Pharma & Medical Device Regulation 2021

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LEXOLOGY
Getting The Deal Through

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

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First published 2019
Second edition
ISBN 978-1-83862-379-1

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

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Lexology Getting The Deal Through is delighted to publish the second edition of *Pharma & Medical Device Regulation*, 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 Brazil, China, France, India, Italy and New Zealand.

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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 editors, Alexander Ehlers of Ehlers, Ehlers & Partner and Ian Dodds-Smith of Arnold & Porter Kaye Scholer LLP, for their continued assistance with this volume.

LEXOLOGY
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London
October 2020

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This article was first published in October 2020
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Serbia

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BDK Advokati

HEALTH SERVICES FRAMEWORK AND COMPETENT AUTHORITIES

Healthcare bodies

1 Describe the bodies and their responsibilities (public and private sector) concerned with the delivery of healthcare and appropriate products for treatment.

The public healthcare network comprises public healthcare institutions and private practice, and is governed by three main institutions:

- the Ministry of Health (the Ministry), in charge of policy making, standards and quality control;
- the Institute for Public Health, tasked with conducting analysis and measures related to public health; and
- the National Health Insurance Fund, competent for financing of healthcare.

Medical centres and hospitals provide public healthcare services at three functional levels. State-owned primary health centres (clinics, pharmacies and health offices) provide services at the primary level for the territory of one or more municipalities. At the secondary level, general and specialised hospitals provide inpatient and specialist consultation services. At the tertiary level, hospital medical centres provide the highly specialised healthcare services.

Competent authorities for authorisation

2 Identify the competent authorities for approval of the marketing of medicinal products and medical devices. What rules apply to deciding whether a product falls into either category or other regulated categories?

The Medicines and Medical Devices Agency (ALIMS) issues marketing authorisations, conducts registration of medical devices, performs quality control of medicines and medical devices, and provides information with the aim of their safe and rational use.

The Medicines and Medical Devices Act of 2010 (as amended) (MMDA) defines medicines and their categories, while the Medical Devices Act of 2017 (MDA) does the same with respect to medical devices. ALIMS conducts categorisation and sub-categorisation of medicines and medical devices.

Approval framework

3 Describe the general legislative and regulatory framework for approval of marketing of medicinal products and medical devices.

The MMDA and a series of implementing by-laws adopted by the Ministry govern the marketing authorisation and placing of medicines on the market. These regulations rely in good part on the relevant EU law, most importantly Directive 2001/83/EC on the Community code relating to medicinal products for human use. ALIMS is the competent authority for issuing marketing authorisations.

To be granted a marketing authorisation, a medicinal product must undergo pharmaceutical (pharmaceutical, chemical and biological), pharmacotoxicological and clinical trials and satisfy conditions related to its quality, safety and efficacy.

The patient information leaflet and the labelling of the packaging constitute an integral part of a marketing authorisation. Medicines must be labelled in the Serbian language. The MMDA regulates general labelling of outer and inner packaging, as well as the additional labelling regarding the reimbursement, manner of prescription and identification and authenticity of medicines. The patient information leaflet must be enclosed in the packaging in the Serbian language, and must be comprehensible and compliant with the summary of the product's characteristics. Implementing by-laws additionally regulate labelling and the contents of patient information leaflets.

The obligation to obtain a marketing authorisation does not apply to medical devices. To be placed on the market or in use, a medical device must comply with essential requirements of the MDA regarding conformity assessment, labelling and supporting documents. Also, the device must be properly procured and installed and maintained, and used in accordance with its purpose. For medical devices for which a conformity assessment was carried out, registration is not a condition for placing them on the market or putting them to use, but a manufacturer or its representative must submit the application for registration to ALIMS. The MDA contains an exhaustive list of medical devices that do not need to be registered to be placed on the market or put to use.

The MDA prescribes detailed rules on the manner of labelling of medical devices and the form and contents of a patient information leaflet. Labelling and the contents of patient information leaflets are additionally regulated in the Rulebook on Labelling and Contents of the Patient Information Leaflet for the Use of a Medical Device of 2019.

