable subject matter, on condition that they meet the relevant patentability criteria.

Infringement of a second and subsequent patent of a pharmaceutical product may occur where an infringing party exploits the patented invention without the permission of the patent owner. This may include activities such as manufacturing, importing, offering for sale, selling or using the patented invention. The scope of the patent and the alleged infringing activity will be assessed by the courts in order to determine whether infringement has occurred.

9.3 Patent Term Extension for Pharmaceuticals

South African law does not make provision for, or include any mechanism whereby the term of a patent can be extended in any way. In fact, Section 69A of the Patents Act (a so-called Bolar provision) provides that certain non-commercial scale acts which are reasonably related to the obtaining, development and submission of regulatory information required under law will not be considered patent infringement. The proviso to this section is that no product may be stockpiled in anticipation of the first sale upon patent expiry.

9.4 Pharmaceutical or Medical Device Patent Infringement

A pharmaceutical or medical device patent may be infringed by unauthorised:

- making;
- use;
- exercise;
- disposition (eg, sale);
- offering to dispose (eg, advertisement); or
- importation.

Applying for marketing authorisation in itself does not constitute patent infringement. It may in certain instances, along with other factors, contribute to an apprehension that the applicant may launch an infringing product once marketing authorisation has been obtained, which may form one of the grounds for applying for an interim interdict (injunction), pending the outcome of a final action. Such an application, by its very nature, requires urgency, and amongst other things, it must be shown that there is a well-grounded apprehension of irreparable harm if the interim relief is not granted and ultimate relief is eventually granted.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

Defences to Patent Infringement

Specific defences to patent infringement in relation to pharmaceuticals and medical devices include Bolar-type defences. Acts conducted for the purpose of acquiring regulatory approval do not constitute patent infringement. However, the acts must be conducted in good faith, on a non-commercial scale and solely for the purposes reasonably related to obtaining regulatory approval.

Compulsory Licences

Compulsory licences of patents, including those relating to pharmaceutical products and medical devices, are provided for in South African patent law. Application may be made for a compulsory licence on two grounds:

- where the working of a patent without the infringement of a prior patent is dependent on obtaining a licence under the prior patent; and
- where patent rights are abused.

Patent rights are considered abused if:

- the patented invention is not worked to an adequate extent after a certain period subsequent to the application or grant of the patent, without satisfactory reason;
- the demand for the patented article is not adequately met;
- the trade or industry or agriculture is prejudiced by the refusal of the patentee to grant a licence reasonably or at all, and it is in the public interest that a licence be granted; or
- the demand for the patented article is met by importation, but at excessive prices.

9.6 Proceedings for Patent Infringement

Who May Institute Proceedings?

Patent infringement proceedings may be brought by the patentee, or in certain instances by a licensee under a licence of right, where the patentee refuses to institute proceedings after being called upon by the licensee to do so.

Relief

A successful plaintiff may obtain an interdict, delivery up, damages or a reasonable royalty instead of damages, and may recover legal costs.

Procedure

Patent infringement proceedings are typically instituted by way of action, commenced by issuing a combined summons, together with a particulars of claim. The defendant has an opportunity to defend the action, and will be required to deliver a plea to the particulars of claim, and

a counterclaim, if any. The plaintiff is afforded an opportunity to replicate to the defendant's plea, and plea to the counterclaim, following which the defendant may replicate to the plea in reconvention. This is followed by discovery and expert summaries, and any other interlocutory proceedings, and thereafter a trial date may be allocated.

Invalidity is available as a defence in an infringement action, and is instituted by way of counterclaim.

9.7 Procedures Available to a Generic Entrant

South African patent law makes provision for a declaration as to non-infringement should an applicant wish the courts to adjudicate on the question of whether or not there is or will be patent infringement. "Clearing the way" is not a requirement for generic market entry (ie, for obtaining marketing authorisation). The authorisation procedure for pharmaceuticals and medical devices does not take account of patent protection; ie, no provision is made in South African law for patent linkage.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Counterfeiting refers to the intentional and illegal production, or mislabelling, of goods regarding their identity and origin in order to appear as genuine and deceive customers into buying them. The pharmaceutical industry is worth almost USD1 trillion in sales annually, but the World Health Organisation (WHO) estimates that counterfeit medicines constitute more than 50% of the global drug market; a sizeable portion is experienced in developing countries. The groups distributing counterfeit medicines thrive mostly in countries where there are weak anti-counterfeiting laws; the legal actions are ineffective; and the pharmaceutical regulatory agencies are not efficient through being underfunded or understaffed. A similar trend is demonstrated with medical devices whereby, in 2010, the WHO revealed that 8% of the medical devices in circulation were known to be fake, but this is likely be an underestimate and also likely to be a much larger figure now.

There are three main sources of counterfeits entering channels of commerce: (i) national production; (ii) imported products which enter via the country's ports and borders; and (iii) independent manufacturers who produce counterfeit products. The first source refers to the manufacturing of counterfeit products in the domestic market and can be a consequence of outsourcing manufacturing to non-reputable manufacturers; the second pertains to the importation of fake items through the country's ports and borders; and the third relates to independent manufacturers producing counterfeit goods.

The similarity between these two industries, especially within the realm of counterfeits, is that they enter the market through the supply chain. With medical devices, criminals can invade the ecosystem through sneaking counterfeit medical devices into local hubs and, due to the complexity of the healthcare supply chain and the equipment involved with that industry, it becomes attractive for counterfeiters to bring their products in at a fraction of the price. In respect of pharmaceuticals, a study conducted on the supply chain of counterfeit medicine also demonstrated that the distribution side of the business concerns non-reputable doctors and pharmacies who seek to purchase stock for a lower price than the genuine product, whereas

another case identified the counterfeit goods being imported.

A burgeoning concern is the proliferation of counterfeit medical devices and pharmaceuticals becoming available online. E-commerce has grown into a key channel for counterfeiters to reach larger audiences and the advertising of pharmaceuticals and medical devices – which are ordinarily expensive – are attractive to the less affluent, especially since e-commerce circumvents the geographical border and enables them to obtain these goods. Counterfeiters have adopted strategies where they can receive stock by a supplier only when they have an order and can thus act as a front selling directly to the consumer but not holding any of the counterfeit goods in their possession. Corroborating this issue is the ability to leave little or no record to trace back to the end-user and, with the lack of a regulatory environment/oversight mechanism on these transactions, the sale of these goods is likely to continue.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

The Trade Marks Act 194 of 1993 (the "Trade Marks Act") was enacted to improve on the protection of trade marks and illuminate the intellectual property landscape in terms of what is permissible to be registered and the rights granted thereto. The Trade Marks Act permits a variety of different representations of a mark to be registered, and this is inclusive of shapes. However, Section 10 of the Trade Marks Act specifically provides for instances where the registration of a trade mark may be refused and, when it comes to registering a shape, pharmaceutical companies have encountered difficulties. One particular hurdle to overcome is the registrability of the shape of a medical pill because, regardless of the extensiveness and consistency of use, this is not a registrable trade mark. For a shape mark to be registered, it must overcome Section 10(5) of the Trade Marks Act, which stipulates that a mark which consists exclusively of the shape of the goods, where such a shape is necessary to obtain a specific result, may not be registered. In Beecham Group Plc v Triomed (Pty) Limited, it was held that the unique shape of a medical tablet, which was designed to make swallowing easier, is not registerable as a trade mark. Therefore, a pharmaceutical manufacturer cannot trademark the shape of the tablets that they use, nor the container utilised, thereby making them susceptible to counterfeits of their products being created.

Another hurdle to surmount is Section 10(11) of the Trade Marks Act which allows for a refusal to register a shape, container for goods, configuration, colour or pattern of goods where the registration of the mark will limit the development of an industry. The issue resides in the "colour depletion doctrine", which limits the number of colours available to an industry and forces the owners of the brand to operate within such parameters. This undoubtedly results in many of the same colour schemes for trade marks being utilised by the many entities in the industry and curtails, to a degree, the ability of the proprietor to act.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

Trade Dress

In South Africa, instances of trade dress infringement are enforced by way of the "passing-off" course of action. This is a common law remedy which was defined in Capital Estates v Holiday Inns as a representation by a person that their business is that of another, or associate thereof, to the extent that members of the public may be

confused into believing that one business is that of another. To be successful with a passing-off claim, it must be proven that:

- there was a reputation existing in the mark;
- there is evidence of misrepresentation by the other mark to the extent that there exists a likelihood of confusion or deception; and
- that there was damage, assuming that misrepresentation was established.

The Supreme Court of Appeal case of Koni Multinational Brands (Pty) Ltd v Beiersdorf AG examined these factors in relation to two personal care items and concluded that, on the basis of inter alia shape, product type, colour and reputation, the products were deceptively confusing, and such parameters would likely also be canvassed when considering the trade dress of pharmaceuticals or medical devices. However, it is worth considering the dissenting judgment which, whilst only persuasive, had a valid point in finding from leading literature on the topic that the public will tend to focus primarily on the brand name of any other product, as supposed to the entire get up. This lends itself to the conclusion that a competitor utilising a different and distinguishable brand name from another is likely to avoid a finding of passing-off.

Designs

IP protection is also available for the design of pharmaceuticals (for example tablets), medical devices or their packaging, in the form of design registrations. In addition to being new and original, or new and not commonplace, the articles to which the design applies must also be intended to be multiplied by an industrial process.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

South African law does not provide for any form of data exclusivity for pharmaceuticals or medical devices. No provision is made for Orphan Drug or similar status. In fact, the South African regulatory landscape favours early market entry and includes provisions for the more affordable supply of medicines. In addition to Section 69A referred to above, the Act provides a system for the potential parallel importation, under certain circumstances, of medicines registered in South Africa but imported by a person other than the holder of the registration certificate, and that such importation will not be considered patent infringement.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

South Africa did not enact any special rules or regulations to aid the commercialisation or distribution of medicines and medical devices during the COVID-19 pandemic, nor were any rules relaxed. However, the SAHPRA did make use of the relevant provision in the Act which allows them to authorise the sale of unregistered medicines, medical devices and IVDs. The SAHPRA also partnered with other leading regulatory agencies during this time to ensure the availability of the medicines and devices required to respond to the pandemic. The SAHPRA made use of the provisions to allow for the supply of unregistered medicines to approve the use of several vaccines, ivermectin, and medical devices. Several of the vaccines initially approved under this process have now undergone full registration.

11.2 Special Measures Relating to Clinical Trials

The SAHPRA issued special guidelines relating to the inspection of clinical trial sites and other on-site inspections. In particular, in order to ensure safe on-site inspection of sites for compliance with Good Clinical Practice guidelines, the SAHPRA provided for remote virtual inspection of such sites, as well as the following of strict protocols for on-site inspection.

Furthermore, for ongoing trials, the SAHPRA issued a communication to all investigators requiring them to consider the circumstances of the trial and modify the study conduct accordingly, including amending patient monitoring standard operating procedures, providing for virtual safety assessments and where possible, alternative delivery methods.

In addition, the SAHPRA provided for expedited review of COVID-19-related clinical trial applications, with a review timeline of seven to ten working days.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

South Africa had regulatory pathways applicable for emergency approvals of pharmaceuticals or medical devices prior to the COVID-19 pandemic. The SAHPRA had provisions for expedited review of applications for registration of medicines and medical devices in cases of a public health emergency, such as epidemics or pandemics. Under these provisions, the SAHPRA can waive certain requirements for the registration of medicines and medical devices and fast-track the review process to ensure availability of essential medical products in emergency situations. The expedited review is applicable for products already approved by certain international regulatory authorities, or in cases of new products for which there is a strong scientific rationale and evidence of safety and efficacy.

In response to a public health emergency, the SAHPRA may allow for an expedited regulatory process to enable faster approvals for medicines that are not yet available for use in South Africa. The expedited process allows for the accelerated evaluation of applications for registration or emergency use authorisations of diagnostics, therapeutics and vaccines.

Applicants must submit a complete dossier for evaluation, and the SAHPRA will prioritise the evaluation of these dossiers. The authority may also waive certain requirements, such as the need for local clinical data, depending on the product's nature and urgency. However, safety, quality and efficacy requirements are still maintained, and products authorised through this pathway must meet these requirements before being allowed on the market.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

SAHPRA introduced certain flexibilities relating to manufacturing certifications for pharmaceutical and medical device manufacturers during the pandemic to ensure that production of essential products could continue. SAHPRA provided for the extension of validity period of GxP certificates, and introduced remote GxP inspections of manufacturing facilities to reduce the need for in-person inspections during the pandemic.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

South Africa implemented various import/export restrictions and flexibilities in relation to medicines and medical devices due to the COVID-19 pandemic. In March 2020, the South African government issued regulations restricting the export

of certain medical supplies, including personal protective equipment (PPE) and ventilators, to ensure that these supplies remained available in the country during the pandemic.

The South African government also implemented measures to expedite the importation and registration of essential medical products and devices, including COVID-19 diagnostic tests and vaccines. In addition, the SAHPRA introduced several expedited review processes for COVID-19-related products to facilitate quicker regulatory approval of medicines and medical devices. These processes included:

- expedited review of clinical trial applications;
- expedited review of applications for the use of unregistered medical products in the course of an emergency situation;
- COVID-19 emergency use authorisations; and
- fast-track registration of COVID-19 vaccines.

These expedited review processes were put in place to respond to the urgent public health needs created by the COVID-19 pandemic.

11.6 Drivers for Digital Health Innovation Due to COVID-19

Numerous systems were introduced or improved upon to facilitate digital healthcare solutions during and subsequent to the COVID-19 pandemic:

- introductions of mobile health apps, or more features in respect of existing apps;
- developments in telemedicine;
- WhatsApp and SMS-based systems; and
- utilisation of various social media platforms.

These solutions provided access to medical assistance virtually, improved communications, assisted in screening and monitoring of diseases, bettering electronic prescriptions and ensuring compliance with medicines or treatments, or were used simply for educational or awareness campaigns.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

In 2020, South Africa joined with India in petitioning the World Trade Organisation (WTO) to temporarily suspend intellectual property rights in order to ensure accessibility of COVID-19 vaccines and other new technologies for poorer countries. In 2022 the WTO adopted a limited waiver for patents on COVID-19 vaccines, however it is not clear whether this has resulted in additional vaccines being registered or produced in South Africa.

Although the South African Patents Act provides for compulsory licences in certain instances, no such licences have been applied for in respect of COVID-19 vaccines or therapeutics to date. The requirements for the issue of a compulsory licence in South Africa are set out in the Patents Act.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

In order to secure a supply of COVID-19 vaccines, the South African government had to exempt vaccine manufacturers from liability. The mechanism for exempting manufacturers from liability was introduced under the regulations promulgated in terms of the Disaster Management Act, 2002. In an amendment to the regulations published on 22 April 2021, government introduced the COVID-19 Vaccine Injury No-Fault Compensation Scheme. In terms of the published regulations the scheme will only come to an end upon publication of a notice to that effect in the Government Gazette, after the period for submitting claims has expired, and all claims have been finalised.

11.9 Requisition or Conversion of Manufacturing Sites

There were no special provisions relating to the requisition or conversion of manufacturing sites in South Africa in response to the pandemic. However, the South African government did introduce measures aimed at encouraging the local production of pharmaceuticals and other medical supplies during the pandemic. The establishment of a dedicated fund, the COVID-19 Solidarity Fund, assisted with funding for companies to repurpose their existing facilities to manufacture certain essential medical supplies. SAHPRA also produced updated guidelines specifically directed at the licensing of personal protection products such as masks and sanitisers. Some examples of successful efforts to increase local production include the National Ventilator Project (NVP) between the Department of Trade and Industry (DTI) and The Council for Scientific and Industrial Research (CSIR), and an agreement between a local pharmaceutical manufacturer, Aspen Pharmacare, and Johnson & Johnson to manufacture COVID-19 vaccines in South Africa.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

On 15 March 2020, the president of the Republic of South Africa, President Cyril Ramaphosa, declared a national state of disaster in South Africa following the WHO declaring that the COVID-19 outbreak was considered a pandemic. The pronouncement of a state of disaster allowed for emergency procurement of certain named classes of goods (including personal protective equipment, digital thermometers, sanitisers and disinfectants, and body bags) in terms of the Disaster Management Act and an instruction from National Treasury. The national state of disaster as it relates to COVID-19 has since been lifted.

SOUTH KOREA

Law and Practice

Contributed by:
Keum Nang Park, Eileen Jaiyoung Shin, Jeonghoon Hong and Soo Yeon Park
Lee & Ko

Contents

Lee & Ko has become one of Korea's premier full-service law firms, widely recognised for its leadership and outstanding success in every area of legal practice. As has been confirmed in numerous reviews conducted by Korea's major media outlets, as well as ratings produced by international law firm rating services, Lee & Ko enjoys one of the highest levels of client satisfaction and a particularly excellent reputation for the quality of the firm's legal services. Lee & Ko's healthcare practice group of more than 70 professionals focuses on providing legal services expertly tailored to meet the needs of clients with specific concerns around healthcare and related matters, including pharma, bio, medical devices, food and beverage products, medical data with AI application, genome analysis, DTC, tobacco and cosmetics.

Authors

Keum Nang Park is co-head of the healthcare and life science group at Lee & Ko, and is a leading expert in the areas of intellectual property law and pharmaceutical affairs law. She is a licensed pharmacist and a licensed pharmacist in Eastern medicine with a Master's degree in Pharmacology. Her unique background gives her the edge to effectively represent clients in complex, multi-jurisdictional litigation. Ms Park has been widely recognised for her expertise and received recognition from the Minister of Ministry of Food and Drug Safety.

Eileen Jaiyoung Shin is a partner of the healthcare and life sciences practice group of Lee & Ko specialising in the areas of general corporate matters, commercial transactions and healthcare industry regulatory compliance. She has extensive experience advising clients in the pharmaceutical, medical device, cosmetic, tobacco and food industries on regulatory compliance and transactional matters. In addition, Ms Shin regularly advises multinational clients on new drug pricing and after-launch life cycle management with the firm's active market access practice.

Jeonghoon Hong is a partner in the healthcare and life sciences practice group at Lee & Ko. He obtained his Master's degrees in Biostatistics from Seoul National University, and Applied Mathematics from Harvard University. He specialises in statistical methods to address various challenges and questions in biomedical research, clinical trials, epidemiology, public health, genetics, and other related areas. He has experience designing studies to investigate the efficacy and safety of new drugs or medical treatments, analysing data from clinical trials to assess treatment effects and potential adverse reactions, conducting population-based studies to understand disease patterns and risk factors, and developing statistical models to predict health outcomes or assess the impact of interventions.

Soo Yeon Park is a partner of the healthcare and life sciences practice group at Lee & Ko, specialising in the areas of assisting clients with regard to regulatory, transactional and IP-related matters relating to pharmaceuticals, medical devices, and other healthcare products. She has extensive experience in advising clients in the pharmaceutical, medical device, cosmetic, tobacco and food (including functional food products and nutritional supplement) industries on regulatory compliance and corporate transactional matters. Prior to joining Lee & Ko in 2015, she worked as a pharmacist for Hallym University Medical Centre.

Lee & Ko

Hanjin Building
63 Namdaemun-ro
Jung-gu Seoul
04532
South Korea

Tel: +82 2 772 3036
Fax: +82 2 772 4001/2
Email: keumnang.park@leeko.com
Web: www.leeko.com

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The primary legislation governing pharmaceuticals in Korea is the Pharmaceutical Affairs Act (PAA). The Act on the Safety of and Support for Advanced Regenerative Medicine and Advanced Biological Products (AABP) regulates cutting-edge biopharmaceutical products such as cell therapy, gene therapy, and tissue engineered products. The Medical Devices Act and the In-Vitro Medical Devices Act (collectively, MDA) regulate medical devices. All Acts, together with related presidential decrees, regulations and guidelines, are promulgated by the Office of the Prime Minister and the Ministry of Food and Drug Safety (MFDS).

On a related note, the Digital Medical Product Act was newly enacted on 23 January 2024. It aims to define and regulate digital medical products, including digital medical devices, digital integrated drugs, and digital medical/healthcare support devices. Such products were previously governed by the existing PAA, Medical Device Act, In Vitro Diagnostic Medical Devices Act, their subordinate regulations, and MFDS guidelines. The Digital Medical Product Act will now have precedence over those regulations. It will first be effective for digital medical devices and digital integrated drugs on 24 January 2025, and sequentially for digital medical/healthcare support devices on 24 January 2026.

The Ministry of Health and Welfare (MHW) and the MFDS (which is overseen by the MHW) are the main regulatory bodies in relation to pharmaceuticals and medical devices, and they are responsible for issuing and enforcing most of the regulations, guidelines and administrative orders for pharmaceuticals and medical devices. Local governments (such as the Seoul Metropolitan government) also monitor pharmaceutical and medical device entities within their jurisdiction.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Administrative orders issued by the MFDS, MHW or local governments to entities in violation of the PAA, AABP or MDA may be challenged via an administrative appeal to the competent administrative appeals commission under the Administrative Appeals Act, or via administrative litigation to the competent court under the Administrative Litigation Act. In most cases, either action will request that the competent commission or court revoke or declare null the administrative order. Rulings rendered by an administrative appeals commission may also be appealed to the competent court.

In general, these challenge procedures are applicable to other regulated products, such as food products.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals are categorised into over-the-counter (OTC) drugs and prescription drugs. In principle, all pharmaceuticals must be delivered to patients by licensed pharmacists at pharmacies, except in some cases such as administration of pharmaceuticals to patients by doctors within medical institutions. While prescription drugs require a prescription from physicians, OTC drugs can be supplied to consumers without a prescription. Additionally, the MHW has designated certain OTC drugs as emergency drugs to treat light symptoms in urgent situations at patients' discretion, and such OTC drugs may be sold at 24-hour convenience stores by non-

pharmacists after such stores' registration with the local government.

Medical devices are classified into Classes I to IV, based on their intended use and the risk level associated with the device. Class I devices present the lowest risk, while Class IV devices are considered the highest risk and are subject to the greatest scrutiny.

The prospective Digital Medical Product Act, to be implemented for digital medical devices and digital integrated drugs on 24 January 2025, and for digital medical/healthcare support devices on 24 January 2026, allows the Minister of Food and Drug Safety to classify digital medical products into different tiers depending on their purpose, function, and potential risk, among other factors.

2. Clinical Trials

2.1 Regulation of Clinical Trials

The PAA, the MDA, the Bioethics and Safety Act (BSA) and relevant regulations govern clinical trials of medicinal products and medical devices, and the MFDS oversees approval for clinical trials.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

To conduct a clinical trial, the relevant clinical trial protocol must be reviewed and approved by an institutional review board (IRB) of the MFDS. The materials required to be submitted by the applicant for clinical trial approval include the following:

- for medicinal products, the clinical trial protocol, development plan, investigator's brochure, material on manufacturing and quality of the investigational drug, preclinical trial data, materials on medical institution conducting the clinical trial, institute analysing the clinical trial sample, and the investigator and Contract Research Organisation (CRO), policies and forms regarding the clinical trial subjects, etc; and
- for medical devices, the clinical trial protocol, materials proving that the clinical trial medical device is being manufactured in accordance with the facility, manufacturing and quality management system standards, purpose of use, working principle and technical documents to verify performance and safety.

Once approved, clinical trials must be conducted in accordance with the protocol and standards regarding good clinical practice for medicinal products and medical devices, as applicable.

2.3 Public Availability of the Conduct of a Clinical Trial

All clinical trials are registered with the MFDS. Basic information regarding clinical trials such as sponsor information, information on the clinical trial including its title, purpose and use, information of drug used, plan for clinical trial, method to arrange the participants subject to experimental group or control group, the status of the clinical trial (eg, on-going, completed), method to administer and evaluate the clinical test (eg, primary and secondary end point), and subject inclusion and exclusion criteria can be searched at the medicinal products comprehensive information system, which is a website of the MFDS.

2.4 Restriction on Using Online Tools to Support Clinical Trials

No restriction exists on using online tools to support clinical trials. However, it is generally required that clinical trials are to be conducted by doctors or hospitals with in-person

interviews, and written informed consents from clinical trial subjects. Recruitment of clinical trial subjects can be conducted online.

When a crisis alert level of serious magnitude or higher is declared, and if deemed necessary to protect patients, medical personnel, and medical institutions from the risk of infection, the protocols allowing provisional "untact" medical care (a term coined by a research team in Korea for non-face-to-face contact) under Article 49–3 of the Infectious Disease Control and Prevention Act may be implemented. This may apply to clinical trials, where the treatment for and monitoring of patients during clinical tests may be converted to untact treatment and monitoring.

2.5 Use of Data Resulting From Clinical Trials

The data from clinical trials is considered as personal and sensitive data and the institutions conducting clinical trials are subject to the Personal Information Protection Act (PIPA) for the collection, use, provision, etc, of such personal and sensitive information. In addition, information with respect to the participant's identity or sponsor's intellectual property, etc, shall not be disclosed to third parties unless there is explicit permission granted to access that information. Further, in order to protect the clinical trial subjects' identity, unique identity numbers need to be assigned to subjects instead of their name.

When obtaining consent on the clinical trial from its subjects, the medical institution conducting the clinical trial must explain that the records of subjects' personal information will be kept confidential, stipulate the same in writing, and make it clear that such personal information shall be maintained confidential even if results of the clinical trial become publicly available. It further needs to inform that the records relating to clinical trial including the subjects' medical record can be accessed by the sponsor's monitoring agent or inspector through an institutional review board (IRB) of the medical institution, and that the MFDS may also access and review such information and relevant materials.

2.6 Databases Containing Personal or Sensitive Data

In addition to the requirements described in **2.5 Use of Data Resulting From Clinical Trials**, according to clinical trial management standards, such database needs to have a security system which prevents unauthorised persons from accessing the information, and matters as prescribed by the chief of MFDS for proper management of electronic records must be complied with. The sponsor also has to use identifier code for clinical trial subjects.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

Under Article 2 of the PAA, "drugs" are defined as those other than quasi-drugs, among the articles listed in the Korean Pharmacopoeia, or articles, other than appliances, machinery or equipment, used for the purposes of diagnosis, treatment, alleviation, care or prevention of diseases of human beings or animals, or used for the purpose of exerting pharmacological effects upon the structure or functions of humans or animals.

A "medical device" is defined under the MDA as an instrument, machine, apparatus, material, software or any other similar product specified in the following:

- a product used for the purpose of diagnosing, curing, alleviating, treating or preventing a disease;
- a product used for the purpose of diagnosing, curing, alleviating or correcting an injury or impairment;
- a product used for the purpose of testing, replacing or transforming a structure or function; and/or
- a product used for the control of conception.

With regard to medical devices, sometimes it is difficult to distinguish medical devices from personal healthcare products (which do not require medical device approval) even when considering the purpose of use and the risk to the human body. In such case, guidance or administrative interpretation from the MFDS may be requested.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

To market biological drugs in Korea, the initial marketer is required to obtain marketing approval the same as that for chemical drugs. Key factors to consider when reviewing an application for market approval are:

- data on origin or discovery and development process;
- data on structure and physicochemical properties;
- data on stability;
- toxicological data;
- data on pharmacological mechanism;
- data on clinical trial results; and
- data on domestic and overseas usage and approval status.

For some biologics such as the botulinum toxin, additional strict requirements on use, transfer, etc, apply. Meanwhile, unlike generic drugs, a bioequivalence test does not replace data on stability and efficacy in order to obtain market approval for biosimilars.

On the other hand, cell therapy products (medicine manufactured by physical, chemical, or biological manipulation, such as cultivation, proliferation, or screening of living cells of humans or animals in vitro), gene therapy products (medicine containing genetic material or drug-containing cells into which genetic material has been modified or introduced), tissue-engineered products (medicine manufactured by applying engineering technology to living cells or tissues of humans or animals for the purpose of regenerating, restoring or replacing tissues), advanced bio-convergence products (cell therapy products, gene therapy products, tissue engineered products, and medicinal products formed through physical and chemical combination (including fusion, complex, combination) with medical devices under the MDA) are regulated by AABP, and marketing authorisation must be obtained accordingly. (For those not regulated by AABP, PAA applies.)

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

Under the PAA, marketing authorisation for pharmaceuticals is valid for five years, and renewal is required after five years. For renewal, safety data, domestic manufacturing/import data, and a GMP compliance certificate must be submitted to the MFDS at least six months before the expiration date. If the marketing authorisation holder does not file the application for renewal or fails to meet the requirements, the marketing authorisation is cancelled.

In the case of medical devices, no renewal system existed previously, but since 8 October 2020, marketing authorisation for medical devic-

es is to be valid for five years from the marketing authorisation date. Similar to pharmaceuticals, for medical devices, data proving that safety and efficacy has continued to be the same since the initial issuance of the marketing authorisation, and data on production/import performance, etc, must be submitted for renewal at least 180 days before the expiration date.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

Data proving safety and efficacy, such as clinical trial results, must be submitted to the MFDS for obtaining marketing authorisation. In some cases, such as generic drugs or incrementally modified drugs, however, safety and efficacy data can be replaced with bioequivalence test result data.

The procedure for assessing marketing authorisation on medical devices varies depending on the risk they pose to human bodies. In the case of high-risk medical devices (Class III/IV), a higher level of scrutiny will apply, such as requesting and reviewing more data, including clinical data proving the efficacy and safety, compared to low-risk medical devices (Class I/II) where various data such as clinical trial data is exempted.

In the event that the indications for drugs or medical devices are changed after marketing authorisation, it is possible to file an approval for change, and the procedure is similar to the procedure for new marketing authorisations.

It is also possible to transfer a market approval from one market approval holder to another.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

In Korea, even if no marketing authorisation has been obtained, investigational drugs can, after relevant clinical trials are implemented and approved, be used as part of a compassionate use programme. The compassionate use programme is permitted only in the following cases:

- when treating patients with life-threatening conditions such as an end-stage cancer or acquired immunodeficiency syndrome (AIDS);
- when treating emergency patients, such as those in a critical condition or for whom there are no alternative treatment options; and
- when attempting to use investigational drugs for research or analysis (referring to research or analysis not involving human subjects).

In addition, certain orphan drugs and drugs for the treatment of rare diseases that are directly imported and distributed by the Korea Orphan & Essential Drug Center (KOEDC), as well as drugs that the MFDS admits for urgent introduction for the treatment of patients, are exempted from the requirement for obtaining marketing authorisation.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

Pharmaceuticals and medical devices are subject to PMS during the following re-examination periods, starting from the date of issuance of the market approval:

- new drugs – six years;
- pre-approved prescription drugs with a new indication – four years; and
- new medical devices – four to seven years.

Of note, the National Assembly passed an amendment to PAA on 1 February 2023, which will repeal the drug re-examination system and introduce a comprehensive risk management system which integrates the safety management policy after the drug's commercial release. The amendment has not been officially announced yet, but MFDS stated that it will be officially announced sometime in February 2024. Once announced, it will go into effect in one year from the announcement.

Approved pharmaceuticals or medical devices may be subject to re-evaluation if the MFDS finds it necessary to re-evaluate the safety and efficacy of the product. To re-evaluate, the MFDS reviews not only documents and materials submitted before the marketing authorisation, but other post-approval information, including side-effect data since launch, status in other countries and amendments to the marketing authorisation made in relation to safety and efficacy.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

Under the PAA and MDA, if the applicant files a request in writing to protect information or data contained in the application for marketing authorisation against disclosure, such information or data should not be disclosed unless otherwise required by the public interest. The PAA and MDA even impose criminal penalties for breaching the non-disclosure obligation above.

Further, the Korean Criminal Act (KCA) punishes a public official or former public official who divulges secrets obtained in the course of performing their official duties.

While the contents of the application are not disclosed, third parties may infer from the following circumstances that certain marketing authorisations may be granted shortly:

- clinical trial approval status for drugs is published on the MFDS website; in particular, it can be inferred that generic drugs are scheduled to be released from the clinical trial approval status, since the submission of bioequivalence test results is required for approval of generic drugs; and
- the MFDS notices the DMF registration of APIs on its website.

