Life Sciences 2021

Contributing editor
Alexander Ehlers

LEXOLOGY
Getting The Deal Through

Publisher
Tom Barnes
tom.barnes@lbresearch.com

Subscriptions
Claire Bagnall
claire.bagnall@lbresearch.com

Senior business development manager
Adam Sargent
adam.sargent@gettingthedealthrough.com

Published by
Law Business Research Ltd
Meridian House, 34-35 Farringdon Street
London, EC4A 4HL, UK

First published 2009
Twelfth edition
ISBN 978-1-83862-360-9

Printed and distributed by
Encompass Print Solutions
Tel: 0844 2480 112

Life Sciences
2021

Contributing editor
Alexander Ehlers
Ehlers, Ehlers & Partner

Lexology Getting The Deal Through is delighted to publish the twelfth edition of *Life Sciences*, which is available in print and online at www.lexology.com/gtdt.

Lexology Getting The Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique Lexology Getting The Deal Through format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes new chapters on Canada, China, the European Union, Israel, and South Korea.

Lexology Getting The Deal Through titles are published annually in print. Please ensure you are referring to the latest edition or to the online version at www.lexology.com/gtdt.

Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Lexology Getting The Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to the contributing editor, Alexander Ehlers of Ehlers, Ehlers & Partner, for his continued assistance with this volume.

LEXOLOGY
Getting The Deal Through

London
November 2020

Reproduced with permission from Law Business Research Ltd
This article was first published in December 2020
For further information please contact editorial@gettingthedealthrough.com

Contents

Global overview 3
Alexander Ehlers
Ehlers, Ehlers & Partner

Canada 4
Sara Zborovski and Ian Trimble
Stikeman Elliott LLP

China 10
Cindy Hu and Jason Gong
East & Concord Partners

European Union 15
Annabelle Bruyndonckx, Jérémie Doornaert, Vladimir Murovec and Koen Platteau
Simmons & Simmons LLP

Germany 23
Alexander Ehlers and Julian Bartholomä
Ehlers, Ehlers & Partner

Ireland 31
Kate McKenna, Maria Kennedy and Emma Doherty
Matheson

Israel 37
Dovev Apel and Katia Leokumovich
S Horowitz & Co

Italy 43
Laura Opilio and Maria Letizia Patania
CMS Italy

Japan 51
Junichi Kondo, Yoshikazu Iwase, Yoshinori Aoyagi and Saori Ikeda
Anderson Mōri & Tomotsune

Mexico 57
Alejandro Luna and Erwin Cruz
OLIVARES

Netherlands 65
Hein Van den Bos and Petra den Boer
Hogan Lovells

New Zealand 72
Robert Andrew Bycroft and Tina Liu
Tompkins Wake

Serbia 78
Bogdan Ivanišević and Bisera Andrijašević
BDK Advokati

Singapore 84
Tony Yeo and Benjamin Gaw
Drew & Napier LLC

South Korea 92
Keum Nang Park, Eun Kyoung Lyu and Hyun Ah Song
Lee & Ko

Sweden 98
Camilla Appelgren Mannheimer Swartling
Odd Swarting Cirio

Switzerland 105
Frank Scherrer and Dominique Roos
Wenger & Vieli Ltd

Turkey 111
Özge Atılgan Karakulak and Dicle Doğan
Gün + Partners

Serbia

Bogdan Ivanišević and Bisera Andrijašević
BDK Advokati

ORGANISATION AND FINANCING OF HEALTHCARE

Organisation

1 | How is healthcare in your jurisdiction organised?

The Serbian healthcare system aims to provide universal healthcare, guaranteed by article 68 of the Serbian Constitution. Regulation and provision of healthcare is within the competence of the central government, but local self-government authorities also have certain powers related to the organisation and provision of healthcare. The healthcare system in Serbia comprises public healthcare institutions, higher education healthcare institutions and other institutions established by special laws to perform healthcare services, private practice, health workers and associates, as well as the organisation and financing of healthcare. The public healthcare network is organised and governed by three main institutions:

- the Ministry of Health: in charge of policymaking, standards' adoption and quality control;
- the Institute for Public Health: tasked with the collection and analysis of public health data and the proposal of relevant measures; and
- the National Health Insurance Fund (NHIF): competent for healthcare financing at every level.