CLINICAL PRACTICE

Applicable rules

4 What legislation controls and which rules apply to ethics committee approval and performance of clinical trials in your territory for medicinal products and medical devices?

Clinical trials for medicines and medical devices are regulated in the Medicines and Medical Devices Act of 2010 (as amended) (MMDA) and the Medical Devices Act of 2017 (MDA), respectively. Detailed rules related to ethics committee approval and performance of clinical trials are additionally regulated in by-laws. For medicines, the regulation is the Rulebook on the Contents of the Application and the Documentation for Approval of Clinical Trials for Medicines and Medical Devices, as well as the Method of Implementation of Clinical Trials for Medicines and

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Medical Devices of 2011 (as amended) (the part of the Rulebook related to medical devices has ceased to apply). The Rulebook on Clinical Trials for Medical Devices of 2018 (as amended) regulates the matter in relation to medical devices.

Pursuant to the Healthcare Act of 2019, the competence of ethics committees of healthcare institutions in relation to clinical trials of medicines was transferred to the Ethics Committee of Serbia, which is a professional body appointed by the government to oversee provision of healthcare in line with principles of professional ethics, respect for human rights and values, and children's rights on the national level. Ethics Committee of Serbia makes decisions on conducting clinical trials in accordance with the MMDA and implementing by-laws.

The Ethics Committee of Serbia also has the responsibility of protecting the rights, safety and well-being of subjects involved in clinical trials of medical devices, conferred to it by the MDA.

Reporting requirements

5 What requirements exist for reporting the commencement of a trial and its results to the competent authorities or the public?

Sponsors must request authorisation for conducting a clinical trial from the Medicines and Medical Devices Agency (ALIMS) in the case of:

- clinical trials for medicines that 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; and
- interventional post-marketing clinical trials, 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.

For the conduct of a non-interventional post-marketing clinical trial of a medicine with a marketing authorisation, conducted in accordance with the approved summary of product characteristics, the sponsor must only notify the commencement of a trial to ALIMS.

A sponsor is required to report quarterly to ALIMS on the conduct of a clinical trial. The sponsor must communicate to ALIMS and the ethics committee the completion of the clinical trial within 90 days, and submit a final report on the results of a clinical trial within one year of its completion. In the case of early completion or interruption, the sponsor must notify ALIMS and the ethics committee within 15 days of the date of the trial's early completion or interruption.

Consent and insurance

6 Are there mandatory rules for obtaining trial subjects' consent to participate? Must sponsors arrange personal injury insurance to a particular limit?

The MMDA contains mandatory rules for obtaining trial subjects' consent to participate, which is one of the conditions for conducting a clinical trial. Subjects, or their legal representatives, must be fully informed about the clinical trial and of their right to withdraw their consent to participate at any moment, in writing and in a language they can understand. Consent must be in written form, signed and dated, while an illiterate person must give oral consent in the presence of at least one witness. Special provisions provide for protection of minors and of adults who are not able to give written consent to participation in clinical trials because of unconsciousness or a physical or learning disability.

Prior to the commencement of a clinical trial, the sponsor of a clinical trial must insure the persons subjected to the clinical trial against personal injury, where the damage to health is caused by the clinical trial.

MARKETING AUTHORISATION

Time frame

7 How long does it take, in general, to obtain an authorisation from application to grant, what fees are payable and what is the normal period of validity of the authorisation?

The Medicines and Medical Devices Agency (ALIMS) conducts a formal review of an application for marketing authorisation within 30 days. The deadline for the substantive review is 210 days, which is paused from the day of request of additional documents from the applicant, until submission of those documents. The accelerated procedure for obtaining a marketing authorisation takes 150 days from receipt of a complete application, for a medicinal product that obtained a marketing authorisation in accordance with the EU centralised procedure, and for medicines for human use of utmost importance for public healthcare.