3.8 Rules Against Illegal Medicines and/or Medical Devices

A person who sells medicinal products or medical devices without marketing authorisation shall be punished by imprisonment for not more than five years or by a fine not exceeding KRW50 million. Also, the MFDS may suspend the manufacturing business for six months as an administrative sanction (licence may be revoked for repeat offenders).

It should be noted that, unlike criminal punishment, an administrative sanction can be imposed regardless of the violator's intent.

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

The PAA and MDA have no regulation on the importation or exportation of counterfeit pharmaceuticals and medical devices.

However, the Korea Customs Service (KCS) should notify the owner of IP rights when discovering suspected counterfeits of the medical devices or pharmaceuticals which are protected by valid IP rights. Upon notification, the right-holder can request the KCS not to provide customs clearance to such counterfeits.

4. Manufacturing of Pharmaceuticals and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

A manufacturing plant of pharmaceutical products is subject to an authorisation for manufacturing pharmaceuticals under the PAA, and a manufacturing plant of medical devices needs an authorisation for manufacturing medical devices under the MDA. The MFDS grants such authorisation. When a person, who intends to manufacture pharmaceuticals or medical devices, prepares and files the application for manufacturing authorisation and necessary documents with the local district of MFDS to which the manufacturer belongs, such local district MFDS reviews whether the applicant for manufacturing approval (in the case of a company, the representative) is qualified, whether all necessary documents are satisfied, and assesses whether the applicant has necessary facilities and labour force, and if appropriate, it grants authorisation. Once authorisation is granted, it will be valid without any other special renewal procedure unless grounds for revocation occur under the PAA or the MDA.

Of note, separate from MFDS's authority under PAA/MDA with regard to requirements for facilities and labour force, other license/authorisations will be required for plant construction (such as those related to environment and safety).

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

Wholesale of pharmaceuticals is subject to authorisation from the head of Si/Gun/Gu (ie, the local government) in Korea. To obtain such authorisation, the applicant should meet qualifications and have a business place, warehouse and other facilities as prescribed by Presidential Decree of the PAA. The authorised wholesaler is in principle required to employ a pharmacist to manage the relevant tasks. Such authorised wholesaler can sell or acquire pharmaceuticals for sales purposes which comply with the standards for quality management of pharmaceuticals in distribution. There is no validity period for the authorisation of wholesale of pharmaceuticals.

For the wholesale of medical devices, the wholesaler should file a notification of distribution with the competent Special Self-Governing Mayor, Special Self-Governing Province Governor, or the head of a Si/Gun/Gu. Once such notification of distribution is accepted, the person can distribute medical devices and there is no period of validity for wholesale notification.

5.2 Different Classifications Applicable to Pharmaceuticals

Pharmaceuticals are classified into OTC drugs and prescription drugs under the PAA.

OTC drugs refer to any of the following drugs, which meet the standards determined and publicly notified by the Minister of Food and Drug Safety, following consultations with the Minister of Health and Welfare:

- a drug, the misuse or abuse of which is of little concern, and whose safety and efficacy

can be expected even when used without a prescription by a physician;
- a drug that may be used to treat a disease without a physician's or dentist's professional knowledge; and/or
- a drug which has a relatively small side effect on human bodies in light of their dosage form and pharmacological action.

Emergency drugs among the OTC drugs are used mainly for minor symptoms at the sole discretion of patients, and are publicly notified and prescribed by the Minister of Health and Welfare. Such emergency drugs can be purchased at places other than pharmacies. Conversely, prescription drugs mean drugs which are not OTC drugs and require a physician's prescription.

Meanwhile, orphan drugs mean either drugs used for the purposes of diagnosis or treatment of rare diseases under the Rare Disease Management Act or drugs with rare subject of application, whose alternative drug does not exist or whose safety or efficacy has been significantly improved compared to its alternative drug, which are designated by the Minister of Food and Drug Safety.

Other than the above, drugs essential for health and medical treatment, whose stable supply is difficult based only on market function, are designated and managed as national essential drugs.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The PAA and MDA are the primary laws governing the import and export of pharmaceuticals and medical devices, while the Customs Act and Integrated Public Announcement promulgated by the Ministry of Trade, Industry and Energy (MOTIE) pursuant to the Foreign Trade Act, apply the requirements of the PAA and MDA to the actual customs process.

In principle, pharmaceuticals and medical devices manufactured abroad are subject to the same regulations as those manufactured domestically. The importers of such products are responsible for obtaining the necessary licences from the MFDS, such as import business licences and marketing authorisation for particular products, and complying with all obligations under the PAA or MDA, such as quality testing. In addition to the above, importers also need to register overseas manufacturing facilities and undergo inspections of those facilities.

A manufacturing business licence and manufacturing authorisations for particular products are required for the manufacture of pharmaceuticals or medical devices, whether for domestic use or export. However, manufacturing authorisations for pharmaceuticals or medical devices that are only exported, and not sold or distributed domestically, are exempted from certain requirements and do not require renewal.

The MFDS regulates licences and authorisations for both pharmaceuticals and medical devices,

while the Korean Customs Service enforces the relevant regulations at the point of entry for imports.

6.2 Importer of Record of Pharmaceuticals and Medical Devices

Only those with an import business licence from the MFDS for pharmaceuticals or medical devices can act as their importer of record.

In order to receive an import business licence for either pharmaceuticals or medical devices, the entity applying for the licence must fulfil certain requirements, such as having the required storage facilities, quality testing facilities and equipment, and personnel such as import managers and safety managers. Additionally, local presence is required in order to hold an import business licence for pharmaceuticals and medical devices.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

In principle, only entities with an import business licence and marketing authorisation for the particular imported product can import pharmaceuticals or medical devices into Korea.

Exceptions of varying degrees to this rule include imports for the treatment of rare diseases, emergency use, clinical trials, research and testing, and personal use.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

The Customs Act requires those who import products required by law to have approval, licence, labelling or fulfil other requirements for their importation to show proof of the fulfilment of such conditions to the head of the competent customs office, which for pharmaceuticals and medical devices are the requirements imposed by either the PAA (for pharmaceuticals) or the MDA (for medical devices), see **6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies** to **6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices**.

Whether the imported product is subject to the regulations and requirements of either the PAA or MDA would be determined by whether the product satisfies the criteria for pharmaceuticals or medical devices as defined in the respective acts.

6.5 Trade Blocs and Free Trade Agreements

As of February 2024, Korea has entered into 22 economic partnership agreements and free trade agreements with other countries, all 22 of which (the RCEP and FTAs with Chile, Singapore, EFTA, ASEAN, India, the European Union, Peru, the United States, Türkiye, Australia, Canada, China, New Zealand, Vietnam, Colombia, MERCOSUR, the United Kingdom, RCEP, Israel, Cambodia and Indonesia) are in force.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

The government's price control for pharmaceuticals is based on the relevant laws such as the National Health Insurance Act (NHIA), the Rules on the Standards of National Health Insurance Medical Benefits, and the Standards for Decision or Adjustment on Drugs. Also, the government's price control for medical devices is in accordance with NHIA, the Rules on the Standards

of National Health Insurance Medical Benefits, and the Standards for Decision or Adjustment on Activity and Medical Materials for Treatment, etc. The MOHW, the Health Insurance Review and Assessment Service (HIRA) and national healthcare insurance system (NHIS) control the price of pharmaceuticals and medical devices.

Prices for the majority of medical services provided and pharmaceuticals sold in Korea are reimbursed by the Korean NHIS, and most legal residents of Korea are insured by NHIS. If a medical service or a pharmaceutical product is covered by NHIS, a patient cannot be charged more than the co-payment amount corresponding to the maximum reimbursement price published by the MOHW. If a medical service or pharmaceutical is not covered by NHIS, the healthcare provider is free to determine the price of such product or service.

For pharmaceuticals and medical services to be reimbursed, the HIRA and the MOHW determine whether to reimburse the costs for medical services or pharmaceuticals after evaluating clinical efficacy, cost-effectiveness, and other factors.

Regarding medical devices covered by the NHIS, the device may be subject to its own maximum reimbursement price, or the cost of the medical device may be included in the maximum reimbursement price for the relevant medical service that utilises such a device.

7.2 Price Levels of Pharmaceuticals or Medical Devices

For drugs, foreign prices may be referenced in the negotiation of the drug's maximum reimbursement price. In general, the economic evaluation for pharmaceuticals takes precedence over such external price referencing in determining the price of drugs. Foreign prices have direct effect only when deciding the price of drugs whose economic evaluation can be exempted under relevant pricing regulations.

Meanwhile, in the case of pricing of medical devices, foreign prices are not referenced but the import price or the price of listed products with similar function are considered.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

A substantial part of the costs of pharmaceuticals and medical services (using medical devices) is covered by the national health insurance scheme. However, even when covered by the national health insurance scheme, the full amount is not paid by the health insurance, as the patient is responsible for the applicable co-pay amount.

There is a difference in the way pharmaceuticals and medical services are covered by health insurance. In the case of pharmaceuticals, products not listed on the reimbursement list are not covered by health insurance (positive-listing system), however, in the case of medical services, the MOHW stipulates medical services not covered by health insurance (negative-listing system).

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Where drugs are concerned, it is the principle of the positive listing system to determine the eligibility for reimbursement and reimbursement amount on the basis of HTA (health technology assessment – ie, cost-utility analysis). In the case of pharmaceuticals for treatment of cancer or orphan diseases, however, economic evaluation may be omitted if certain criteria are met.

Meanwhile, for medical devices, the cost-effective analysis would play a minor role only to a limited extent in determining the eligibility for reimbursement and reimbursement amount.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

After the separation of prescribing and dispensing in 2000, only physicians can prescribe drugs in hospitals, and only pharmacists can dispense drugs in pharmacies (this applies to the case of outpatient only, and dispensing drugs in pharmacies within the hospital is possible for inpatients). In order to prevent the over-prescription of narcotic or psychotropic drugs such as propofol, monitoring of prescription details is performed through HIRA's big data management system.

8. Digital Healthcare

8.1 Rules for Medical Apps

There are currently no specific rules which regulate medical apps. However, a medical app may be treated as a medical device if the medical app satisfies requirements for medical devices as prescribed by the MDA. That is, in a case that a medical app is used for the purpose of diagnosing, curing, alleviating, treating or preventing a disease, it may be treated as a medical device under Article 2 of the MDA. If it is not used for the purpose above, however, it would not fall under the definition of a medical device.

Please note that medical apps could be subject to the prospective Digital Medical Product Act (to be implemented for digital medical devices and digital integrated drugs on 24 January 2025, and for digital medical/healthcare support devices on 24 January 2026). If medical apps meet the requirements for medical devices, they will be deemed digital medical devices; if they do not meet the requirements for medical devices but still aim to support healthcare and maintain/improve health, they will be considered as digital medical/healthcare support devices. Both cases are subject to the prospective Digital Medical Product Act.

8.2 Rules for Telemedicine

In principle, the Medical Service Act (MSA) does not allow telemedicine between physician and patient. However, due to the COVID-19 pandemic, the Korean government temporarily allowed limited telemedicine until 1 June 2023. Since then, telemedicine is being tested through pilot programmes within a limited scope.

According to the non-face-to-face medical treatment pilot project guidelines revised in December 2023, for clinic-level medical institutions, the target patients are principally limited to those who have received face-to-face treatment within the past six months at the same medical institution. However, exceptions apply to certain geographical areas, patient classes, and time periods where access to medical institutions is difficult. Under these exceptions, non-face-to-face treatment is possible even without prior history of face-to-face treatment.

On the other hand, at hospital-level medical institutions, non-face-to-face treatment is available only to patients with rare diseases who have received face-to-face treatment within the past year at the same medical institution, as well as patients who require continuous management after surgery or treatment and have received face-to-face treatment within the past 30 days at the same medical institution.

8.3 Promoting and/or Advertising on an Online Platform

The Fair Labelling and Advertising Act (FLAA) applies to advertising of all products including pharmaceuticals and medical devices. Also, product advertising on an online portal, company webpage, social network, etc, will be subject to "Evaluation Protocols on Online Advertising", the regulation of the Korean Fair Trade Commission (KFTC).

The advertising and promotion of pharmaceuticals are also regulated by the PAA and supervised by the MFDS. Further, advertising and promotion of medical devices are regulated by the MDA, and online advertising of medical devices via online portal, company webpage, social network, etc, are required to receive an in-advance review of voluntary review institution under the MDA.

8.4 Electronic Prescriptions

Electronic prescriptions with digital signatures prescribed by physicians or dentists are regulated under Article 17-2 of the MSA. However, as there is no officially authorised system which transfers electronic prescription data from a medical institution to a pharmacy, filling prescriptions via electronic prescription is not currently implemented. At the moment, MOHW is reviewing the introduction of an official electronic prescription transfer system.

8.5 Online Sales of Medicines and Medical Devices

Online sales of medicines are not permitted under the PAA. Conversely, medical devices can be sold by a person who notified such distribution to the mayor or governor of the local government in the area where their business place is located. However, as for some products designated under Article 38 of Enforcement Rules of the MSA such as a thermometer, electronic automatic tonometer, etc, online sales are possible without notification of distribution of medical devices.

8.6 Electronic Health Records

Electronic health records contain extensive information on a patient's health. The PIPA considers such information sensitive data and therefore imposes strict regulation by preventing any use without consent from patients in principle. Having stated that, the PIPA stipulates that in the case of pseudonymisation of sensitive data, such data may be processed without the consent of data subjects for statistical, scientific research purposes, etc. However, discussions are ongoing on whether using pseudonymised electronic records without patients' consent would violate the MSA.

Meanwhile, if medical institutions satisfy the standards as set forth in "Guidelines for Facilities and Equipment Necessary for Managing and Keeping Electronic Medical Records", as published by MHW, they can store and keep such electronic medical records (EMR) in an outside system. Accordingly, in the event that medical institutions meet technical standards as prescribed by the above Guidelines (eg, network and system security equipment and back-up storage device), they can transmit EMR of patients to a cloud platform for storage.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices

The PAA and the Patent Act (PA) are the main laws governing patents on pharmaceuticals and

medical devices in Korea. Every patent is subject to the PA. The main legal issues regarding patents on pharmaceuticals and medical devices are patent application and registration, patent validity and term as well as invalidation actions and lawsuits.

Meanwhile, Korea implements the Drug Approval-Patent Linkage programme, and the PAA regulates the programme.

There are no patentability requirements that are specific to pharmaceuticals or medical devices, and general patentability requirements will apply.

9.2 Second and Subsequent Medical Uses

It is possible to obtain an improvement patent in Korea for novel medical uses, dosage regimes and selected patient populations. For this, the novel medical uses, dosage regimes or selected patient populations must be specifically described in the claim of the patent while satisfying the general requirements of novelty and inventiveness. In addition, experimental results supporting the effects of the drug, such as pharmacological data or some form of specific information that can substitute such experimental results, must be described in the patent specification.

The act of selling such patented pharmaceuticals labelled with the registered medical uses, dosage regimes or selected patient population without permission from the patent owner constitutes patent infringement.

9.3 Patent Term Extension for Pharmaceuticals

Korea implements a system where the patent term for pharmaceuticals may be extended by up to five years for periods that meet certain requirements in the drug approval process during which the patent inevitably could not be practiced. Specifically, in the case of a pharmaceutical manufactured with a novel active substance as its active ingredient which has received marketing authorisation for the first time in Korea, a term extension equal to the sum of the period elapsed for clinical trials and review by MFDS may be granted a single time.

An application for patent term extension must be filed with the Korean Intellectual Property Office (KIPO) within three months from the date of market approval, and the application must be made under the name of all co-owners when it is jointly owned. A third party may file a lawsuit seeking the revocation of the patent term extension.

9.4 Pharmaceutical or Medical Device Patent Infringement

Patent infringement on pharmaceuticals or medical devices occurs when a patent is practised without the consent of the patent owner. A patent is practised when a pharmaceutical or a medical device is manufactured, sold, used, leased, imported or offered for sale. In Korea, applying for marketing authorisation itself does not constitute patent infringement. It is possible to file a lawsuit based on the threat of infringement even if actual infringement has yet to materialise. The party claiming the threat of infringement should establish that there is a "likelihood of infringement" by a third party. A decision ordering product disposal and facility removal can be obtained.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

Patent infringement is not found for:

- practising of the patent for research and experimental purposes;
- existing pharmaceuticals or devices at the time of patent application;
- acts of combining two or more pharmaceuticals; and
- pharmaceuticals resulting from the combination of two or more pharmaceuticals.

The Korean government can grant to itself or third parties compulsory licences on patents whose non-commercial practice is necessitated for public good during times of emergency or crises. Upon the decision by the chief of KIPO, compulsory licences can be granted to third parties in the following cases:

- if a patent is not sufficiently practised in Korea for three years without justifiable grounds;
- if there are findings of unfair trade practices by the executive or judicial authorities that call for remedial measures; or
- if the practice of the patent is necessary for exporting pharmaceuticals to the importing countries.

9.6 Proceedings for Patent Infringement

The patent owner or the exclusive licensee can seek compensation of damages and an injunction by filing an infringement lawsuit. A preliminary injunction can be separately filed to expeditiously prevent the infringing product from entering the market by way of product disposal and facility removal. It is typical for the party accused of patent infringement to defend its action by filing a patent invalidation action or lawsuit. There are multiple cases in which the patent owner and the exclusive licensee file the patent infringement lawsuit and request a preliminary injunction at the same time.

9.7 Procedures Available to a Generic Entrant

The PAA provides that the generic entrant should declare its position on the patent of the original that is listed on the drug patent list on which the MFDS registers and maintains patents on drugs. In other words, the generic entrant should specify whether it plans to enter the market after the expiration of the patent term, obtain a grant of licence or challenge the validity of the patent. The generic entrant should establish that it has notified the patent owner of such declaration to obtain market approval.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

The owner of valid intellectual property rights on pharmaceuticals or medical devices can make both civil (request for injunction and compensation of damages) and criminal claims against the manufacturer or seller of the counterfeits. Moreover, the Korea Customs Service should notify the owner of IP rights if its agents discover suspected counterfeits. Upon notification, the right-holder can request that such counterfeits do not receive customs clearance.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

The Trademark Act provides that a trade mark which indicates, in a common manner, the quality, efficacy or usage of the product, lacks distinctiveness and thus cannot be registered. The provision also applies to pharmaceuticals and medical devices. In addition, for pharmaceuticals and medical devices, it is not permitted to register as a trade mark a brand name that is widely known among consumers.

In the case of parallel importation of authentic goods, whether such importation is allowed varies among cases. If the owner of the Korean trade mark and the foreign trade mark is the same, products distributed overseas can also be sold locally. However, if such is not the case, the importation and local sale of the products that were distributed overseas is prohibited under the principle of territoriality.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

Like other products, pharmaceuticals and medical devices can receive IP protection under trade dress or design. The Unfair Competition Prevention and Trade Secret Protection Act (UCPA) provides for trade dress rights, whereas the Design Act provides for design rights.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

In Korea, data exclusivity is protected during the period for post-marketing surveillance (PMS). PMS periods vary depending on the types of pharmaceuticals:

- six years for a new drug, a new combination drug and a drug with a different route of administration;
- four years for a drug having a new indication; and
- ten years for orphan drugs (11 years for children's orphan drugs).

Korea does not distinguish between chemical drugs and biologics when it comes to data exclusivity.

Of note, the National Assembly passed an amendment to the PAA on 1 February 2023, which will repeal the drug re-examination system and introduce a comprehensive risk management system that integrates safety management policies after the drug's commercial release. This amendment repeals re-examination-related policies and introduces provisions for an independent data exclusivity system, which previously relied on drug re-examination. Furthermore, the new provisions expand the scope to ensure that drugs approved with new clinical data also benefit from data exclusivity, in addition to conventional drugs subject to re-examination.

The amendment to the PAA sets the data exclusivity period for each drug type to be the same as the current re-examination period, and drugs approved with new clinical trial data newly subject to data exclusivity can obtain a data exclusivity period of four years. While this amendment has not been officially announced yet, the MFDS stated that it will be officially announced sometime in February 2024. Once announced, it will go into effect in one year from the announcement.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

In order to effectively respond to pandemic issues such as COVID-19, the Special Act for the Promotion of Development and Emergency Supply of Medical Products to Respond to Public Health Crisis was both enacted and implemented on 9 March 2021. In the case of pharmaceuticals and medical devices designated as public health emergency response medical products:

- an expedited review procedure will apply; and
- the MFDS may take necessary measures to improve distribution with respect to the

distributors, sales procedures, sales volumes and sales conditions of the relevant products.

11.2 Special Measures Relating to Clinical Trials

The MFDS had published its clinical trial follow-up policy for 2021. According to the policy, in consideration of the difficulties in visiting hospitals due to the spread of COVID-19, phone counselling and prescriptions, proxy prescriptions and drug delivery to trial participants would be temporarily permitted during the clinical trials. In addition, the MFDS published guidelines titled "Considerations for Development of a COVID-19 Treatment" (14 April 2021) and "Considerations for Development of a COVID-19 Vaccine" (15 June 2021) detailing the pre-clinical and clinical trial requirements for market authorisation of COVID-19 treatments and vaccines.

Of note, the "Temporary Untact Treatment Permission Plan" (MOHW Notice No 2020-889, 16 December 2020) ended on 1 June 2023. Consequently, a new guideline for untact clinical trial operation seems to be necessary, as its legal basis no longer exists. However, there appears to be no plan for such a guideline at the moment.

Relatedly, the FDA announced a guideline for Decentralised Clinical Trials (DCT) in May 2023, defined as a "clinical trial where some or all of the trial-related activities occur at locations other than traditional clinical trial sites". MFDS has also announced its intention to enact a guideline for companies to pursue DCT in Korea, although it has not provided a detailed timeline.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

Based on the Special Act for the Promotion of Development and Emergency Supply of Medical Products to Respond to Public Health Crisis, emergency approvals for the use of pharmaceuticals or medical devices can be granted if it is deemed necessary for appropriately responding to a public health emergency or if there is a request from the chiefs of the relevant authorities in the central government. In the case of pharmaceuticals or medical devices that received emergency approval, it is possible to supply them either through importation or manufacture without obtaining market approval.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

MFDS officials have traditionally been required to conduct an on-site inspection on overseas manufacturing plants for pharmaceuticals and medical devices. As a result of COVID-19, since 2020, the MFDS implemented a policy of document reviews rather than on-site inspections. However, it announced the plan to resume the on-site inspection on overseas manufacturing plants in 2023 as Korea and most of the other countries are phasing out of COVID-19, although a detailed timeline for resuming the on-site inspections has not been solidified in Korea.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

There are no restrictions or flexibilities concerning import/export procedures that have been introduced in relation to medicines or medical devices due to COVID-19, other than the special provision on authorisation for importation explained in **11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices** and **11.3 Emergency Approvals of Pharmaceuticals and Medical Devices**.

11.6 Drivers for Digital Health Innovation Due to COVID-19

Under the PAA, telemedicine between the doctor and the patient is not allowed in principle.

However, around March 2020, the MOHW made a public notice titled "Measures on Temporarily Allowing Phone Counselling, Prescription and Proxy Prescription". Pursuant to the public notice, telemedicine, drug prescription and courier delivery of drugs were temporarily allowed during COVID-19 pandemic. The temporary untact diagnosis ended on 1 June 2023, with the decreased COVID-19 threat level. Currently, untact diagnosis is allowed in a limited scope via temporary pilot programmes.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

Around December 2021, the National Assembly proposed an amendment to the Patent Act, which allows compulsory licences in cases of national emergency or extreme emergency if non-commercial practice of patents is necessary for public good. However, the amendment was not passed. There has not yet been any other announcement by the Korean government on compulsory licences.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

There are no liability exemptions introduced in connection with COVID-19 vaccines or treatments.

11.9 Requisition or Conversion of Manufacturing Sites

There are no regulations regulating the requisition or conversion of manufacturing sites due to COVID-19.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

There are no notable changes to the system of public procurement of medicines and medical devices due to COVID-19.

SPAIN

Law and Practice

Contributed by:
Anna Gerbolés, Joan Carles Bailach, Claudia Gonzalo and Juan Martínez
Faus Moliner Abogados

Contents

Contributed by: Anna Gerbolés, Joan Carles Bailach, Claudia Gonzalo and Juan Martínez,
Faus Moliner Abogados

Faus Moliner Abogados is a modern boutique law firm based in Barcelona that specialises in advising the pharmaceutical industry and companies that operate in the life sciences sector. The firm was founded in 1997 and currently has 15 members. It focuses on pharmaceutical law, commercial contracts, corporate transactions, corporate governance, compliance, competition law, public procurement, product liability, advertising, litigation and arbitration. The firm advises pharmaceutical and healthcare clients, large companies and smaller biotech start-ups, and is frequently called upon to advise public authorities on matters such as draft legislation. It combines legal skills and specialisation with a practical and business-oriented manner of practising law. Since its foundation, Faus Moliner has been recognised in several international publications as the market leader in pharmaceutical law in Spain.

The authors appreciate the collaboration of Sergio Miralles of Intangibles Legal and Pablo Mansilla and Laia Rull of Faus Moliner.

Authors

Anna Gerbolés is a senior associate at Faus Moliner and specialises in pharmaceutical and food law. Her experience in these sectors includes the provision of legal advice on regulatory issues and the advertising of medicinal products, medical devices, food products and other borderline products. Since becoming part of the Faus Moliner team in 2021, she has been providing highly specialised advice to companies operating in the life sciences sector. Anna is a member of the Barcelona Bar Association.

Joan Carles Bailach is a senior associate at Faus Moliner and specialises in market access, pricing and reimbursement, commercial contracts and pharmaceutical and life sciences law. He has regularly advised national and international companies on these matters since joining the firm in 2019. Joan Carles is a member of the Barcelona Bar Association, the Section of Health Law, and the Young Advocacy Group of the Barcelona Bar Association.

Contributed by: Anna Gerbolés, Joan Carles Bailach, Claudia Gonzalo and Juan Martínez,
Faus Moliner Abogados

Claudia Gonzalo is a senior associate at Faus Moliner, specialising in pharmaceutical and healthcare regulations. She has experience in advising national and international companies ion regulatory matters, public procurement, and corporate transactions and contracts. Claudia has a master's in public economic law and an executive MBA in pharmaceutical, biotechnological and medical device companies, and is a member of the Spanish Compliance Association.

Juan Martínez is a senior associate at Faus Moliner and regularly advises national and international companies on litigation and arbitration procedures. He specialises in conflicts related to contracts, unfair competition, product liability and regulatory matters. Since becoming part of the Faus Moliner team in 2017, he has been providing highly specialised advice to companies operating in the life sciences sector. Juan is a member of the Barcelona Bar Association.

Faus Moliner Abogados

Rambla de Catalunya 135
08008
Barcelona
Spain

Tel: +34 93 292 21 00
Email: bcn@faus-moliner.com
Web: www.faus-moliner.com

Contributed by: Anna Gerbolés, Joan Carles Bailach, Claudia Gonzalo and Juan Martínez,
Faus Moliner Abogados

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Key Legislation

The following legislation and regulations govern medicinal products and medical devices in Spain:

- Law 14/1986, General on Public Health;
- Royal Legislative Decree 1/2015, which approves the consolidated version of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices;
- Law 10/2013 on pharmacovigilance and on the prevention of the entry into the legal supply chain of falsified medicinal products;
- Law 16/2003, of 28 May, on the cohesion and quality of the National Health System;
- Royal Decree 192/2023, which regulates medical devices;
- Royal Decree 1616/2009 on active implantable medical devices (partially repealed);
- Royal Decree 1662/2000 on "in vitro" diagnostic medical devices;
- Royal Decree 824/2010 on pharmaceutical companies, manufacturers of active ingredients, foreign trade of medicines and investigational medicinal products;
- Royal Decree 1090/2015, which regulates clinical trials, the Ethics Committees for Research and the Spanish registry for clinical trials;
- Royal Decree 967/2020, which regulates observational studies with medicinal products for human use;
- Royal Decree 1345/2007, which regulates the authorisation, registry and dispensation conditions of medicinal products for human use prepared industrially for human use;
- Royal Decree 782/2013, which regulates the distribution of medicinal products;
- Royal Decree 1416/1994, which regulates the advertising of medicinal products;
- Royal Decree 870/2013, which regulates online sales to the public of non-prescription medicinal products;
- Royal Decree 577/2013, which regulates pharmacovigilance of medicinal products for human use;
- Royal Decree 1015/2009 on access to medicinal products in special situations;
- Royal Decree 271/1990, which regulates the prices of medicinal products reimbursed by the National Health System;
- Royal Decree 177/2014, which regulates the reference price system and homogeneous groups of medicinal products in the National Health System and information systems on reimbursement and prices of medicinal products and medical devices;
- Royal Decree 823/2008, which establishes the margins, deductions and discounts corresponding to the distribution and dispensation of medicines for human use;
- Royal Decree 1718/2010, on medical prescriptions; and
- Royal Decree 477/2014, which regulates the authorisation of medicinal products for advanced therapies not prepared industrially.

Regional authorities (Spain is divided into 17 autonomous regions) may also enact and enforce regulations that are applicable at their level, particularly concerning pharmacy offices or healthcare provision.

Furthermore, there is a self-regulatory framework established by trade associations that enforce their own codes of good practices. These codes have a binding effects on their members, and primarily govern advertising and interactions

with healthcare organisations, healthcare professionals and patients' organisations.

Regulatory Authorities

At a national level, the regulatory authorities responsible for applying and enforcing regulations on medicinal products and medical devices are mainly the Ministry of Health (MOH) and the Spanish Agency for Medicines and Medical Devices (AEMPS).

Among other things, the MOH is responsible for drafting and implementing the rules on pricing and reimbursement of medicinal products financed by public funds, while the AEMPS is responsible for the issuance of marketing authorisations for medicinal products in Spain, which includes overseeing the authorisation process through national, mutual recognition and/or decentralised procedures.

At a regional level, regional regulatory authorities enforce regulations in the abovementioned areas. Moreover, as financing for reimbursing medicinal products comes from the budgets allocated to the autonomous regions in Spain, these regions participate in the MOH committee responsible for evaluating applications concerning the pricing and reimbursement of medicines.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Decisions of regulatory bodies are subject to challenge through both administrative appeal and judicial review. In some cases, the administrative appeal is mandatory, and it must be filed within one month from receiving notice of the decision.

After administrative proceedings, the interested party may go to court within two months of receiving notice from the decision.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Medicinal Products

Article 8.1 of Royal Legislative Decree 1/2015 distinguishes between four types of medicinal products:

- medicinal products for human and veterinary use that are industrially manufactured, or in the manufacture of which an industrial process is involved;
- magistral formulae;
- officinal preparations; and
- special medicinal products (eg, vaccines and other biological medicinal products, advanced therapy medicinal products, radiopharmaceuticals, homeopathic medicinal products or medicinal gases).

In relation to prescription and dispensing conditions, Royal Legislative Decree 1/2015 contemplates the same classification set forth in Article 70 of Directive 2001/83/EC.

Medical Devices

Two special categories of medical devices are subject to specific regulations:

- implantable medical devices; and
- "in vitro" diagnostic medical devices.

2. Clinical Trials

2.1 Regulation of Clinical Trials

In Spain, clinical trials of medicinal products are mainly regulated by Royal Legislative Decree 1/2015 and Royal Decree 1090/2015. Clinical

trials of medical devices are governed by Royal Decree 192/2023 and Circular 7/2004 on clinical investigations with medical devices. Moreover, the AEMPS has issued the Document of Instructions for the conduct of clinical trials in Spain.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Medicinal Products

To initiate a clinical trial of medicinal products, the following will be required:

- a favourable opinion issued by a Research Ethics Committee with Medicines (CEIm) in Spain;
- prior authorisation by the AEMPS, after a scientific and ethical evaluation in accordance with Regulation (EU) No 536/2014; and
- a written agreement between the sponsor and the sites.

The authorisation procedure by the AEMPS is divided into two parts:

- Part I of the Assessment Report is evaluated by the AEMPS and an Ethics Committee; and
- Part II is evaluated only by an Ethics Committee, and refers to aspects such as subject recruitment, insurance, etc.