Financing

2 | How is the healthcare system financed in the outpatient and inpatient sectors?

Serbia has a mixed system of healthcare financing, with compulsory and voluntary health insurance. The contributions for the compulsory health insurance paid to the NHIF account for more than 90 per cent of the financing of medical care in both outpatient and inpatient sectors. At the same time, the Constitution provides that children, women during pregnancy and maternity leave, single parents with children up to the age of seven and the elderly are entitled to healthcare financed from the state budget. The Healthcare Act 2019 identifies additional vulnerable groups with respect to which healthcare is financed from the budget. People with disabilities, certain serious diseases, the uninsured, Roma, refugees, displaced persons, and victims of domestic violence, terrorism or trafficking, are classed as among these vulnerable groups.

Compulsory health insurance contributions are charged in the form of a premium levied on employees' salaries. The employer and the employee contribute in equal parts. The Health Insurance Act 2019 also requests from other groups, such as entrepreneurs, artists and farmers, to pay mandatory contributions. The NHIF allocates the funds to healthcare institutions based on contracts, which are usually entered into for a period of one calendar year.

The percentage of expenses paid by the citizens 'out-of-pocket' is very high. According to the World Health Organization, Serbia's total health expenditure in 2014 was 10.4 per cent of gross domestic product, out of which about 40 per cent was 'out-of-pocket' expenditure.

Basic structures

3 | What are the basic structures of the provision of care to patients in statutory and private care?

Public healthcare institutions may be established as:

- community health centre;
- polyclinic;
- pharmacy;
- hospital (general and specialised);
- healthcare centre;
- health office;
- public health office;
- clinic;
- institute;
- clinical-hospital centre;
- university medical centre; and
- military health institution or a medical corps unit and institution of the Serbian armed forces, in line with a special law.

Within the scope of statutory care, public healthcare institutions provide public healthcare services at three functional levels:

- at the primary level, services are provided by state-owned primary healthcare institutions (clinics, primary health centres, pharmacies and health offices), established for the territory of one or more municipalities or towns;
- at the secondary level, general and specialised hospitals provide stationary and specialist consultation services; and
- at the tertiary level, hospital medical centres, clinics, institutes and university medical centres provide the highly specialised healthcare services.

Different health offices provide healthcare services on all three levels. Under the Healthcare Act 2019, public healthcare institutions may also be established upon the law governing public-private partnerships.

Private practice entities may be established as any of the following:

- medical practice (general, specialist and subspecialist);
- dental medicine practice (general and specialist);
- health centre;
- laboratory;
- pharmacy;
- clinic (for healthcare and rehabilitation); or
- dental laboratory.

Both public and private healthcare entities must be registered within the Unique Healthcare Registry kept by the Serbian Business Registers Agency.

HEALTHCARE SERVICES

Authorisation

4 What steps are necessary to authorise the provision of health services, and what law governs this?

The Healthcare Act 2019 lays down conditions for the establishment of entities for the provision of healthcare services. Public healthcare institutions may be established by the Serbian government, an autonomous province, or a local self-governing authority, in line with a healthcare institution network plan to be adopted by the government. A private practice may be established by either an unemployed or retired health worker under the conditions prescribed by the Healthcare Act 2019.

Both healthcare institutions and private practice may provide services if the Ministry of Health confirms in a decision that the prescribed conditions for their provision related to staff, equipment, premises, medicinal products and medical devices have been met. The decision on the fulfilment of these conditions is adopted by a healthcare inspector, and applicants may file an appeal to the Minister. Based on the fulfilment decision of the prescribed conditions, founders of a healthcare institution or private practice may register it before the Serbian Business Registers Agency.

Structure

5 Which types of legal entities can offer healthcare services?

Public healthcare institutions may be established as:

- community health centre;
- polyclinic;
- pharmacy;
- hospital (general and specialised);
- healthcare centre;
- health office;
- public health office;
- clinic;
- institute;
- clinical-hospital centre;
- university medical centre; and
- military health institution or a medical corps unit and institution of the Serbian armed forces, in line with a special law.