Marketing authorisation is valid for five years. It may be renewed based on the reassessment of the risk-benefit ratio of the medicine. If ALIMS determines that a medicine is safe (based on the available pharmacovigilance data), it grants a permanent marketing authorisation.

The fee for marketing authorisation for a medicinal product on the basis of complete documentation for pharmaceutical form, strength and package of the medicine is 460,000 Serbian dinars. Additional fees are payable for each additional pharmaceutical form (240,000 Serbian dinars), each additional strength of the same pharmaceutical form (150,000 Serbian dinars), each type of additional inner package of the same pharmaceutical form and strength (30,000 Serbian dinars), and each additional package size (30,000 Serbian dinars). The same fees apply for issuing a conditional marketing authorisation, marketing authorisation under exceptional circumstances and a temporary marketing authorisation. Reduced fees apply for issuance of a marketing authorisation based on reduced documentation.

Protecting research data

8 What protection or exclusivities apply to the data submitted by originators to gain initial approval and, on variation or new application, to add indications or pharmaceutical forms?

For manufacturers without a seat in Serbia, the exclusivity period for the data submitted by originators to obtain marketing authorisation in Serbia is 10 years from the issuance of the initial marketing authorisation. 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, do not extend the exclusivity period. An applicant for issuance of a marketing authorisation with reduced documentation (for a generic medicinal product, generic hybrid medicinal product or biologically similar medicinal product) may apply for marketing authorisation after at least eight years have elapsed from the date the initial marketing authorisation for the reference medicinal product had been issued in Serbia, the European Union or countries that have the same or similar requirements for the issuance of the authorisation, and may obtain a marketing authorisation after 10 years from the date of issuance of the initial marketing authorisation. The period of 10 years may be extended (cumulatively) for one more year, if, during the eight years from the issuance of the marketing authorisation for the reference medicinal product, the marketing authorisation holder (MAH) of the reference medicinal product obtains a new marketing authorisation for one or more new indications that show a significant improvement in the therapeutic indication of the reference medicinal product.

For manufacturers with a seat in Serbia, the rules above will apply from the accession of Serbia to the European Union. Until then, a manufacturer with a registered seat in Serbia can be granted marketing

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authorisation for a biotechnological medicinal product upon expiry of the ten-year period from the date of receiving the first marketing authorisation, and for other medicinal products after the expiry of six years from the date of receiving the first marketing authorisation for the reference medicinal product.

Freedom of information

9 To what extent and when can third parties make freedom of information applications for copies of research data submitted by applicants for authorisation to market medicinal products or medical devices?

The Serbian Freedom of Information Act of 2004 (as amended) provides that public authorities must not allow access to information in its possession when a law considers such information as classified.

The Medicines and Medical Devices Act of 2010 (as amended) (MMDA) provides that all the data in the documentation enclosed within a marketing authorisation application, as well as in other procedures carried out before the ALIMS or competent ministries, must be treated as classified.

Public authorities may make classified information available to third parties with the consent of the applicant in a procedure before ALIMS. Data available to the expert and general public for the purpose of providing the information necessary for the use or handling of a medicinal product, or required for the protection of health in humans and animals, may not be considered classified.

Regulation of specific medicinal products

10 Are there specific rules for approval, and rewards or incentives for approval, of particular types of medicinal products, such as traditional herbal and homeopathic products, biologicals and biosimilars, controlled drugs, orphan drugs and those for paediatric use?

Marketing authorisation is not required for traditional herbal medicines or homeopathic medicines. The ALIMS keeps special registries for these types of medicines. There are no specific rules for approval, and rewards or incentives for approval, for biologicals and biosimilars, controlled drugs, orphan drugs or drugs for paediatric use.

Post-marketing surveillance of safety

11 What pharmacovigilance or device vigilance obligations apply to the holder of a relevant authorisation once the product is placed on the market?