Based on the above, the AEMPS issues a decision that could result in authorisation, authorisation with conditions, or rejection.

Medical Devices

Two different situations can be distinguished for clinical trials involving medical devices:

- trials of medical devices without CE marking for conformity assessment have identical requirements to clinical trials of medicinal products; and
- trials of medical devices that have CE marking and are used in accordance with their instructions for use and within the approved intended purpose when the CE marking was issued require a favourable Ethics Committee opinion and a written agreement between the sponsor and the sites. The AEMPS approval is exempted.

If the AEMPS approval is required, the sponsor must submit the documentation described in Chapter II of Annex 15 of Regulation (EU) No 2017/745. The AEMPS shall evaluate the documentation submitted and decide to either authorise or reject the clinical trial.

If the AEMPS approval is not required but patients will undergo procedures beyond those applied under normal conditions of use, and these procedures are invasive or burdensome, the sponsor shall communicate this to the AEMPS through the database for clinical investigations with CE-marked medical devices (NEOPS).

2.3 Public Availability of the Conduct of a Clinical Trial

The Spanish Registry of Clinical Studies (REec) is a public database containing information on all clinical trials of medicinal products authorised by the AEMPS in Spain as of 1 January 2013. It can be accessed through the AEMPS website.

The sponsor must publish the results of the clinical trial, whether positive or negative, preferably in scientific journals, before disclosure to the general public, as well as in the REec.

For medical devices, there is currently no publicly available database.

2.4 Restriction on Using Online Tools to Support Clinical Trials

The decentralisation of clinical trials (including the use of online tools for monitoring purposes) began with the COVID-19 pandemic, when the AEMPS amended its Document of Instructions to introduce exceptional measures regarding:

- patient visits for ongoing clinical trials during the pandemic;
- access to trial medication;
- the transfer of patients between sites; and
- the procedure for obtaining patients' informed consent.

In view of the positive experience acquired, it has been considered convenient to facilitate the use of these decentralised aspects in clinical trials beyond the COVID-19 pandemic period.

2.5 Use of Data Resulting From Clinical Trials

Provided that it is not aggregated or anonymised, the resulting data from clinical trials is recognised as a special category of personal data and is therefore subject to restrictive guarantees by the personal data protection regulations applicable in the EU (GDPR) and Spain – ie, Law 3/2018, on the Protection of Personal Data.

Generally, personal data resulting from clinical trials may not be transferred to a third party or an affiliate situated in a country that does not provide an adequate level of protection, without complying with the provisions of Chapter V of the GDPR. In such cases, the sponsor must adopt one of the safeguards set out in Article 46 of the GDPR.

In those cases where there is an intention to use participants' data in future research, that future processing must be grounded in one of the lawful bases set forth in the GDPR.

2.6 Databases Containing Personal or Sensitive Data

Provided that no data analysis that could assimilate it to a clinical investigation is conducted, the creation of a database containing personal or sensitive data (eg, patient registries) is subject to the GDPR and Law 3/2018.

In this regard, it will be necessary to obtain the patient's informed consent prior to its entry in the database, or to rely on another lawful basis for the processing of the data (Article 6.1 of the GDPR), plus a valid exception to the prohibition of processing health data (Article 9.2 of the GDPR).

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

Products are classified as medicinal products or as medical devices on a case-by-case basis. The application of medicinal product legislation is preferable, due to the level of development, safety and greater consumer protection it offers compared to legislation for other products.

According to Directive 2001/83/EC, a product shall be classified as a medicinal product if it achieves its intended effect by means of a pharmacological, immunological or metabolic action (medicinal product by function), or if it is presented as having therapeutic properties typical of medicinal products (medicinal product by presentation). Those are alternative conditions, meaning that a given substance or combination

will be considered a medicinal product if either or both definitions apply to it.

The AEMPS is responsible for attributing the status of medicinal product to a substance in Spain. This can occur within the framework of a national marketing procedure or subsequently within the scope of the market surveillance functions of the AEMPS.

However, in the centralised procedure, it is the European Medicines Agency (EMA) that determines whether a substance is a medicinal product. Moreover, the EMA has the power to intervene in disputes arising during decentralised authorisation procedures.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

The granting of a marketing authorisation (MA) for biologic products is not subject to any obligations other than those for an MA in general. Most biologic medicinal products have to be authorised by the European Commission through the centralised procedure.

Advanced therapy medicinal products (which can also be biologic products) that are non-industrially manufactured are regulated by Royal Decree 477/2014, which sets out that their individual use and manufacture must be authorised on a case-by-case basis.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

Medicinal Products

The MA of a medicinal product is valid for an initial period of five years. The marketing authorisation holder (MAH) may apply for a marketing authorisation renewal, pursuant to Article 27 of Royal Decree 1345/2007, at least nine months before expiration.

Once renewed, the MA will be valid for an unlimited period of time, unless the AEMPS requires an additional five-year renewal based on duly justified pharmacovigilance-related reasons. An MA shall be revoked if the product it refers to is not marketed for three consecutive years.

In addition, Royal Decree 1345/2007 imposes an obligation to keep the market duly supplied. In practice, each October the MAHs shall declare whether they intend to market the product during the following year. If they do not do so, they will be deemed to have requested a suspension of the validity of the MA.

Royal Decree 1345/2007 also empowers the AEMPS to keep MAs in force for reasons of public health interest, such as the creation of a treatment gap, either in the market in general or in the pharmaceutical provision of the National Health Service (NHS). This could contravene the provisions of Directive 2001/83/EC, which allows marketing cessation if notified two months in advance.

Medical Devices

The certificate of conformity for medical devices issued by the Notified Bodies is valid for a maximum of five years in line with provisions set out at the EU level.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

Medicinal Products

The AEMPS is in charge of granting MAs in Spain, which are regulated by Royal Decree 1345/2007. Some provisions of such Royal Decree also affect medicines authorised by the

European Commission pursuant to the centralised procedure.

The AEMPS shall authorise a specific product if it:

- fulfils the established quality requirements;
- is safe under normal conditions of use;
- is effective in the therapeutic indications;
- is correctly identified; and
- provides the patient with the necessary information.

The positive therapeutic effects of the medicinal product shall be assessed under a risk-benefit perspective.

The key stages of the authorisation procedure are as follows:

- submission of the application to the AEMPS;
- validation and acceptance of the submission;
- issuance of the evaluation report; and
- resolution of the application and granting, where appropriate, of the MA.

The maximum period to notify the applicant of the resolution of the authorisation procedure is 210 calendar days.

The main requirements for the different types of variations of MAs of medicinal products are regulated in Royal Decree 1345/2007, in respect of the elements to be submitted by the MAH for each type of variation (ie, Types IA, IB and II, and extensions).

Applications for variations must be submitted to the AEMPS, which has 30 days to approve or deny Type IA and Type IB variations, and 60 days for Type II variations.

Transfers of MAs require prior authorisation by the AEMPS. The application is to be conducted through the RAEFAR platform, where the data and documentation supporting the proposed transfer must be uploaded.

Medical Devices

Medical devices are divided into four classes (III, IIb, IIa and I), depending mainly on the level of invasiveness of the device, the part of the body it is in contact with and the duration of such contact.

Except for custom-made devices, medical devices must bear a "CE" marking of conformity when they are placed on the market in Spain, which provides evidence of the device's conformity with the applicable requirements. The evaluation and variation approval of medical devices are governed at EU level in accordance with Regulation (EU) 2017/745.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

Medicinal products cannot be placed on the Spanish market without obtaining an MA. Exceptionally, uses not covered by an MA outside a clinical trial might be permitted in three situations regulated by Royal Decree 1015/2009:

- compassionate use;
- off-label use; and
- access to foreign products.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

Medicinal Products

Royal Decree 577/2013 imposes the following main pharmacovigilance obligations on MAHs:

- respect the good practices on pharmacovigilance published by the AEMPS;
- have an adequate pharmacovigilance system;
- have a suitably qualified person responsible for pharmacovigilance in both the EU and Spain;
- submit periodic safety reports to the EMA;
- have a risk management system for each medicinal product;
- notify and record suspected adverse reactions;
- monitor scientific literature worldwide;
- carry out post-authorisation studies of efficacy and safety; and
- perform a continuous evaluation of the risk-benefit parameters of the medicinal product.

The MAH shall conduct post-authorisation efficacy studies required by member states or the European Commission in the following circumstances:

- as a condition of the MA, where questions about the efficacy of the medicinal product arise that can only be resolved after the medicinal product has been placed on the market; and
- subsequent to the granting of an MA, where knowledge of the disease or clinical methodology indicates that previous assessments of efficacy may need to be significantly revised.

Products subject to additional monitoring requirements must include a black inverted triangle in their package leaflet and data sheet, accompanied by the sentence "this medicine is subject to additional monitoring".

Medical Devices

Manufacturers, authorised representatives, importers or distributors of medical devices must notify the AEMPS of:

- any malfunction or alteration of the characteristics of the product, as well as any inadequacy of the labelling or instructions for use that could lead to death or serious damage to health; and
- any reason of a technical or health-related nature linked to the characteristics or performance of a device that has led the manufacturer to take systematic action on devices of the same type.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

EU Level

The EMA assesses each individual request for access to documents submitted in accordance with Regulation (EC) No 1049/2001, and its policy on access to documents.

EU case law supporting access to documents has noted that the companies involved usually fail to give any concrete evidence of how the release of the contested documents would undermine their commercial interests. Documentation requests could be rejected if the affected party demonstrates that disclosure could undermine their commercial interests, which has to be analysed on a case-by-case basis.

As per medical devices, the EU is currently deploying the European database on medical devices (EUDAMED), which will be composed of six modules related to:

- actor registration;
- unique device identification (UDI) and device registration;
- notified bodies and certificates;
- clinical investigations and performance studies;
- vigilance and post-market surveillance; and

- market surveillance.

National Level

The AEMPS processes access to public information requests in accordance with Law 19/2013 on Transparency.

In general terms, there is no public database listing pending authorisations. It is possible to request the number of pending applications for a given active substance, which is usually granted on a non-name basis.

If the authorisation has been granted, there is a public database named "CIMA" where information relating to authorised medicinal products is made available to the public. There are no provisions on access where an application has been refused.

In all scenarios, the dossier and expert reports are confidential (Article 15 of Royal Decree 1345/2007).

3.8 Rules Against Illegal Medicines and/or Medical Devices

Medicinal Products

Directive 2011/62/EU amending Directive 2001/83/EC, as regards the prevention of the entry into the legal supply chain of falsified medicinal products ("Falsified Medicines Directive"), introduced the following measures:

- MAHs are obliged to place two safety features on the packaging of most prescription medicines and some over-the-counter medicines in the EU – a unique identifier (a two-dimension barcode) and an anti-tampering device;
- manufacturers shall upload the information contained in the unique identifier for a medicinal product to a central EU repository;
- new responsibilities for wholesalers and a definition of brokering activities, as well as new responsibilities for brokers; and
- an obligatory logo that will appear on the websites of legally operating online pharmacies and approved retailers in the EU.

Medical Devices

The legal framework in force is less developed when dealing with counterfeit medical devices.

The main measure to check medical devices is the CE mark, which is used to show compliance with the essential requirements for safety. Therefore, users are encouraged to verify that the CE mark is authentic and supported by the appropriate certification from the manufacturer.

Another measure to limit counterfeit medical devices is the European Medical Device Nomenclature (EMDN), which is the nomenclature of use by manufacturers when registering their medical devices in the EUDAMED database and provides an additional layer of traceability.

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

EU Level

The Falsified Medicines Directive introduces EU-wide rules for the importation of active substances. In practice, imports may occur only if they are accompanied by written confirmation from the competent authority of the exporting country attesting that the standards of good manufacturing practice and control of the manufacturing site are equivalent to those in the EU. This requirement is waived for certain third countries listed by the Commission.

National Level

Royal Legislative Decree 1/2015 and Royal Decree 824/2010 regulating foreign trade establish border measures to tackle counterfeit medicinal products and medical devices. Furthermore, Circular 1/2015 sets out that authorisation for the import of finished medicinal products must be requested by the importing pharmaceutical laboratory or by the laboratory holding the MA, in accordance with the MA for the medicinal product.

Please see **6. Importation and Exportation of Pharmaceuticals and Medical Devices** for more detail.

4. Manufacturing of Pharmaceuticals and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

Medicinal Products

Any manufacturer of medicinal products or products under investigation, or any manufacturer that is involved in any of the processes that this may entail (ie, fractionation, packaging and presentation for sale) (Article 63 of Royal Legislative Decree 1/2015), shall be considered as a manufacturing pharmaceutical laboratory and authorised by the AEMPS. This authorisation shall be required even if the medicinal product is manufactured exclusively for export.

Obtaining the authorisation requires:

- applying to the AEMPS specifying the medicinal products and pharmaceutical forms to be manufactured or imported, as well as the place, establishment or laboratory where they are to be manufactured or controlled;
- having suitable and sufficient premises and technical and control equipment for the activity intended to be carried out; and
- having a technical director, manufacturing manager and quality control manager with sufficient qualifications.

The AEMPS will validate that the formal requirements of the application are correct within a maximum period of ten days. Subsequently, it will carry out an inspection at the corresponding facilities. The AEMPS will then issue the authorisation resolution, which will be communicated immediately to the autonomous regions. The maximum period for notification of the resolution is 90 days from the date of receipt of the application by the AEMPS. The validity of this authorisation is indefinite, unless revoked.

Medical Devices

Companies engaged in the manufacture, importation, grouping or sterilisation of medical devices, and the facilities involved, require a prior operating licence from the AEMPS.

The AEMPS will review the applications submitted and notify the resolution within three months of the application. The AEMPS shall refuse, suspend or revoke operating licences when the documentation provided or the corresponding inspection reports do not guarantee that the appropriate facilities, means, procedures and personnel are available to carry out the respective activities or when the conditions under which the licence was granted, its modifications or revalidations are not maintained.

Operating licences shall be valid for a period not exceeding five years.

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

Medicinal Products

Wholesalers and contract warehouses are subject to prior authorisation by the autonomous region in which the warehouse is domiciled. This authorisation will detail the distribution activities for which the entity is authorised in accordance with the European format. Such entities shall also notify the AEMPS of the start of their activities.

Royal Decree 782/2013 establishes that a prior assessment of applications for authorisation will be carried out to verify that the entities have the appropriate personnel, material and operational means to guarantee the correct development of their activity and that the entity is capable of providing a quality service in its field of action. In addition, a physical inspection of the premises where the distribution activity will be carried out.

The maximum period for notification of the resolution is 90 days from the date of receipt of the application by the competent health authority. Once this 90-day period has elapsed without notification of the resolution, the applicant may consider their application to have been accepted.

The validity of these authorisations is indefinite. However, the Administration may suspend them in the following circumstances:

- if it is found that the entity does not fully, effectively and continuously carry out all the distribution activities for which it has been authorised, one year after the authorisation is granted; or
- when it no longer meets the requirements that were taken into account to grant said authorisation or fails to comply with the legally established obligations.

Medical Devices

Distributors engaged in the sale of medical devices must make a prior notification of the commencement of activity to the health authorities of the autonomous region where the registered office of the company is located and of the autonomous region where the warehouse or warehouses are located. This notification shall contain:

- identification of the distribution establishment;
- the types of products it distributes or sells; and
- identification and qualification of the responsible technician, when applicable.

In addition, if the distributor places the product on the market, it must be registered in the AEMPS Marketing Register prior to the start of its activity.

5.2 Different Classifications Applicable to Pharmaceuticals

Please see **1.3 Difference Categories of Pharmaceuticals and Medical Devices**.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The importation and exportation of medicinal products and medical devices is governed by Royal Legislative Decree 1/2015 (in particular, Articles 72 and 73 relating to exports) and Royal Decree 824/2010.

The AEMPS applies and enforces regulations regarding the import, export and intra-Community trade of medicinal products and medical devices. In the exercise of its duties, the AEMPS has issued the following guidelines:

- Circular 1/2015, which sets forth the procedures that must be completed for requesting authorisation from the AEMPS for imports/exports prior to international trade controls;
- Circular 1/2015 on the foreign trade of medicines; and
- Circular 2/2012 on the prior notification of shipments of medicines to other member states.

6.2 Importer of Record of Pharmaceuticals and Medical Devices

Medicinal Products

Any individual or legal entity can apply for an import licence from the AEMPS if it complies with Article 63 of Royal Legislative Decree 1/2015. Requirements to obtain the import licence are the same as those listed for the application for manufacturing authorisations – please see **4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices** for more detail.

Medical Devices

The importation of medical devices is subject to obtaining a prior licence from the AEMPS covering the premises where importation activities are performed.

Importers of medical devices established in Spain and placing Class I or custom-made medical devices must be included in the registry of responsible persons. Also, the distribution of remaining medical devices requires a prior notification for commercialisation, which must include information regarding the premises, activities, type of products and responsible technician.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

The importation of medicinal products and medical devices is subject to a prior licence issued by the AEMPS, as referred to in **6.2 Importer of Record for Pharmaceuticals and Medical Devices**.

Moreover, importers of medical devices established in Spain and placing class I or custom-made medical devices must be included in the registry of responsible persons, and the distribution of remaining medical devices requires a prior notification for commercialisation.

The AEMPS issued extraordinary import authorisations for medical devices during the COVID-19 crisis; please see **11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19**.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Imports of healthcare products are controlled by the Pharmaceutical Inspectorate at customs, which will verify that the products comply with the requirements established in applicable Euro-

pean legislation, and that the importer has an operating licence.

Ministerial Order SPI/2136/2011 lays down the procedures for health control at the border by the Pharmaceutical Inspectorate and regulates the computerised pharmaceutical inspection system for border health controls. Annex I contains a non-exhaustive list of the headings subject to control. The products are classified according to the CN code, according to Council Regulation (EEC) No 2658/87.

6.5 Trade Blocs and Free Trade Agreements

The import authorisation referred to in **6.2 Importer of Record of Pharmaceuticals and Medical Devices** is not required if the product originates from another EU country (intra-Community trade) or from Norway, Iceland or Liechtenstein, by virtue of the Agreement on the EEA recognising the free movement of goods between the contracting parties, signed in Porto on 2 May 1992. In this case, a distribution licence is sufficient. For more information on distribution requirements, please see **5.1 Wholesale of Pharmaceuticals and Medical Devices**.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

Medicinal Products

Medicinal products supplied to the NHS have a maximum ex-factory price (PVL) set by the MOH. Spain has always been said to follow a "cost plus" system, under which the maximum PVL should respond to the cost of the product plus a given profit margin. This is what Royal Decree 271/1990 contemplates in accordance with the provisions of Directive EEC 89/105 relating to the transparency of measures regulating the pricing of medicinal products for human use.

As a matter of practice, the price-approval process entails a negotiation with the authorities, where the cost and the profit margin are not really the variables that are considered. Companies should be prepared for prices mainly to be determined by the following two issues:

- a comparative pharmaco-economic evaluation of the medicine in which the advantages of the new product should be quantified; or
- the price of the product in other EU member states.

Companies must also be ready for the authorities to consider other issues, such as the activities performed by the company in Spain (R&D, manufacturing, etc) and the relationship with a local company through a co-marketing or licensing arrangement.

The margin corresponding to the distribution of industrially manufactured medicinal products is regulated in Article 1 of Royal Decree 823/2008. For presentations of medicinal products whose PVL is equal to or less than EUR91.63, the margin is set at 7.6% of the wholesaler's selling price excluding taxes ("wholesaler price"). If the PVL is higher than EUR91.63, then the wholesaler's margin is fixed at EUR7.54 per package.

The margin for retail pharmacies is regulated in Article 2 of Royal Decree 823/2008, as follows:

- 27.9% of the retail price excluding taxes ("retail price") for those medicines whose PVL is equal to or less than EUR91.63;

- EUR38.37 per package for those medicines whose PVL is higher than EUR91.63 and equal to or lower than EUR200;
- EUR 43.37 per package for those medicines whose PVL is higher than EUR200 and equal to or lower than EUR500; and
- EUR48.37 for those medicinal products whose PVL is higher than EUR500.

The proceeding may start ex officio (for new medicinal products) or at the request of an applicant (eg, for medicinal products with a previous decision of non-reimbursement).

If the proceeding starts ex officio, the applicant may submit any documentation it deems appropriate, including the value dossier, within ten business days from the date the applicant receives the letter from the MOH informing that the pricing and reimbursement proceeding has begun. This period may be extended up to 15 business days.

If the proceeding starts at the request of the applicant, the applicant may submit any documentation it deems appropriate jointly with the request for initiation of the proceeding. Pricing and reimbursement proceedings are completed once the MOH issues a ruling with its decision on the reimbursement of a medicinal product.

Medical Devices

The reimbursement of medical devices is regulated in Royal Decree 9/1996 and Royal Decree 1030/2006, which establish the proceeding to reimburse medical devices and the criteria to be considered for the establishment of a maximum price.

According to Royal Decree 9/1996, only certain types of medical devices may be reimbursed, and this does not include products that are advertised to the general public. Annex I and Annex II of this Royal Decree include a list of medical devices that shall be reimbursed (eg, bandages, gauze, catheters, urine collection bags).

Royal Decree 1030/2006 refers to surgical implants, external orthoprostheses for use in hospitalised patients and external orthoprostheses for outpatient use (eg, wheelchairs).

7.2 Price Levels of Pharmaceuticals or Medical Devices

Spanish law does not allow the MOH to reference prices internationally. However, in practice, external reference pricing is a relevant factor influencing price rulings in Spain. The fact that this practice has no legal basis hinders traceability on how exactly the MOH proceeds regarding international prices.

It seems that the MOH requests the MAH to provide information about pricing in other EU countries, and that EU prices operate as a cap for Spanish prices. Prices in Spain are rarely fixed above the price of the same medicinal product in other EU countries.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Please see **7.1 Price Control for Pharmaceuticals and Medical Devices**.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Until 2023, the cost-benefit assessment (HTA) of medicinal products was carried out in so-called “Therapeutic Positioning Reports” (IPTs). These IPTs included a therapeutic evaluation section and an economic evaluation section. HTA was

carried out jointly by the AEMPS, the MoH and the autonomous regions.

According to Law 10/2013, these reports will have a "scientific-technical" basis and will be binding but not mandatory. In 2020, the MOH approved the Plan for the Consolidation of IPTs ("the Plan"), which reviewed the whole HTA process in Spain and consolidated IPTs as a key element of such HTA. However, a judgment of the Spanish National High Court in 2023 ruled that this Plan had been issued without following the established procedure for drafting laws and regulations. Consequently, a joint clinical and economic evaluation cannot be conducted in Spain. Since this ruling, the IPTs being carried out by the AEMPS do not include an economic evaluation section.

In relation to medical devices, the criteria for inclusion are more explicitly conditioned to the requirement of efficiency. In this sense, Law 16/2003 establishes that a prior assessment will be required for the inclusion of new technologies in the NHS. The requirements established by Law 16/2003 for this evaluation include the need for the new technologies to provide an improvement in terms of safety, efficacy, effectiveness, efficiency or proven usefulness compared to other available alternatives.

A new Royal Decree is expected to be issued in 2024 to fully regulate the HTA procedure for medicinal products and medical devices in Spain.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Royal Legislative Decree 1/2015 governs the prescription and dispensing of medicinal products. The general rule is that prescription in the NHS should be done in the most appropriate way for the benefit of patients, while protecting the sustainability of the system.

Prescriptions are made by active ingredient. Prescription by trade name will be possible if the principle of greater efficiency for the NHS is respected and for medicinal products considered as non-substitutable.

When the prescription is made by active substance, the pharmacist shall dispense the lowest-priced medicinal product in the so-called "Homogeneous Groups", which are lists of products that may be substituted.

Generics and biosimilars have different substitution regimes. Biological medicinal products are non-eligible for substitution, with the general rule being that the pharmacist must dispense the medicinal product prescribed by the doctor. Exceptionally, when the prescribed medicinal product is not available in the pharmacy due to shortages or when there is an urgent need to dispense it, the pharmacist may replace it with a generic medicinal product. In any case, it must have the same composition, pharmaceutical form, route of administration and dosage.

According to Article 1 of MOH Order SCO/2874/2007, biological products shall not be substituted when dispensed without the express authorisation of the prescribing doctor.

To achieve greater efficiency for the NHS, the MOH can establish "singular reserves" for the dispensing of some medicinal products. When deciding on the reimbursement of a medicinal product, it is common for the MOHto stipulate that some medicinal products may only be dispensed in NHS hospitals, rather than in retail pharmacy offices.

No special rules apply to the prescription and dispensing of medical devices.

8. Digital Healthcare

8.1 Rules for Medical Apps

In Spain, there are no specific rules for medical apps, medical devices software or mobile health apps. If a particular software qualifies as a medical device, its regulatory framework will apply.

Some of the most common "health apps" (eg, medication reminders, pregnancy tracking, remote patient monitoring, telemedicine) may qualify as a medical device or an in vitro diagnostic medical device, and shall be CE marked. Guidance in this regard has been provided at EU level, by the Medical Device Coordination Group (MDCG) established by Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices.

In general terms, apps that do not perform an action on data or perform an action limited to storage, archiving, communication or simple search do not qualify as medical device software. The fact that the app alters data for embellishment purposes does not render it a medical device either, but altering data or its representation for medical purposes might. Apps that are not for the benefit of individual patients will also not qualify as medical device software; this excludes software or apps intended to aggregate population data, provide generic diagnostic or treatment pathways, serve as scientific literature, templates, models, etc.

8.2 Rules for Telemedicine

Telemedicine or teleconsultation services are not specifically regulated in Spain.

The Spanish Code of Medical Ethics does provide some guidance on what is permitted in the field of telemedicine. According to Article 23 thereof, the use of telematic means or other non-face-to-face communication systems aimed at aiding decision-making within the professional scope complies with medical ethics if the identification of those involved is unambiguous, confidentiality is ensured, and communication channels guarantee maximum available security.

Law 44/2003, on the organisation of the health professions, establishes that the exercise of health professions shall be carried out in full technical and scientific autonomy, subject only to the limitations set out by law and to the principles and values set out in the applicable regulatory and deontological framework. Therefore, there is a consensus that physicians can perform telemedicine services if they consider it appropriate from a scientific and technical point of view and in light of the ethical regulations.

8.3 Promoting and/or Advertising on an Online Platform

In essence, advertising on the internet is held to the same standards and requirements as advertising through traditional channels.

The advertising and promotion of medicinal products and medical devices is subject to the general rules on advertising contained in General Law 34/1988 on advertising and in Law 3/1991 on Unfair Competition. For medicinal products, Royal Decree 1416/1994 must also be followed, and the advertising of medical devices is regulated by the general regulatory framework for medical devices.

As regards advertising directed to healthcare professionals through the internet, it is noteworthy that companies must use valid channels

within a context that is basically scientific or professional. Those channels must be intended exclusively for healthcare professionals authorised to prescribe or dispense medicinal products. These need to identify themselves in order to have access to the information. Companies can also establish a healthcare professional status verification system. Furthermore, a company will be liable for the content of the websites accessed through links from its own website.

8.4 Electronic Prescriptions

Electronic prescriptions are regulated by Royal Decree 1718/2010, which establishes a system for electronic prescriptions made in the context of the healthcare services of the National Health System and in private medical practice.

8.5 Online Sales of Medicines and Medical Devices

Only online sales of non-prescription medicinal products are permitted, and under the conditions set out in Royal Decree 870/2013. Moreover, the AEMPS has issued a Q&A document on the online sale of medicinal products. At a regional level, Aragon and Catalonia have issued specific guidelines governing the online sale of medicinal products.

There is currently no specific regulation governing the online sale of medical devices. However, such sales are permitted and are subject to the basic rules and requirements for sale outlined in the general regulatory framework for medical devices (ie, RD 192/2023, RD 1662/2000 and 1616/2009).

8.6 Electronic Health Records

There are no specific rules for patients' electronic health records other than the general requirements set out in Royal Decree 1093/2010, the GDPR and Law 3/2018; please see **2.5 Use of Data Resulting From Clinical Trials** and **2.6 Databases Containing Personal or Sensitive Data**.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices

The main laws applicable to patents in Spain are Law 24/2015 on Patents and Royal Decree 316/2017.

The requirements to obtain a patent in Spain are that the invention must be new in a field of technology (novelty), involve an inventive step and be susceptible to industrial application.

Among others, Article 5 of Law 24/2015 excludes the following as being non-patentable, under certain conditions:

- inventions for which the commercial exploitation would be contrary to public order or morality principles (eg, processes for cloning human beings);
- methods for treatment of the human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body – however, it is possible to patent products for use in any such methods, in particular substances, compositions, apparatus or instruments;
- the human body, at the various stages of its formation and development, and the simple discovery of one of its elements – however, it is possible to patent an element isolated from the human body or otherwise produced by a technical process, including the sequence or partial sequence of a gene, even if the

structure of that element is identical to that of a natural element; and
- a mere DNA sequence, without indicating any biological function.

9.2 Second and Subsequent Medical Uses

The first medical use of a substance or composition already known may be patentable per se. The second or a subsequent medical use of a substance or composition already known for use in the treatment of another disease (second medical indication) may be patentable if the second or subsequent use is new and inventive.

9.3 Patent Term Extension for Pharmaceuticals

For medicinal products, it is possible to extend patent rights through a supplementary protection certificate (SPC). This confers the same rights as those conferred by the patent and is subject to the same limitations and obligations. The rules applicable to SPCs are contained in Regulation (EC) 469/2009, amended by EU Regulation 933/2019, which introduces the exception known as the "SPC manufacturing waiver".

An SPC starts from expiry of the relevant patent. Its duration is the period between the patent application filing date and the date of first marketing authorisation of the relevant medicinal product in the EU up to a maximum of five years. An SPC can be extended once by a period of six months if there is a paediatric investigation plan for the medicinal product (eg, Regulation (EC) 1901/2006 on medicinal products for paediatric use).

SPCs are granted on a product basis. Each product requires a separate SPC, even if they are all covered by the same patent.

9.4 Pharmaceutical or Medical Device Patent Infringement

A patent is infringed when there is an unauthorised use of the invention protected by the patent during its validity. Patent infringement can occur directly and/or indirectly.

Direct infringement occurs when there is an unauthorised use of the patented invention through:

- manufacturing, offering for sale, marketing or using a product that constitutes the patented invention, or importing or possessing such a product for any such purposes;
- using a procedure that constitutes the patented invention, when the person using the procedure knows or can be reasonably expected to know that the use is prohibited without the patent holder's consent;
- offering for sale, marketing or using a product directly obtained from a procedure that constitutes the patented invention, or importing or possessing such a product for any such purposes; and
- exporting a product that is the subject matter of a patent in Spain or that has been obtained through a process protected by a patent in Spain. This has been considered by courts as an act of marketing, and is therefore an infringement of a patent in Spain.

Indirect infringement occurs when a person makes unauthorised use of a patented invention by giving or offering to give to other person(s) the means to put the patented invention into practice, if:

- the means are an essential element of the patented invention; and
- the other person(s) to whom the means are offered knows or can be reasonably expected

to know that it is possible to put the patented invention into practice through such means, and they intend to do so.

The mere application for a MA of a medicinal product does not constitute a patent infringement per se, but it can be a relevant factor if the patent holder demonstrates that the infringing activity is imminent. In case of litigation of innovators v generics, the parties usually exchange letters prior to initiating ligation and the generic operator undertakes not to launch its product prior to a certain date to try to avoid the arguments of the patent holder that the launch is imminent.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

The main defences to a patent infringement action include the following.

Research Exemption

Patent rights do not extend to acts carried out for experimental purposes relating to the patented invention. In particular, patent rights are not infringed by acts relating to performing the studies and trials necessary to obtain an MA for medicines in or outside Spain, and the practical requirements arising from them, including the preparation, obtaining and use of the active substance for these purposes.

The Bolar exception (a special case of the experimental use exception) relates specifically to experiments and trials, both pre-clinical and clinical, conducted to seek regulatory approval for a generic or similar bio-equivalent medicinal product.