Within the scope of statutory care, public healthcare institutions provide public healthcare services at three functional levels:

- at the primary level, services are provided by state-owned primary healthcare institutions (clinics, primary health centres, pharmacies and health offices), established for the territory of one or more municipalities or towns;
- at the secondary level, general and specialised hospitals provide stationary and specialist consultation services; and
- at the tertiary level, hospital medical centres, clinics, institutes and university medical centres provide the highly specialised healthcare services.

Different health offices provide healthcare services on all three levels. Under the Healthcare Act 2019, public healthcare institutions may also be established upon the law governing public-private partnerships.

Private practice entities may be established as any of the following:

- medical practice (general, specialist and subspecialist);
- dental medicine practice (general and specialist);
- health centre;
- laboratory;
- pharmacy;
- clinic (for healthcare and rehabilitation); or
- dental laboratory.

Both public and private healthcare entities must be registered within the Unique Healthcare Registry kept by the Serbian Business Registers Agency.

Services of foreign companies

6 What further steps are necessary for foreign companies to offer health services?

Foreign companies must have a registered seat in Serbia to offer health services. They are subject to the same requirements as national legal entities regarding the fulfilment of conditions for the provision of services, obtaining of approval from the Ministry of Health and registration in the Business Registers Agency.

ADVERTISING

Legislation

7 Which legislation governs advertising of medicinal products to healthcare professionals?

Advertising of medicinal products is regulated by:

- the Medicines and Medical Devices Act 2010, available at https://www.alims.gov.rs/eng/regulations/law-on-medicines-and-medical-devices/; and
- the Rulebook on the Manner of Advertising of Medicines and Medical Devices 2010 (the Rulebook on Advertising).

In addition, the Serbian Association of Manufacturers of Innovative Drugs (INOVIA), currently composed of 17 pharmaceutical companies doing business in Serbia, adopted in 2014 the Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (the INOVIA Code on Promotion and Interactions). The Code is binding on the member companies. INOVIA is a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA). The Code is based on EFPIA's Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals.

Main principles

8 What are the main rules and principles applying to advertising of medicinal products aimed at healthcare professionals?

The use of any promotional material aimed at healthcare professionals (HCPs) must be previously approved by the Medicines and Medical Devices Agency. The material must be labelled 'Professional public only'. Promotion of a medicinal product to the professional public must include the basic information about the product contained in the marketing authorisation. Information provided to HCPs must be accurate, up to date, verifiable and sufficiently complete to allow the HCPs to assess the therapeutic value of a medicine. If a pharmaceutical company is introducing a new medicine on the market, the company may accompany the information about the medicine with one smallest available packaging of the medicine with the disclaimer 'Free sample, not for sale'. The Rulebook on Advertising prohibits any encouragement of HCPs to prescribe, issue, order or recommend the medicine's use or purchase through offering, giving or promising money or any other form of benefit.

The Healthcare Act 2019 provides that HCPs may not accept money or gifts, except for small non-monetary gifts each valued at less than 5 per cent of the average Serbian monthly net salary or in the aggregate value not exceeding an average monthly net salary. It remains unclear whether the aggregate value of permitted gifts is calculated in relation to a single gift provider and single gift occasion, or in relation to all gifts received in a particular period (the reference period, if relevant, is not specified).

The INOVIA Code on Promotion and Interactions sets the monetary limit on value of informational or educational material provided to HPCs at €30.

The Rulebook on Advertising allows for the sponsorship of professional events. At the same time, the Rulebook on Advertising prohibits companies to ask for, and HCPs to provide, any material or non-material benefit as a consideration for the sponsorship. Likewise, the Rulebook on Advertising prohibits the sponsor to affect the content of the event. Companies may sponsor professional events only up to the amount needed to cover the necessary costs of travel, accommodation and participation in the event, and only for the duration of the event, including two days for travel. The Rulebook on Advertising also requires all pharmaceutical companies to publish information on their websites about all professional events they have sponsored in the current and previous year, including the amount of funds used for those purposes. The INOVIA Code on Promotion and Interactions prohibits companies from providing or offering to HCPs any food and beverages exceeding €50. The company sponsoring or organising an event may not offer accommodation in five-star hotels.