In the post-marketing phase, MAHs are obliged to:

- organise continued monitoring of adverse drug reactions (ADRs) and have a permanently employed person with adequate qualifications responsible for pharmacovigilance;
- keep records on all suspected ADRs notified in Serbia, EU countries or any third country, and provide 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 promptly report this information to the ALIMS no later than 15 days following the receipt of information;
- submit to the ALIMS periodic drug safety reports in 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 medicine on the market, then annual reports for another two years and finally submit reports in three-year intervals.

For medical devices, a manufacturer 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. The designated person keeps records of any measures taken and informs ALIMS accordingly.

The manufacturer or its authorised representative must also inform the notified or appointed body that carried out the conformity assessment of any changes in the system of vigilance that affect the conformity assessment. In the case of incidents, the manufacturer or its authorised representative must, without delay, inform ALIMS of any initiated field safety corrective action taken to reduce the risk of death or serious deterioration of health related to the medical device.

Other authorisations

12 What authorisations are required to manufacture, import, export or conduct wholesale distribution and storage of medicinal products and medical devices? What type of information needs to be provided to the authorities with an application, what are the fees, and what is the normal period of validity?

A licence is required for the manufacturing of medicines and the Ministry of Health (the Ministry) may issue these to legal entities only. The applicants for manufacturing must accompany the application with information and documents regarding their location and premises, equipment, personnel, medicines to be produced and relevant procedures, as well as other information required by the MMDA and the relevant rulebook. The fee payable for the manufacturing licence is 80,030 Serbian dinars and the licence is valid for an indefinite period.

A licence to manufacture medical devices may be issued to a legal entity or an individual. The Ministry issues manufacturing licences for Class I medical devices (other than Classes Is and Im), other in vitro diagnostic medical devices, medical devices for which no conformity assessment is 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 systems or kits. The applicant must support its application with information and documents regarding the location and premises, equipment, personnel, medical devices to be produced and relevant procedures, as well as other information required by the Medical Devices Act of 2017 (MDA). The fee payable for the manufacturing licence is 80,030 Serbian dinars, and the licence is valid for five years.

Wholesale of medicines and medical devices encompasses purchase, storage, distribution, imports and exports of medicines. A wholesale licence issued by the Ministry is required to perform wholesale. Exceptionally, manufacturers may distribute medicines or medical devices that they manufacture without a wholesale licence. However, manufacturers of medical devices with a registered seat in Serbia that do not need a manufacturing licence must obtain a wholesale licence to sell their medical devices. Legal entities performing only import or export activities on behalf of and for the account of a medicines wholesale licence holder do not have the obligation to obtain a wholesale licence. Applicants for wholesale licences for medicines and medical devices must support their applications with information and documents regarding the legal entity, location and premises, supply territory, products for which the wholesale licence is sought, personnel, equipment and plan for an urgent withdrawal of products from the market, as well as other information of relevance for issuance of the wholesale licence.

The Ministry issues wholesale licences for medicines for an indefinite period, and for medical devices for a period of five years. The fees for both, payable to the Ministry, amount to 40,020 Serbian dinars.

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Sanctions

13 What civil, administrative or criminal sanctions can authorities impose on entities or their directors and officers for breach of the requirements concerning controlled activities?

Placement on the market, manufacturing or trade of medicines contrary to the rules imposed under the MMDA constitute a commercial offence for which a fine ranging from 1.5 million to 3 million Serbian dinars may be imposed. Conformity assessment, manufacturing, trade, labelling, presentation, conduct of vigilance or advertising of medical devices contrary to the MDA constitute a commercial offence and a fine ranging from 1.5 million to 3 million Serbian dinars may be made against a legal entity, while a fine ranging from 300,000 to 500,000 Serbian dinars may be imposed on an individual as a manufacturer of medical devices. Furthermore, performance of the relevant business activity for the legal entity manufacturing medicines or medical devices may be forbidden for three to 10 years, and for the individual manufacturer of medical devices, from six months to three years.

Exemptions

14 What, if any, manufacture and supply of medicinal products is exempt from the requirement to obtain an approval to market?