IP Exhaustion

A patent holder cannot claim infringement against acts relating to a product that has been commercialised in the EEA by the patent holder or with their consent (patent exhaustion), unless there are legitimate grounds for the proprietor to oppose the marketing of the product.

Other Exemptions

Further exemptions include:

- stockpiling and manufacturing for export under the conditions set forth in Regulation (EU) 2019/933;
- acts done for strictly private and non-commercial purposes; and
- the extemporaneous preparation in a pharmacy of a medicine for an individual according to a medical prescription, or acts relating to a medicine so prepared.

9.6 Proceedings for Patent Infringement

A patent holder can bring actions to defend its patent in the competent Spanish courts. The following remedies, among others, are available:

- cessation action to stop the infringing activity;
- compensation for damages caused by the infringement; and
- seizure of the infringing articles and the means used for the infringement.

Interim relief can also be requested through a preliminary injunction application.

Pre-trial discovery proceedings to gather facts necessary to prepare the claim on the merits are available.

9.7 Procedures Available to a Generic Entrant

The generic entrant may file an action seeking the nullity of the patent/s expected to be enforced against the product intended to be commercialised. The defendant in such proceedings would normally file a counterclaim seeking the declaration of infringement.

The generic entrant may also file an action seeking a judicial declaration of non-infringement of a given patent by its product. Prior to the filing of the action, the interested party shall request the patent holder to give its opinion on the enforceability of the patent against the industrial exploitation that the applicant is carrying out on Spanish territory or against the serious and effective preparations that it is making for that purpose.

If no decision is made after one month or if the applicant is unsatisfied with its reply, the interested party will be entitled to bring an action for the declaration of non-infringement. This option is not available to those already sued for patent infringement.

There is no requirement under Spanish law for any prior legal action for the generic entrant regarding patents that may be infringed.

Patent linkage in MA procedures is prohibited under EU law.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

The ordinary legal tool used to tackle counterfeiting is the Spanish Criminal Code. Infringement committed knowingly is punishable with a fine and/or imprisonment (six months to two years). In serious cases, higher penalties may be imposed, namely higher fines and imprisonment of two to four years, temporary closing of the production plant or establishment concerned (up to five years) or even permanent closing thereof, and disqualification from exercising the profession related to the infringement.

Regulation (EU) No 608/2013 took effect throughout the EU in January 2014 and provides that patent owners may file an application to have Customs watch for imports of goods that infringe registered patents.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Law 14/2011 on Trademarks offers the trade mark holder a series of actions to defend the exclusivity it holds over the name and/or logo that is the subject matter of the protection. If the medicinal product or medical device is branded with a sign that infringes a valid trade mark, the holder of said mark will be entitled to file infringement actions against the entity responsible for the product or device.

Remedies include the cessation of the activity and damages. Contrary to patent law enforcement, the trade mark holder will not be able to impede the re-commercialisation of the same product or device with a different brand (unless the infringed right is a 3D trade mark or a registered design for protecting the shape of the product – see **10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices**).

The trade mark holder may oppose the importation of non-infringement product from non-EU countries based on its trade mark rights since Spanish law limits the defence of exhaustion to the territories of the EU.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

The right of industrial designs may be a source of protection regarding the shape of the medicinal products and medical devices – specifically the appearance of the whole or a part of a product resulting from the features of, in particular, the lines, contours, colours, shape, texture and/or materials of the product itself and/or its ornamentation.

In order to be protectable, designs must be new and possess individual character. These conditions are established and defined at both EU and national levels: at the EU level, they are established in Articles 6 and 7 of EU Regulation 6/2002, while at a national level they are regulated in Articles 5 and 6 of Law 20/2003 on the Legal Protection of Industrial Design.

3D trade marks may be registered, but shapes that are imposed by reasons of a technical order or by the nature of the goods themselves or that may affect the intrinsic value of the goods cannot be registered as a trade mark.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Spanish legislation (Articles 17.3 and 18.1 of Royal Legislative Decree 1/2015 and Article 7 of Royal Decree 1345/2007) does not include any material difference from regulatory data protection regulations in the EU (Article 11.14 of Regulation (EC) 726/2004 and Article 10.1 of Directive 2001/83/EC).

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

In the context of the COVID-19 pandemic, Royal Decree-Law 21/2020 and Law 2/2021 were enacted to temporarily regulate the home delivery of hospital-prescribed and/or dispensable medications. Under these regulations, regional authorities were empowered to establish appropriate measures for the non-face-to-face dispensing of medicinal products, ensuring optimal care by delivering, if necessary, medicinal products at healthcare centres, authorised healthcare establishments for dispensing medications near the patient's home, or at the patient's own home.

Consequently, several regional authorities adopted resolutions, guidelines or other legal instruments to regulate home delivery activities. For example, Catalonia issued a Resolution in June 2020 authorising the home delivery of hospital medicinal products, as well as the "Document of Good Practices for the Delivery of Outpatient Dispensed Hospital Medication" in April 2021. Andalusia entered into a collaboration agreement with the Andalusian Council of Pharmacists' Associations in March 2021, enabling and regulating the home delivery of hospital medicinal products.

11.2 Special Measures Relating to Clinical Trials

The Document of Instructions for the conduct of clinical trials in Spain was updated in March 2020 to allow special measures; please see **2.6 Databases Containing Personal or Sensitive Data** for more detail.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

The EMA has created a specific expedited procedure for the approval of medicines, which is characterised by significantly shorter timeframes for the review and approval process. The AEMPS has not adopted additional requirements, measures or exceptions in connection with national proceedings.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

Within the context of the COVID-19 pandemic, the AEMPS has established a temporary and abbreviated procedure for the certification of medical devices that are essential to answer the needs caused by the pandemic (namely, medical devices such as surgical masks and surgical gowns). In addition, Order SND/326/2020 established special measures for the granting of prior operating licences for facilities and for the commissioning of certain medical products without CE marking on the occasion of the health crisis caused by COVID-19.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

Because of the COVID-19 crisis, the AEMPS issued extraordinary import authorisations for medical devices that do not comply with some of the marketing requirements for medical devices (such as authorisation for products without CE marking or for importers without import licences).

11.6 Drivers for Digital Health Innovation Due to COVID-19

Telemedicine services were already in use before the COVID-19 pandemic but their use became widespread during this period.

The MoH issued information notes providing guidance to health centres on how to manage COVID-19 cases telematically (Technical document "Management and home care of Covid-19", dated June 2020) and encouraging medical centres to promote telephone and telematic consultations, leaving the need for a face-to-face assessment to the discretion of the professional after an initial telephone assessment.

Also in 2020, the Medical Association of Catalonia published a document named "Deontological considerations in relation to information, consent and virtual consultation during the COVID-19 pandemic", and the Madrid Medical Association issued a document providing guidance on the use of telemedicine services because of the pandemic.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

There is no intention to issue compulsory licences for COVID-19-related treatments or vaccines.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

No liability exemptions have been introduced in existing or new provisions regarding COVID-19 vaccines or treatments.

11.9 Requisition or Conversion of Manufacturing Sites

During the COVID-19 pandemic period, many companies offered their technology to Spanish authorities to manufacture respirators, masks, protective equipment and hydroalcoholic gel. For example, Spanish car manufacturer "SEAT" dedicated itself to the production of emergency respirators.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

Under Royal Decree-Law 7/2020, measures to make public procurement more flexible were adopted to ensure the immediate availability of goods and services urgently needed to respond to the pandemic. Royal Decree-Law 7/2020 stipulated that all public contracts to address COVID-related needs would be processed through the emergency procedure. This procedure was already regulated in public procurement law, but because of Royal Decree-Law 7/2020, COVID-19 was accepted and established as a general criterion for justification for processing public contracts through the emergency proceeding.

Trends and Developments

Contributed by:
Anna Gerbolés, Joan Carles Bailach, Claudia Gonzalo and Juan Martínez
Faus Moliner Abogados

Faus Moliner Abogados is a modern boutique law firm based in Barcelona that specialises in advising the pharmaceutical industry and companies that operate in the life sciences sector. The firm was founded in 1997 and currently has 15 members. It focuses on pharmaceutical law, commercial contracts, corporate transactions, corporate governance, compliance, competition law, public procurement, product liability, advertising, litigation and arbitration. The firm advises pharmaceutical and healthcare clients, large companies and smaller biotech start-ups, and is frequently called upon to advise public authorities on matters such as draft legislation. It combines legal skills and specialisation with a practical and business-oriented manner of practising law. Since its foundation, Faus Moliner has been recognised in several international publications as the market leader in pharmaceutical law in Spain.

The authors appreciate the collaboration of Sergio Miralles of Intangibles Legal and Pablo Mansilla and Laia Rull of Faus Moliner.

Authors

Anna Gerbolés is a senior associate at Faus Moliner and specialises in pharmaceutical and food law. Her experience in these sectors includes the provision of legal advice on regulatory issues and the advertising of medicinal products, medical devices, food products and other borderline products. Since becoming part of the Faus Moliner team in 2021, she has been providing highly specialised advice to companies operating in the life sciences sector. Anna is a member of the Barcelona Bar Association.

Joan Carles Bailach is a senior associate at Faus Moliner and specialises in market access, pricing and reimbursement, commercial contracts and pharmaceutical and life sciences law. He has regularly advised national and international companies on these matters since joining the firm in 2019. Joan Carles is a member of the Barcelona Bar Association, the Section of Health Law, and the Young Advocacy Group of the Barcelona Bar Association.

Contributed by: Anna Gerbolés, Joan Carles Bailach, Claudia Gonzalo and Juan Martínez,
Faus Moliner Abogados

Claudia Gonzalo is a senior associate at Faus Moliner, specialising in pharmaceutical and healthcare regulations. She has experience in advising national and international companies ion regulatory matters, public procurement, and corporate transactions and contracts. Claudia has a master's in public economic law and an executive MBA in pharmaceutical, biotechnological and medical device companies, and is a member of the Spanish Compliance Association.

Juan Martínez is a senior associate at Faus Moliner and regularly advises national and international companies on litigation and arbitration procedures. He specialises in conflicts related to contracts, unfair competition, product liability and regulatory matters. Since becoming part of the Faus Moliner team in 2017, he has been providing highly specialised advice to companies operating in the life sciences sector. Juan is a member of the Barcelona Bar Association.

Faus Moliner Abogados

Rambla de Catalunya 135
08008
Barcelona
Spain

Tel: +34 93 292 21 00
Email: bcn@faus-moliner.com
Web: www.faus-moliner.com

Faus Moliner

Contributed by: Anna Gerbolés, Joan Carles Bailach, Claudia Gonzalo and Juan Martínez,
Faus Moliner Abogados

Life Sciences in Spain: an Introduction

General pharma legislation

The Ministry of Health (MOH) opened a public consultation on the first draft of the law that will amend the current Royal Legislative Decree 1/2015. The document published by the MOH shows that the reform that is being considered will have the following three principal axes.

Public financing of medicines

The MOH document refers to adopting new measures to rationalise pharmaceutical expenditure and promote rational use of public funds. In this regard, it is proposed to modify the reference price system by introducing elements that increase competition and value the contributions that represent an incremental benefit in the use of medicines. The document envisages modifying the system of the co-payment of medicines, with the purpose of protecting the persons that are more in need. The document does not refer to whether the co-payment system may also be used as an instrument that may help in modulating the demand of certain products. The document also announces measures to apply additional pressure to the industry by stating that quarterly contributions may also apply to medicines dispensed in healthcare centres.

COVID-19 and the impact of new technologies

The pandemic created great challenges related to the availability of medicinal products and medical devices. In this sense, the MOH aims to consolidate the non-presential dispensing of medicines for hospital dispensing and telepharmacy in the National Health System.

Implementation of EU law

The text published by the MOH proposes to make the necessary amendments to incorporate the amendments and definitions of Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro medical devices into Spanish law.

The process to approve this new law will be lengthy; the government is expected to provide a first draft law around Q4 2024.

Pricing and reimbursement

The MOH has publicly announced its intention to issue a new Royal Decree regulating the financing and pricing of medicinal products. However, the recently published Annual Regulatory Plan for 2024 does not include this Royal Decree as a priority for this year and is expected to be adopted in 2025.

This regulation would regulate the inclusion of medicinal products in the pharmaceutical provision, the establishment of special reserves and special financing conditions, the system for revising the minimum ex-factory price (PVL), the inclusion of new indications, and the exclusion of medicines from the pharmaceutical provision, among other matters.

In March 2024, the MOH opened a public consultation on the first draft of the Royal Decree regulating the procedure for the selective financing of medical devices for non-hospitalised patients and determining the margins corresponding to their distribution and dispensation. The objectives of this regulation are twofold:

- to set the retail price of financed medical devices and the margins corresponding to the activities of wholesale distribution and dispensing to the public; and
- to update the content of pharmaceutical provision by including new medical devices, altering them and excluding those that are not marketed.

Health technology assessment

The MOH has launched a public consultation on the draft Royal Decree on health technology assessment. The aim of this regulation is to regulate the procedure for the evaluation of medicines and medical devices.

This new Royal Decree responds to the need to address the Spanish National High Court (*Audiencia Nacional*) ruling of 2023 that annulled the Therapeutic Positioning Reports Consolidation Plan ("IPT Consolidation Plan"). This IPT Consolidation Plan established the procedure to be followed to carry out the clinical and economic evaluation of medicines and their content. The National High Court ruled that the IPT Consolidation Plan had been issued without following the established procedure for drafting laws and regulations. For this reason, a regulation with the status of Law or Royal Decree is required to establish the procedure/content of the health technology assessment reports.

The Director General of Pharmacy of the MOH recently publicly announced that the draft Royal Decree has already been drawn up. The draft is expected to be published in a Public Hearing in the coming months, so that citizens can make contributions and suggestions on the text.

Advertising of medicinal products and medical devices

The MOH has recently commenced the public consultation phase for the draft Royal Decree governing the advertising of medical devices. This draft encompasses several elements, such as streamlining the process for obtaining prior approval for the public promotion of medical devices, introducing a requirement for a responsible declaration in advertising specific devices, and prohibiting hospitality in promotional meetings except for professional-scientific events. It also explicitly bans off-label promotion and offers detailed guidelines on permissible and prohibited content in advertisements directed to the public.

In April 2023, the MOH invited all interested parties to make their proposals regarding the preparation of the draft bill amending Royal Decree 1416/1994 on the promotion of medicinal products for human use. The interested parties submitted the proposals in May 2023, and the new draft law is currently under preparation.

According to the public consultation call initiated by the MOH on the amendment of the regulation, the new proposed draft bill is aimed to address the need to tackle digital advertising, the use of social media and audiovisual means, the necessity of addressing the distribution of competencies between the state and autonomous communities, and the inclusion of obligations for accessibility in advertising for individuals with sensory disabilities.

Cannabis

In February 2024, the MOH launched a public consultation on the draft Royal Decree that is expected to establish the conditions for the elaboration and dispensation of magistral formulae based on standardised cannabis preparations. According to the MOH, although there are already industrial medicinal products with cannabis as an active ingredient, there is an expectation that cannabis in other presentations will improve the symptoms and quality of life of certain patients.

The aim of this regulation is to establish the criteria for the elaboration of magistral formulae as a way of guaranteeing the correct dosage, stability and processing of these substances, and the limitation of their formulation to cases in which

there is a monograph with technical specifications in the National Formulary. The consultation also includes, as an objective, the establishment of therapeutic indications and conditions for the preparation, prescription and dispensing of magistral formulae.

Transparency and confidentiality of prices of medicinal products

One of the hottest topics is the debate on transparency and confidentiality of the price and conditions of medicinal products in Spain.

Following freedom of information requests from citizens, several court rulings have been issued in 2023–2024 obliging the MOH to provide access to the price and reimbursement conditions of certain medicinal products. These rulings are not final and have been appealed. A Supreme Court ruling is expected in the coming years.

So far, the MOH has maintained a firm stance in defence of the confidentiality of this information, arguing that providing access to it would be detrimental to its ability to negotiate with pharmaceutical companies when setting prices for medicinal products. Therefore, making the price and reimbursement conditions of medicinal products public would reduce the negotiating capacity of the MOH and damage the economic sustainability of the NHS.

Despite this, in an appearance before the Health Commission of the Spanish Parliament (*Congreso de los Diputados*) in January 2024, the new Minister of Healthtook a clear position in favour of transparency in the price and conditions of medicinal products. However, at the inauguration of CEFI's Course on Pharmaceutical Law in March 2024, the General Director for the Common Portfolio of NHS Services and Pharmacy spoke in favour of the advantages of confidentiality in this area, stating that confidentiality increases the MOH's bargaining power when negotiating with pharmaceutical companies and generates savings for the NHS.

Spanish recovery and resilience plan

At its meeting on 17–21 July 2020, the European Council agreed to create Next Generation EU, a temporary recovery fund in additional to the EU multi-annual budget for 2021–2027. Such funds are envisaged to be used to tackle the consequences of the COVID-19 pandemic and boost economic recovery. To access these resources, member states were required to design "recovery and resilience plans" to be evaluated by the European Commission (EC).

Spain presented its first version of its "recovery and resilience plan", which includes several references to the pharmaceutical sector under the section "strengthening of the capabilities of the National Health System". Later, the Spanish government published a document outlining all the strategic projects related to health that it wants to promote with the Next Generation funds – the "PERTE for Cutting-edge Health".

One of the most noteworthy measures of this plan is to create a public-private capital company to develop new advanced therapy medicinal products in Spain. In March 2024, the Spanish government approved the agreement authorising public participation in the creation of the first commercial company for advanced therapies with public-private capital in Spain. It will be promoted because of a shareholders' agreement to be formalised between the Ministry of Science, Innovation and Universities and two pharmaceutical companies.

Contributed by: Anna Gerbolés, Joan Carles Bailach, Claudia Gonzalo and Juan Martínez,
Faus Moliner Abogados

The new company will be owned 51% by the private partners and 49% by public investment from the Ministry of Science, Innovation and Universities. It is expected to mobilise an initial public-private contribution of more than EUR74 million, EUR36,685,000 of which will be provided by the Spanish government and EUR38,182,346 of which will be made up of private capital contribution, contributed equally by the private shareholders. In addition, the Carlos III Health Institute (a public institution devoted to scientific investigation) will collaborate in the contribution of scientific knowledge and participate in the company's scientific and technological decision-making bodies. In the near future, the Spanish government is expected to make an additional contribution of up to EUR71 million, so that the new company could mobilise up to EUR220 million, with a total public contribution of EUR107 million.

SWITZERLAND

Law and Practice

Contributed by:
Oliver M Brupbacher, Claudia Götz Staehelin, Djamila Batache and Christine Schweikard
Bär & Karrer AG

Contents

Contributed by: Oliver M Brupbacher, Claudia Götz Staehelin, Djamila Batache and Christine Schweikard,
Bär & Karrer AG

Bär & Karrer AG is a leading Swiss law firm with more than 200 lawyers in Zurich, Geneva, Lugano, Zug, Basel and St. Moritz. The firm's core business is advising clients on innovative and complex transactions and representing them in litigation, arbitration and regulatory proceedings. Clients range from multinational corporations to private individuals in Switzerland and around the world.

Authors

Oliver M Brupbacher is a dispute resolution and investigation partner at Bär & Karrer AG with extensive experience in the life sciences and healthcare sectors, including complex commercial and cross-border litigation, investigations and arbitration, as well as regulatory, corporate and compliance counselling, and risk management. Oliver's practice focuses on representing national and multinational clients in heavily regulated industries and at various stages of dispute resolution and investigations, including pre-dispute advice, crisis management and information governance. As a former senior litigation counsel, global product lawyer and head of global discovery at Novartis, Oliver combines expertise in his areas of practice with an intimate understanding of the industry and clients' needs.

Claudia Götz Staehelin is a dispute resolution and investigation partner at Bär & Karrer AG with extensive experience in the life sciences and healthcare sectors. Based on her experience as former head of litigation at Novartis, Claudia's practice focuses on complex investigation and litigation matters in civil, criminal and regulatory proceedings. She leads large-scale internal investigations, supports clients in crisis management and advises on all aspects of compliance. She represents and advises her clients in domestic and cross-border litigation, in international judicial and administrative matters, and in internal and regulatory investigations led by Swiss and foreign authorities. In the healthcare and life sciences industry, her focus is pharma regulatory and compliance.

Contributed by: Oliver M Brupbacher, Claudia Götz Staehelin, Djamila Batache and Christine Schweikard,
Bär & Karrer AG

Djamila Batache is an associate in the life sciences and litigation team at Bär & Karrer AG. Her practice focuses on advising and representing clients in the healthcare and life sciences sector in the areas of contract law, regulation and (product) liability law. She is also regularly involved in conducting internal investigations and assisting clients in compliance matters. Djamila is an expert in the field of AI governance and regulation, in particular with regard to liability implications of the use of AI systems.

Christine Schweikard is an associate in the intellectual property and life sciences practice group at Bär & Karrer AG. She frequently drafts and negotiates licensing, research, distribution and other commercial contracts for clients from the pharmaceutical, biotech, medical device and information technology sectors, advises on intellectual property, product and healthcare regulatory law, and supports healthcare providers and health insurers in the digitalisation of healthcare.

Bär & Karrer AG

Lange Gasse 47
4052 Basel
Switzerland

Tel: +41 61 261 50 50
Email: basel@baerkarrer.ch
Web: baerkarrer.ch

Contributed by: Oliver M Brupbacher, Claudia Götz Staehelin, Djamila Batache and Christine Schweikard,
Bär & Karrer AG

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Swiss healthcare regulation is spread over various statutes, ordinances and guidelines, including self-regulatory instruments such as best practice codes and references to international provisions. This makes navigating the life sciences landscape depend in large part on legal and regulatory expertise, as well as extensive practical industry experience.

The following key acts provide the principles of the national regulation of pharmaceuticals and medical devices, whereby the legal terminology in Switzerland refers to "therapeutic products" as the generic term encompassing both "medicinal products" (pharmaceuticals) and "medical devices".

- Medicinal products – Therapeutic Products Act (TPA), Ordinance on Medicinal Products (OMP), Medicinal Products Licensing Ordinance (MPLO), Ordinance on the Requirements of Marketing Authorisation of Medicinal Products (OMAMP), Ordinance on Advertising of Medicinal Products (OMPA), and the Ordinance on Integrity and Transparency (OIT).
- Medical devices – TPA, Medical Devices Ordinance (MedDO) and Ordinance on In Vitro Diagnostic Medical Devices (IvDO). Switzerland recently revised its medical devices law to align it with Regulation (EU) 2017/745 on medical devices (EU-MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (EU-IVDR).

Duties and responsibilities for Swiss healthcare are divided among the federal, cantonal and municipal authorities, whereas this practice guide focuses on the federal level. As part of the Federal Department of Home Affairs (FDHA), the Federal Office of Public Health (FOPH) is responsible for public health in Switzerland. The Swiss Agency for Therapeutic Products (Swissmedic) is the Swiss authority responsible for the authorisation and supervision of therapeutic products. As a federal public law institution, Swissmedic is autonomous with respect to its organisation and management.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Administrative decisions of regulatory bodies are usually issued in the form of a ruling and can be challenged in administrative procedures or administrative court proceedings. The appropriate legal action depends on whether a federal or a cantonal regulatory body has issued the decision. If issued by a federal authority, decisions can be appealed to the Federal Administrative Court. Decisions of the Federal Administrative Court are subject to further appeal to the Federal Supreme Court.

These challenge procedures in general also apply to other regulated products. In certain areas, such as public procurement or social security, special provisions may apply. Besides, criminal procedure rules may apply to administrative and criminal sanctions issued by regulatory bodies.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Medicinal products are divided into four dispensing categories:

- category A – medicinal products that may be dispensed on a one-time basis on a physician's prescription (Article 41 OMP);

- category B – medicinal products that require a prescription and can be obtained several times, whereby medicinal products on list B+ can also be dispensed without a prescription (Article 42 OMP);
- category D – medicinal products that may be dispensed without a prescription, but after specialist advice (Article 43 OMP); and
- category E – medicinal products that may be dispensed without a prescription and without specialist advice (Article 44 OMP).

The assignment to a particular category determines who is authorised to dispense, prescribe and use the medicinal product (Articles 24 et seq TPA). Non-prescription medicinal products, known as "over-the-counter" medicinal products, are intended for self-medication. The classification into the different categories is made by Swissmedic (Article 23a TPA).

The TPA further contains special provisions for blood and blood products (Articles 34 et seq TPA) as well as for veterinary medicinal products (Articles 42 et seq TPA).

Medical devices are divided into different categories (classes I, IIa, IIb, III) for which different conformity assessment procedures apply. The classification follows the respective regulation in the EU-MDR (Article 16 paragraph 1 MedDO) and is based on the intended purpose and the associated risk. Certain medical devices may be classified as intended for use by healthcare professionals (HCPs) only.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials are mainly governed by the TPA, the Human Research Act (HRA), the Human Research Ordinance (HRO), the Clinical Trials Ordinance (ClinO) and the Ordinance on Clinical Trials with Medical Devices (ClinO-MD). In principle, clinical trials with therapeutic products require prior authorisation from Swissmedic (Article 54 paragraph 1 TPA) and the competent ethics committee (Articles 24 et seq ClinO and Articles 9 et seq ClinO-MD). Regarding medicinal products, Swissmedic examines whether the Good Manufacturing Practice and safety requirements are met (Article 54 paragraph 4 lit a TPA); regarding medical devices, the assessment includes the conformity of the products with the safety requirements (Article 54 paragraph 4 lit b, Article 45 paragraphs 1 and 3 TPA).

Clinical trials must be conducted in line with the rules of good clinical practice as set out, with regard to medicinal products, in the ICH Guideline on Good Clinical Practice of 9 November 2016 and the WMA Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects (Article 5 paragraph 1 ClinO; Article 3 ClinO-MD). With regard to medical devices, the applicable rules on good clinical practice were incorporated into Swiss legislation by way of reference to Article 72 and Annex XV Chapters I and III of Regulation (EU) 2017/745 on medical devices (MDR) as well as in EN ISO 14155.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

In order to secure authorisation for the conduct of a clinical trial, the investigator must submit an application to the ethics committee in the canton in whose territory the study is conducted (Articles 24 et seq ClinO; Articles 10 et seq ClinO-MD):

- acknowledgment of receipt/possible deficiencies' notification within seven (medici-

nal products) or ten (medical devices) days respectively; and
- decision within 30 (medicinal products) or 40 (medical devices) days respectively and information of Swissmedic in case an authorisation by Swissmedic is necessary; in case of multi-centre clinical trials with medicinal products, the deadline is extended to 45 days.

The submission of the application to Swissmedic is made by the sponsor:

- acknowledgment of receipt/possible deficiencies' notification within seven (medicinal products) or ten (medical devices) days respectively;
- as a general rule, decision within 30 (medicinal products) or 45 (medical devices) days respectively; and
- in certain circumstances, Swissmedic must obtain the opinions from the Swiss Expert Committee for Biosafety (SECB), the Federal Office for the Environment (FOEN) or the FOPH before granting the authorisation.

2.3 Public Availability of the Conduct of a Clinical Trial

Sponsors of authorised clinical trials with medicinal products are subject to registration obligations (Articles 64-67 ClinO). Before conducting a clinical trial with medicinal products, the sponsor must enter the clinical trial either in a primary register recognised by the World Health Organisation (WHO) or in the register of the National Library of Medicine of the United States of America as well as in the supplementary Swiss federal database using a Swiss national language. The publicly accessible portal SNCTP (Swiss National Clinical Trials Portal) displays studies that are being conducted in Switzerland as soon as they have been approved by the cantonal ethics committee and released for publication by the researchers. The data originates from (i) the cross-cantonal application submission platform BASEC and (ii) the international study database ICTRP (WHO database comprising 17 worldwide primary registers). The operation of the portal – as well as the supplementary federal database – is guaranteed by the co-ordination office Kofam (Article 67 paragraph 3 ClinO). The following data may be accessed publicly: a brief description of the clinical trial, the site(s) where the clinical trial is conducted, the criteria for the participation in the clinical trial, the disease category and the health condition investigated, as well as an indication of whether the clinical trial includes rare diseases.

Sponsors of clinical trials with medical devices are subject to analogous registration obligations (Article 41 ClinO-MD). Public access to the results of the clinical trials is ensured by publication in one of the above-mentioned registers (Article 42 ClinO-MD).

Generally, the results of clinical trials are not publicly available. However, physicians that are member of the Swiss Medical Association (FMH) are subject to a publication obligation contained in the ethical guidelines of the Declaration of Helsinki (2013) regarding the results of human research.

2.4 Restriction on Using Online Tools to Support Clinical Trials

Personal data held for research purposes must be protected by appropriate operational and organisational measures (cf. Article 5 paragraph 1 HRO). The applicable ICH Guideline explicitly refers to the increasingly widespread use of electronic data handling and remote electronic trial data systems and outlines the additional requirements that must be met by the sponsor when using such tools (see Section 5.5.3 of the

Guideline for Good Clinical Practice EG(R2) of 9 November 2016). In addition, the use of online and electronic tools is subject to the limitations imposed by Swiss data protection law (in particular the Federal Act on Data Protection (FADP) and the respective Ordinance (DPO) both of which have been completely revised as of 1 September 2023).

2.5 Use of Data Resulting From Clinical Trials

Health data is considered personal data requiring special protection. The HRA regulates in detail the further use and disclosure of health data that falls within its scope of application. In principle, the disclosure of health data is permissible both within an organisation and to third parties depending on the type of health data, the intended further use and the assignability to a specific person. The data protection provisions do not apply to anonymised and pseudonymised data, insofar as the data subjects are no longer identifiable.

2.6 Databases Containing Personal or Sensitive Data

According to the HRA and its implementing provisions (Article 43 HRA; Article 5 HRO), anyone who stores biological material or health-related personal data for research purposes must take appropriate technical and organisational measures to prevent the unauthorised use thereof, and must fulfil certain operational and professional requirements.

Since 2016, the Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks has complemented the Declaration of Helsinki.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The decisive criterion for the classification of a product as a therapeutic product – ie, as a medicinal product or as a medical device, is the intended purpose of the product, which – considering all objective (nature of a product) and subjective (designation and promotion of a product) circumstances of the individual case – must be the medical effect or application on the human organism.

As regards the distinction between medicinal products and medical devices, the decisive factor is not the material composition of the product, but whether its intended main effect in or on the human body is caused by pharmacological, immunological or metabolic means (medicinal products), or rather through mechanical, physical or physico-chemical effects (medical devices; Article 4 paragraph 1 lit a and b TPA; BVGE C-2093/2006, E. 3.5).

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

No specific requirements need to be met for the authorisation of biological medicinal products (Article 2 paragraph 1 lit d Ordinance on the Simplified Marketing Authorisation Procedures (OSMA)). It is, however, necessary that an equilateral black triangle standing on its apex is included in the package leaflet and information, which is accompanied by the statement that this medicinal product is subject to additional monitoring (Article 14a lit b OMAMP).

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

The authorisation of medicinal products is initially valid for a period of five years and is subject to subsequent renewal upon application (Article 16 paragraph 2, Article 16b paragraph 1 TPA). If a medicinal product is not placed on the market within three years of the granting of the authorisation, or if it is no longer actually on the market during a period of three consecutive years after it has been placed on the market, Swissmedic may revoke the authorisation (Article 16a paragraph 1 lit a TPA). Medicinal products must fulfil their authorisation requirements for each production unit during the entire distribution period, whereby such requirements may only be modified, extended or restricted by a formal amendment procedure. Swissmedic may at any time review the authorisation, adapt it to changed circumstances or revoke it (Article 16c TPA).

Regarding medical devices, the necessary certificates of conformity (see **3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices**) are valid for a maximum of five years and are extended following a re-assessment (Article 26 MedDO). If a designated body finds that a manufacturer no longer fulfils the requirements of the MedDO, it must set a deadline for correction and otherwise suspend, revoke or restrict the certificate (Article 27 MedDO).

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

An authorisation to place medicinal products on the Swiss market is granted based on a respective application (Article 11 TPA) and after a detailed examination by Swissmedic. Applicants must hold a manufacturing, import or wholesale licence issued by Swissmedic (see **4. Manufacturing of Pharmaceuticals and Medical Devices**), have a registered address, office or branch office in Switzerland and must prove that the medicinal product is of high quality, safe and effective (Article 10 TPA).

