Life Sciences

Contributing editor
Alexander Ehlers

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GETTING THE DEAL THROUGH

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Preface

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Tenth edition

Getting the Deal Through is delighted to publish the tenth edition of *Life Sciences*, which is available in print, as an e-book and online at www.gettingthedealthrough.com.

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 **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 a new chapter on Serbia.

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

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.

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 Alexander Ehlers of Ehlers, Ehlers & Partner Rechtsanwaltsgesellschaft mbB, the contributing editor, for his continued assistance with this volume.

GETTING THE DEAL THROUGH

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Serbia

Bogdan Ivanišević and Bisera Andrijašević
BDK Advokati

Organisation and financing of healthcare

1 How is healthcare in your jurisdiction organised?

The Serbian healthcare system aspires to provide universal healthcare, guaranteed by article 68 of the Serbian Constitution. The central government is in charge of regulation and provision of healthcare, but local self-government units also have certain powers related to the organisation and provision of healthcare.

The healthcare service in Serbia comprises public healthcare institutions and private practice.

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

The public healthcare network is organised and governed by three main institutions:

- the Ministry of Health (the Ministry), in charge of policymaking, adoption of standards and quality control;
- the Institute for Public Health, tasked with collection and analysis of public health data and proposing of relevant measures; and
- the National Health Insurance Fund (NHIF), competent for financing of healthcare on all levels.

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

Serbia has a mixed system of healthcare financing. The contributions for the compulsory health insurance paid to the NHIF account for more than 90 per cent of the financing of medical care in both outpatient and inpatient sectors. At the same time, the Constitution provides that children, women during pregnancy and maternity leave, single parents with children up to seven years and the elderly are entitled to healthcare financed from the state budget. The Healthcare Act of 2005 identifies additional vulnerable groups with respect to which healthcare is financed from the budget. Persons with disability, persons suffering from certain serious diseases, uninsured persons, Roma population, and refugees and displaced persons, are among such vulnerable groups.

Compulsory health insurance contributions are charged in the form of premium levied on salaries of employees. The employer and the employee contribute in equal parts. The Health Insurance Act of 2005 also requests from other groups, such as entrepreneurs, artists and farmers, to pay mandatory contributions. The NHIF allocates the funds to healthcare institutions on the basis of contracts, usually entered into for a period of one calendar year.

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

Compliance – pharmaceutical manufacturers

3 Which legislation governs advertising of medicinal products to the general public and healthcare professionals?

Advertising of medicinal products is regulated by:

- the Medicines and Medical Devices Act of 2010 (MMDA); and
- the Rulebook on the Manner of Advertising of Medicines and Medical Devices of 2010 (the Rulebook on Advertising).

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

4 What are the main rules and principles applying to advertising aimed at healthcare professionals?

Use of any promotional material aimed at healthcare professionals (HCPs) must be previously approved by the Medicines and Medical Devices Agency (ALIMS). The material must be labelled 'Professional public only'. Promotion of a medicinal product to the professional public must include the basic information about the product contained in the marketing authorisation. Information provided to HCPs must be accurate, up to date, verifiable and sufficiently complete to allow the HCPs to assess the therapeutic value of a medicine. If a pharmaceutical company is introducing a new medicine on the market, the company may accompany the information about the medicine with one smallest available packaging of the medicine with the disclaimer 'Free sample, not for sale'. The Rulebook on Advertising prohibits any encouragement of HCPs to prescribe, issue, order the medicine or recommend its use or purchase through offering, giving or promising money or any other form of benefit. The INOVIA Code on Promotion and Interactions sets the monetary limit on value of informational or educational material provided to HPCs at €30.

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

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5 What are the main rules and principles applying to advertising aimed at the general public?

The MMDA explicitly forbids advertisement of prescription-only medicines to the general public in any form. The same rule applies to advertisement of the medicines issued at the expense of health insurance, medicines containing opiates or psychotropic substances and medicines for tuberculosis, sexually transmitted diseases, infectious diseases, chronic insomnia or diabetes and other metabolic diseases. Exceptionally, in situations of disease of epidemic or epizootic proportions, the ministries competent for health and agriculture may authorise provision of information on the usage of certain prescription-only medicines to the general public. The law does not consider use of the name of the medicinal product, international non-proprietary name (INN) or trademark, with the sole intent of designating the product, as advertising of a medicinal product.

Other over-the-counter medicines with valid marketing authorisation can be advertised in the media or in other ways. The Rulebook on Advertising lays down detailed rules for advertising of medicines or medical devices to the general public, including the minimum content of the advertisement, prohibited content, as well as the content of the obligatory accompanying warning. Provision of free samples of medicines and medical devices to the general public is prohibited, except for the medical devices that may be sold outside of pharmacies and specialised stores, as well as those used for implementation of prevention programmes. Companies must keep records of all advertisements.

6 What are the most common infringements committed by manufacturers with regard to the advertising rules?

The most frequent infringements in the ALIMS's practice relate to the non-conformity of promotional materials with the law, such as:

- off-label promotion;
- non-conformity with the approved summary of product characteristics;
- sensationalism in description of effects;
- undocumented superiority over competitive drugs;
- inadequate presentation of results of clinical trials;
- purposefully printing errors in order to change the meaning of the statement; and
- use and misuse of children and photos.