Marketing of magistral and galenic medicines, traditional herbal and homeopathic medicines (unless otherwise stipulated in the MMDA), as well as other products and substances enlisted under article 39 of the MMDA, is exempt from the obligation to obtain a marketing authorisation.

Parallel trade

15 Are imports allowed into your jurisdiction of finished products already authorised in another jurisdiction, without the importer having to provide the full particulars normally required to obtain an authorisation to market? What are the requirements?

Parallel trade of medicines is no longer prohibited in Serbia. The Trademarks Act of 2020 provides for the principle of international exhaustion of rights instead of the principle of national exhaustion. As a result, a trademark does not entitle its holder to prohibit its use on the goods that were placed on the market anywhere in the world by the trademark holder or another person authorised by the holder.

An exception may be made if the trademark holder has a justified reason to object to the placing of the market of the goods marked by the trademark, especially if the goods were spoilt or substantially altered after its first placing on the market.

AMENDING AUTHORISATIONS

Variation

16 What are the main requirements relating to variation of authorisations for medicinal products and medical devices?

Marketing authorisation holders (MAHs) can apply to the Medicines and Medical Devices Agency (ALIMS) for variations of authorisation in line with the Medicines and Medical Devices Act of 2010 (as amended) (MMDA) and the Rulebook on Conditions, Contents of Documentation and the Manner of Approval of Variation of Marketing Authorisation of 2012. MAHs are obliged to market the medicinal product in accordance with the approved variation, at the latest, within 12 months of delivery of the ALIMS's approval of the variation. Failure to do so constitutes a commercial offence and a fine ranging from 800,000 to 2 million Serbian dinars may be imposed against a legal entity, while a fine ranging from 80,000 to 150,000 Serbian dinars may be imposed against a responsible person in that legal entity. Furthermore, performance of the relevant business activity may be forbidden for three to 10 years.

MAHs must:

- report type-IA variations within 12 months 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 ALIMS' approval for type-IB 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.

Renewal

17 What are the main requirements relating to renewal of authorisations for medicinal products and medical devices?

MAHs must renew marketing authorisations following the expiry of the initial five-year period of validity, based on the reassessment of the risk-benefit ratio. The application must contain professional reports on quality, safety and efficacy of the medicinal product, as well as a list of all the variations applied for and approved by ALIMS. The request for approval must be submitted a maximum of 180 days before, and no later than 90 days after, the expiry of the marketing authorisation. ALIMS conducts a formal assessment within 15 days of application and a substantive review within 90 days of the application being deemed complete. The MAH is obliged to place the medicinal product on the market in accordance with the approved renewal within 12 months of ALIMS' positive decision.

If the Agency determines that a medicinal product is safe, based on pharmacovigilance data in the five-year period following the date of issuance or renewal of the medicinal product, the Agency may issue a permanent marketing authorisation. Otherwise, it will decide on renewal for another five years. A marketing authorisation may only be renewed once for a five-year period. After that, if the Agency still has reasonable grounds to suspect that a medicinal product is unsafe, it will terminate the marketing authorisation.

Transfer

18 How easy is it to transfer the existing approvals or rights to market medicines and medical devices? How long does this take in general?

The procedure for a transfer of a marketing authorisation may be initiated before ALIMS at the request of the existing MAH. The procedure is based on the assessment of whether the prospective new holder meets the requirements prescribed by the MMDA and the relevant by-laws. ALIMS conducts a formal assessment of the application within 15 days of receiving the application and a substantive review within 60 days of the application being deemed complete.

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RECALL

Defective and unsafe products

19 What are the normal requirements for handling cases of defective or possibly unsafe products, including approvals required for recall and communication with health professionals?

The manufacturer of a medicinal product is obliged to inform the Ministry of Health (the Ministry) of any accident or error in the manufacturing and of other occurrences that could bring into question the quality, safety or efficacy of a medicinal product. The wholesaler must promptly inform the Ministry of any incident that might affect quality or safe handling of a medicinal product.