Advertising of medical devices

9 Is the advertising of medical devices to healthcare professionals regulated as rigorously as advertising in the pharmaceuticals sector? What are the main differences?

The Medical Devices Act 2017, available at https://www.alims.gov.rs/eng/regulations/law-on-medicines-and-medical-devices/, and the Rulebook on Advertising of a Medical Device 2018 regulate the advertising of medical devices as rigorously as with the advertising of medicinal products. There are no significant differences, because the relevant provisions on the advertising of medical devices were drafted to mirror the advertising rules on medicinal products. The INOVIA Code on Promotion and Interactions does not apply to manufacturers of medical devices.

DATA PROTECTION, PRIVACY AND DIGITISATION IN HEALTHCARE

Digitisation

10 What are the legal developments regarding digitisation in the healthcare sector and industrial networks or sales channels?

Digitisation of public healthcare sector is regulated by the E-Government Act 2018 and the Electronic Document, Electronic Identification, and Trust Services in Electronic Transactions Act 2017. The Medicines and Medical Devices Agency has enabled applicants in procedures in the field of medicines and medical devices to use e-services (eg, submit information, documents, submit requests, and schedule appointments before the authority though the e-portal on its website). The Health Documentation and Records in the Area of Health Act 2014 (as amended) provides for an electronic medical dossier, which represents an excerpt from the general medical documentation kept in electronic form for an individual patient and encompasses all health information related to the patient's long-term health. The same Act provides that the electronic medical dossier should contain information kept in health institutions, private practice and other legal persons providing healthcare service, as well as the data kept in the systems of health statistics and health insurance bodies.

Provision of digital health services

11 Which law regulates the provision of digital health services, and to what extent can such services be provided?

The provision of digital health services is not regulated in Serbia and there is no possibility at the moment to provide such services.

Authorities

12 Which authorities are responsible for compliance with data protection and privacy, and what is the applicable legislation? Have the authorities issued specific guidance or rules for data protection and privacy in the healthcare sector?

The competent authority for compliance with data protection and privacy legislation is the Commissioner for Information of Public Importance and Personal Data Protection. The main piece of legislation in this area is the Personal Data Protection Act 2018, which for the most part mimics the provision of the EU General Data Protection Regulation. To date, the Commissioner has issued no specific guidance or rules for data protection and privacy in the healthcare sector.

Requirements

13 What basic requirements are placed on healthcare providers when it comes to data protection and privacy? Is there a regular need for qualified personnel?

Healthcare providers as data controllers must comply with the obligations prescribed under the Personal Data Protection Act related to organisational, technical and staffing measures, as well as protection measures in order to ensure that data processing is performed in accordance with the law. They must appoint a data protection officer, notify data breaches to the Commissioner and the individuals and conduct a data protection impact assessment. The meaning of 'staffing measures' is unclear and is open to interpretation. Under a narrower (and more likely) interpretation, 'staffing measures' could be interpreted to mean that training is required only in those instances in which the employees cannot process data properly (ie, in compliance with the law), unless they receive prior training. Under a broader, more radical (but less likely) interpretation, 'staffing measures' could mean an obligation on the part of the data controller (and data processor) to educate on data protection matters all employees (staff) who are likely to process personal data, regardless of the degree of complexity of their data processing tasks.

Healthcare providers as data processors must maintain records of the processing activities, appoint a data protection officer, notify data breaches to the data controller and abide by the rules of cross-border transfers of personal data.

Common infringements

14 What are the most common data protection and privacy infringements committed by healthcare providers?

Healthcare providers often lack efficient mechanisms for ensuring data safety and restricting access to patients' data. In one of several similar cases, the Commissioner initiated misdemeanour proceedings in September 2017 against a medical centre that kept hard copies of patients' files without employing protective measures and accessible to ambulance visitors. As a result, patients' data was published online. Healthcare providers in some instances have shared patients' data with marketing agencies or, in the case of celebrities, with the media. There has been at least one recent case in which a hospital gave police personal data of patients suffering mental health issues, although the requesting authorities lacked a valid legal basis for the processing of the requested data.