Different authorisation procedures apply depending on the characteristics and the application of the medicinal product.

- Ordinary procedures for first authorisations of new active pharmaceutical ingredients (APIs) and major deviations (Article 9 paragraph 1, Articles 11 et seq TPA).
- Compassionate use authorisations (in a simplified procedure, Articles 14 et seq TPA) for a limited period – ie, for life-threating or debilitating diseases if they are compatible with the protection of health, their use is expected to have a major therapeutic benefit, and no authorised, alternative or equivalent medicinal product is available in Switzerland (Article 9a TPA; Articles 18 et seq OSMA).
- Fast-track procedures for first authorisations of new APIs and major deviations on request, available for promising therapies for the prevention or therapy of a severe, debilitating or life-threatening disease with a high therapeutic benefit and where the standard treatment is either unavailable or unsatisfactory (Article 7 OMP).
- Simplified procedures for certain categories of medicinal products where this is compatible with the quality, safety and efficacy requirements and where there is no conflict with Swiss interests or international agreements, in particular for generics (but not for biosimilars), orphan drugs and certain categories of medicinal products authorised and/or used in foreign countries (Articles 14 et seq TPA; Articles 12 et seq OSMA).

- The authorisation procedure on the basis of a notification, in particular for certain complementary medicines without indications and other medicinal products with a low-risk potential (Article 15 TPA).

Changes to an authorisation that have no or only minimal consequences for the quality, safety or efficacy of a medicinal product must be communicated to Swissmedic within 12 months of their implementation (Article 21 OMP). Substantial variations require an additional marketing authorisation procedure. Marketing authorisations are in principle transferable upon approval of a respective application by Swissmedic.

Medical devices do not require an authorisation by a public authority prior to being placed on the Swiss market. Instead, they must bear a respective conformity (MD or CE) marking testifying the conformity of the device with the general safety and performance requirements.

The conformity assessment procedure is based on Articles 52 and 54 and Annexes IX-XI of the EU-MDR (Articles 21 et seq MedDO; Articles 17 et seq IvDO). Depending on the risk qualification of the medical device (see **1.3 Different Categories of Pharmaceuticals and Medical Devices**), the conformity is either to be declared by the manufacturer or by a private body certified to conduct conformity assessments.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

In principle, ready-to-use medicinal products may only be placed on the market after they have been authorised (Article 9 paragraph 1 TPA). However, there are a number of exceptions to this general rule.

- Medicinal products for which a review of the ordinary approval requirements (of high quality, safe and effective) is not necessary or useful – eg, formula magistralis, officinalis and hospitalis products or products intended for clinical trials (Article 9 paragraphs 2 et seq TPA).
- Orphan use – the use of medicinal products for the treatment of diseases that are so rare that there is hardly any incentive for a regular marketing authorisation to be approved in Switzerland for a limited period in a simplified approval procedure (Article 9a, Article 14 paragraph 1 lit f TPA).
- Temporary authorisation for use outside of clinical trials – Swissmedic may temporarily authorise the use of yet unauthorised medicinal products intended for clinical trials outside the scope of a clinical trial (Article 9b paragraph 1 TPA; Articles 52 et seq MPLO).
- Temporary authorisation to bridge temporary unavailability – medicinal products may be temporarily or quantitatively authorised by Swissmedic to bridge the unavailability of an identical medicinal product in Switzerland, provided that they are authorised in another country with an equivalent medicinal product control and no essentially identical medicinal product is authorised and available in Switzerland (Article 9b paragraph 2 TPA).
- Off-label use – off-label use – eg the use of a (properly) authorised medicinal product for other indications, is generally permissible within the scope of Articles 3 and 26 TPA.
- Unlicensed use – an unlicensed medicinal product may be imported under the restrictive requirements of Article 20 paragraph 2 TPA and Articles 48 et seq MPLO.

Manufacturers of medical devices must generally carry out a conformity assessment before placing the device on the market (see **3.4 Pro-**

cedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices). However, in the interest of public health or patient safety or health, Swissmedic may, upon application, grant an authorisation even though the relevant conformity assessment procedure has not been carried out (Article 22 paragraph 1 MedDO; Article 18 paragraph 1 IvDO).

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

Holders of marketing authorisations for medicinal products, as well as medical device manufacturers, must have a post-market surveillance system (ie, pharmacovigilance and materiovigilance plans) in place (Article 11 paragraph 2 lit a no 5 TPA; Article 56 MedDO; Article 49 IvDO).

Holders of marketing authorisations for medicinal products with a new API or a biosimilar must periodically and automatically file safety update reports (PSURs) with Swissmedic on the safety and risk-benefit ratio for four years after authorisation (Article 60 OMP). With its marketing authorisation, Swissmedic may impose additional conditions or obligations on the applicant, including further product evaluations (eg, in Phase IV clinical trials). Depending on the classification of a medical device, its manufacturer has similar trend report, periodic summary report and PSUR obligations to the designated body involved in the conformity assessment (Articles 59 et seq MedDO; Articles 52 et seq IvDO).

As for incident notification requirements, manufacturers of medicinal products, distributors of ready-to-use medicinal products and HCPs must notify Swissmedic of adverse events, adverse drug reactions and quality defects within 15 days in case of serious adverse reactions and within 60 days of non-serious reactions. Similarly, anyone placing medical devices on the Swiss market must report to Swissmedic all serious incidents as well as all field safety corrective actions that are undertaken in Switzerland (Article 66 MedDO; Article 59 IvDO).

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

Authorities must in principle treat all data collected within the framework of the TPA and its implementing regulations as confidential, including all data communicated to the authorities in the context of a marketing authorisation application (Article 62 TPA). Granted marketing authorisations for medicinal products are published in the monthly Swissmedic Journal, together with essential information about the medicinal product. Swissmedic publishes an assessment report (SwissPAR) for all medicinal products with a new API, as well as for transplant products, for which a decision to approve or reject authorisation has been issued. The SwissPAR includes the evaluation results of the application for new authorisation or additional indication of a medicinal product, but not the applicant's commercial or manufacturing secrets or personal data.

Regarding medical devices, the conformity assessment procedures by Swiss or European assessment bodies are not accessible to third parties. The successful completion of a conformity assessment is made public together with the issuance of the declaration of conformity for the respective product (Article 90 lit f MedDO).

3.8 Rules Against Illegal Medicines and/or Medical Devices

Switzerland has signed and ratified the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (Medicrime-Convention).

Accordingly, several provisions were introduced into the TPA, including mandatory licensing for persons trading medicinal products in foreign countries from Switzerland or acting from Switzerland as brokers or agents for medicinal products (Article 18 paragraphs 1 and 2 TPA), the designation of Swissmedic as the national contact point under the Medicrime Convention (Article 69 paragraph 4 TPA), and criminal provisions (Articles 90 et seq TPA).

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

Customs authorities are involved in monitoring the importation, the transit and the exportation of therapeutic products. In particular, they monitor whether the medicinal products are authorised or compliant and whether the quantity lies within the maximum limit. In the case of suspicious shipments of goods, the customs office notifies Swissmedic and holds back the products in question. Decisions in application of healthcare regulations are, however, made exclusively by Swissmedic.

Following the ratification of the Medicrime-Convention (see **3.8 Rules Against Illegal Medicines and/or Medical Devices**), the Federal Office for Customs and Border Security (FOCBS) was granted the competence, alongside Swissmedic, to order secret surveillance measures (Article 90a TPA).

4. Manufacturing of Pharmaceuticals and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

The manufacture of medicinal products in Switzerland is subject to a mandatory licence (Article 5 paragraph 1 lit a TPA). The same applies to anyone withdrawing blood from humans for the purpose of transfusion or the manufacture of therapeutic products or for supply to a third party (Article 34 TPA). The licence is issued if Swissmedic has successfully verified during an inspection that the necessary technical and operational conditions have been fulfilled and an appropriate system of quality assurance exists (Article 6 TPA; Articles 3 et seq MPLO). The licence is issued for an unlimited period of time, whereby Swissmedic performs periodic inspections and may revoke licences if the requirements are no longer fulfilled.

Manufacturers of medical devices are not subject to licensing requirements in Switzerland. However, if a manufacturer is not established within Switzerland, its devices may only be placed on the market if it has appointed an authorised representative in Switzerland that is responsible for the related formal and safety-related aspects and is registered with Swissmedic (Articles 51 and 55 MedDO; Articles 44 and 48 IvDO; Article 11 EU-MDR/ EU-IVDR).

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

Any person engaged in the wholesale trade of medicinal products must possess a licence (Article 28 paragraph 1 TPA). The licence is issued following an inspection by Swissmedic (Article 28 paragraph 2 TPA; Articles 11 et seq MPLO).

No licences are required for the wholesale (Article 4 paragraph 1 lit i MedDO; Article 4 paragraph 1 lit h IvDO) of medical devices. Foreign manufacturers, however, need to appoint an authorised representative domiciled in Switzerland (see **4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices**).

5.2 Different Classifications Applicable to Pharmaceuticals

See **1.3 Different Categories of Pharmaceuticals and Medical Devices**.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

Importation and exportation of medicinal products and medical devices are mainly governed by the TPA, MPLO, MedDO and the Swiss customs legislation. At the point of entry, the responsibility for the application and enforcement of the respective regulations lies with the FOCBS. The competent governmental authority for any subsequent market surveillance is Swissmedic. FOCBS and Swissmedic co-operate closely in their joint areas of competence (cf. Article 65 MPLO).

6.2 Importer of Record of Pharmaceuticals and Medical Devices

Any person that professionally imports medicinal products intended for distribution or dispensing must possess a licence issued by Swissmedic (Article 18 paragraph 1 lit a TPA) following an inspection confirming that the necessary technical and operational conditions have been fulfilled and that an appropriate system of quality assurance exists (Article 19 paragraph 1 TPA; Articles 11 et seq MPLO).

Importers of medical devices (Article 4 paragraph 1 lit h MedDO; Article 4 paragraph 1 lit. g IvDO) are not subject to licensing requirements in Switzerland. However, if a manufacturer is not established within Switzerland, its devices may only be placed on the market if it has appointed an authorised representative in Switzerland that is responsible for the related formal and safety-related aspects and if the importer is registered with Swissmedic and is assigned a CHRN (Article 55 MedDO; Article 48 IvDO; see **4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices**).

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

In principle, only medicinal products that have been granted a marketing authorisation by Swissmedic can be imported into Switzerland (Article 9 TPA), and importation is subject to a specific licence (Article 18 paragraph 1 lit a TPA). Subject to certain exceptions, in particular in connection with an official batch release from a foreign control authority belonging to the

Official Control Authority Batch Release Network (OCABR), anyone wishing to import immunological medicinal products or blood and blood products generally requires a special licence for each individual shipment (Article 44 MPLO). Under certain circumstances, ready-to-use medicinal products without a marketing authorisation in Switzerland may be imported in small amounts by persons for private use or by HCPs (cf. Articles 48 and 49 MPLO).

While no licence for the import of medical devices is required (see **6.2 Importer of Record of Pharmaceuticals and Medical Devices**), medical devices must, prior to their placing on the Swiss market, undergo a conformity assessment to ensure that general safety and performance requirements are met (Articles 6, 21 et seq MedDO; Articles 6, 21 et seq IvDO). Certifications of conformity (CE markings) issued by bodies from EU/EEA countries are unilaterally recognised in Switzerland (Article 25 paragraph 4 MedDO; Article 21 paragraph 4 IvDO).

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Non-tariff restrictions are set forth in the Swiss customs tariff. The entries in the relevant Harmonised Tariff Schedule (HTS) line will determine which market surveillance authority is competent to examine and approve import. The product-related laws and implementing ordinances set out the restrictions in detail.

6.5 Trade Blocs and Free Trade Agreements

Switzerland is a member of the European Free Trade Association (EFTA) and is, amongst others, signatory to the Free Trade Agreement with the EU of 1972 as well as to a network of currently 33 free trade agreements with 34 partners. The EU has unilaterally ceased the application of the Mutual Recognition Agreement as regards medical devices. As a result, exportation of medical devices from Switzerland into the EU has become more burdensome. Negotiations are currently taking place between the USA and Switzerland on a free trade agreement concerning the pharmaceutical sector, which is intended to facilitate market access for Swiss pharmaceutical companies.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

Under Swiss law, prices of therapeutic products are controlled to the extent that they are reimbursed by the compulsory health insurance. With regard to therapeutic products not reimbursed by compulsory health insurance, manufacturers, wholesalers and retailers are, in principle, not restricted in their pricing.

Pharmaceuticals are reimbursed subject to a listing on the Specialties List (SL) where ready-to-use medicinal products are included. Medicinal products that are manufactured in a pharmacy are reimbursed if their APIs are included in the List of Medicines with Tariff (LMT). The requirements for price fixing are mainly contained in the Health Insurance Act (HIA), the Health Insurance Ordinance (HIO) and the Ordinance on the Benefits under the Mandatory Health Insurance (OBHI). The SL determines the ex-factory price as well as the public price, which is the maximum amount (including VAT) that must be reimbursed by health insurers.

The FOPH decides on the inclusion of a medicinal product on the SL after consultation with the Federal Drugs Commission (EAK), except

in case of certain medicinal products, such as generics and new galenic forms or package sizes of already listed medicinal products (Article 31 paragraph 2 OBHI). An accelerated procedure applies in case of an accelerated market authorisation (Article 31a OBHI). The procedure is initiated by the market authorisation holder (Article 31 paragraph 1 OBHI). Medicinal products can only be included in the SL if the criteria of efficacy, appropriateness and cost-effectiveness are met (Article 32 paragraph 1 HIA). The prices are reviewed every three years (Article 65d HIO), and additional reviews take place upon patent expiry and in case of the authorisation of further indications.

The List of Items and Tools (LIT) determines which devices are covered by the compulsory health insurance. Unlike the SL, the LIT does not fix the ex-factory and public price, but only sets the maximum reimbursement amount. In principle, higher prices may be charged and the difference is borne by the patient. There are specific provisions governing the application for inclusion on the LIT. The FDHA decides upon consultation of the Federal Commission for Analyses, Instruments and Tools (FCAIT) on the addition, change, or delisting (cf. Articles 21 et seq OBHI). The criteria of efficacy, appropriateness and cost-effectiveness also apply to medical devices.

7.2 Price Levels of Pharmaceuticals or Medical Devices

When setting and reviewing the prices of the medicinal products included in the SL, the FOPH relies on the following comparisons: (i) a therapeutic comparison in which the effectiveness of the medicinal products is assessed in relation to other medicinal products used for the same indication (Article 65b paragraph 4bis HIO); and (ii) a price comparison with the same medicinal product abroad (cf. Article 34a and 34b OBHI). The two comparisons are given the same weight. The latter comparison is carried out according to the guidance of the EAK taking into account foreign countries whose pharmaceutical sector is economically comparable with Switzerland.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Under the compulsory health insurance, insurers must reimburse costs for prescribed medicinal products listed in the SL and the LMT at the maximum amount set out therein. The reimbursement may be restricted to specific indications, quantities or durations. Reimbursement is, in general, only granted for listed medicinal products under the condition that they are used in connection with indications approved by Swissmedic and within approved quantities. Exceptions from this general rule apply on a case-by-case basis subject to the conditions set out in Article 71a HIO. In addition, there is also room for reimbursement in individual cases of medicinal products not yet authorised, not yet included in the SL or used outside their marketing authorisation (Articles 71b-d HIO).

Medical devices applied by the patient are reimbursed under the condition that they belong to a specific group of medical devices in the LIT, are prescribed by a physician or chiropractor and are dispensed by an authorised provider. The reimbursement of listed medical devices may be restricted to specific medical indications, quantities or durations. Case law has not yet addressed the question of whether the provisions of Article 71a-d HIO are also applicable to medical devices by analogy.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Among the conditions for the inclusion of medicinal products on the SL are their efficacy, appropriateness and cost-effectiveness, and the existence of these conditions must be periodically reviewed (Article 32 HIA). Medicinal products that no longer meet these criteria are removed from the SL by the FOPH. The same applies to medical devices (to be) included on the LIT.

It is usually undisputed that an authorised medicinal product is effective and appropriate. In practice, the main focus is therefore on the criterion of cost-effectiveness, including the respective comparisons with other medicinal products and markets (see **7.2 Price Levels of Pharmaceuticals or Medical Devices**).

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

While the main purpose of the prescribing and dispensing regulations is to safeguard patient welfare and safety in the dispensing and use of medicinal products by requiring that only HCPs with sufficient education, training and continuing education are involved (Articles 24-26 TPA), HCPs are required by their professional duties and corresponding provisions in their self-regulations to also observe the aspect of economic efficiency. Furthermore, the legal provisions on the advertising of medicinal products explicitly provide for the inadmissibility of advertising, including to HCPs, which may encourage the excessive use of medicinal products (cf. Article 32 paragraph 1 lit b TPA). Lastly, the integrity provisions (cf. Article 55 TPA; OIT) prohibit the excessive prescribing of medicines.

In general, physicians may prescribe any authorised medicinal product for a given indication without regard to its price, and they are not obliged to propose a more affordable (generic) alternative. That said, if the SL contains different medicinal products containing the same API, the cost share that must be borne by the patient may vary. Physicians must inform their patients accordingly. Equally, for medicinal products that are not included in the SL or that are used off-label or off-limitation, HCPs must inform the patients that the costs might not be reimbursed under the compulsory health insurance. According to Article 52a HIA, pharmacists are allowed, but not obliged, to substitute a prescribed original medicinal product listed on the SL with a generic unless there is an explicit request by the prescribing physician or chiropractor to dispense the original.

8. Digital Healthcare

8.1 Rules for Medical Apps

Medical apps are not subject to specific regulation in Switzerland, but are considered medical devices provided that the app is intended to be used for a medical purpose as set out in the TPA (see **3.1 Product Classification: Pharmaceuticals or Medical Devices**; Federal Administrative Court decision C-669/2016 of 17 September 2018). Therefore, such apps must comply with the legal requirements for medical devices, including regarding conformity assessments.

8.2 Rules for Telemedicine

While telemedicine is established in Switzerland, only few cantons have issued specific regulation (eg, § 8 Health Care Act of the Canton of Basel-Landschaft). Thus, telemedicine is governed by general healthcare law and the medical code of ethics. As soon as the treating physician can no longer assume that a patient can be treated carefully by means of telemedicine, the treatment must be adjusted and the patient must be

either physically examined or referred to another physician. The provisions of data protection and medical secrecy (Article 321 Swiss Criminal Code (SCC)) are also applicable to treatments using telemedicine methods.

8.3 Promoting and/or Advertising on an Online Platform

Electronic advertising of medicinal products, such as via online portals and social networks, without any access restriction, qualifies as advertising to the general public (Article 15(c) OMPA), which is prohibited for prescription medicines (Article 32 paragraph 2 lit a TPA). Access to professional advertising via electronic means must be restricted by appropriate technical and password protection to professionals authorised to dispense or apply medicinal products (Article 5a OMPA). The same applies to media releases and press kits which directly or indirectly reference the prescription of specific medicinal products (Swissmedic Guidance "Advertising of medicinal products on the internet").

There are no specific regulations governing online promotion and advertising of medical devices. The promotion to the general public of products intended solely for the use by HCPs is prohibited (Article 51 TPA; Article 69 paragraph 3 MedDO; Article 62 paragraph 3 IvDO).

8.4 Electronic Prescriptions

Rules on electronic prescription are part of the regulation on the electronic patient record. The FMH and the Pharmacists Association "Pharmasuisse" announced in a 2022 statement that they intend to create an electronic prescription, and initial pilot tests have already been launched. The most recent draft revision of the TPA, for which consultation was opened in December 2023, intends to create a legal basis for electronic prescriptions and their digital transmission.

8.5 Online Sales of Medicines and Medical Devices

The online sale of medicinal products is, in principle, prohibited (Article 27 TPA). By exception, a licence may be granted by the competent cantonal authorities to persons already in possession of a cantonal retail authorisation to run a public pharmacy if (Article 27 paragraphs 2 and 4 TPA; Article 55 paragraph 2 OMP):

- there is a physician's prescription for the medicinal product (irrespective of whether it qualifies as a prescription-only product);
- no safety requirements oppose it; and
- appropriate consultation and sufficient medical supervision of the effect of the medicinal product are guaranteed.

The online sale of medical devices is, in principle, permitted (Article 7 MedDO; Article 7 IvDO).

8.6 Electronic Health Records

In 2017, the Federal Act on the Electronic Patient Record (EPR) and the related ordinances came into force and regulate the conditions for the introduction and implementation of the electronic patient dossier (EPD). The EPD is a filing system for treatment, with relevant information containing copies of medical records, whereby the decision whether to open an EDP is left to the patients (opt-in). The data is stored in encrypted form and can only be viewed by the patients and authorised HCPs. The EPR is currently being revised.

Health-related data is regarded as sensitive data pursuant to the FADP and the DPO, provided that the data directly or indirectly references an identified or identifiable person's physical or mental health. This means that, in principle, anonymised data is not regarded as sensitive data.

More stringent requirements apply to sensitive data, including requiring data controllers to:

- inform the person concerned about the collection of their data;
- ensure that the disclosure of sensitive data to third parties is based on a legal justification; and
- comply with specific registration and notification obligations with the Federal Data Protection and Information Commissioner (FDPIC).

Moreover, the general provisions of the FADP must be complied with. The transfer and storage of health data on a cloud platform is, in principle, permitted under the FADP. However, this is only possible if, among others, no legal or contractual confidentiality obligation prohibits such transfer. Physicians are bound by professional secrecy regarding the medical history or the contents of the patient file (Article 321 SCC). They remain responsible for keeping confidentiality even when transferring the data and therefore must ensure that the patient data is protected against unauthorised processing. The FMH recommends that physicians do not store health data of their patients in clouds located abroad.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices

The Federal Act on Patents and Inventions (PatA) and the Ordinance on Patents and Inventions (PatO) apply to patents in Switzerland. Further, Switzerland is a member of the major international patent treaties, such as the European Patent Convention (EPC) and the Patent Co-operation Treaty (PCT).

Most patents in Switzerland are granted within a harmonised procedure under the EPC. Generally, patents are granted for new inventions with an industrial application.

Certain inventions, such as gene sequences, are excluded from patent protection. Accordingly, the patentability of medicinal products developed from human gene sequences is subject to a scrutinous examination. Methods for medical treatment and diagnostics are also excluded from patent protection. While it is in essence undisputed that the exclusion from patentability only refers to the methods, and not to products used in such methods, it can be difficult to draw a clear distinction between device-related methods and functional device features.

9.2 Second and Subsequent Medical Uses

Pharmaceutical substances or compositions that – even though they are part of the state of the art as such – do not yet form the state of the art in relation to a specific use in a surgical, therapeutic or diagnostic method are deemed to be new and, hence, patentable, provided they are intended for use in the manufacture of a means to a surgical, therapeutic or diagnostic end (Article 7c PatA). Any subsequent new surgical, therapeutic or diagnostic use for which the substance or composition is not considered state of the art can also be claimed as new (Article 7d PatA). Consequently, the use of a substance or composition for the manufacturing of a means for a medical procedure is patentable. Such claims are referred to as Swiss-type claims.

New dosage regimes and the indication for a new or selected patient population as such cannot be patented. However, if a dosage regime or indication is new and based on an inventive step, such new dosage regime or new indication

can be patented. In most cases, however, a new dosage regime will be considered obvious and, hence, not patentable.

To date, it is unclear what activities constitute infringement of second and subsequent patents of medicinal products. More specifically, it has yet to be decided whether and to what extent the exclusive rights conferred by a traditional substance claim, by a claim for second and subsequent medical use under Articles 7c and 7d PatA and by a purpose-oriented substance claim under Article 54(5) of the EPC differ from each other.

9.3 Patent Term Extension for Pharmaceuticals

In principle, patent protection is granted for a term of 20 years from the filing date of the application and cannot be extended. Unlike other jurisdictions, Switzerland does not have a patent linkage system. However, for medicinal products, the Swiss Intellectual Property Institute (IPI) can grant a supplementary protection certificate (SPC) for a patent-protected API or combination of APIs (or manufacturing process or use of such API or API combination) contained in a medicinal product authorised in Switzerland. An SPC takes effect on expiry of the maximum patent term for a period equal to the period which elapses between the date of filing and the date of the first authorisation of the medicinal product in Switzerland minus five years, but for a maximum term of five years. Subject to statutory conditions, the SPC's term of protection may be extended once for a period of six months. The application for an SPC must be filed with the IPI (i) within six months of the first marketing authorisation of a medicinal product containing the API or API combination in Switzerland; or (ii) within six months of the grant of the patent if the patent was granted later than the first marketing authorisation. On certain conditions, patent holders can also apply for a paediatric SPC or extension of a non-paediatric SPC with a term of six months.

9.4 Pharmaceutical or Medical Device Patent Infringement

Medicinal products and medical device patents confer the exclusive right to commercially use the invention in Switzerland. This exclusive right can be infringed through direct or indirect misconduct. A direct infringement occurs when an unauthorised party uses a patent commercially by, inter alia, manufacturing, storing, offering, advertising to Swiss customers, placing on the market, importing, exporting and carrying in transit a patent-protected product, or by possessing the patent-protected product for any of these purposes. An indirect infringement occurs if a party contributes to a direct patent infringement – ie, if a party instigates, participates in, favours, facilitates or contributes in other ways to a direct patent infringement (aiding or abetting). Such contribution must have an adequate causal link to the direct patent infringement.

Apart from actual patent infringements, the mere threat of infringement is actionable as well. In such cases, the claimant must deliver proof of a sufficient interest in legal protection. Such an interest exists if the unlawful act is imminent – ie, if the alleged infringement of rights is to be seriously expected.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

In practice, key defences to patent infringement relate to the invalidity of a patent as well as the lack of an infringement.

Further, defendants may invoke statutory exemptions, such as the so-called "experimental use exemption", according to which the effect of a patent does not extend to acts undertaken for research or experimental purposes under Swiss law (Article 9 paragraph 1 lit b PatA). Additional exemptions and respective defences are, inter alia, provided for:

- acts necessary for obtaining a marketing authorisation for a medicinal product in Switzerland or in countries with equivalent medicinal product control – ie, EU/EEA countries, USA, Singapore, New Zealand, Canada, Japan, and Great Britain (Article 9 paragraph 1 lit c PatA);
- acts undertaken as part of a medical activity by legally authorised persons concerning an individual person and involving a medicinal product (compassionate or off-label use) (Article 9 paragraph 1 lit g PatA); and
- the direct individual preparation of medicinal products in pharmacies in accordance with a physician's prescription (Article 9 paragraph 1 lit h PatA).

9.6 Proceedings for Patent Infringement

Patent infringement proceedings may be initiated by the patent owner and by a patent licensee who holds an exclusive licence and whose right to initiate an infringement action is not explicitly excluded in the licence agreement. Exclusive and non-exclusive licensees are eligible to join a pending infringement proceeding in order to claim their own losses or damages.

Through a patent infringement proceeding, a claimant may seek a variety of remedies, such as injunctive relief, the remedying of an unlawful situation, damages or a declaratory judgment. Further statutory remedies are the provision of information and accounting, the destruction of infringing goods, the recall of patent infringing goods or the publication of the decision.

Typical patent infringement actions are carried out in the form of inter partes preliminary injunction proceedings for interim relief, followed by ordinary proceedings on the merits.

A defendant may raise the defence of invalidity in preliminary injunction proceedings. If such a defence is raised, the Federal Patent Court examines both the question of validity and the question of infringement in almost as much detail as in ordinary proceedings on the merits. In ordinary proceedings on the merits, the invalidity may be invoked either as a defence or by way of a counteraction. Unlike courts in other jurisdictions, the Federal Patent Court is competent to rule on both the validity and the infringement of a patent. Accordingly, plaintiffs need not bring validity and infringement actions before different courts.

9.7 Procedures Available to a Generic Entrant

There is no requirement of a declaratory action for a generic product to enter the Swiss market. While a prior marketing authorisation is required for a medicinal product to enter the market, the authorisation procedure as such is not considered to constitute a patent infringement.

At the same time, the simplified authorisation procedure used for generic entry in Switzerland (Articles 14 et seq TPA; Articles 12 et seq OSMA) is based on references to the marketing authorisation documents of the medicinal product with the known APIs. These documents can benefit from regulatory data protection for a certain period. Accordingly, the marketing authorisation for generic entrants can, in principle, only

be granted upon expiry of the regulatory data protection.

For medical devices, Swiss law does not provide for a marketing authorisation procedure. It is for the competitor to decide on its market entry, and for the holder of a patent in the original medical device to take legal action.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

In Switzerland, various intellectual property laws and procedures are in place to combat the counterfeiting of medicinal products and medical devices, including the following: the PatA, the Trade Mark Protection Act (TmPA), the Federal Design Act, the Federal Act on Copyright and Related Rights, and the Federal Unfair Competition Act (UCA).

In case of infringements, these statutes grant civil law remedies such as injunctions, damages and account of profits.

In addition to civil law remedies, under criminal law, counterfeiting medicinal products and medical devices constitutes a criminal offence. The Swiss intellectual property laws provide for criminal penalties against counterfeiters, including custodial sentences of up to five years and monetary penalties.

Under customs laws, the FOCBS is responsible for enforcing intellectual property rights at the Swiss border – eg, by withholding goods and notifying the proprietor of the intellectual property right if there is a suspicion that the import, export or transit of such goods infringes rights in Switzerland.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

In principle, trade marks for medicinal products and medical devices are subject to generally applicable trade mark and unfair competition laws.

Notably, the IPI can refuse the registration of a trade mark if the registered sign is (i) in the public domain, (ii) misleading, (iii) contrary to public policy, morality or applicable law, (iv) technically necessary or representing the nature of the goods themselves (Article 2 TmPA). Inter alia, trade mark protection can be withdrawn for lack of use or infringement of a prior trade mark.

In addition to generally applicable standards, the name of a medicinal product (unlike the name of a medical device) is subject to prior authorisation by Swissmedic as part of the marketing authorisation proceedings. Swissmedic can reject or request amendments to a contemplated name if there is a risk of confusion between medicinal products or if the name is considered (i) misleading about the product's composition, quality, efficacy, risks, or safety, or (ii) promoting improper consumption.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

In principle, the design of medicinal products and medical devices, as well as their packaging, are eligible for trade mark, design and/or copyright protection, as well as protection under the UCA. The scope of protection will generally depend on the (intellectual property) right that is being claimed and on the level of distinctiveness of the specific design or trade dress.

Upon registration, trade mark protection is granted in Switzerland to protect the use of a

registered sign for a specified class of products and/or services. The trade mark can, in principle, consist in packaging or trade dress elements. In order to be protected, the trade mark must be distinctive.

Upon registration, design protection is granted in Switzerland to protect the appearance of a product and/or its packaging. A design is protected to the extent that it is new and has an individual character.

Copyright protection is granted as of the moment of the creation of a design. No registration is required. To benefit from protection, the design must, however, qualify as an original work of authorship.

Where an imitation of a medicinal product or medical device trade dress violates fairness principles (eg, if the user is intentionally misled about a product's origin or if the imitator intentionally exploits the reputation of a competing product), protection can be sought under the UCA.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

The documents that are submitted to obtain marketing authorisation for new active substances are generally protected for a period of ten years from the granting of the marketing authorisation in Switzerland (Article 11a TPA). New indications, modes of administration, dosages or dosage forms can benefit from regulatory data protection of three years. Further document protection can be granted for important orphan medicinal products (15 years), medicinal products specifically and exclusively for paediatric use (ten years), and medicinal products that are expected to have a significant clinical benefit compared to existing therapies (ten years) (Article 11b TPA).