The Ministry must prohibit marketing and order withdrawal of medicines on its own initiative or at the proposal of the Medicines and Medical Devices Agency (ALIMS) when, among other situations, a specific medicinal product is harmful when applied in normal conditions. The Ministry may opt to withdraw only a certain series of the product or to withdraw the product completely from the market. Wholesalers must recall the medicinal product and abolish the marketing of the medicinal product prohibited and withdrawn by the Ministry.

The Ministry prohibits marketing and requires recall of medical devices from the market if, among other cases, a medical device is harmful under the normal conditions of use, if it fails to perform or if its qualitative and quantitative composition does not correspond to the composition prescribed by the manufacturer in the technical documentation, the certificate of conformity or any other certificate for that medical device. The Ministry may recall the medical device from the market completely or only with respect to a certain series. The importer of a medical device is responsible for recall of a medical device that is not registered in Serbia.

A manufacturer or its authorised representative may decide to recall the medical device from the market on its own initiative. In that case, the manufacturer (ie, its representative) must inform ALIMS and the Ministry without delay.

PROMOTION

Regulation

20 Summarise the rules relating to advertising and promotion of medicinal products and medical devices, explaining when the provision of information will be treated as promotional. Do special rules apply to online advertising?

Advertising of medicines and medical devices is regulated in the Medicines and Medical Devices Act of 2010 (as amended) (MMDA) and the Medical Devices Act of 2017 (MDA), respectively, while detailed rules are provided in the relevant by-laws. 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).

The MMDA defines advertising as any form of provision of accurate information about a medicinal product or medical device to the general or professional public to encourage prescription, supply, sale or consumption of the product (ie, device). Stating the name of a medicinal product, its international non-proprietary name or a trademark, if it serves only as a reminder, does not amount to advertising.

The Medicines and Medical Devices Agency (ALIMS) must approve promotional materials and other documentation supporting the advertising of medicines. Advertising may be directed towards the general public via media, and to the professional public via promotion to health and veterinary professionals who prescribe medicines. The MDA has abolished the former obligation to request ALIMS' approval of promotional materials for medical devices.

It is forbidden to advertise a medicine without a marketing authorisation or a medical device that does not conform with essential requirements and registered in the ALIMS' register of medical devices. Advertising medicines and medical devices in a misleading manner or advertising the success of a medicine treatment in an exaggerated way is also impermissible. The advertiser may not suggest that the medicine can be classified as food, cosmetics or another item of general use. It is prohibited to give or promise financial, material or other benefits in order to encourage prescription and issuing of a medicinal product.

The MMDA contains an exhaustive list of medicines for which advertising is forbidden, including prescription medicines, medicines issued at the expense of health insurance, medicines containing opiates or psychotropic substances, and medicines for diseases such as tuberculosis, sexually transmitted or infectious diseases, chronic insomnia, diabetes and other metabolic diseases. It is also forbidden to advertise medicines used for the treatment of children by addressing children directly, and to give free samples of medicines (ie, medical devices) to the general public.

Promotion of a medicinal product to the professional public must include the basic data contained in the marketing authorisation and be consistent with the summary of product characteristics. That information must be accurate, updated, verifiable and sufficiently complete as to enable the recipient to form his or her own opinion on the therapeutic value of a medicinal product. It is permitted to give a healthcare professional (HCP) one minimal package of a new medicine being introduced on the market containing a note: 'A free sample, not for sale'.

There are no special rules applicable to online advertising.

Inducement

21 What regulations exist to discourage the provision of inducements to healthcare professionals to prescribe, sell, supply or recommend use of a particular medicinal product or medical device?

The MMDA and the relevant by-law prohibit any encouragement of HCPs to prescribe, issue, order a specific medicine or recommend its use or purchase through offering, giving or promising money or any other benefit. Companies may not ask, and HCPs may not provide, any material or non-material benefit as a consideration for the sponsorship of professional events. The sponsor may not 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 new Healthcare Act of 2019 provides that HCPs may not accept money or gifts, except for small non-monetary gifts of an individual value below 5 per cent of the average net monthly salary in Serbia or of an aggregate value not exceeding one average net monthly 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 at all, is not specified).

