PHARMA & MEDICAL DEVICE REGULATION

Serbia

LEXOLOGY
Getting The Deal Through

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Quick reference guide enabling side-by-side comparison of local insights, including into the regulatory framework; clinical practice; marketing authorisation; amending authorisations; recall; promotion; enforcement of advertising rules; pricing and reimbursement; off-label use and unlicensed products; sale and supply; and recent trends.

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Table of contents

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Serbia

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REGULATORY FRAMEWORK

Competent authorities for authorisation

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 to ensure their safe and rational use.

The Medicines and Medical Devices Act of 2010 (as amended) (Medicines Act) defines medicines and their categories, while the Medical Devices Act of 2017 (Medical Devices Act) does the same with respect to medical devices. ALIMS conducts categorisation and sub-categorisation of medicines and medical devices within the scope of marketing authorisation or registration procedure.

Law stated - 19 September 2024

Approval framework

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

The Medicines Act and a series of implementing by-laws adopted by the Ministry of Health govern the marketing authorisation and placing of medicines on the market. These regulations rely substantially on the relevant EU law, most importantly Directive 2001/83 on the Community Code relating to medicines for human use. The Medicines and Medical Devices Agency is the competent authority for issuing marketing authorisations.

In order to be granted a marketing authorisation, a medicinal product must undergo pharmaceutical (pharmaceutical, chemical and biological), pharmaco-toxicological and clinical trials and satisfy conditions related to its quality, safety and efficacy.

A patient information leaflet and the labelling text of the packaging constitute an integral part of marketing authorisation. Medicines must be labelled in Serbian. The Medicines Act regulates the 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 Serbian and must be comprehensible and compliant with the summary of the product's characteristics. Implementing by-laws also regulate labelling and the contents of patient information leaflets.

The obligation to obtain a marketing authorisation does not apply to medical devices. Instead, medical devices must be registered with the Medicines and Medical Devices Agency. To be placed on the market or in use, a medical device must comply with essential requirements prescribed in the Medical Devices Act regarding conformity assessment, labelling and supporting documents. Also, the device must be properly procured, installed, maintained and used in accordance with its purpose. The Medical Devices Act contains an exhaustive list of medical devices which do not need to be registered in order to be placed on the market or put to use.

The Medical Devices Act 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 are additionally regulated in the Rulebook on Labelling and Contents of the Patient Information Leaflet for the Use of a Medical Device of 2019.

Law stated - 19 September 2024

CLINICAL PRACTICE

Applicable rules

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 by the Medicines Act of 2010 (as amended) and the Medical Devices Act of 2017, respectively. Detailed rules related to ethics committee approval and performance of clinical trials are additionally regulated in by-laws. For medicines, the relevant regulation is the Rulebook on the Clinical Trials for Medicines for Human Use of 2022 (as amended in 2023). The Rulebook on Clinical Trials for Medical Devices of 2018 (as amended in 2019) regulates the matter in relation to medical devices.

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

The Ethics Committee of Serbia is also responsible for protecting the rights, safety and well-being of subjects involved in clinical trials of medical devices. This responsibility is conferred on it by the Medical Devices Act.

Requests for approval or amending clinical trials are submitted to the Agency for Medicines and Medical Devices in electronic form in the Serbian language; however, some required supporting documents may be in English. Requests to the Ethics Committee of Serbia are submitted at the same time through the Agency for Medicines and Medical Devices.

Law stated - 19 September 2024

Reporting requirements

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 clinical trials from the Medicines and Medical Devices Agency 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 the Medicines and Medical Devices Agency.

A sponsor is required to report quarterly to the Medicines and Medical Devices Agency on the conduct of a clinical trial. The sponsor must inform the Medicines and Medical Devices Agency and the ethics committee about 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 the Medicines and Medical Devices

Agency and the ethics committee within 15 days of the date of the trial's early completion or interruption.

Law stated - 19 September 2024

Consent and insurance

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

The Medicines Act 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 the protection of minors and adults who are not able to give written consent to participation in clinical trials due to unconsciousness or 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.