During the respective data protection period, the simplified procedure allowing for a reference to marketing authorisation documents of a known API is unavailable and a marketing authorisation for another product cannot be granted based the protected data, including trial data for the protected authorised product, unless the marketing authorisation holder consents. Unlike jurisdictions providing for market exclusivity, the Swiss system only protects the data and does not prevent other manufacturers from entering the market based on independently generated data.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

Numerous (temporary) regulations were issued in connection with the COVID-19 pandemic, also affecting the marketing and distribution of therapeutic products. As of today, the key regulation in this respect is the Ordinance 3 on Measures to Combat the Coronavirus (COVID-19 Ordinance 3), which is intended to ensure that Switzerland can maintain adequate medical care for the population and sufficient essential medical supplies. To this end, the COVID-19 Ordinance 3 establishes notification requirements for stocks of essential medical supplies, procurement and distribution requirements and simplifying exemptions for the placing on the market and importation of medicinal products and medical devices for the prevention and control of COVID-19. The COVID-19 Ordinance 3 will cease to apply as of 1 August 2024.

11.2 Special Measures Relating to Clinical Trials

Swissmedic and Swissethics issued joint recommendations for the handling of clinical trials

with medicinal products during the COVID-19 pandemic ("Joint Guidance"). The Joint Guidance provided, among other things, that applications for clinical trials related to COVID-19 were prioritised and that applications for clinical trials could be submitted electronically and in bundles of multiple applications. Furthermore, for the period of the pandemic, specific amendments regarding the distribution of investigational medicinal drug products and the monitoring of clinical trials were provided.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

During the pandemic, different exemptions from the general authorisation requirement for medicinal products were issued.

- Certain medicinal products used for the treatment of COVID-19 patients, can already be placed on the market during the approval process (Article 21 paragraph 1 of the COVID-19 Ordinance 3).
- The same applies to medicinal products that prevent the COVID-19 infection of immunosuppressed persons under certain conditions (Article 21 paragraph 1bis COVID-19 Ordinance 3).
- Variations to the authorisation for certain authorised medicinal products can be implemented immediately upon application (Article 21 paragraph 2 COVID-19 Ordinance 3).
- Swissmedic was enabled to approve the import of essentially identical medicinal products as a short-term solution for any temporary non-availability of medicinal products (Article 22 paragraph 3 COVID-19 Ordinance 3).

Likewise, certain exemptions were introduced for medical devices.

- Subject to approval by Swissmedic, medical devices that have not (yet) undergone the required conformity assessment procedure in Switzerland or in a recognised third country (eg, the EU) may nevertheless be placed on the Swiss market under certain requirements (Article 23 paragraph 1 COVID-19 Ordinance 3).
- Face masks that have not undergone a conformity assessment procedure can be placed on the market, provided that they are not used in the medical field and are labelled accordingly (Article 23 paragraph 4 COVID-19 Ordinance 3).

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

No simplifications regarding manufacturing licences were introduced in connection with the pandemic. However, for a short period of time, Swissmedic inspections were suspended or modified, and Swissmedic confirmed that all GMP certificates issued in 2017/2018 would remain fully valid until the end of 2021 or the next routine inspection. In January 2023, Swissmedic provided an update according to which all planned routine inspections in Switzerland were carried out and that it was no longer necessary to generally extend GMP certificates. Extended EU GMP certificates are, however, accepted by Swissmedic.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

Different regulations were introduced during the pandemic to facilitate the import of medicinal products.

- Following the submission of an authorisation application according to Article 21bis COVID-19 Ordinance 3, the applicant can import the medicinal product before the decision

on the authorisation or entrust a company carrying a wholesale or import licence with the import (Article 22 paragraphs 1 and 2bis COVID-19 Ordinance 3).
- Pharmacists who have pharmaceutical responsibility in a hospital pharmacy are authorised to import certain medicinal products (Article 22 paragraph 1bis COVID-19 Ordinance 3).
- For the temporary non-availability of a medicinal product, Swissmedic may allow the temporary import of an identical medicinal product, provided no other essentially identical medicinal product is authorised and available in Switzerland (Article 22 paragraph 3 COVID-19 Ordinance 3).
- Article 22 paragraph 4 Covid-19 Ordinance 3 permits the import and storage of COVID-19 vaccines before their authorisation, under certain conditions.

11.6 Drivers for Digital Health Innovation Due to COVID-19

Under the pandemic, a wider range of remote services delivered by HCPs was reimbursed by the compulsory health insurance in order to comply with the requirements of social distancing.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

Applicants may bring action before Swiss courts for a compulsory non-exclusive licence for the manufacture of patent-protected medicinal products and for their export to a country that has insufficient or no production capacity of its own in the pharmaceutical sector and which requires these products to combat public health problems, in particular those related to epidemics (Article 40d paragraph 1 PatA). However, no such licence has been granted to date in the medicinal products area, including for COVID-19-related treatments or vaccines.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

No liability exemptions were introduced for COVID-19 treatments and vaccines in Switzerland, and the general product liability rules continue to apply.

In addition to these general rules, the Epidemics Act (EpA) provides a special ground for liability claims for vaccines. Accordingly, anyone who is harmed by an officially ordered or officially recommended vaccination is entitled to damages, and also to moral compensation of maximum CHF70,000, if the severity of the impairment justifies it (Articles 64 et seq EpA). However, the Swiss State only grants compensation if the damage cannot be covered otherwise with reasonable efforts – eg, by the vaccine manufacturer. While this compensation scheme existed already prior to the COVID-19 pandemic, it has attracted greater attention since.

11.9 Requisition or Conversion of Manufacturing Sites

There was no requisition or conversion of manufacturing sites due to COVID-19.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

The Swiss Armed Forces Pharmacy has been granted extended rights in connection with the procurement of essential medical goods if requirements cannot be covered through the normal procurement channels (Article 14 COVID-19 Ordinance 3).

UK

Trends and Developments

Contributed by:
Charlotte Weekes, Sarah Taylor, Sunjay Malhotra and Robert Vidal
Pinsent Masons

Pinsent Masons as a solutions-driven life sciences team that brings together experts in the field to provide clients with solutions to unprecedented legal challenges. Working in 20 EMEA offices, the team comprises more than 120 sector-focused lawyers, who understand the technical as well as legal issues – with many having scientific backgrounds, in-house industry experience and strong relationships with industry bodies. Pinsent Masons' team acts for some of the most innovative life sciences companies in the world, including pharmaceuticals, generic and biosimilar, biotech and medtech companies. The work aligns with the firm's purpose, leading on precedent-setting litigation and market-leading transactions that make a real difference in the world. Pinsent Masons offers businesses a holistic approach, with transactional, tax, competition, IP, medicines regulatory, dispute resolution, employment, product liability, cyber and data, public policy and compliance professionals working seamlessly together to support life sciences companies that push the boundaries of science and law.

Authors

Charlotte Weekes is the head of Pinsent Masons' life sciences group and a key partner in the firm's IP practice. Charlotte acts on ground-breaking patent and Supplementary Protection Certificate (SPC) litigation before the High Court and the UK Court of Appeal and has been involved in many of the precedent-setting life sciences patent cases in the UK. She has also represented clients in the Supreme Court of the United Kingdom and in the ECJ. Charlotte manages a busy and growing patent and SPC litigation practice, advising major pharmaceuticals clients such as Teva, Accord, and Fresenius Kabi.

Sarah Taylor is a senior practice development lawyer in Pinsent Masons' European IP practice. Sarah specialises in European patent litigation, and advises and supports her team and clients on all aspects of patent law, case theory and litigation strategy in the life sciences sector. With a degree in natural sciences (physiology), she was a practising litigator before transitioning into a knowledge role. Sarah is a recognised expert in her field and is often asked to comment on patent issues by the main IP and industry press as well as by the wider media.

Contributed by: Charlotte Weekes, Sarah Taylor, Sunjay Malhotra and Robert Vidal, **Pinsent Masons**

Sunjay Malhotra is a partner at Pinsent Masons and a corporate lawyer who advises listed and private companies, investors and intermediaries in the life sciences sector. He has extensive experience advising on transactions on the Alternative Investment Market and the Main Market, including IPOs, secondary fundraisings, venture capital and public M&A, as well as private company financings and M&A. Sunjay also advises boards of directors on corporate governance matters and their legal and regulatory obligations.

Robert Vidal leads Pinsent Masons' competition practice for the life sciences sector and brings a rare depth of experience and competition law capability in life sciences. Robert has more than 20 years' experience advising on all aspects of competition law and the interplay with IP, with extensive expertise in relation to the pharmaceuticals sector, in particular. This includes EU/UK investigations and contentious competition law – both claimant and defence – before the Competition Appeal Tribunal and the High Court. He also has an exemplary track record of clearing mergers before the Competition and Markets Authority and the EC.

Pinsent Masons

30 Crown Place
Earl Street
London
EC2A 4ES
UK

Tel: +44 (0)20 7418 7000
Fax: +44 (0)20 7418 7050
Email: sarah.taylor@pinsentmasons.com
Web: www.pinsentmasons.com

Contributed by: Charlotte Weekes, Sarah Taylor, Sunjay Malhotra and Robert Vidal, **Pinsent Masons**

Overview

That life sciences will be "one of the great drivers of growth in the 21st century" was acknowledged by the UK government's Life Sciences Vision in 2021. However, navigating the challenges of limited funding in a competitive field has been a focus of the industry in recent times. Buoyed by government plans and significant investment packages in the sector, despite prevailing headwinds in investment markets and the continuing impact of rising inflation and cost pressures on the National Health Service (NHS), political uncertainty and global unrest, the life sciences industry is well positioned to cement the UK's place as a science and technology superpower by 2030.

In addition, embracing the use of advanced technologies is not new to the life sciences industry. The urgent health issues that presented during the COVID-19 pandemic have caused the life sciences sector to become the sector with the greatest uptake of AI, which is proving to be transformational by providing opportunities for businesses throughout the life sciences life cycle. However, these rapid technological advances mean that the sector has to grapple with the legal and policy issues they pose.

Brexit has also led to regulatory changes in the UK. Going forwards, there are increasing opportunities for the UK legislature and judiciary to depart from EU laws in the life sciences space.

This article will consider key developments and emerging trends that make the UK an attractive venue for the life sciences industry in this post-Brexit and post-pandemic era.

Cautious Optimism of the UK Financial Markets

After an underwhelming 2022 and slow start to 2023 (with a transatlantic dearth of IPOs and a drag on share prices and deal valuations as a result of limited funding sources), M&A and investment activity in the life sciences sector experienced something of an awakening in the second half of 2023. As such, 2024 promises to be a buoyant year for M&A in the market.

Large life sciences multinationals once again began to dominate M&A activity. Average acquisition size increased by 77% in 2023, even though deal volumes were lower than 2022 (with EY's How Life Sciences Can Make the Right Deals in a Time of Change report recording just 116 deals in 2023 compared with 126 in 2022).

Focusing on the UK market, there were eight M&A offers made for listed UK healthcare companies in 2023, with consideration totalling GBP7.4 billion. In contrast, only four offers were made in 2022, with consideration totalling GBP5.9 billion.

Several factors contributed to this and will continue to affect the 2024 landscape. Firstly, due to an upcoming volley of product patents set to expire in the next four to seven years (such as Merck & Co's top-selling cancer medicine Keytruda and AbbVie's anti-inflammatory treatment Humira), multinational life sciences companies have been proactively filling gaps in their portfolios by shifting towards acquiring late-stage development biotech assets or early-stage commercial assets that have the potential to quickly become approvable drugs. Biotech valuations have declined almost 70% since their peak (see McKinsey's Life Sciences M&A Shows New Signs of Life paper), so many of these assets are now increasingly attractive to multina-

tionals, owing to their ability to accelerate R&D, reduce projected timelines for pipeline assets and accelerate the launch of commercially scaling products. AstraZeneca's recent acquisition of Fusion Pharmaceuticals Inc, a clinical-stage biopharmaceutical company, is a good example of this.

Additionally, multinationals in the sector have also found themselves with unparallelled cash flows, meaning they are well positioned for M&A activity. Companies such as Eli Lilly and Novo Nordisk are experiencing substantial cash influxes due to the high demand for their obesity treatments.

Life sciences companies will continue advancing AI opportunities and there have been several AI drug development partnerships. By way of example, September 2023 saw the announcement that AI pioneer Verge Genomics would collaborate with Alexion (AstraZeneca Rare Disease) to identify novel drug targets for rare neurodegenerative and neuromuscular diseases through the AI-enabled platform and data from patient tissue samples.

Scientists continue to produce paradigm-shifting technologies, and great science will always attract finance. The UK is the first country to approve CRISPR gene editing as a potential cure for two inherited blood disorders. Cell and gene therapies will continue to shore up the UK M&A market in 2024 and beyond, particularly when it comes to rare diseases M&A activity (following examples such as the acquisition by Alexion (AstraZeneca Rare Disease) of a portfolio of preclinical rare disease gene therapies).

Life Sciences Businesses Benefit From R&D Tax Incentives

Despite the cautious optimism in the UK M&A market, such funding is not available to all. Alternative sources of finance should, of course, always be borne in mind in competitive sectors such as the life sciences industry. One such source is tax relief, which – where available – broadly means that businesses will be able to claim a tax credit and (in certain circumstances) a cash repayment for costs relating to R&D undertaken in the UK.

The UK's R&D tax relief system is in a state of flux. The two existing schemes – the "SME Scheme" (for small and medium-sized businesses) and the "Research and Development Expenditure Credit" (RDEC) scheme (predominantly for larger companies) – are effectively being merged. For accounting periods beginning on or after 1 April 2024, companies wishing to claim tax relief for expenditure on qualifying R&D will claim under the newly merged scheme.

Under the current system, where certain conditions are met, tax relief is available for SMEs by way of an additional deduction of 86% on qualifying R&D costs. Loss-making SMEs may also be able to claim a cash repayment of the tax credit in return for surrendering R&D related losses – this is capped at 10% of the losses available for surrender. The RDEC uses a different method of calculating corporation tax relief on R&D expenditure. The "above the line" RDEC is brought into account as a trade receipt, increasing taxable profits (or, conversely, reducing losses). A credit of 20% of the qualifying R&D expenditure is then credited to the company.

The new merged scheme is based on the existing RDEC and will provide a 20% tax credit for qualifying R&D costs for eligible companies. The

merged scheme will incorporate a restriction on claiming tax relief for overseas R&D.

Additional tax relief has been available for certain research-intensive SMEs since April 2023. Loss-making R&D-intensive SMEs can claim an enhanced tax credit of 27% on qualifying R&D expenditure.

SMEs are commonly considered research-intensive if 30% of total expenditure is on qualifying R&D. These changes to the UK R&D tax relief system will therefore continue to provide a valuable source of financing for life sciences businesses, particularly start-ups with limited access to alternative sources of funding.

Medtech, Digital Health and the Impact of AI

The prospects offered by AI in the life sciences space – including making processes more efficient, saving time and resources, and providing better patient healthcare – led to the announcement in October 2023 by the UK Prime Minister of a new AI Life Sciences Accelerator Mission. This aims to provide funding to accelerate the use of AI in life sciences to tackle "the biggest health challenges of our generation". The AI Life Sciences Accelerator Mission feeds into the Life Sciences Vision, and its role in supporting the goal of driving novel AI research into earlier diagnoses and better treatments for conditions such as dementia and cancer will be monitored throughout this next period.

Generative AI tools have created an inflection point, changing the way businesses work, communicate, and advance efficiencies within healthcare. The fact that generative AI tools can predict the properties of new compounds, identify potential treatment targets, and model other factors such as bioavailability means they may be used for drug discovery. At the same time, the software could also be used to support human clinical decision-making in the healthcare space by analysing patient data, suggesting diagnoses, and providing treatment information.

Although AI tools have the potential to make a positive impact in healthcare, businesses should also be aware of their ethical limitations. There are many legal and policy issues that AI developers and users should understand – one of which is the IP issues that arise. In March 2023, the UK government committed to a copyright and AI code of practice, which is expected to be published in 2024. This aims to balance the rights of content creators with the desire of AI developers to train their systems using quality data. The code is currently being developed by a UK Intellectual Property Office (UKIPO) working group, which has said the code will aim to "make licences for data mining more available" and help to "overcome barriers that AI firms and users currently face and ensure there are protections for rights holders". The contract terms on which the tools are procured also require careful scrutiny.

Further, businesses will need to consider the regulatory hurdles to be overcome following the imminent implementation of the EU Artificial Intelligence Act, as well as how this may interact with further responses from the UK government on AI regulation.

The use of AI also raises unique governance and ethics issues. As ethics and trust are essential in the life sciences sector, such issues will rise to the top of management agendas.

UK Courts Remain an Attractive Venue for Patent Disputes

The recent focus of the patent world has been on the Unified Patent Court (UPC), which opened

on 1 June 2023. Although the UK is not participating in the UPC, it is notable – given the global nature of many patent disputes – that some litigants (including disputes between, for example, Dexcom and Abbott, AIM Sport Vision and Supponer) have related proceedings both before the UK courts and the UPC. This, and the rising number of patent cases before the UK High Court (as reported by JUVE Patent in Patent Case Numbers Rising at UK High Court on 19 March 2024), reinforces the continuing role of the UK courts in international disputes. The extent to which UPC judges take into consideration UK decisions, and whether UK decisions are impacted by UPC jurisprudence, will be monitored carefully during the next period.

Outside the UPC, there have been significant developments in UK patent jurisprudence, with pharmaceuticals companies continuing to view the UK as a valued and influential dispute resolution forum. 2023 saw the courts issue decisions in cases including Gilead v NuCana (2023) EWHC 611 (Pat) (nucleoside analogues for cancer treatment) and Teva & Sandoz v Astellas (2023) EWHC 2571 (Pat) (mirabegron for overactive bladder treatment).

Interestingly, the UK Patents Court has seen a recent increase in medical device cases, including between:

- Abbott and Dexcom (continuous glucose monitoring devices) (Abbott Diabetes Care Inc v Dexcom Inc (2023) EWHC 2591 (Ch) and Abbott Diabetes Care Inc v Dexcom Inc (2024) EWHC 36 (Pat));
- Advanced Bionics and Med-El (cochlear implants) (Advanced Bionics Ag v Med-El Elektromedizinische Gerate GmbH (2023) EWCA Civ 637); and
- Advanced Cell Diagnostics (ACD) and Molecular Instruments, Inc (RNA diagnostics assay methods and kits) (HP-2022-000026).

The past year has seen precedent-setting patent decisions in the UK, which –although not binding outside of the jurisdiction – will inevitably be considered by international courts.

First, one issue considered by the UK courts in 2023 was plausibility. In Sandoz & Teva v Bristol Myers Squibb (2023) EWCA Civ 472 (apixaban), the UK Court of Appeal followed an earlier UK Supreme Court life sciences precedent (Warner-Lambert v Actavis (2018) UKSC 56), which held that plausibility is a legal concept, and upheld the High Court's earlier decision where plausibility was the single ground on which validity was determined. Permission to appeal to the UK Supreme Court was denied and, as it stands, the UK's approach to plausibility diverges from the European Patent Office (EPO) Enlarged Board of Appeal decision in G2/21 and that of European national courts. Plausibility is expected to again come before the UK Patents Court in 2024, where the implications of the Sandoz & Teva v Bristol Myers Squibb decision for the life sciences sector will be tested.

Second, given the increasing use of AI tools in the life sciences sector, the impact of recent landmark AI-related patent decisions will be of interest. In Thaler v Comptroller (2023) UKSC 49, the UK Supreme Court confirmed that AI systems cannot be the owner of patent rights in the UK. This was the first Supreme Court-level decision in the world to consider this issue and international conversations as to whether patent laws are fit for purpose in the context of the rapid advances in AI across all sectors, including life sciences, will evolve.

Further, in 2024, the Court of Appeal will hear the appeal against the High Court's decision in Emotional Perception AI Ltd v Comptroller (2023) EWHC 2948 that an aspect of AI (a trained artificial neural network (ANN) implementing a recommendation system) is not excluded from patentability as a program for a computer. Should the High Court's decision be upheld, patenting AI systems in the UK may be easier. This decision will be significant, and an appeal to the UK Supreme Court is possible.

The UK Patents Court will also be occupied in 2024 by the first disputes in relation to mRNA COVID-19 vaccines and treatments. Proceedings are due to be heard between BioNTech and CureVac, as well as between Moderna and Pfizer.

Going forwards, the so-called "patent cliff" for biologics – as described earlier in the context of M&A activity – is also starting to bite before the UK Patents Court. The UK has seen a recent uptick in patent revocation actions aiming to clear the way for biosimilar products. Some of those actions are likely to come to trial in the near future and further actions are expected to follow, demonstrating the competitiveness of the UK biosimilars market, where healthcare budgets are increasingly squeezed and the need for more cost-effective medicines is becoming more critical.

Increasing Need for Cost-Effective Medicines

This requirement for more cost-effective medicines is not only reflected in the increase in patent disputes and enhanced M&A activity in the biologics space, but also by the steps taken in the UK in relation to the pricing of branded medicines.

In early 2024, the Association of the British Pharmaceutical Industry (ABPI), UK government and the NHS finalised a new non-contractual agreement – the "Voluntary scheme for branded medicines pricing, access and growth" (VPAG) – to enable NHS expenditure on branded medicines to stay within an agreed limit by pharmaceuticals companies paying rebates on their sales of branded medicines. The purpose of the scheme is to promote innovation and access to cost-effective medicines, while also supporting the sustainability of NHS finances. This is a significant shift in UK pricing strategy, offering dynamic pricing rebates that vary depending on the types of product commercialised by a company; however, the only alternative for companies selling branded medicines is the more expensive "Statutory Scheme" under the Branded Health Service Medicines (Costs) Regulations 2018.

Prospect of Divergence From Europe Post-Brexit

Legal and regulatory divergence from the EU has been a universally accepted consequence of Brexit, but the extent to which the UK might – in reality – deviate has always been unclear. However, life sciences-focused issues are continuing to arise and the response of the legislature and judiciary will be monitored with interest.

In 2023, the first judgment relating to supplementary protection certificates (SPCs) was issued since Brexit. In Merck Serono v Comptroller (2023) EWHC 3240 (Ch), the High Court upheld the UKIPO's decision to refuse Merck Serono's SPC application for cladribine based on previous ECJ case law. The upcoming appeal will provide the Court of Appeal with an opportunity to either approve or diverge from CJEU jurisprudence on the issue of SPCs for new therapeutic indications.

As regards legislative changes in the sector, the EU proposed important reforms to pharmaceutical regulation in April 2023. These include plans to shorten the standard marketing and data exclusivity terms relating to regulatory approvals for placing medicinal products on the market. The reforms also included proposals to change SPC legislation, with the introduction of centralised SPC examination and a new unitary SPC. The SPC proposals were approved by the European Parliament in early 2024, but now need to be considered by other EU legislative bodies, so revisions are possible. It will be interesting to see how the UK responds to these proposals.

Another area where the UK has been able to stand firm is in its robust approach to allowing damages if injunctions should not have been granted. The ECJ recently considered questions referred in Bayer (Case C-688/17) and Mylan (Case C-473/22).

Leading the Way on Excessive Pricing

A cycle of Competition and Markets Authority (CMA) decisions against pharmaceuticals companies is reaching an end, with the UK leading the way in defining what constitutes excessive pricing.

In Pfizer and Flynn Pharma (Case CE/9742-13), the CMA originally fined the companies GBP84.2 million and GBP5.2 million respectively after finding they excessively priced phenytoin sodium, a major epilepsy drug. Two years ago, the CMA fined them again after additional evidence-gathering and analysis showed that the companies abused their dominant position by over-charging the NHS for the supply of the tablets (Case 50908). That decision is now being challenged in the Competition Appeals Tribunal (CAT).

Advanz Pharma (Case 50395) is another landmark excessive pricing ruling. The company was fined GBP84 million for its excessive pricing of liothyronine tablets. Advanz, the sole supplier to the NHS, increased prices by more than 1,000% from GBP20 per pack in 2009 to GBP248 per pack in 2017. The CAT unanimously upheld the CMA's decision.

Another ongoing case relates to the excessive pricing of hydrocortisone tablets by Waymade plc, Advanz, Allergan plc, Auden Mckenzie (Pharma) Limited, Cinven and Intas Pharmaceuticals Limited. The CMA imposed fines totalling more than GBP260 million after finding they over-charged the NHS by more than 10,000% (Case 50277). In September 2023, the CAT upheld the CMA's findings on liability, resulting in fines of almost GNP130 million (Auden Mckenzie (Pharma) Limited & Another v Competition and Markets Authority (2023) CAT 56); however, in March 2024, it allowed appeals against some of the CMA's findings (Auden Mckenzie (Pharma) Limited & Another v Competition and Markets Authority (2024) CAT 17). The Court of Appeal's decision in relation to this commonly prescribed medicine is pending and awaited with interest.

Excessive pricing investigations have increased in the UK during the past few years. This again reflects concerns about over-charging the NHS and restricting patient access to medicines.

Sustainability Shaping the Life Sciences Business Environment

In common with all sectors, sustainability is moving into the legal and compliance function of life sciences businesses. This is in part because the regulatory burden is increasing and companies are having to deal with a maelstrom of rules, regulations and standards.

In the year ahead, life sciences legal teams should familiarise themselves with a number of notable issues, including:

- Greenwashing – in the UK, the CMA and Advertising Standards Authority (ASA) both have ambitious programmes in the Advertising Codes and the Green Claims Code to tighten compliance. Legal teams should understand the implications of their sustainability-related commitments and obligations as regulators become more aggressive.
- EU Regulation impacting UK operations – certain EU directives, including the Sustainability Reporting Directive (Directive (EU) 2022/2464), set the bar high in terms of reporting, disclosure and due diligence obligations. Although these are EU Directives, their impact is extending across supply chains and well beyond the EU.
- Litigation – a study ("Impacts of Climate Litigation on Firm Value", May 2023) conducted by the Centre for Climate Change Economics and Policy at the University of Leeds and the Granthan Research Institute on Climate Change and the Environment at the London School of Economics reported that there are an increasing number of cases being brought against companies by activist groups aiming to inflict reputational damage.
- Public sector contracts – for government clients in the UK, and in many other jurisdictions, sustainability is going to be a big evaluation issue and contractors who score poorly may suffer. Contractors are often being asked to sign up to very punchy sustainable targets within their contracts and those who supply the NHS are grappling with the NHS' targets. In 2022, it was the first health system to embed net zero into legislation.
- Supply chain and value chain – even if businesses are not contracting with government clients, they are in the supply or value chain with businesses that are or with businesses that have regulatory obligations to financiers or investors that require detailed transparent reporting of sustainability data. The sourcing of financial and non-financial data for these purposes is an increasing burden.

Although there is political and policy uncertainty on the horizon, the trend towards increased regulation of sustainability measures will require businesses to continue to take action to mitigate risk and capitalise on new opportunities in 2024.

USA

Law and Practice

Contributed by:
Daniel A Kracov, David R Marsh and Alice Ho
Arnold & Porter

Contents

Arnold & Porter is a 1,000-lawyer firm with a global reach and extensive experience in virtually every area of life sciences law. Arnold & Porter offers renowned regulatory, white-collar defence, product liability and commercial litigation, antitrust, IP and transactional capabilities to clients who include a wide variety of pharmaceuticals, biotech, medical device and diagnostic companies and trade associations, as well as non-profits and universities. The firm has nearly 200 attorneys who provide integrated counselling to life sciences companies and represent 80% of the top 50 leading life sciences companies (in addition to representing numerous emerging companies). The lawyers at Arnold & Porter help clients navigate their day-to-day legal problems as well as their most complex and high-stakes matters.

Authors

Daniel A Kracov s a partner at Arnold & Porter, where he chairs the life sciences industry practice. Daniel's practice focuses on assisting pharmaceuticals, biotech, medical device and diagnostic companies – including global manufacturers, trade associations and emerging companies – in negotiating challenges relating to the development, approval and marketing of US Food and Drug Administration (FDA)-regulated products. In addition to day-to-day counselling on regulatory strategies and concerns, he regularly handles product- and compliance-related government and internal investigations, the development of global corporate compliance programmes, and due diligence in financings and M&A. Daniel has widely recognised experience in biomedical public policy matters, including Congressional investigations and advising on FDA-related legislation.

David R Marsh is a partner at Arnold & Porter. He focuses extensively on IP counselling, patent prosecution, interferences, inter partes and ex parte matters, Hatch-Waxman issues, and patent procurement in the biotechnology, business methods, chemical, clothing, computer media, consumer products, pharmaceuticals, and medical device areas. David's experience includes lead counsel for numerous post-allowance proceedings at the US Patent and Trademark Office, appeal counsel at the US Patent and Trademark Office Board of Patent Appeals and Interferences, and lead co-ordinating counsel for multiple European opposition proceedings and other worldwide dispute resolution proceedings – as well as worldwide patent prosecution, non-infringement and invalidity analysis, and multiple due diligences.

Alice Ho is a senior associate at Arnold & Porter and her practice focuses on a range of IP legal issues, including patent prosecution, litigation, transaction, and IP portfolio counselling in the areas of biotechnology, medical devices, pharmaceuticals, and life sciences. She also supports litigation efforts in interferences, inter partes reviews, and other post-grant proceedings before the US Patent and Trademark Office Board of Patent Appeals and Interferences and the federal district courts. Alice's further experience includes negotiating licence and collaboration agreements, preparing non-infringement and invalidity opinions, and performing freedom-to-operate and due diligence analyses. In her practice, Alice has prosecuted and analysed patents involving a range of technologies, including medical devices, antibodies, pharmaceuticals, and medical diagnostics.

Arnold & Porter

601 Massachusetts Ave NW
Washington
DC 20001-3743
USA

Tel: +1 202 942 5120
Fax: +1 202 942 5999
Email: daniel.kracov@arnoldporter.com
Web: www.arnoldporter.com

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The primary legislation governing the authorisation, marketing, sale and supply of pharmaceutical products by the US Food and Drug Administration (FDA) is the Federal Food, Drug, and Cosmetic Act (the "FD&C Act"), which has been amended many times throughout the years to reflect increasing FDA mandates for the regulation of pharmaceutical products. The Public Health Service Act (the "PHS Act") is the specific authority used to approve or license biologic (including biosimilar) products.

The primary FDA regulations governing drugs and biologics are found in Chapter 21 of the Code of Federal Regulations. Controlled substances, such as opioids, are also scheduled and subject to quotas and distribution controls under the Controlled Substances Act administered by the Drug Enforcement Administration (DEA).

A drug is defined as:

- an article recognised in the US Pharmacopoeia, the Homeopathic Pharmacopoeia of the United States, or the National Formulary;
- an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease;
- an article (other than food) intended to affect the structure or any function of the body; and
- an article intended for use as a component of a drug but not as a device (or a component, part or accessory of a device).

A biologic is defined under the PHS Act as "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component (or derivative), allergenic product, protein (or analogous product), or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound) applicable to the prevention, treatment or cure of a disease or condition of human beings". Notably, a protein is any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size. Biological products also fall within the drug definition and are generally covered by most of the same laws and regulations; however, differences exist in the regulatory approach.

Medical devices are also regulated by the FDA under the FD&C Act and – although subject to similar intent standards – such products are primarily intended to act via mechanical rather than chemical or biological modes of action. Medical devices are classified by risk and may be:

- exempt from FDA review;
- subject to a "510(k)" pre-market notification process if they show substantial equivalence to a "predicate" device;
- subject to down-classification via the de novo submission process; or
- eligible for full approval via a pre-market approval application (PMA).

Although the FDA has traditionally been given significant independence as an agency, and the Commissioner is confirmed by the Senate, the FDA is part of the Department of Health and Human Services (HHS).

The government agencies touching on pricing and reimbursement vary, depending upon the payer programme, and include the Centers for Medicare & Medicaid Services (CMS) (also part of the HHS), the Veterans Health Administration, and state Medicaid agencies. In addition, the

HHS Office of Inspector General oversees laws governing fraud and abuse in the sale of biomedical products and healthcare services. The Federal Trade Commission (FTC), an independent agency, regulates the advertising of non-prescription drugs and non-restricted medical devices.

1.2 Different Categories of Pharmaceuticals and Medical Devices

Although the default status for drug approvals is technically OTC (ie, non-prescription), most initial drug approvals specify that new drug products are subject to prescription drug controls. Prescription drugs must be labelled as such and are subject to physician prescribing, pharmacy dispensing, and substitution controls under state law.