The INOVIA Code sets the monetary limit on value of informational or educational material provided to HCPs at approximately 3,500 Serbian dinars, and also prohibits companies from providing or offering HCPs any food and beverages of which the value exceeds approximately 5,870 Serbian dinars. The company sponsoring or organising an event may not offer accommodation in five-star hotels. The INOVIA Code also imposes industry rules on donations and grants to individual HCPs outside the sponsorship for attending professional events, as well as donations and grants to associations of HCPs or entities that provide healthcare or conduct research. The aim of the Code is to help prevent

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companies from inducing HCPs to recommend, prescribe, purchase, supply, sell or administer specific medicines.

Reporting transfers of value

22 What requirements apply to recording and publishing details of transfers of value to healthcare professionals and organisations by companies marketing medicinal products or medical devices?

The Rulebook on the Manner of Advertising of Medicines and Medical Devices of 2010 requires 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 also encourages companies to make information about donations and grants publicly available.

ENFORCEMENT OF ADVERTISING RULES

Enforcers

23 Describe the bodies involved in monitoring and ensuring compliance with advertising controls for medicinal products and medical devices, distinguishing between any self-regulatory framework and control by the authorities.

The Medicines and Medical Devices Agency is competent for ensuring compliance with the rules on advertising of medicines and medical devices, and it must approve promotional materials for the advertising of medicines. The Ministry of Health conducts inspection control through its health inspectorate.

Within the self-regulatory framework, the Serbian Association of Manufacturers of Innovative Drugs (INOVIA) monitors compliance of its members with the INOVIA Code.

Sanctions

24 What are the possible financial or other sanctions for breach of advertising and promotional controls for medicinal products or medical devices?

Advertising of medicines contrary to the rules imposed under the Medicines and Medical Devices Act of 2010 (as amended) constitutes a commercial offence for which a fine ranging from 800,000 to 2 million Serbian dinars may be imposed against a legal entity, and a fine ranging from 80,000 to 150,000 Serbian dinars may be imposed against a responsible person of the legal entity. For a commercial offence of advertising of medical devices contrary to the Medical Devices Act of 2017, a fine ranging from 1.5 million to 3 million Serbian dinars may be imposed against a legal entity, while a fine ranging from 300,000 to 500,000 Serbian dinars may be imposed on an individual as a manufacturer of medical devices. Furthermore, performance of the relevant business activity for legal entities manufacturing medicines (ie, medical devices), may be forbidden for the period of three to 10 years, and for the individual manufacturer of medical devices from six months to three years.

PRICING AND REIMBURSEMENT

Pricing

25 What are the controls imposed on pricing of medicines and medical devices and reimbursement by national social security systems that are applicable to manufacturers, distributors and pharmacists?

The pricing regime depends on whether a medicine is classified as prescription-only or over-the-counter (OTC), and does not differ between the outpatient and inpatient sectors. The government regulates the prices of prescription-only medicines. The Ministry of Health (the Ministry) calculates the maximum wholesale price for prescription-only medicines based on a number of criteria, including the comparable wholesale prices in reference countries (Slovenia, Croatia and Italy) and the current wholesale price in Serbia. Marketing of a prescription-only medicine for which the government did not determine the maximum wholesale price is prohibited. Marketing authorisation holders freely determine the prices of OTC medicines and must notify the Ministry before 31 March of the current year of the price for the previous year.

For the cost of medicine to be reimbursed, the medicine must be included in the positive reimbursement list of medicines (the Positive List). The Central Medicines Commission established by the National Health Insurance Fund conducts the health technology assessment of medicines when reviewing applications for inclusion of medicines on the Positive List. The general criteria for adding a medicine to the Positive list are:

- pharmacotherapeutic justification of the medicine;
- pharmacoeconomic justification of the medicine; and
- financial resources provided by the annual financial plan of the National Health Insurance Fund.