Law stated - 19 September 2024

MARKETING AUTHORISATION

Time frame

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 which 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, a marketing authorisation under exceptional circumstances and a temporary marketing authorisation. Reduced fees apply for the issuance of a marketing authorisation based on reduced documentation.

Law stated - 19 September 2024

Marketing exclusivity

What protections or exclusivities apply to the marketing period of an approved medicinal product or variation?

The regulatory data exclusivity period for a reference medicinal product in Serbia is eight years, while the market exclusivity period is 10 years. Namely, an applicant for a marketing authorisation in a summary procedure (ie, a manufacturer of generics, hybrids, or biosimilars) may submit a request for issuance of a marketing authorisation after the lapse of eight years from the date of issuance of a global marketing authorisation in Serbia, the European Union, or a country with the same or similar requirements for issuing marketing authorisation. The marketing authorisation following an application may be issued after 10 years from the issuance of global marketing authorisation.

However, there is an exception to the marketing exclusivity period for a reference medicinal product for manufacturers with a registered seat in Serbia, which may apply for the marketing authorisation after the expiry of six years from the day of issuance of the global marketing authorisation for the reference medicinal product. This exception applies to large molecules, while for a biotechnological medicinal product, the period of market exclusivity is 10 years. The Medicines and Medical Devices Act of 2010 (as amended) (Medicines Act) provides in transitional provisions that the regulatory data protection period of eight years and market exclusivity period of 10 years will be applicable to manufacturers with a seat in Serbia from the day of accession of Serbia into the European Union.

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 will not extend the exclusivity period.

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 of the reference medicinal product obtains a new marketing authorisation for one or more new indications that show a significant improvement in that referent medicinal product therapy, or is a new classification has been determined on the basis of significant pre-clinical tests of clinical trials.

Law stated - 19 September 2024

Protecting research data

What protections 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?

The exclusivity period for data submitted by originators to gain initial approval of a reference medicinal product is eight years from the day of issuance of a marketing authorisation. There is an exception for manufacturers of generic products with a seat in Serbia, which may apply for marketing authorisation after six years.

From the day of accession of Serbia to the European Union, that protection will be extended to eight years with respect to all manufacturers of generics. After the expiry of eight years from the date when 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, an applicant for a marketing authorisation issuance with reduced documentation (for a generic medicinal product, generic hybrid medicinal product or biologically similar medicinal product) will be able to apply for marketing authorisation and will be able to obtain the marketing authorisation after 10 years from the date of issuance of the initial marketing authorisation.

Law stated - 19 September 2024

Freedom of information

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 their possession when a law considers such information as classified.

The Medicines Act provides that all the data in the documentation enclosed within a marketing authorisation application, as well as in other procedures carried out before 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.

Law stated - 19 September 2024

Regulation of specific medicinal products

What are the specific requirements and processes for marketing approval of the major categories of regulated products?

Medicinal products

Marketing authorisation for medicinal products may be obtained through regular and accelerated procedures before ALIMS. The Medicines Act and a series of implementing by-laws govern the granting of a marketing authorisation. In order to be granted marketing authorisation, a medicinal product must undergo pharmaceutical (ie, pharmaceutical, chemical and biological), pharmaco-toxicological and clinical trials in order to prove that it has the required quality, safety and efficacy. ALIMS conducts a formal review of an application for marketing authorisation within 30 days, while the substantive review must be completed within the next 210 days. If ALIMS requests additional documents from the applicant, it will give a 30-day deadline for the submission, and the deadline for issuing the marketing authorisation will be paused until the documents are submitted.

The accelerated procedure for obtaining a marketing authorisation is reserved for medicinal products that 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. If the application is not complete, ALIMS will ask the applicant to complete the application within 30 days, and the deadline for issuing the marketing authorisation will paused from the day of request until the submission of the requested documents.