7 Under what circumstances is the provision of information regarding off-label use to healthcare professionals allowed?

The provision of information regarding off-label use to HCPs is prohibited. The marketing authorisation holder (MAH) may not market a medicine for a new indication until the ALIMS has approved and registered the amendments to the marketing authorisation.

Under the Rulebook on Advertising, any promotion of medical products to HCPs must be carried out in accordance with the summary of product characteristics. The summary must contain, inter alia, approved indications of the medicine. It follows that the provision of information regarding off-label use to HCPs is not allowed under any circumstances. The INOVIA Code on Promotion and Interactions also states that a medicinal product must not be promoted outside of its approved indications.

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

The MMDA and the Rulebook on Advertising contain the rules on the collaboration between the pharmaceutical industry and HCPs. INOVIA has introduced further detailed rules in the Code on Promotion and Interactions. Collaboration of the pharmaceutical industry and HCPs is regulated in the same manner for the outpatient and inpatient sectors.

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

In addition to rules on advertising and sponsorship issues described in question 4, the rules on collaboration of the pharmaceutical industry with HCPs regulate sponsorships, donations and grants in support of health research, consulting and other services, as well as gifts to medical professionals.

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

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

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

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

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

10 What are the most common infringements committed by manufacturers with regard to collaboration with healthcare professionals?

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

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

Collaboration of the pharmaceutical industry with patient organisations is regulated by the Code of Practice on the Relationship between the Pharmaceutical Industry and Patient Organisations adopted by INOVIA (the INOVIA Code of Practice).

The INOVIA Code of Practice is based on the principles of full independence of patient organisations, mutual respect between the parties, non-promotion of prescription drugs and transparency of the provision of any financial or non-financial support. Also, a pharmaceutical company must not seek to be the sole financier of a patient organisation or any of its main programmes.

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

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

12 Are manufacturers' infringements of competition law pursued by national authorities?

Yes. The competent authority, the Commission for Protection of Competition (CPC) has so far issued one decision on the infringement of competition law in pharmaceutical industry. In the decision, from 2008, the CPC found that eight manufacturers concluded a restrictive

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agreement on the relevant market of the wholesale of medical products in Serbia. The fines imposed on the manufacturers were 2 per cent of their relevant turnovers. In 2013, the CPC opened an investigation against Actavis for the alleged abuse of a dominant position owing to its refusal to issue an approval to the wholesaler for participation in a public procurement procedure. The CPC terminated the proceedings as it found that there was no infringement. In September 2018, the CPC initiated antitrust proceedings against four pharmaceutical companies in order to investigate suspected bid-rigging in the public procurement for haemophilia medicines.

13 Is follow-on private antitrust litigation against manufacturers possible?

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

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

14 What are the main mandatory anti-corruption and transparency rules applicable to pharmaceutical manufacturers?

Serbia does not have dedicated anti-corruption legislation. Anti-corruption and transparency rules are dispersed between various laws and implementing regulations. Particularly important is the Criminal Code of 2005 (as amended). The Criminal Code criminalises influence peddling, as well as active and passive bribery, both within the scope of commercial activity and in dealings with public officials.

The Rulebook on Advertising regulates the obligations of manufacturers with respect to transparency of information related to their relationship with HCPs (see question 9). The INOVIA Code on Promotion and Interactions and the Code for Patients Organisations introduce the industry guidelines with respect to transparency (see question 11).

Compliance – medical device manufacturers

15 Is the advertising of medical devices and the collaboration of manufacturers of medical devices with healthcare professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

The advertising of medical devices and the collaboration of manufacturers of medical devices with HCPs and patient organisations is regulated as rigorously as in the pharmaceuticals sector. Currently, the MMDA provisions on advertising and collaboration with HCPs with respect to medicines apply accordingly to medical devices. The Rulebook on Advertising also addresses both pharmaceuticals and medical devices. However, the new Medical Devices Act, which will enter into force in December 2018, regulates medical devices separately from medicines, in line with the EU legislation.

Pharmaceuticals regulation

16 Which legislation sets out the regulatory framework for granting marketing authorisations and placing medicines on the market?

Market authorisation and placing medicines on the market is governed by the MMDA and a series of related implementing by-laws adopted by the Ministry. The by-laws include the following:

- the Rulebook on Conditions for Manufacturing of Medicines, Contents of the Form for Marketing Authorisation and the Registry of Issued Marketing Authorisations of 2012 (as amended);
- the Rulebook on the Contents of the Request and Documents, as well as the Manner of Obtaining Marketing Authorisation of 2012 (as amended); and
- the Rulebook on the Contents of a Marketing Authorisation of 2012 (as amended).

These regulations rely in good part on the relevant EU regulations and directives, most importantly Directive 2001/83 on the Community Code relating to medicinal products for human use.

17 Which authorities may grant marketing authorisation in your jurisdiction?

The ALIMS is the competent authority for issuing marketing authorisations.