When the resources are insufficient for inclusion in the list of medicines that comply with general criteria, the National Health Insurance Fund further considers two special factors: existence, if any, of a managed entry agreement and the priority for adding the medicine to the list. The Fund gives priority to medicines based on:

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

OFF-LABEL USE AND UNLICENSED PRODUCTS

Off-label use

26 May health professionals prescribe or use products for 'off-label' indications? May pharmaceutical companies draw health professionals' attention to potential off-label uses?

Serbian law does not regulate 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 provision of information regarding off-label use to healthcare professionals (HCPs) is prohibited. A marketing authorisation holder may not market a medicine for a new indication until the Medicines and Medical Devices Agency (ALIMS) has approved and registered the amendments to the marketing authorisation. Any promotion of medical products to HCPs must be carried out in accordance with the summary of product characteristics, including the approved indications of the medicine. It follows that the provision of information regarding off-label use to HCPs is not allowed under any circumstances.

Unlicensed products

27 What rules apply to the manufacture and importation and supply to healthcare providers of unlicensed medicines or medical devices?

An importer may submit a request for importation of a non-registered medicine to ALIMS if one of the following four conditions is met:

- there is no registered medicine of the same international non-proprietary name, strength, pharmaceutical form and packaging size on the market in Serbia;

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- the medicine is intended for treatment of rare human diseases;
- it is necessary to ensure sufficient quantities and types of medicine for epidemics, natural disasters and other emergency situations; or
- there are insufficient quantities and types of medicines with marketing authorisation on the market in Serbia.

The import of medicines not registered in Serbia is also permitted as a donation or humanitarian aid to a health institution for the benefit of a patient or a group of patients who are not eligible to participate in the ongoing clinical trial for that medicinal product in Serbia. Medicines for which competent authorities in Serbia, the European Union, or a country with similar or identical requirements have suspended or prohibited a clinical trial, cannot be imported in this manner.

ALIMS may also authorise the import of a medical device:

- not registered in Serbia, which is intended for a particular patient or group of patients;
- as a donation or humanitarian aid;
- as part of a donation programme in the European Union; or
- for scientific research or emergency situations.

To be imported, these medical devices must have been subjected to conformity assessment.

Compassionate use

28 What rules apply to the establishment of compassionate use programmes for unlicensed products?

ALIMS may approve import of medicines not registered in Serbia for the purpose of treating specific patients or a group of patients that are afflicted by life-threatening diseases, such as AIDS, cancer and other malignant or autoimmune diseases. The approval can be issued for medicines that:

- 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 such country;
- are currently subject to a centralised marketing authorisation procedure in the European Union; or
- have received a marketing authorisation in the EU centralised procedure.

A proposal for the importation of a medicine must be signed by the director of the health institution that recommended the import.

SALE AND SUPPLY

Regulation

29 Are there special rules governing the dispensing or sale of particular types of medicinal products or medical devices?

Special rules apply only to the dispensing and sale of prescription-only medicines. The Medicines and Medical Devices Agency (ALIMS) decides whether a medicine is to be dispensed only on prescription during the marketing authorisation procedure. It is prohibited to dispense or sell medicines contrary to the classification of prescription-only and over-the-counter medicines.

Online supply

30 What laws and guidelines govern online dispensing, sale and supply of medicinal products and medical devices?

Online sale of medicines and medical devices is prohibited in Serbia.

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UPDATE AND TRENDS

Forthcoming legislation and regulation

31 Is there any current or foreseeable draft legislation or other rules that will affect the regulation of pharmaceuticals and medical devices? What is likely to change, and what steps need to be taken in preparation?

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

Coronavirus

32 What emergency legislation, relief programmes and other initiatives specific to your practice area has your state 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 has implemented several temporary emergency measures related to medicines and medical devices in response to the pandemic.

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

The government 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 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 fighting the virus and curing infected persons, to purchase and use medicines and medical devices that had not been manufactured in accordance with prescribed standards.

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

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ISBN 978-1-83862-379-1

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