Medical devices

Medical devices are not subject to marketing authorisation, but they must be registered with ALIMS in order to be placed on the market. Medical devices must comply with essential requirements set out in the Medical Devices Act of 2017 (Medical Devices Act 2017) regarding conformity assessment, labelling and supporting documents; be properly procured, installed and maintained; and used in accordance with their purpose.

Biologicals

Biologicals 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.

Other products

Marketing authorisation is not required for traditional herbal medicines or homoeopathic medicines. ALIMS keeps special registries for these types of medicines.

Dietary supplements are not subject to an approval process, but their safety and controls are governed by the Food Safety Act of 2009 (as amended) and the Rulebook on the Health Safety of Dietary Supplements of 2010 (as amended).

Law stated - 19 September 2024

Rewards and incentives

What rewards or incentives for approval are applicable to the major product categories, including orphan drugs, drugs for paediatric use, generic drugs and biosimilars?

There are currently no special incentives for approval of any specific product category. The Patents Act of 2011 (as amended) contains an incentive for approval of drugs for paediatric use, however, this provision will only be applicable from the day of accession of Serbia to the European Union. The incentive offered will be in the form of an extension of a supplemental protection certificate for an additional six months if all necessary trials have been conducted in accordance with an approved paediatrics research plan in the EU member states, under the condition that the marketing authorisation for the medicinal product has been issued in all member states, in accordance with the relevant rules.

Law stated - 19 September 2024

Post-marketing surveillance of safety

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, marketing authorisation holders (MAHs) are obligated 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 promptly report this information to ALIMS no later than 15 days following the receipt of information;
- submit to 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 who must 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 which carried out the conformity assessment of any changes in the system of vigilance which affect the conformity assessment. In case of incidents, the manufacturer or its authorised representative must without delay inform ALIMS on any initiated field safety corrective action taken to reduce the risk of death or serious deterioration of health related to the medical device.

Law stated - 19 September 2024

Other authorisations

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 may issue it only to legal entities. The applicants for manufacturing must accompany the application with information and documents regarding their location and premises, equipment, personnel, medicines to be produced, relevant procedures, as well as other information required by the Medicines Act 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 license 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 Is and Im class), 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;
- medical devices for clinical trials; and
- a system or a kit.

The applicant must support its application with information and documents regarding the location and premises, equipment, personnel, medical devices to be produced, relevant procedures, as well as other information required by the Medical Devices Act. The fee payable for the manufacturing licence is 80,030 Serbian dinars, and the licence is valid for five years.

The wholesale distribution of medicines and medical devices encompasses the purchase, storage, distribution, importation and exportation of medicines. A wholesale licence issued by the Ministry of Health is required to perform wholesale activities. Exceptionally, manufacturers may distribute medicines or medical devices from their production programmes without a wholesale licence. However, manufacturers of medical devices with registered seats in Serbia that do not need a manufacturing licence must obtain a wholesale licence for medical devices from their production programme.

Legal entities only performing importing or exporting activities on behalf of, and for the account of, a medicines wholesale licence holder are not obliged to obtain a wholesale licence. The 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, plan for an urgent withdrawal of products from the market, as well as the other information of relevance for the issuance of a wholesale licence.

The Ministry of Health issues wholesale licences for medicines for indefinite periods and for a period of five years for medical devices. The fee for each licence is 40,020 Serbian dinars and is payable to the Ministry.

Law stated - 19 September 2024

Sanctions

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

The placement on the market, manufacturing or trade of medicines contrary to the rules imposed under the Medicines Act constitutes 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 the advertising of medical devices contrary to the Medical Devices Act constitutes a commercial offence, for which a legal entity fine of between 1.5 million to 3 million Serbian dinars may be issued against a legal entity. A fine of between 300,000 to 500,000 Serbian dinars may be imposed on an individual who is the manufacturer of medical devices in a misdemeanour procedure.

Furthermore, a legal entity may be forbidden from performing business activities related to the manufacturing of medicines or medical devices for between three to 10 years, while an individual manufacturer may be prohibited for between six months to three years.