However, it is possible to seek an initial FDA approval for the sale of a drug product OTC or to seek to "switch" a prescription product to OTC status by demonstrating that the condition can be self-diagnosed and treated in accordance with labelling. Moreover, throughout the decades, the FDA has also developed OTC monographs that permit the marketing – without approval – of certain OTC drugs that meet the specific terms (eg, ingredients, dosing, and directions for use) for that class of drug and associated labelling under the relevant monograph. Such drugs remain subject to establishment registration, listing, labelling and current Good Manufacturing Practice (cGMP) requirements. Recent legislation liberalised the processes for amending OTC monographs and this could help reinvigorate OTC product development in the US.

Additionally, the FDA has issued a proposed rule that – if finalised – would permit OTC drugs with an "additional condition for non-prescription use" (ACNU). The purpose of this is to increase options for the development and marketing of safe and effective non-prescription drug products via the use of tools (such as digital apps) that support patient self-diagnosis and treatment.

Medical devices may also be assigned to non-restricted (including OTC) or restricted status, depending on their classification and the FDA's determination as to appropriate status under clearance and approval processes.

2. Clinical Trials

2.1 Regulation of Clinical Trials

For drugs and biologics, unless subject to specific exemptions, an investigational new drug (IND) application must be submitted to obtain FDA clearance prior to engaging in clinical research. Such submissions typically include extensive pre-clinical data, information on chemistry, manufacturing and controls, prior human data, and the proposed protocol(s). The FDA has 30 days either to allow the clinical study to proceed or to impose a clinical hold until outstanding issues are resolved.

Similar rules apply to medical device research and, depending upon the risk posed by the device, a device study may require the submission of an investigational device exemption (IDE) prior to initiating clinical research. Non-significant risk device studies may be conducted with just Institutional Review Board (IRB)/Ethics Committee approval. The FDA maintains an array of good clinical practice regulations governing clinical research, including study sponsor, IRB, and investigator responsibilities.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

As noted, in addition to obtaining clearance to proceed with clinical research by filing an IND or IDE application (as appropriate), virtually all studies must be reviewed by one or more IRBs prior to initiation. FDA regulations specify the requirements applicable to the composition and activities of IRBs.

2.3 Public Availability of the Conduct of a Clinical Trial

The US National Institutes of Health maintains a database at clinicaltrials.gov, where most controlled, interventional clinical investigations – other than Phase I clinical investigations – of drugs or biologic products subject to FDA regulation must be registered and study results must be posted. Although there is no general requirement to publish clinical trial data in journals, the industry has pledged to seek such publications wherever possible, as matter of practicality.

2.4 Restriction on Using Online Tools to Support Clinical Trials

Online tools may be used as long as they comply with applicable requirements – for example, privacy, data security, auditability, informed consent and other good clinical practice requirements, as well as establishing lawful status if such tools incorporate certain regulated medical device functionalities. Particular requirements apply to recruiting subjects for clinical studies, whether online or otherwise.

2.5 Use of Data Resulting From Clinical Trials

The personal data resulting from clinical trials is considered protected. However, as long as any transfer of resulting data to a third party or an affiliate is consistent with contractual obligations, informed consent, and privacy protections, transfers are permitted. In certain scenarios the sponsor and the FDA will have access to such information (including patient-identifiable information) in order to conduct and analyse the data from the study properly and ensure that subjects are protected.

2.6 Databases Containing Personal or Sensitive Data

A database containing personal or sensitive data may be subject both to contractual and statutory protections obliging maintenance of data security and privacy.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

Such determinations are typically made by assessing the primary mode of action of the product and whether it works by chemical, biological, mechanical or other means. If the product combines chemical, biological and/or mechanical modalities, a Request for Designation may be submitted to determine how the FDA believes the product should be regulated.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Drug products are approved via New Drug Applications (NDAs). Additional indications, dosage forms, etc, may be added via NDA supplements. Biologic products are approved in a virtually identical process via Biologics License Applications (BLAs). The standard for approval is "substantial evidence" of safety and effectiveness (technically, "safety, purity and potency" for biologics), resulting from at least one – and typically several – adequate and well-controlled clinical

studies. The typical drug or biologic review process takes ten months after initial acceptance for filing (a 60-day period); however, a priority review of six months is given to certain drugs and biologics intended to treat serious or life-threatening conditions.

Substantial user fees – USD4,048,695 in Fiscal Year 2024 for an NDA or BLA containing clinical data – are required to facilitate a review of applications.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

There is no mandatory re-authorisation process for approved products. However, the FD&C Act and FDA regulations include processes for the withdrawal or revocation of an approval based upon a significant safety or effectiveness issue or non-compliance with approval requirements. These processes can be expedited in certain scenarios, such as an applicant's failure to confirm the efficacy of an accelerated approval product in a post-market study, or where there is an imminent hazard. In general, a marketing authorisation may not be revoked merely because the product has not been placed on the market – although a failure to market an orphan drug could result in a loss of orphan exclusivity.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

As noted, the pathways for approval of drugs consist of:

- the submission of an NDA (including a 505(b)(2) NDA relying on data for which the applicant does not have a right of reference); and
- the Abbreviated New Drug Application (ANDA) for generic products, which demonstrates equivalence to a reference listed drug.

A biologic is licensed via the submission of a BLA; however, that process is largely the equivalent of an NDA submission. A biosimilar application demonstrates that, based on the totality of the evidence, the biosimilar is either "highly similar" to – or interchangeable with – a reference biologic.

The FDA is authorised to require paediatric studies of drugs or biologics when other approaches are insufficient to ensure that the products are safe and effective for use in children. The agency may also issue a written request for paediatric research and, if the sponsor fulfils the data request, it may obtain six months of paediatric exclusivity.

As noted, changes to an existing marketing authorisation may be obtained through supplements or amendments to existing applications. As regards medical devices, the submission of additional 510(k) submissions can result in the clearance of significant changes to previously cleared device products. A PMA may also be supplemented or amended. In many cases, the transfer of a clearance or approval without manufacturing site or significant product changes requires only fairly simple notifications to the FDA.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

The FDA maintains regulations permitting expanded access to investigational products. Such expanded access to INDs and IDEs may relate to an individual patient (often called a "compassionate use") or may allow broader

use by patients not eligible for controlled clinical trials, depending upon the seriousness of the disease and the availability of alternative treatments. Sponsors of such INDs may not charge patients for the investigational drug without specific authorisation from the FDA permitting cost recovery only.

In addition, the 2018 "Right to Try" Act permits certain eligible terminally ill patients to have broad access to eligible investigational drugs in certain circumstances when manufacturers are willing to supply. To date, most companies have shown a reluctance to permit their products to be used via this pathway in lieu of the more traditional IND pathway.

There is also a very limited Humanitarian Device Exemption (HDE) pathway for approval of a Humanitarian Use Device (HUD) intended to benefit patients in the treatment or diagnosis of a disease or condition that affects – or is manifested in – not more than 8,000 individuals in the USA per year.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

Every drug, biologic or device product is subject to ongoing requirements relating to establishment registration, product listing, compliance with cGMPs/quality systems, track-and-trace requirements, and safety/adverse event reporting regulations. In certain cases, the FDA may require closer, ongoing oversight of a drug or biologic under a Risk Evaluation and Mitigation Strategy (REMS) or may mandate post-market studies or trials.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

While the FDA does release approval letters and – after review for redaction of confidential and trade-secret information – summary review and approval documents, it does not currently publish "complete response letters" that reject an application under review. Available information on approved products may be obtained via the FDA's Drugs@FDA website. Often, extensive information about pending applications is released in the form of briefing papers and presentations used at FDA Advisory Committee meetings. The FDA does not reveal the existence of pending INDs or IDEs unless the sponsor has publicly acknowledged the filings.

Third parties may submit requests for information under the Freedom of Information Act (FOIA); however, there are a variety of exceptions from disclosure, as well as a major FDA backlog of requests. Most importantly, the FDA has an obligation under the FOIA to refrain from publication of trade secrets or confidential commercial or financial information. Sponsors/applicants are afforded an opportunity to review potential releases of information and request confidential treatment under those FOIA exceptions.

3.8 Rules Against Illegal Medicines and/or Medical Devices

The Drug Supply Chain Security Act (DSCSA) mandated a system to identify and trace certain prescription drugs as they are distributed in the USA. The aim is to enhance the FDA's ability to:

- help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated or otherwise harmful; and
- improve detection and removal of potentially dangerous drugs from the drug supply chain.

Under this framework, drug manufacturers have a responsibility to rapidly report "suspect" and "illegitimate" products.

A Unique Device Identification System has been implemented for medical devices. This identification system serves various purposes, including:

- providing a standardised identifier that will allow manufacturers, distributors and healthcare facilities to manage medical device recalls more effectively; and
- providing a foundation for a more secure distribution chain to help address counterfeiting and diversion.

The FDA's Office of Criminal Investigation (OCI) has primary responsibility for policing drug and medical device counterfeiting and diversion. At times, companies will approach the OCI and other law enforcement bodies to seek an investigation and enforcement action.

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

The FDA and Customs and Border Protection work together to identify and detain counterfeit medical products. It is possible to work with those agencies to seek enhanced surveillance with regard to the potential importation of such products. The FDA has extensive powers to stop products at the border if they are suspected of being adulterated or misbranded.

In addition, companies may file actions seeking an investigation under Section 337 of the Tariff Act with regard to unfair acts in the importation of articles. However, such actions may fail if positioned as an attempt to enforce the FD&C Act privately.

4. Manufacturing of Pharmaceuticals and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

In general, manufacturing plants are not subject to a separate authorisation from the related product approvals – although they must be registered with the FDA (and the products produced at the facility must be listed as associated with the establishment). Moreover, in most cases, the FDA will conduct a pre-approval inspection of the facility before approving a drug or device. Such establishments are also subject to both routine (typically every two years) and for-cause (eg, in response to a product defect and recall) inspections.

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

In general, wholesale activities are subject to licensure requirements at the state level and registration as distributors at the federal level. The requirements and length of such licences vary by state.

The FDA may inspect any facility holding drugs for shipments – although state inspection activities and fees vary greatly. Significant additional requirements administered by the DEA and states apply to wholesale trade in controlled substances.

The authorisation to trade in pharmaceuticals varies greatly by state; however, most pharmaceutical distributors must hold a state licence.

Such requirements often do not apply to entities that are not physically handling drug products.

5.2 Different Classifications Applicable to Pharmaceuticals

Drugs may be either prescription – ie, as defined under state law, generally subject to prescription by a designated healthcare practitioner and dispensing by a licensed pharmacist – or OTC (permitting sale without intervention by a healthcare practitioner or pharmacist). Certain products (eg, pseudoephedrine) must be kept behind the pharmacy counter, owing to specific statutory requirements. The FDA has issued a proposal that could expand direct availability of drug products via, for example, use of mobile apps as well as kiosks in pharmacies that permit education and diagnostic screening.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The FD&C Act and general import and export administration laws govern the import/export of pharmaceuticals and medical devices. Typically, imported medicines and medical devices must be subject to an approval or clearance (if applicable) in the USA. Only the original manufacturer of a drug may re-import a drug product back into the USA, subject to limited programmes – aimed at demonstrating how the importation of certain drugs can be accomplished in an attempt to reduce prices – that may nor may not proceed in the coming years. The importation of even an identical drug produced at a facility that is not inspected in the course of the US approval would be considered unlawful. Limited exceptions are permitted for individuals to engage in personal, physical importation of foreign products for their own use, if based upon a prescription from a healthcare professional and a lack of alternatives in the USA.

Note that a developing potential exception to these rules is the FDA's decision to authorise Florida's drug importation programme from Canada for a period of two years pursuant to a 2020 final rule establishing this pathway, with the goal of lowering drug prices in the USA. Additional steps must be implemented before such importation occurs, and the products at issue have yet to be disclosed. Moreover, the success of this pathway is highly uncertain, given that Health Canada has made clear in a statement that it will take "all necessary action to safeguard the drug supply and ensure Canadians have access to the prescription drugs they need" and arguing that "bulk importation will not provide an effective solution to the problem of high drug prices in the US[A]".

At the border, the primary regulators are the FDA (administering the FD&C Act for potential violations) and US Customs and Border Protection (administering the broad array of US laws governing customs matters). Other agencies – for example, the Department of Commerce and the Department of Agriculture – may have responsibilities as well, depending on the nature of the imported article.

6.2 Importer of Record of Pharmaceuticals and Medical Devices

Importers of record may be designated by the manufacturer or distributor and they have specific responsibilities. A US importer of record (ie, the owner, purchaser, or licensed customs broker designated by the owner, purchaser or

consignee) files entry documents for the goods with the port director at the goods' port of entry. It is the importer of record's responsibility to arrange for the examination and release of the goods. Initial importers may also be responsible for meeting registration and listing requirements. US Customs and Border Protection requires the importer of record to file an importation bond that is typically equal to at least three times the invoice value of the goods.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

In order to be lawfully imported, a drug or medical device must be either:

- cleared or approved (and the product properly listed in association with a registered establishment); or
- the subject of an active IND or IDE.

Exceptions are made for importation of a very limited amount of a product for personal use. The FDA will also work with potential importers in certain situations (eg, compassionate use or short supply) to expedite the satisfaction of regulatory requirements.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Upon entry into the USA, declarations and information must utilise the Customs Harmonised Tariff Schedule codes according to the Harmonized Tariff Schedule of the US (HTSUS) and FDA product codes. Such declarations are subject to specific regulations issued by US Customs and Border Protection and the FDA. A failure to classify a product properly may result in an improper payment of Customs duties and, consequently, associated penalties.

6.5 Trade Blocs and Free Trade Agreements

The USA is a member of the WTO and has free trade agreements in effect with 20 countries. Some are bilateral agreements, but others are multilateral in nature. The USA is also party to Trade and Investment Framework Agreements that provide frameworks for governments to discuss and resolve trade and investment issues at an early stage, as well as bilateral investment treaties that help protect private investment, develop market-oriented policies in partner countries, and promote US exports. Additionally, the FDA is party to various Memoranda of Understanding and mutual recognition agreements aimed at facilitating global discussions and risk assessments with regard to, for example, inspections.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

Until recently, the USA had little in the way of pricing limitations on pharmaceutical products and medical devices. Therefore, in most cases, the manufacturer of a product sets the initial price and adjusts prices (including rebates and other price concessions) over time in response to market conditions. However, in a major shift, the Inflation Reduction Act 2022 (IRA) incorporated provisions to lower prescription drug costs for those covered by Medicare and reduce drug spending by the federal government. Among others, the IRA includes the following provisions.

- The federal government has already begun to negotiate 2026 pricing for certain drugs. This will establish a "maximum fair price" for certain drugs covered under Medicare Part

B and Part D with the highest total spending (excluding specific categories of drug). Under this Drug Price Negotiation Programme, the number of drugs subject to price negotiation include ten Part D drugs for 2026, another 15 Part D drugs for 2027, another 15 Part D and Part B drugs for 2028, and another 20 Part D and Part B drugs for 2029 and later years. The drugs will be chosen from the 50 drugs with the highest total Medicare Part D spending and the 50 drugs with the highest total Medicare Part B spending. A prohibitive excise tax will be levied on drug companies that do not comply with the negotiation process.
- Drug companies are now required to pay rebates to Medicare if prices rise faster than inflation for drugs used by Medicare beneficiaries.
- Out-of-pocket spending will be capped for Medicare Part D enrollees and other Part D benefit design changes will be made as of 2024.
- Monthly cost sharing for insulin is now limited to USD35 for people with Medicare.

Various aspects of the IRA have been quite controversial, including provisions that disadvantage certain orphan drugs as well as small molecules relative to biologics. The IRA drug pricing provisions are currently being challenged in multiple lawsuits under a wide variety of theories.

There are also other federal laws that cap pharmaceutical prices for certain purchasers or require minimum rebate levels in the following ways.

- Subject to ongoing litigation over the scope and terms of the programme, manufacturers sell their outpatient drugs to "covered entities" (typically, certain clinics and hospitals believed to serve safety-net functions) at or below a statutorily set ceiling price under the 340B Drug Pricing Programme.
- Manufacturers must sell brand name drugs to four federal agencies (the Department of Veterans' Affairs, the Department of Defence, the Public Health Service, and the Coast Guard) at or below a "federal ceiling price" determined by a statutory formula.
- Manufacturers must pay a rebate set by a statutory formula on each unit of their outpatient drugs paid for by the Medicaid programme. This is not literally a "price control" programme because it only controls the rebate paid to Medicaid after the drug has been dispensed or administered. As such, the price that Medicaid pays upfront to the dispensing pharmacy or to a physician's office or clinic that administers a drug is not affected by the Medicaid rebate programme.

7.2 Price Levels of Pharmaceuticals or Medical Devices

In the USA, companies typically set their prices based on a wide range of factors, and the price level of a pharmaceutical product or medical device does not depend on the prices for the same product in other countries. Although reference-pricing schemes have previously been proposed in the USA, the provisions of the IRA described in **7.1 Price Control for Pharmaceuticals and Medical Devices** are currently the primary vehicle for industry/government price negotiations under US law.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

The largest healthcare programme in the USA today is the Medicare programme, which provides healthcare coverage for people who are 65 and older, are disabled (for two years or more),

or have end-stage renal disease. Medicare accounts for roughly 20% of US health spending. Most pharmaceutical products are eligible for some form of Medicare coverage, either through:

- Part B (Medicare's traditional outpatient benefit, which covers a small but important set of drugs, including physician-administered drugs);
- Part D (the Medicare drug benefit, which has provided broad coverage for pharmacy-dispensed oral drugs since 2006); or
- Part A (Medicare's inpatient benefit, which covers drugs provided as part of covered inpatient hospital stays and in certain other inpatient settings).

The second-largest healthcare programme today – accounting for roughly 17% of US health spending – is the Medicaid programme, which is a joint federal–state programme providing coverage for certain low-income individuals (with the specific eligibility criteria varying by state). Medicaid is run chiefly by states, with federal government oversight, and state Medicaid programmes generally provide broad coverage for prescription drugs. Medicaid programmes have sometimes imposed coverage restrictions on high-cost drugs that arguably conflict with their statutory obligations.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

The process and evidence that US payors use to make decisions about pharmaceuticals and medical device coverage varies widely by payor (and is not always entirely transparent). These variations can include:

- the criteria considered appropriate for evaluation (eg, whether a product's cost or cost-effectiveness is taken into account in coverage decisions);
- the scientific rigour of the evidence considered and the weight placed on the types of evidence considered;
- the decision-making body and the processes for making coverage decisions; and
- the legal standards that apply to the coverage decision-making process and the resulting package of covered products and services.

Many organisations are engaged in developing value-assessment tools of various sorts, and the Centers for Medicare and Medicaid Services is experimenting with outcome-based models, such as a developing Medicaid Cell and Gene Therapy Access Model. Essentially, these tools are designed to help payors, healthcare providers, and patients assess outcomes of competing pharmaceuticals on a systematic basis and thereby reach conclusions about their value in a more systematic and rigorous way than is currently usual.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Pharmacists are paid for dispensing prescriptions by the patient's insurer (assuming the patient is insured and the product is covered) and the patient. The circumstances in which pharmacists may dispense a substitute for the prescribed product without obtaining the prescriber's authorisation are governed by state law. State laws on this issue can vary but, in general, they permit pharmacists to substitute a product approved by the FDA as a generic equivalent for the prescribed product (unless the prescription specifically states "dispense as written" or a similar phrase indicating no substitution).

During the past several years, the standards for permitting pharmacists to substitute a "biosimi-

lar" product for a prescribed biological product have been a topic of considerable debate. The provisions of these laws vary but often only permit biosimilar pharmacy-level substitution if:

- the substituted product has been designated as "interchangeable" with the prescribed biological product by the FDA;
- the prescriber and the patient are both notified of the substitution; and
- the pharmacist maintains records of the substitution.

8. Digital Healthcare

8.1 Rules for Medical Apps

The FDA has been very active in providing guidance in this area and has carved out defined categories of apps and platforms from regulation. The FDA has issued several guidance documents designed to "encourage innovation" and "bring efficiency and modernisation" to the agency's regulation of digital health products. The guidance documents address, in part, the important changes made by Section 3060 of the 21st Century Cures Act (the "Cures Act") to the medical device provisions of the FD&C Act – whereby five distinct categories of software or health products were espressly excluded from the definition of medical device. The FDA's extensive guidance documents in this area include guidance on Clinical and Patient Decision Support software, regulation of software as a medical device (SaMD), and general wellness products – establishing common principles for regulators to use in evaluating the safety, effectiveness and performance of SaMD. The FDA also has an action plan concerning the regulation of SaMD incorporating AI and machine learning.

8.2 Rules for Telemedicine

The FDA does not regulate the practice of medicine and generally defers to the states in order to determine what is a valid physician–patient relationship and prescription. Telemedicine expanded enormously in the USA during the pandemic, with more and more physician consultations now being provided online via chat-based or video examinations. The regulation of these activities varies by state and such laws govern issues including the corporate practice of medicine, minimum rules for a genuine patient relationship, cross-border prescribing and lab orders, privacy, and payments and referrals to telemedicine physicians. The availability of electronic prescribing also varies by state; nonetheless, states generally permit online dispensing of approved drugs and medical device products pursuant to valid prescriptions.

8.3 Promoting and/or Advertising on an Online Platform

Medicinal and medical device products may usually be promoted online, on company websites, and via social media. However, such media present special challenges when ensuring that the promotion is fairly balanced, truthful and non-misleading, as well as transparent with regard to the company's involvement, and adequately provides safety information.

The FDA has developed several guidance documents in this area for the purpose of informing companies about when the agency considers user-generated information on a company's web page or social media to be promotional (largely based on the level of control over the site and placement of information) and how to convey information properly in a character-limited social media environment. Additional rules apply to online marketing practices – for example, the FDA and FTC requirements pertaining to

endorsements and testimonials by paid "influencers" in online promotion.

8.4 Electronic Prescriptions

Electronic prescribing of drug products is governed by state laws and Board of Pharmacy rules. Most states do permit some form of electronic prescribing, even though the specific rules (such as those for specifying use of the brand-name drug) vary by state. Special rules may apply to interstate prescribing, particularly with regard to controlled substances, and licensure in multiple states may be required where reciprocity in licensure recognition is not provided.

8.5 Online Sales of Medicines and Medical Devices

Online sales of prescription drug and device products are permitted if there is otherwise a valid prescription for the product and the pharmacy is duly licensed in the states to which the products are shipped. Special rules apply to certain controlled substances. To the extent that prescribing of the drug or device also occurs online, the prescriber must satisfy state requirements pertaining to valid physician–patient relationships and telemedicine-based prescribing. Special rules apply to controlled substances sales. Online sales of drugs into the USA from ex-US pharmacies, whether or not pursuant to a valid prescription, are generally prohibited. As regards controlled substances, the DEA is currently evaluating rules – which have been temporarily extended through 2024 – permitting flexibilities in the prescription of such products via telemedicine.

8.6 Electronic Health Records

In addition to the previously mentioned FDA rules regarding digital tools that convey health records and images, there are many other aspects involved in the regulation of electronic health records in the USA. Specifically, the HHS Office of the National Co-ordinator (ONC) for Health Information Technology is responsible for implementing statutory provisions related to advancing inter-operability, clarifying the Health Insurance Portability and Accountability Act (HIPAA) privacy rules, prohibiting information-blocking, and enhancing the usability, accessibility, privacy and security of health IT.

The Health Information Technology for Economic and Clinical Health (HITECH) Act 2009 provided the HHS with the authority to establish programmes in order to improve healthcare quality, safety and efficiency through the promotion of health IT, including electronic health records and private and secure electronic health information exchange.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices

The statutory framework for US patent law is mainly set out in United States Code (USC) Title 35. The Leahy-Smith America Invents Act (AIA) effected sweeping changes to US patent law. One of the most significant of these changes was to bring the USA largely into compliance with the rest of the world with regard to prior art determinations. Prior to the AIA, the USA was considered a "first inventor" jurisdiction (ie, the first person to invent the invention was entitled to the patent). Following the AIA, the USA is a "first inventor to file" jurisdiction that uses the "first to file" methodology employed virtually everywhere else in the world.

As explained in further detail later, in the USA, patent protection and certain regulatory exclusivities may share certain traits but they are distinct. The Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, amended the FD&C Act and affected the government's regulation of generic drugs. Hatch-Waxman provides for brand product exclusivities, as well as 180-day exclusivity to companies that are the "first to file" an ANDA against branded drug patent holders. This regulatory exclusivity is in addition to the patent term of patents claiming the branded drug and a statutory 30-month stay of approval permitted in the event of patient litigation.

Similarly, the Biologics Price Competition and Innovation Act 2009 (BPCIA) amended the PHS Act to create an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product.

To be patentable under US law, an invention must be:

- patentable subject matter;
- novel; and
- not obvious.

Patentable subject matter includes "any new and useful process, machine, manufacture, or composition of matter" (35 USC Section 101). Novelty requires that the invention has not previously been "patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention" (35 USC Section 102). Finally, an invention must not be obvious – ie, it cannot be the case that "the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains" (35 USC Section 103).

In addition to these requirements, a patent must "contain a written description of the invention – and of the manner and process of making and using it – in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains (or with which it is most nearly connected) to make and use the same" and "set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention" (35 USC Section 112).

There are no requirements specific to pharmaceutical products or medical devices. Nevertheless, various claim-drafting structures and statutory requirements are commonly at issue in cases involving pharmaceuticals or medical devices.

In the wake of two 2012 Supreme Court decisions regarding what constitutes patentable subject matter, companies have sought to distinguish their inventions from laws of nature and unpatentable phenomena through narrower claim drafting. As of the beginning of 2024, method-of-treatment claims involving treatment steps are patent-eligible even if they also recite diagnostic steps. Nonetheless, method-of-diagnostic claims remain patent-ineligible, while certain method-of-preparation claims have been held patent-eligible.

9.2 Second and Subsequent Medical Uses

Patent protection is available for new uses of known compounds, processes, manufactures, etc, that satisfy the general requirements for

patentability (including novelty and non-obviousness). As noted in **9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices**, claims may be directed to "methods of treatment".

A new dosage regime may be patentable if it satisfies the requirements for patentability; however, such claims are often subject to obviousness challenges. A claim could be directed to a method of treating a patient suffering from new disease X by administering an effective amount of known compound Y to the patient. A claim could also be directed to a method of treating a selected patient with disease X by administering compound Y at dose Z to the patient, whereby the selected patient has tested positive for a biomarker.

Direct or indirect infringers (as well as inducers of infringement) may be sued – although induced infringement can be found only when one "party" performs every step of a patent.

9.3 Patent Term Extension for Pharmaceuticals

35 USC Sections 154 and 156 address certain adjustments and extensions of patent term, with Section 156 being particularly applicable to drugs and biologics. Certain medical devices may also be eligible for patent-term extension; however, such devices must be reviewed and approved via PMA. The FDA assists the United States Patent and Trademark Office (USPTO) in determining a product's eligibility for patent-term restoration and provides information to the USPTO regarding a product's regulatory review period. The USPTO is responsible for determining the period of extension, subject to statutory requirements.

A third party may file a due diligence petition challenging the FDA's regulatory review period determination by alleging that an applicant for patent-term restoration did not act with due diligence in seeking FDA approval of the product during the regulatory review period.

9.4 Pharmaceutical or Medical Device Patent Infringement

Infringement may occur if the defendant has made, used, sold, offered to sell, or imported an infringing invention or its equivalent. A generic applicant may file an ANDA, which allows that applicant to rely on the safety and efficacy studies supplied by the brand name manufacturer if the generic manufacturer shows that its generic product contains the same active ingredient as – and is bio-equivalent to – the brand-name drug listed in the Approved Drug Products with Therapeutic Equivalence Evaluations publication, commonly known as the "Orange Book".

In doing so, the generic applicant must make one of four certifications with regard to any patents associated with the drug. The fourth is that the "patent is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted" (21 USC Section 355(j)(2)(A)(vii)). Such a "Paragraph IV" certification is deemed a constructive act of infringement and the patent holder then has 45 days to file an infringement lawsuit against the ANDA applicant. If such a lawsuit is filed, the FDA generally may not grant final approval of the ANDA for 30 months after the filing date or until the ANDA filer prevails in litigation. If patent validity and infringement remain unresolved after the 30-month stay, the FDA may approve the ANDA.

The BPCIA provides a conceptually similar (albeit procedurally very different) framework – accord-

ing to which, the filing of a biosimilar application by an applicant is an artificial act of infringement giving rise to a statutorily prescribed process that governs subsequent patent-infringement litigation and biosimilar regulatory approval. A BLA sponsor is required to provide certain patent information regarding the reference product to the FDA within 30 days of such information being provided to the biosimilar applicant as a part of the "patent dance". The FDA must then include this patent information when it updates the Purple Book every 30 days. There is no equivalent statute and regime for medical devices.

As regards patent infringement, the threat of infringement can form the basis of a declaratory judgment action, which can examine the validity of patents and whether the action constitutes infringement. As this action is brought by the alleged infringer, the alleged infringer is able to select the venue for the case, which can have great strategic value in US patent litigation. However, given that many patent owners desire to avoid a declaratory judgment action, notice letters and cease-and-desist letters are not as commonly used as in the past, and patent-litigation suits are often filed before the alleged infringer has the chance to claim that the threat of infringement exists.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

Under 35 USC Section 271(e)(1), it is not an act of infringement to make, use, sell, or offer to sell within the USA or import into the USA a patented invention "solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use or sale of drugs or veterinary biological products". In Merck KGaA v Integra Lifesciences I Ltd, the US Supreme Court held that the statute exempts from infringement all uses of compounds that are reasonably related to submission of information to the government under any law regulating the manufacture, use or distribution of drugs.

This safe harbour continues to be narrowed in recent district court decisions. In an early 2022 decision, the District Court of Delaware excluded the use of patented host cells to produce gene therapy product from safe-harbour protection, after it reasoned that the patented host cells are merely tools used in the preparation of the product to be approved.

Compulsory licences are available only in very specific situations and generally not under patent law. By way of an example, the US National Institutes of Health may – under certain circumstances – threaten to issue a compulsory licence if a licensee has failed to take effective steps to pursue the government-licensed invention or in certain scenarios involving public health need. It has never done so, however. A draft proposal was issued by the National Institute of Standards and Technology in December 2023 allowing such rights to be exercised to curb drug prices.

9.6 Proceedings for Patent Infringement

Typically, the patent owner brings the suit alleging patent infringement. Depending on the wording of the licence agreement, an exclusive licensee may also have standing to enforce the licensed patent. Remedies may include a temporary or permanent injunction, destruction of infringing articles, the award of damages (including the infringer's profits) and, in certain limited circumstances, attorney's fees.

Patent litigation is much like other civil litigation in the federal district courts in the USA

(including a very high settlement rate). First, the plaintiff files a complaint alleging infringement of one or more US patents. Then, the plaintiff serves the complaint on the defendant, who typically answers by alleging non-infringement and asserting defences such as patent invalidity and other equitable defences. Common invalidity defences include invalidity based on ineligible patentable subject matter, combination of prior art references, and double patenting. The defendant may also assert a counterclaim, such as a declaratory judgment of non-infringement. The defendant may also file a motion to dismiss for improper venue. A case management conference regarding scheduling, among other matters, is required. Certain district courts may have local patent rules that set forth additional requirements. Next, fact and expert discovery are conducted, which typically includes depositions, document requests, interrogatories, expert reports and the like. Often, a claim construction hearing (also known as a Markman hearing) occurs, in which the parties ask the court to interpret certain terms of claims in the patent(s) at issue. The parties also typically file various motions, such as a summary judgment motion of patent invalidity.

If the case proceeds, pre-trial briefing and then trial (by judge or jury) and post-trial practice occur. A jury may render an opinion as to whether the patent is invalid. An appeal may be taken to the Federal Circuit and then to the Supreme Court if the Supreme Court grants a petition for certiorari.