COLLABORATION

Legislation

15 Which legislation governs the collaboration of the pharmaceutical industry with healthcare professionals? Do different rules apply regarding physicians in the outpatient and inpatient sectors?

The Medicines and Medical Devices Act 2010 and the Rulebook on the Manner of Advertising of Medicines and Medical Devices 2010 (the Rulebook on Advertising) contain the rules on the collaboration between the pharmaceutical industry and healthcare professionals (HCPs). The Serbian Association of Manufacturers of Innovative Drugs (INOVIA) has introduced further detailed rules in the Code on Promotion and Interactions. Collaboration of the pharmaceutical industry and HCPs is regulated in the same manner for the outpatient and inpatient sectors.

Collaboration with healthcare professionals

16 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with healthcare professionals?

In addition to rules on advertising and sponsorship issues, the rules on collaboration of the pharmaceutical industry with HCPs regulate sponsorships, donations and grants in support of health research, consulting and other services, as well as gifts to medical professionals.

The Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (the INOVIA Code on Promotion and Interactions) prohibits donations and grants to individual HCPs outside the sponsorship for attending professional events. Donations and grants (in cash or in kind or otherwise) to institutions, organisations or associations that are composed of HCPs or that provide healthcare or conduct research are only allowed if:

- the purpose is to support healthcare or research;
- the donor (ie, the grantor) documents and keeps on record the donation (ie, the grant); and
- the donations and grants do not amount to inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

The Code encourages companies to make information about donations and grants publicly available.

Under the Code, contracts with institutions, organisations or associations of HCPs that include the provision of HCPs' services to pharmaceutical companies are only allowed if the purpose of the services is to support healthcare or research. The payment for the services may not represent an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. It is also permitted to use HCPs as consultants and advisers for services such as speaking at and chairing meetings, participation in medical or scientific studies, clinical trials or training services, participation at advisory board meetings and participation in market research, where this participation involves remuneration or travel. These arrangements must adhere to the criteria prescribed by the INOVIA Code on Promotion and Interactions.

Pharmaceutical companies may not provide, offer or promise any gift or pecuniary advantage (in cash or benefit in kind) to HCPs.

Collaboration with patient organisations

17 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

Collaboration of the pharmaceutical industry with patient organisations is regulated only by the industry regulations within the framework of INOVIA, namely in the INOVIA Code of Practice.

The INOVIA Code of Practice is based on the following principles:

- full independence of patient organisations;
- mutual respect between the parties;
- non-promotion of prescription drugs; and
- transparency of the provision of any financial or non-financial support.

In addition, a pharmaceutical company must not seek to be the sole financier of a patient organisation or any of its main programmes.

Contracts on the basis of which patient organisations provide services to companies are allowed only for the purpose of support to healthcare or research. The contract must be signed in advance and specify, inter alia, the nature of the service to be provided, legitimate need to services, the basis and the amount of compensation. The engagement of patient organisations must not serve as inducement to recommend a medicine.

To enforce the Code of Practice, INOVIA has established national procedures and structures for the submission and processing of complaints, sanctioning of companies and publication of infringements.

Common infringements

18 What are the most common infringements committed by pharmaceutical manufacturers regarding collaboration with healthcare professionals?

The most common infringements relate to the lack of transparency. This occurs when the manufacturers fail to fully comply with the obligation under the Rulebook on Advertising to publish on their official website the up-to-date information for the current and previous year on the professional gatherings they have sponsored and the total amount of funds allocated for each sponsorship.

Collaboration on medical devices

19 Is the collaboration of manufacturers of medical devices with healthcare professionals and patient organisations regulated as rigorously as collaboration in the pharmaceuticals sector? What are the main differences?

The Medical Devices Act 2017 and the Rulebook on Advertising of a Medical Device 2018 regulate the collaboration of manufacturers of medical devices with healthcare professionals as rigorously as it is the case with collaboration in the pharmaceuticals sector. There are no significant differences. However, INOVIA codes do not apply to manufacturers of medical devices, and the collaboration between them and patient organisations is not regulated.