Law stated - 19 September 2024

Exemptions

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 homoeopathic medicines (unless otherwise stipulated in the Medicines Act), as well as other products and substances enlisted under the Medicines Act, article 39, is exempt from the obligation to obtain marketing authorisation.

Law stated - 19 September 2024

Parallel trade

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 on the market of the goods marked by the trademark, especially if the goods were spoilt or substantially altered after their first placing on the market.

However, the Medicines Act and its implementing by-laws have not yet been aligned with the amendments in the Trademarks Act. Therefore, in practice, the parallel imports are not yet regulated and therefore may not be affected. A new Medicines Act has been in development for a while and the government is expected to publish a draft. It remains to be seen whether the new law will regulate parallel imports in detail.

Law stated - 19 September 2024

AMENDING AUTHORISATIONS

Variation

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) (Medicines Act) and the Rulebook on Conditions, Contents of Documentation and the Manner of Approval of Variation of Marketing Authorisation of 2012 (as amended). MAHs are obliged to begin marketing a medicinal product in accordance with the approved variation within 12 months from the delivery of ALIMS' approval of the variation. Failure to do so constitutes a commercial offence, for which a fine of between 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 on a responsible person in that legal entity. Furthermore, performing relevant business activities may be forbidden for a period between three and 10 years.

MAHs 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 ALIMS's approval for IB-type and type-II variations before their application (the 'tell, wait and do procedure'); and
- submit a new request for marketing authorisation for variations related to changes in 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.

Law stated - 19 September 2024

Renewal

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

MAHs must renew marketing authorisations following the expiration of the initial five-year period of validity, based on

the reassessment of the risk-benefit ratio. The application must contain professional reports on the 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 from the date of delivery of ALIMS' positive decision.

Law stated - 19 September 2024

Transfer

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 MAH meets the requirements prescribed by the Medicines Act and the relevant by-laws. ALIMS conducts a formal assessment of the application within 15 days from the day of the application and a substantive review within 60 days of the application being deemed complete.

Law stated - 19 September 2024

RECALL

Defective and unsafe products

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 of any accident or error in manufacturing and of other occurrences that could bring the quality, safety and efficiency of a medicinal product into question. A wholesaler must promptly inform the Ministry of any incident which might affect the quality or safe handling of a medicinal product.

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

The Ministry prohibits marketing and requires the recall of medical devices from the market if, among other cases, a medical device is harmful under 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. An importer of a medical device is responsible for recall in the case of a medical device which is not registered in Serbia.

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

Law stated - 19 September 2024

ADVERTISING AND PROMOTION

Regulation

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) (Medicines Act) and the Medical Devices Act of 2017 (Medical Devices Act), respectfully, 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 Medicines Act defines advertising as every 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 or 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 Medical Devices Act has abolished the obligation for ALIMS to approve promotional materials for medical devices.

It is forbidden to advertise a medicine without a marketing authorisation or a medical device which is not in conformity 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 classed 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 the prescription and issuing of a medicinal product.

The Medicines Act 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 (or 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 opinion on the therapeutic value of a medicinal product. It is permitted to give to a healthcare professional one minimal package of a new medicine being introduced on the market containing a note stating: 'A free sample, not for sale.'

There are no special rules applicable to online advertising.

Law stated - 19 September 2024

Inducement

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 Medicines Act and the relevant by-laws prohibit encouraging healthcare professionals (HCPs) to prescribe, issue or 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 influence the contents 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 Healthcare Act of 2019 provides that HCPs may not accept money or gifts, except for small non-monetary gifts in the individual value below 5 per cent of the average net monthly salary in Serbia or in the aggregate value not exceeding one 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 at all, is not specified).

The INOVIA Code sets the monetary limit on the value of informational or educational material provided to HPCs at approximately 3,500 Serbian dinars and also prohibits companies from providing or offering to HCPs any food and beverages with a value exceeding 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 INOVIA Code is to help prevent companies from inducing HCPs to recommend, prescribe, purchase, supply, sell or administer specific medicines.

Law stated - 19 September 2024

Reporting transfers of value

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.