In addition to raising invalidity as a defence in court, a potential infringer (or any third party) can challenge the validity of a patent in proceedings before the Patent Trial and Appeal Board (PTAB). A "post-grant review" permits a person who is not the owner of a patent to challenge a patent's validity on any ground that could be raised under Section 282(b)(2) or (3) no later than nine months after the date of the grant of the patent (35 USC Section 321). An "inter partes review" (IPR) may be requested by a person who is not the owner of a patent nine months after the grant of the patent or the termination of a post-grant review (whichever is later), if one has been instituted (35 USC Section 311(a), (c)). However, an IPR may not be filed more than one year after the complainant has been served with a complaint alleging infringement. The validity of a patent subject to an IPR can only be challenged on a ground that could be raised under Sections 102 or 103 – and only on the basis of prior art consisting of patents or printed publications (35 USC Section 311(b)).

In SAS Institute Inc v Iancu (SAS), the Supreme Court did away with the PTAB's prior practice of "partial institutions" of IPR challenges. Going forward, the PTAB must decide the validity of all challenged claims when it institutes review of a patent. In light of SAS, the Federal Circuit held in California Institute of Technology v Broadcom Ltd that an infringer is barred under Section 315(e) from challenging the invalidity of a patent in a civil action on all grounds that reasonably could have been asserted against the claims in its previously filed IPR petition.

9.7 Procedures Available to a Generic Entrant

As previously described in **9.4 Pharmaceutical or Medical Device Patent Infringement**, an ANDA filer must make one of four certifications with regard to any patents associated with the drug. It is possible that, after making a Paragraph IV certification, the patent holder may elect not to file an infringement lawsuit. If the patent holder does not bring suit, the FDA may approve the ANDA.

An ANDA filer may not file a declaratory judgment suit during the 45-day period in which the patent holder may elect to bring a suit. If the patent holder files suit against the generic applicant within the 45-day period, the generic may file a declaratory judgment counterclaim, as long as an actual case or controversy continues to exist. A generic drug-maker may be able to request correction or delisting of a patent claim from the Orange Book as part of a counterclaim or non-infringement declaratory judgment action. An ANDA filer and the patent holder may also reach a licensing or other agreement – although such "reverse payment" settlements can be subject to antitrust scrutiny.

The phrase "clearing the way" is not a term of art in US patent law; however, a generic drug manufacturer may launch "at risk" if patent validity and infringement remain unresolved after the 30-month stay and the FDA approves its ANDA. In such cases, the generic may be liable for damages if the patent(s)-in-suit are ultimately held to be valid and infringed.

An NDA includes patent information for listing in the FDA Orange Book and the FDA considers patent listing part of the approval process for brand drug applications. Although not directly involved in the listing process, in November 2023, the FTC issued letters to ten brand pharmaceutical companies regarding improper listing of patents directed to certain drug-device combination products, emphasising the NDA holder's responsibility to ensure proper Orange Book listing. As a result, several companies have delisted certain patents flagged by the FTC. If a patent that covers the drug exists and is listed, marketing approval will not be granted to a generic until the patent has expired or is found to be invalid or not infringed.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Trade mark and trade dress owners can sue manufacturers and sellers of counterfeit pharmaceuticals and medical devices for infringement. Additionally, a general exclusion order can be sought in the International Trade Commission (ITC), which can help to combat counterfeits that are being imported into the USA. Under the general exclusion order, any such infringing articles would be seized at the border by US Customs and Border Protection.

The possession, trafficking and purchasing of counterfeit pharmaceuticals and medical devices can also be criminally actionable at the federal or state level.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Other than general trade mark requirements, the controls on trade marks are usually regulatory in nature. By way of an example, trade marks that could be deemed claims must not be false or misleading (ie, may not misbrand the product). In the case of prescription drugs, the trade-marked brand name – known as the "proprietary name" – is subject to approval by the FDA as part of the drug and biologic approval process. This is done to ensure that it does not misbrand the product or create a risk of medical errors.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

Trade dress protection is available for colour and shape (including pill shape). A "US adopted name" (USAN), which is a non-proprietary name reviewed by the World Health Organization, is necessary in order to market a pharmaceutical in

the USA. The USPTO reviews and registers federal trade marks (pursuant to the Lanham Act). In doing so, the USPTO considers the likelihood of confusion with other marks and whether the mark is:

- distinctive;
- a surname;
- a likeness;
- geographically descriptive of the origin of the goods;
- disparaging or offensive;
- a foreign term that translates to a descriptive or generic term; or
- purely ornamental.

The US Trademark Trial and Appeal Board (TTAB) hears petitions related to the status of trade marks (including their cancellation). The TTAB may cancel a mark if it finds that:

- a registrant was using the mark to misrepresent the source of the corresponding goods; or
- differences with prior marks do not offset the likelihood of confusion.

The FDA has authority under the FD&C Act to determine whether a pharmaceutical is "misbranded" – ie, "its labelling is false or misleading" (21 USC Section 352(a)). This can be due to the proprietary name of the product, which the FDA must approve as part of the drug application.

The Lanham Act and the Tariff Act may provide a basis to bring claims in a federal district court against parallel importers for damages and injunctive relief. Any resulting injunction would be enforced through the federal courts rather than through the Customs and Border Patrol. Sometimes, the district court action is stayed pending the outcome of an ITC proceeding.

Parallel importation may violate Section 337 of the Tariff Act, which grants the ITC jurisdiction to investigate claims of trade mark infringement. The ITC cannot award damages but can issue exclusion orders that are enforced by the Customs and Border Patrol. The ITC can bar the importation of items that infringe US trade marks, copyrights or patents.

The Customs and Border Patrol works with the FDA to prevent parallel import. Trade mark owners typically contact the FDA and then the FDA contacts the Customs and Border Patrol.

Trade dress protection is available for colour, shape (including pill shape) and packaging that identifies the source of the product and otherwise distinguishes the product but is not purely functional or likely to be confused with the trade dress of another product.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

For drugs, under the previously described Hatch-Waxman Act, there is a period of data exclusivity of five years from the date of approval for new chemical entities. There is also a period of data exclusivity of three years from the date of approval for supplemental applications incorporating clinical studies sponsored by the applicant that are essential to the approval. The first approved biologic may be subject to 12 years of exclusivity; however, subsequent supplemental applications for the product will not accrue additional exclusivity without clinically meaningful structural changes to the product. Such periods can run irrespective of – but concurrent with – any patent term associated with the drug or treatment using the drug.

Other exclusivities are available for:

- designated orphan drugs for rare diseases (seven years of market exclusivity);
- designated Qualified Infectious Disease Products (five years of additive exclusivity);
- first generic applicants filing a patent certification (180 days); and
- satisfying paediatric study requests (six months of additive exclusivity).

There is no true exclusivity framework for medical devices, and 510(k)-cleared devices may be designated as predicate devices immediately upon clearance. However, subsequent applicants for a Class III device generally may not rely on data in PMA-approved medical device products.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

During the pandemic emergency, the FDA relaxed various regulatory requirements relating to COVID-19 countermeasures, as well as FDA-regulated products generally. Many of these policies were intended to provide some flexibility, given the limitations of virtual interactions and similar constraints. The US government is now winding down COVID-19 emergency measures and product authorisations, and has issued guidance on the disposition of products authorised for emergency use during the pandemic. In addition, the HHS has issued a fact sheet providing a "roadmap" for transitioning from the COVID-19 public health emergency.

11.2 Special Measures Relating to Clinical Trials

Under the HHS roadmap for transitioning from COVID-19, certain FDA pandemic-related guidance documents have been withdrawn and others temporarily extended. The FDA is addressing which policies are no longer needed and which should be continued (with any appropriate changes) to further facilitate clinical research without undue risk.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

The FDA utilised existing powers to permit unapproved medical products or approved medical products for unapproved uses to be manufactured and distributed under specific conditions and labelling during the period of a declared pandemic or other health emergency. The FDA issued hundreds of such Emergency Use Authorisations for pandemic-related therapeutics, devices, diagnostics and vaccines, and is now winding down such authorisations and overseeing the disposition of products authorised during the emergency (see **11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices**).

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

The FDA does not provide separate certifications for manufacturing, but rather inspects facilities both prior to product approval/licensure and then on a periodic or for-cause basis (see **4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices**). The FDA faced considerable difficulties in accomplishing inspections during the COVID-19 emergency and had been relying largely on record reviews and other measures where inspections were deemed too risky in light of the pandemic. This resulted in delays in

approval of products and supplements in certain cases.

The FDA has been working to catch up on this backlog of inspections, supplementing these efforts with certain tools that proved useful during the pandemic. In particular, the FDA recently issued a revised draft guidance on remote regulatory assessments that permit certain inspections to be conducted entirely remotely without FDA staff being present.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

Although certain emergency measures were initially taken with regard to the export of protective equipment and vaccines, the Biden Administration modified those policies to focus on ensuring an adequate US supply of vaccines and diagnostics, with a selective use of the Defence Production Act (DPA), which put the US government at the "front of the line" as a customer. Since the end of the pandemic emergency, the legislative and regulatory debate has shifted to more general pandemic preparedness and ensuring a more secure and domestic supply chain for products that are needed during an emergency.

11.6 Drivers for Digital Health Innovation Due to COVID-19

There was extensive relaxation of limitations on virtual and telemedicine interactions during the pandemic, as well as policies fostering the use of digital devices to address public health needs during the pandemic. As noted, this has had a significant impact on innovation in clinical trial conduct, use of digital health tools, and telemedicine (among other areas), and many such regulatory innovations are being retained in the post-pandemic setting, with appropriate modifications.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

Under the Bayh-Dole Act, the US government has very limited "march-in" rights with regard to IP licensed from the government. To date, despite some controversies concerning the use of government IP (as well as pressures due to COVID-19 and product pricing generally), this authority has not been utilised despite multiple petitions for march-ins with regard to specific drugs.

However, the Biden Administration's National Institute of Standards and Technology (NIST) recently proposed a new framework for march-in decisions under Bayh-Dole that would directly consider pricing as a factor. The proposal has been widely criticised as undermining the goals of the statute and introducing extra-statutory criteria into these decisions.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

The 2005 Public Readiness and Emergency Preparedness (PREP) Act, which has been invoked in a declaration in the case of COVID-19, provides immunity for the manufacture, testing, development, distribution, administration and use of specific covered countermeasures against threats such as COVID-19. Individuals who suffer injuries from the administration or use of products covered by the PREP Act's immunity provisions may seek redress from the Countermeasures Injury Compensation Program (CICP), which is administered by the Health Resources and Services Administration.

Immunity protections are broad and contrary state and local laws and rulings are widely preempted. In practice, the only time a manufacturer of a COVID-19 countermeasure would not benefit from PREP Act immunity would be if a

suit were brought in the US District Court for the District of Columbia by a plaintiff who has:

- suffered a serious injury or death;
- rejected a payment from the fund; and
- demonstrated by clear and convincing evidence that the manufacturer engaged in "wilful misconduct" (as defined in the statute).

With the end of the public health emergency, the HHS has amended its PREP Act declaration to continue to apply protections until 31 December 2024 to:

- any activities related to a federal agreement for administration of medical countermeasures or vaccines, treatments and tests procured by the federal government;
- the manufacturing, distribution, administration and use of licensed COVID-19 vaccines, approved or cleared in vitro diagnostics and other devices, National Institute for Occupational Safety and Health-approved respiratory protection devices, and all products under Emergency Use Authorisation, regardless of any federal agreement or emergency declaration; and
- authorise pharmacists to continue to administer COVID-19 and seasonal influenza vaccines to individuals aged three and above and to order and administer COVID-19 tests in accordance with an FDA licence, approval, or authorisation.

11.9 Requisition or Conversion of Manufacturing Sites

Existing provisions were used and new ones introduced to allow the requisition or conversion of manufacturing resources owing to COVID-19. The DPA is the primary source of Presidential powers to expedite and expand the supply of materials and services from the US industrial base, including for certain emergency preparedness activities and the protection or restoration of critical infrastructure. These authorities have been invoked with regard to certain diagnostic devices, personal protection equipment, and vaccine production capacity in the USA. In other cases, the US government has funded the development of additional production capacity, such as for vaccine vials.

Under the DPA, the government can impose "rated" or "priority orders" – pursuant to which, the President may compel companies to accept and prioritise contracts for supplies critical to national defence. These orders also flow down the recipient's supply chain, such that subcontractors or suppliers must also prioritise the rated order over competing obligations. The government can also impose "allocation orders" to compel industry, on a proportional basis, to allocate resources – for example, by reserving manufacturing capability or supplies in anticipation of a rated order or by allocating manufacturing capability to a particular purpose. Failure to comply with a DPA order carries a criminal penalty.

Post-pandemic, the Biden Administration's focus is on using authorities to restore the manufacturing of essential medicines in the USA and mitigate supply chain issues and drug shortages.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

As noted throughout **11. COVID-19 and Life Sciences**, the US government has used a wide variety of public procurement and funding strategies for needed medical countermeasures during the pandemic. Many of these have been unprecedented and based upon emergency authorities, and some are being further considered and retained post-pandemic.

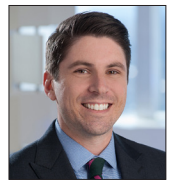
Trends and Developments

Contributed by:
David McIntosh, Matt Byron, Jianing (Jenny) Zhang, Ryan Kramer and Lauren Kimmel
Ropes & Gray LLP

Ropes & Gray LLP is home to one of the world's pre-eminent life sciences groups, with a global platform for innovators at every stage of the development lifecycle. The firm's collaborative approach spanning more than 25 practice areas and touching all offices around the world offers one of the largest and most experienced industry-specific teams, comprised of more than 300 lawyers, subject matter experts and technical advisors, who deliver sophisticated transactional, regulatory, IP, and litigation and enforcement strategies to position industry innovators and investors for success. Ropes & Gray is sought after to lead clients in navigating the complex legal landscape in which the life sciences industry operates.

Authors

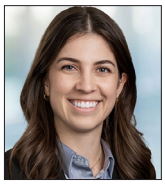
David McIntosh is a partner in Ropes & Gray's life sciences and intellectual property transactions practice groups. Recognised by Chambers and other industry publications as a leading practitioner in his field, David advises a wide range of companies, investors, and institutions in the life sciences industry in strategic transactions involving intellectual property, with a particular focus on strategic collaborations, technology licensing, mergers and acquisitions, joint ventures, supply and distribution arrangements, and co-promotion and marketing agreements. David is an active member of the Licensing Executive Society (LES), and recently presented during their annual meeting. David has led recent transactions for Avidity Biosciences, ImmunoGen, HotSpot Therapeutics, Adaptimmune Therapeutics, Takeda Pharmaceuticals, and The Broad Institute.



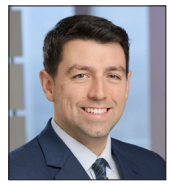
Matt Byron is a partner in Ropes & Gray's strategic M&A group and focuses his practice on representing public and private companies as well as private equity sponsors in a broad range of life sciences transactions, including large cap and middle market acquisitions, divestitures, joint ventures and collaborations. Matt has led recent transactions for Janssen Pharmaceuticals, Vertex Pharmaceuticals, Ginkgo Bioworks, DePuy Synthes, Fibrogen and Biogen.

Contributed by: David McIntosh, Matt Byron, Jianing (Jenny) Zhang, Ryan Kramer and Lauren Kimmel,
Ropes & Gray LLP

Jianing (Jenny) Zhang is an associate in Ropes & Gray LLP's strategic transactions group, with a focus on IP transactions in the life sciences and technology industries. She has experience in licensing, collaborations, venture capital, and M&A deals, with a range of clients in the life sciences sector and academic research institutes. While at Harvard Law School, Jenny was heavily involved with the Harvard Journal of Law & Technology. She also advised start-up companies on corporate and IP matters with the Harvard Law Entrepreneurship Project.



Lauren Kimmel is an associate in Ropes & Gray's strategic transactions group. During law school, Lauren was an editor for the Michigan Law Review and president of the Intellectual Property Students Association. She was a legal intern for the US Food and Drug Administration's Office of Regulatory Policy and Office of Orphan Products Development. Prior to law school, Lauren worked as a researcher with a focus on orphan drug policy and opioid prescribing limits. She has publications in Health Affairs, Pediatrics, and JAMA Surgery.



Ryan Kramer is an associate in Ropes & Gray LLP's strategic transactions group, with a focus on IP transactions in the life sciences and technology industries. Ryan's experience in the industry predates his career as an attorney, where as an undergraduate, he majored in Neuroscience and Medicine, Health & Society and worked as a research assistant in the Vanderbilt University Institute of Imaging Science. During law school, Ryan served as the networking director for the Health Law Association and worked as a research assistant focusing on consumer protection and privacy law.

Contributed by: David McIntosh, Matt Byron, Jianing (Jenny) Zhang, Ryan Kramer and Lauren Kimmel,
Ropes & Gray LLP

Ropes & Gray LLP

Prudential Tower
800 Boylston Street
Boston
MA 02199-3600
USA

Tel: +1 617 951 7000
Fax: +1 617 951 7050
Email: Ashley.Ocvirk@ropesgray.com
Web: www.ropesgray.com

Introduction

The life sciences industry experienced a turning point in 2022 after robust deal activity in the two prior years. The persistent effects of high inflation and a sluggish public market for biotech stocks carried into 2023, forcing many companies to engage in strategic and often distressed deal making to preserve and obtain working capital. Toward the end of 2023, however, deal activity in the life sciences industry showed increasing signs of renewed life, with both an active middle market for M&A deal making and a modest uptick in IPOs and follow-on opportunities in the public equity markets for biotech companies. Barring additional headwinds, this rebound is expected to continue in 2024. This article will take a deep dive into the trends that shaped the life sciences industry in 2023 and that will shape it in 2024.

Market Trends

The year 2023 was one of gradual recovery for the life sciences industry. Market activity generally bounced back to pre-pandemic levels, though still not close to the biotech market exuberance seen in 2021. According to Stifel, annualised 2023 IPO volume as of November reached USD11 billion, compared to USD7 billion in 2022 and USD27 billion in 2021. Life sciences IPOs increased in the third quarter with eight IPOs together raising USD1.1 billion, compared to only three life sciences IPOs in the first half of the year. Follow-on offerings also gained momentum in the second half of the year, giving life sciences companies much-needed capital for deal making and R&D. This general upward trend is likely to continue in 2024, as there is a two-year backlog of biotech companies queued up to go public and an expectation that interest rates will begin to fall. Although 2023 public market activity reached pre-pandemic levels and may continue to rebound, experts are not predicting a return to the record-breaking market activity of 2021.

Historically, biotech companies have not had broad access to debt financing. Therefore, biotech companies are not typically viewed as at risk of bankruptcy. However, low interest rates in 2021 motivated many biotech companies to take on debt, and debt financing became more popular than it had previously been in the life sciences industry. As interest rates rose throughout 2022, debt financing in the life sciences industry pulled back in response, and that trend remained steady through 2023. The unusually

high rate of debt financing in 2021 culminated in 41 bankruptcies in the life sciences industry in 2023. By comparison, there were only 20 such bankruptcies in 2022 and nine in 2021, according to BioSpace. It is possible that this increase in biotech bankruptcies will continue in 2024, as valuations, equity financing, and other deal-making activity continue to be suppressed.

Venture investment into therapeutics totalled USD17 billion across 350 rounds in 2023, according to data from JP Morgan. Further, across all sectors, down rounds and flat rounds were more prevalent in 2023 than previous years. These depressed valuations could reflect a sluggish market, or they could represent a recalibration from overzealous 2021 fundraising. If the life sciences sector of the public markets continues to struggle, with few biotech IPOs, venture equity investors will likely remain cautious about their current investment portfolios and consider alternative exit strategies. Despite cautious investors, life sciences venture capital funds raised over USD20 billion in 2023, on pace with 2022 and higher than pre-pandemic rates. Because venture investors are sitting on a stockpile of cash, many expect investment in biotech companies to increase in 2024. Furthermore, if the life sciences sector of the public equity market continues to rebound, venture investment can be expected to increase as well.

Deal-Making Trends

Life sciences deal-making continues apace

Life sciences M&A transactions were higher in 2023 compared to 2022. Although the year started slowly in January and February, March through June saw steady deal activity, at which point experts began projecting that 2023 could be the biggest M&A year since 2019. The excitement dwindled, however, as the deal market slowed through the rest of the summer, culminating in a nearly dead market by late September. Optimists have pointed out that a large number of biotech companies announced that they were exploring "strategic alternatives" in the third quarter, speculating that a new deal surge could be on the horizon. The data for October and November 2023 proved that speculation to be prescient, as life sciences M&A deal volume got back on track for a year similar to 2021, according to Stifel.

There is reason to believe that life sciences M&A activity will continue apace. It is reported that the top 18 pharmaceutical companies had over USD500 billion in "firepower" (a metric used to determine a company's potential capital resources) available to fund transactions compared to USD411 billion in October 2020. Given the abundance of biotech companies exploring "strategic alternatives," significantly increased firepower in the industry, and the high volume of bankruptcy filings, there is promise that 2024 will continue to see an uptick in M&A deals as the "haves" seek to take advantage of the "have-nots".

Smaller deals lead the way amid shifting FTC scrutiny

In 2023, large pharmaceutical companies focused on pursuing a series of smaller deals or "bolt-ons" rather than "mega" deals valued over USD1 billion. In the first half of 2023, M&A sellers mostly consisted of small-cap public biotech companies and private sellers. According to PwC, the proportion of M&A mega deals declined 56% since 2021's record high, while M&A deals with values less than USD1 billion declined only 20%.

Within this trend, it was also possible to see a rebound in transactions reminiscent of a bygone era, including the rare "merger of equals" of biotechnology companies, in which two pre-

Contributed by: David McIntosh, Matt Byron, Jianing (Jenny) Zhang, Ryan Kramer and Lauren Kimmel,
Ropes & Gray LLP

revenue development-stage biotech companies combine their operations to leverage economies of scale and preserve cash. For example, in July, TCR² Therapeutics and Adaptimmune, both of which develop T-cell-focused drugs, reduced their headcounts to reduce cash burn and announced they would combine into one company for strategic purposes and to extend each company's cash runway. Similarly, 2023 saw an increase in so-called "reverse mergers", in which a private biotechnology company that had struggled to complete a conventional IPO instead "goes public" by merging with a dormant public company with cash on its balance sheet and no active development programme. For example, Korro Bio recently merged into the publicly listed Frequency Therapeutics, which had recently shut down its lead programme and laid off about half of its staff. This merger gave Korro access to public markets without undergoing a traditional IPO.

One potential reason for this trend toward smaller deals is a recent shift in the approach and activity of the Federal Trade Commission (FTC). In 2023, the FTC brought two high-profile enforcement actions: one against Amgen's USD28.3 billion acquisition of Horizon Therapeutics and the other against Pfizer's USD43 billion acquisition of Seagen. In both cases, the FTC explored non-traditional theories of harm. The FTC has departed from the traditional theories of competitive overlap to focus on pricing power as a major concern even when overlap is minimal, such as in the Pfizer-Seagen deal. Considering that transacting parties often use precedent to guide deal making, the possibility of non-traditional theories of harm has led to more uncertainty.

In addition to increasing enforcement activity, the FTC has proposed changes to the Hart-Scott-Rodino (HSR) Premerger Notification Form, which will greatly impact deal pace and compliance efforts. For transactions with a deal value above a certain value threshold, the proposed changes will require companies to produce a much broader spectrum of documents, data, and information than was previously required. It is expected that HSR notifications using the revised form will take four times as long as it used to, turning a weeks-long process into a months-long process.

This trend towards smaller transactions has root causes beyond aggressive FTC scrutiny. Commentators have speculated that smaller deals may be favoured because larger companies with extensive operations and operating expenses are more difficult to efficiently integrate without losing shareholder value. To this end, many of the smaller deals completed in the current market involve targets with only pre-commercial products, which often require a less intensive integration effort. While acquiring revenue-generating businesses is still of paramount importance for large pharmaceutical companies, in recent years, acquirors have increased their focus on acquisitions of companies with pre-commercial products at an early/mid-stage of development. These R&D acquisitions augment a large pharmaceutical company's pipeline through M&A deal making, which can prove to be both cheaper, and result in higher quality therapies, than internal R&D efforts.

Divestitures, spin-outs and licensing

Another factor contributing to the slight uptick in M&A activity is an increase in companies that have strategically engaged in divestitures. Large pharmaceutical companies have strategically divested assets to free up capital to invest in core focus areas and refinance the development of non-core assets. For example, Merck, GSK,

and Novartis divested their consumer groups in recent years. After completing these divestitures, all three companies completed large acquisitions, as Merck acquired Prometheus for USD10.8 billion, GSK acquired Bellus for USD2 billion, and Novartis acquired Chinook for USD3.2 billion. J&J recently spun off its consumer group and now has an additional USD13.2 billion of capital from the spin-off company's IPO.

There has also been an increased volume of spin-outs to new companies ("NewCos") backed by investors. For example, Cyclerion Therapeutics sold its sGC stimulator assets to a NewCo in exchange for cash and equity ownership. Investors in the NewCo agreed to invest USD81 million to develop the assets, and Cyclerion received a cash payment at closing and 10% equity ownership in the NewCo. Investors in the Newco included current Cyclerion shareholders as well as Venrock, J Wood Capital, and Sanofi Ventures. Other companies have announced similar spin-outs. For example, Endonovo agreed to sell their medical device assets to a NewCo to be controlled by Endonovo's current President and the Chief Commercial Officer of its medical division.

Licensing deal volume continued to decline in 2023 from a slow 2022. According to Stifel, the number of life sciences sector licensing and partnership deals with up-fronts of USD100 million or more annualised in 2023 is 20, compared to 23 in 2022, 37 in 2021 and 35 in 2020. There were only 113 life sciences R&D licensing agreements signed in the third quarter of 2023, the lowest quarter since 2018, according to JP Morgan. The volume of in-licence deals in the preclinical, Phase 1, Phase 2 and Phase 3 stages has remained steady, while volume at the platform and discovery stage saw a drop in 2023.

Creative deal-making

With a down market, depressed valuations, and high interest rates, life sciences companies have been turning to creative deal making to obtain capital. One way to do that, while aligning with partners with synergistic capabilities in key markets, is by out-licensing products in split territory deals. These transactions are typically executed after receipt of proof-of-concept data to share the costs of expensive later-stage clinical development. Similarly, biotech companies have pursued out-licenses of non-core assets to extend cash runways.

Another trend in creative deal making by biotech companies has been contracting with private equity investors. Typically, health care private equity firms focus on areas of the industry with steady cash flow, such as patient care. However, private equity investors have recently capitalised on the widening gap between available capital for clinical research and the drug candidates competing for funding, resulting in a steady rise in private equity funding in this sector. Private equity investors have shown particular interest in financing R&D when the candidate is in Phase 3 clinical trials in return for up-front payments and success-based payments, typically milestones and royalty payments.

The Role of AI in Life Sciences

While life sciences companies have been seeking short-term cashflow in 2023, these businesses have also been investing in their future by the increased use of AI. Breakthroughs in 2023 in large language models, such as GPT-4, are reshaping human-computer interactions and once again catapulting artificial intelligence and machine learning (AI/ML) into the mainstream. The Food and Drug Administration (FDA) published an initial paper on AI/ML in May 2023, noting that AI/ML will undoubtedly play a critical

role in drug development, and the FDA plans to develop and adopt a flexible, risk-based regulatory framework that promotes innovation and protects patient safety. Thus far in 2023, the median up-front cash and equity for AI/ML-based drug discovery licensing deals was double that of 2022, making it comparable to 2021 medians. However, AI deal volume is down, as there were only 30 deals in in the first three quarters of 2023 compared to 80 total in 2022, as reported by JP Morgan.

One would expect investment in AI to continue to grow in 2024. In 2022, Morgan Stanley estimated that over the next decade, the use of AI in early-stage drug development could translate into an additional 50 novel therapies worth more than USD50 billion in sales. According to a comprehensive report published by the Boston Consulting Group, AI was most frequently applied to understanding diseases and small molecule design and optimisation from 2018 to 2022. Design and optimisation of vaccines and antibodies have recently accelerated rapidly, driven in part by research efforts in the context of the COVID-19 pandemic. Use of AI in biologics development is also growing, driven by increasing sophistication of AI technology and algorithms, maturing computing power, increasing availability of data, and evolving discovery work-flows. Safety and toxicity use cases has also shown budding growth, which may be driven by the lack of publicly available data to train AI models.

Obesity Drug Development

A final 2023 trend that is likely to continue is investment in drugs and other treatments for obesity, following on the recent blockbuster success of obesity drugs. Companies are also testing obesity drugs for other indications, including Type II diabetes with chronic kidney disease, Alzheimer's disease, and alcohol addiction. There is a large market opportunity for obesity drugs because patients need them for a long period of time, and the cost of the drug often outweighs the potential cost of the long-term health effects of obesity-related diseases. Therefore, increased payor support in addition to increased consumer demand is likely to carry interest in obesity drug development well beyond 2023.

The Effects of the Inflation Reduction Act and Other Regulatory Matters

The Inflation Reduction Act (IRA) continues to be very impactful on the biopharmaceutical industry and a few trends have emerged in response to the IRA. The IRA authorises the United States Department of Health and Human Services (HHS) to negotiate prices for selected drugs that are high expenditure, single source drugs without generic or biosimilar competition. The first group of drugs were selected for price negotiations in 2023 and the negotiated prices will apply from 2026. The IRA has reportedly had a negative impact on R&D spending and deal valuations, as biopharmaceutical companies must anticipate lower returns for investments in innovative therapies.

Single-indication, rare disease assets are unlikely to be subject to IRA price negotiations, and therefore have attracted the interest of deal makers. For example, there is a great volume of deal activity surrounding antibody drug conjugates (ADCs), which are designed to target a specific type of cancer, as ADCs target specific proteins expressed on specific cancer cells and are not designed to be used across multiple indications. This means they are unlikely to be top-selling drugs that the HHS will eventually select for IRA price negotiations. The number of ADCs in Phase 2 clinical trials has increased in the last few years, and there has already been increased

deal activity surrounding ADCs. Just recently, AbbVie agreed to purchase ImmunoGen, a biotech company focused on the development of ADCs, for USD10.1 billion, making it the third largest biopharmaceutical M&A transaction announced this year, trailing Pfizer's proposed USD43 billion acquisition of Seagen, another big player in the ADC space, and Merck's USD10.8 billion acquisition of Prometheus.

Additionally, the European Commission has proposed shortening the period of regulatory exclusivity from ten years to eight years for medicines sold in the EU. Under the proposal, companies could extend their period of regulatory exclusivity if they market their product in all EU member states, the product is directed to diseases with unmet need, they conduct comparative trials, or they market drugs that treat multiple diseases. Industry participants with a global reach have protested, emphasising that the end of the exclusivity is the period of peak sales, and is the only real opportunity to recoup investment in R&D, marketing and sales. Similar to the effect of the IRA, this shortened market exclusivity would likely reduce the amount US companies and investors are willing to invest in researching, developing, and commercialising products in Europe.

Conclusion

After the significant downturn in the life sciences industry in 2022, 2023 saw a slow rebound that appears to be accelerating. While high interest rates and other macroeconomic activity seemed to inhibit deal activity through 2023, there are increasing signs of robust M&A and licensing activity in early 2024. With an improving public equity market for biotechs, and large pharmaceutical companies and VC funds sitting on significant cash and "firepower," the life sciences industry has the potential to overcome headwinds like the increased FTC scrutiny, the IRA and similar government action designed to curb drug prices, as well as persistently high interest rates. While the life sciences industry in 2024 is not expected to return to the exuberance of 2021, there is reason to think there could be significant improvement in deal-making activity and value creation in 2024 as compared to 2023 and 2022.

CHAMBERS GLOBAL PRACTICE GUIDES

Chambers Global Practice Guides bring you up-to-date, expert legal commentary on the main practice areas from around the globe. Focusing on the practical legal issues affecting businesses, the guides enable readers to compare legislation and procedure and read trend forecasts from legal experts from across key jurisdictions.

To find out more information about how we select contributors, email Katie.Burrington@chambers.com