COMPETITION LAW

Authority enforcement

20 Are infringements of competition law by healthcare providers pursued by national authorities?

Yes. In general, the Commission for Protection of Competition (CPC), as the competent authority, pursues infringements of competition law in pharmaceutical industry and healthcare sector. However, to date, the CPC has fined no healthcare provider for infringement of competition. In 2015, the CPC initiated an investigation against Fresenius Medical Care

for suspected bid-rigging on the market for materials and services for haemodialysis, however, that procedure was terminated in 2016 owing to the lack of evidence of infringement. The CPC also initiated several procedures against pharmacies in Serbia owing to suspected restrictive market agreements of baby products.

Private enforcement

21 | Is follow-on private antitrust litigation against healthcare providers possible?

Private enforcement of competition law in Serbia is still undeveloped. Neither follow-on nor stand-alone antitrust actions are adequately regulated. Under the Protection of Competition Act, once the CPC has reached a decision on the infringement of competition, the damaged party may seek compensation of damages in a civil litigation. The CPC's decision on infringement does not create a presumption that damages resulted from the infringement, so the private plaintiff must prove damages. The plaintiff must also prove the causal link between the infringement and the damages suffered.

Serbian law does not contain adequate procedural facilities for collective redress. The existing rules on multiparty litigation are intended for few plaintiffs and are inadequate for mass litigation. The Civil Procedure Act 2011 (as amended) allows claims by qualified associations registered for protection of collective rights of a particular group (eg, consumer associations). However, the relevant rules cannot be effectively used in antitrust damage claims, because the Civil Procedure Act 2011 defines the protected group narrowly to include only individuals but not legal entities that are more likely to seek damages for antitrust infringements, and the plaintiff association cannot claim damages on behalf of the protected group.

Anti-corruption and transparency

22 | What are the main anti-corruption and transparency rules applicable to healthcare providers?

The Healthcare Act 2019 stipulates that healthcare workers or members of managing or professional bodies performing healthcare activities in a publicly owned health institution, as well as members of their immediate families, may not, for themselves or a member of their immediate family, or for natural or legal persons with whom they justifiably might be considered to have affiliated interests, ask or receive money, gifts, services, or any other benefit, which could influence the performance of their duties in an unbiased or professional manner or that could be considered as consideration for performance of their duties and provision of healthcare services.

With exception, healthcare professionals may accept small non-monetary gifts each valued at less than 5 per cent of the average Serbian monthly net salary or in the aggregate value not exceeding one month's average net salary.

In addition, the Healthcare Act 2019 stipulates that the Prevention of Corruption Act 2019 also applies to members of the managing bodies in public healthcare providers.

Additional anticorruption and transparency rules are further dispersed between various laws and implementing regulations, such as the Criminal Code of 2005 (as amended). The Criminal Code criminalises influence peddling, as well as active and passive bribery, both within the scope of commercial activity and in dealings with public officials.

PRICING AND REIMBURSEMENT

Price regulation

23 | To what extent is the market price of a medicinal product or medical device governed by law or regulation?

The pricing regime does not differ between the outpatient and inpatient sectors but depends on whether the medicine is classified as prescription only or over-the-counter. Prices of prescription-only medicines are regulated by the government. The Ministry of Health calculates the maximum wholesale price for prescription-only medicines based on a number of criteria, including the comparable wholesale prices in reference countries (ie, Croatia, Italy and Slovenia) and the current wholesale price in Serbia. The marketing authorisation holder (MAH) has the duty to obtain the relevant data and make it available to the Ministry. Marketing of a prescription-only medicine for which the government did not determine the maximum wholesale price is prohibited.

MAHs freely determine the prices of over-the-counter medicines. They must notify the Ministry before 31 March of the current year of the price for the previous year.

Negotiations between manufacturers and providers

24 | Must pharmaceutical and medical device manufacturers negotiate the prices of their products with public healthcare providers?

Pharmaceutical manufacturers do not, as a rule, negotiate prices of medicines with public healthcare providers, because the government determines the prices of prescription-only medicines. Exceptionally, negotiations take place in relation to the innovative medicines. To introduce to the Serbian market innovative medicines identified as a priority, the National Health Insurance Fund (NHIF) has set up a commission for negotiations with MAHs for the purpose of the conclusion of special managed entry agreements and their inclusion on the positive reimbursement list of medicines (the Positive List). The commission invites the MAHs to submit their offers and to negotiate on a voluntary basis the conclusion of special agreements with the NHIF. Managed entry agreements between the NHIF and the MAH may be in the form of risk-sharing, cost-sharing, volume-cap and value-cap agreements. If the NHIF and the MAH reach an agreement, the medicine is included in the Positive List.