Law stated - 19 September 2024

Enforcers

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.

ALIMS is the competent agency for ensuring compliance with the rules on advertising medicines and medical devices and it must approve promotional materials for the advertising of medicines. The Ministry conducts inspection control

through its health inspectorate.

Within the self-regulatory framework, INOVIA monitors its members' compliance with the INOVIA Code.

Law stated - 19 September 2024

Sanctions

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 Act 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 medical devices contrary to the Medical Devices Act, 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, legal entities may be prohibited from performing relevant business activities involved in manufacturing medicines or medical devices for between three to 10 years, while individual manufacturers of medical devices may be prohibited for between six months to three years.

Law stated - 19 September 2024

OFF-LABEL USE AND UNLICENSED PRODUCTS

Off-label use

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

At the end of December 2022, the government amended the Rulebook on Medical Prescriptions of 2018 to introduce the procedure for off-label prescription of medicines. In June 2023, the government adopted the rules for reimbursements from the Health Insurance Fund for the off-label of medicines. The amended Rulebook on Medical Prescriptions prescribes the conditions that HCPs must satisfy in order to prescribe a medicine for off-label use, including obtaining the opinion of the relevant healthcare institution's ethics committee and the informed consent of the patient, using the form provided in the Rulebook.

The provision of information regarding off-label use to HCPs remains prohibited, pending the expected adoption of the new medicines act and the implementing rulebook on advertising of medicines. An MAH may not market a medicine for new indications until ALIMS has approved and registered amendments to the medicine's 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.

Law stated - 19 September 2024

Unlicensed products

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

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 regarding 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 that is intended for a particular patient or group of patients, import as a donation or humanitarian aid, or a donation programme in the European Union, a medical instrument for scientific research or for emergency situations. To be imported, these medical devices must have been subjected to conformity assessment.

Law stated - 19 September 2024

Compassionate use

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

ALIMS may approve the importation of medicines that are 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 HIV/AIDS, cancer and other malignant or auto-immune 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 a country;
- are currently subject to a centralised marketing authorisation procedure in the EU; or
- has received a marketing authorisation in the EU centralised procedure.

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

Law stated - 19 September 2024

SALE AND SUPPLY

Regulation

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 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 (OTC) medicines.

Law stated - 19 September 2024

Online supply

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

The online sale of medicines and medical devices is prohibited in Serbia.

Law stated - 19 September 2024

Pricing and reimbursement

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 OTC and does not differ between the outpatient and inpatient sectors. The government regulates the prices of prescription-only medicines. 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 (Slovenia, Croatia and Italy) and the current wholesale price in Serbia. The 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 of Health 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 conducts the health technology assessment of medicines when reviewing the applications for medicines to be included in the Positive List. The general criteria for adding a medicine to the Positive List are the:

- 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 all medicines that comply with general criteria, the National Health Insurance Fund further considers two special factors: the 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:

- a lack of medicines from the same pharmacotherapeutic group on the Positive List for a particular medical indication;

- the medicine's significance to public health; and
- ethical aspects.

Law stated - 19 September 2024

UPDATE AND TRENDS

Forthcoming legislation and regulation

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.

A new law on medicines has been announced several times in recent years and is expected to be adopted; however, an official draft or proposal has not yet been made public.

Law stated - 19 September 2024

Jurisdictions

Australia	Clayton Utz
Austria	Preslmayr Attorneys at Law
Brazil	Kasznar Leonardos
China	East & Concord Partners
Colombia	OlarteMoure
Denmark	Accura Advokatpartnerselskab
European Union	DLA Piper
Germany	Ehlers Ehlers & Partner
Greece	PotamitisVekris
India	ANA Law Group
Israel	Pearl Cohen Zedek Latzer Baratz
Italy	Avvocati Associati Franzosi Dal Negro Setti
Japan	Atsumi & Sakai
Kazakhstan	Baker McKenzie
Malaysia	Raja, Darryl & Loh
Mexico	OLIVARES
Serbia	BDK Advokati
South Korea	Lee & Ko
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