Reimbursement

25 | In which circumstances will the national health insurance system reimburse the cost of medicines?

Serbia has a mandatory health insurance system administered by the NHIF. For the cost of medicine to be reimbursed, the medicine has to be included in the Positive List.

Medicines with a marketing authorisation in Serbia and dietetic products may be included on the Positive List. Exceptionally, medicines without marketing authorisation may also be included, if there is no medicine with the same international non-proprietary name (INN) on the market or if the medicine is intended for compassionate purposes and it is necessary in diagnostics and therapy.

Under the Rulebook on Conditions, Criteria, Manner and Procedure for Including of a Medicine on the List of Medicines, Amendments to the List of Medicines, and Removal from the List of Medicines 2014 (as amended), general criteria for adding a medicine to the Positive List are as follows:

- pharmaco-therapeutic justification of the medicine;
- pharmacoeconomic justification of the medicine; and
- financial resources provided by the NHIF's annual financial plan.

When the resources are insufficient for inclusion in the list of medicines that comply with general criteria, the NHIF further considers two special factors:

- existence, if any, of a managed entry agreement; and
- the priority for adding the medicine to the list.

The NHIF gives priority to medicines based on the following criteria:

- the lack of a medicine from the same pharmaco-therapeutic group;
- it is on the Positive List for a particular medical indication;
- the significance of a medicine for public health; and
- ethical aspects.

As a rule, the NHIF does not reimburse the costs of medicines prescribed for off-label use (ie, outside the Positive List). Serbian law does not regulate the off-label prescription of medicines. In practice, healthcare institutions prescribe medicines for off-label use where there are no other medicines on the market approved for specific therapeutic indications. The medicines are prescribed off-label on the basis of an opinion signed by a commission of three physicians.

Price adjudication

26 If applicable, what is the competent body for decisions regarding the pricing and reimbursability of medicinal products?

The competent body for decision-making regarding pricing and reimbursement of medicinal products is the National Health Insurance Fund. Reimbursability of medicines is predicated upon the presence of the medicine on the Positive List. The MAH applies for inclusion of a medicine on the Positive List to the NHIF, with the required documents. The deadline for the formal assessment of application is 30 days from the submission date.

The NHIF may request the MAH to supplement an incomplete application within 30 days from written notice to the applicant, otherwise it will reject the application. Within 10 days from receipt of a complete application, the NHIF publishes on its official website the name and address of the applicant, subject of the request and date of application. The NHIF decides on applications within:

- 90 days from the date of submission of the complete application for a generic medicine with the same INN, the same or similar pharmaceutical form with one already on the list, or for a generic medicine whose INN is not on the list or generic medicines whose INN is on the list but in a different pharmaceutical form; and
- 120 days for original or innovative medicines.

The decision is final in an administrative procedure and can be challenged in administrative judicial proceedings.

The Serbian government has laid down the criteria for the pricing of prescription-only medicinal products for human use that are granted marketing authorisation, as well as the highest prices of these medicinal products. The government determines the reimbursement price for generic and original or innovative medicines based on the wholesale price in the reference countries. The primary reference countries for Serbia are Croatia, Italy and Slovenia. Prices of over-the-counter medicines and dietary products, are decided by the MAH, which informs the Ministry of Health thereof at least once a year.

Discount

27 Are manufacturers or distributors of medicinal products statutorily obliged to give a discount to health insurance schemes or third parties?

There is no statutory obligation for manufacturers or distributors to give a discount. However, many medicines in the inpatient sector are centrally procured through a tendering procedure, with decisions taken by the NHIF, with price being the main criteria for the most favourable bid.

BDK Advokati

Bogdan Ivanišević
bogdan.ivanisevic@bdkadvokati.com

Bisera Andrijašević
bisera.andrijasevic@bdkadvokati.com

Bulevar kralja Aleksandra 28
11000 Belgrade
Serbia
Tel: +381 11 328 4212
www.bdkadvokati.com

UPDATE AND TRENDS

Key developments of the past year

28 Is there any legislation expected in the near future that will have a major impact on the current legal environment for medicines or medical devices?

There is no publicly available information on any draft legislation or other rules that will affect the regulation of pharmaceuticals and medical devices.

Coronavirus

29 What emergency legislation, relief programmes and other initiatives specific to your practice area has been implemented to address the pandemic? Have any existing government programmes, laws or regulations been amended to address these concerns? What best practices are advisable for clients?

The government of Serbia has implemented several temporary emergency measures related to medicines and medical devices for the purposes of addressing the covid-19 pandemic in Serbia.

The government had temporarily prohibited the export of medicines for human use between 17 March 2020 and 24 April 2020, except for medicines manufactured exclusively for foreign markets and medicines dispatched in transit by a foreign entity from the customs territory of Serbia.

The government had also adopted the Decree on Special Technical Requirements, Standards and Application of Medical Devices During the State of Emergency, which was in force between 24 March 2020 and 6 May 2020. The Decree laid down the conditions under which it was possible during the state of emergency, and for the purposes of combatting the epidemics and curing infected persons, to purchase and use for the treatment of patients such medicines and medical devices that were not manufactured in accordance with prescribed standards.

Finally, the Agency for Medicines and Medical Devices issued several instructions for companies related to the procedures before the Agency during and after the state of emergency.

Other titles available in this series

Acquisition Finance
Advertising & Marketing
Agribusiness
Air Transport
Anti-Corruption Regulation
Anti-Money Laundering
Appeals
Arbitration
Art Law
Asset Recovery
Automotive
Aviation Finance & Leasing
Aviation Liability
Banking Regulation
Business & Human Rights
Cartel Regulation
Class Actions
Cloud Computing
Commercial Contracts
Competition Compliance
Complex Commercial Litigation
Construction
Copyright
Corporate Governance
Corporate Immigration
Corporate Reorganisations
Cybersecurity
Data Protection & Privacy
Debt Capital Markets
Defence & Security Procurement
Dispute Resolution
Distribution & Agency
Domains & Domain Names
Dominance
Drone Regulation
e-Commerce
Electricity Regulation
Energy Disputes
Enforcement of Foreign Judgments
Environment & Climate Regulation
Equity Derivatives
Executive Compensation & Employee Benefits
Financial Services Compliance
Financial Services Litigation
Fintech
Foreign Investment Review
Franchise
Fund Management
Gaming
Gas Regulation
Government Investigations
Government Relations
Healthcare Enforcement & Litigation
Healthcare M&A
High-Yield Debt
Initial Public Offerings
Insurance & Reinsurance
Insurance Litigation
Intellectual Property & Antitrust
Investment Treaty Arbitration
Islamic Finance & Markets
Joint Ventures
Labour & Employment
Legal Privilege & Professional Secrecy
Licensing
Life Sciences
Litigation Funding
Loans & Secured Financing
Luxury & Fashion
M&A Litigation
Mediation
Merger Control
Mining
Oil Regulation
Partnerships
Patents
Pensions & Retirement Plans
Pharma & Medical Device Regulation
Pharmaceutical Antitrust
Ports & Terminals
Private Antitrust Litigation
Private Banking & Wealth Management
Private Client
Private Equity
Private M&A
Product Liability
Product Recall
Project Finance
Public M&A
Public Procurement
Public-Private Partnerships
Rail Transport
Real Estate
Real Estate M&A
Renewable Energy
Restructuring & Insolvency
Right of Publicity
Risk & Compliance Management
Securities Finance
Securities Litigation
Shareholder Activism & Engagement
Ship Finance
Shipbuilding
Shipping
Sovereign Immunity
Sports Law
State Aid
Structured Finance & Securitisation
Tax Controversy
Tax on Inbound Investment
Technology M&A
Telecoms & Media
Trade & Customs
Trademarks
Transfer Pricing
Vertical Agreements

Also available digitally

lexology.com/gtdt

an LBR business

ISBN 978-1-83862-360-9