18 What are the relevant procedures?

The ALIMS may issue a marketing authorisation in one of the following procedures:

- a procedure with complete documentation;
- a simplified authorisation procedure, applicable to generics, generic hybrid medicines and biosimilars; or
- a procedure for issuing marketing authorisation under special conditions if the medicinal product has received marketing authorisation in the EU.

The ALIMS may also issue a marketing authorisation in an accelerated procedure within 150 (instead of 210) days of receipt of a duly prepared application. Accelerated procedure is applicable to medicinal products that have been issued a marketing authorisation through the EU centralised procedure, and for medicinal products for human use of utmost importance for public healthcare (primarily therapeutic innovations).

The ALIMS may issue a conditional marketing authorisation under a special agreement with the applicant, which may also be issued in an accelerated procedure. The ALIMS then assesses the continued fulfilment of the requirements agreed upon with the applicant on an annual basis and, if satisfied, renews the authorisation. A conditional marketing authorisation may be issued for:

- medicines used in the treatment, prevention or diagnosing of life-threatening diseases;
- medicines used in emergency cases or for treatment of rare diseases;
- medicines that have received a marketing authorisation under centralised procedure in the EU; or
- other medicines of special public health interest.

If special circumstances so require, the ALIMS may issue a special marketing authorisation for medicines in the specific interest of public health for a period of 12 months, obliging the applicant to report any adverse effects to the ALIMS of the use of such medicine and on the undertaken safety measures.

The deadline for the formal review of an application by the ALIMS is 30 days, and for the substantive review 210 days.

19 Will licences become invalid if medicinal products are not marketed within a certain time? Are there any exceptions?

The agency may adopt a decision to terminate a marketing authorisation if:

- a medicinal product was not marketed in Serbia for three years from the date of issuance of the marketing authorisation; or
- a medicinal product was on the market in Serbia for some time after the marketing authorisation was issued but was subsequently

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withdrawn from the market in Serbia for a period of three consecutive years.

The Ministry may propose to the ALIMS not to terminate the marketing authorisation if it considers that to be necessary for protection of health of citizens and animals. The rules on termination of marketing authorisation do not apply to medicinal products that the MAH markets exclusively outside the territory of Serbia.

20 Which medicines may be marketed without authorisation?

Marketing authorisation is not issued for magistral and galenic medicinal products, traditional herbal and homeopathic medicinal products (unless otherwise stipulated in MMDA), as well as other products and substances enlisted under article 39 of the MMDA.

21 Are any kinds of named patient programmes in place? If so, what are the requirements for pre-launch access?

The 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 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 with regard to issuance of a marketing authorisation for such medicine;
- have completed a clinical trial procedure in such a country;
- are currently subject to a centralised marketing authorisation procedure in the EU; or
- have received a marketing authorisation in the EU centralised procedure.

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 medicine in Serbia. Medicines with regard to which competent authorities in Serbia, the EU, or a country with similar or identical requirements have suspended or prohibited a clinical trial, cannot be imported in this manner.

The request for importation of a non-registered medicine may be submitted to the ALIMS if one of the following four conditions is met:

- there is no registered medicine of the same INN, strength, pharmaceutical form and packaging size on the market in Serbia;
- the medicine is intended for treatment of rare diseases in human medicine;
- it is necessary to ensure sufficient quantities and type of medicine in the case of epidemics, natural disasters and other emergency situations; and
- there are no sufficient quantities and types of medicines with marketing authorisation on the market in Serbia.

Pricing and reimbursement of medicinal products

22 To what extent is the market price of a medicinal product governed by law or regulation?

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

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

23 Must pharmaceutical manufacturers negotiate the prices of their products with the public healthcare providers?

Pharmaceutical manufacturers do not, as a rule, negotiate prices of medicines with public healthcare providers, because the government determines the prices of prescription-only medicines.

Exceptionally, negotiations take place in relation to the innovative medicines. In order to introduce to the Serbian market innovative medicines identified as a priority, the NHIF has set up a commission for negotiations with MAHs for the purpose of conclusion of special managed entry agreements and their inclusion on the positive reimbursement list of medicines (the Positive List). The commission invites the MAHs to submit their offers and to negotiate on a voluntary basis the conclusion of special agreements with the NHIF. Managed entry agreements between the NHIF and the MAH may be in the form of risk-sharing, cost-sharing, volume-cap and value-cap agreements. If the NHIF and the MAH reach an agreement, the medicine is included in the Positive List.

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

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

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

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

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

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

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

As a rule, the NHIF does not reimburse the costs of medicines prescribed for off-label use (ie, outside of the Positive List). 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 medicines are prescribed off-label on the basis of an opinion signed by a commission of three physicians.

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

Reimbursability of medicines is predicated upon presence of the medicine on the Positive List. The MAH submits an application for inclusion of a medicine on the Positive List to the NHIF, with the required documents. The deadline for the formal assessment of application is 30 days from the submission date.

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

- 90 days from the date of submission of the complete application for a generic medicine with same INN, the same or similar pharmaceutical form with one already on the list, or for a generic medicine

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Update and trends

A new Law on Medical Devices (the LMD) was adopted in November 2017, and is expected to enter into force on 1 December 2018. The LMD and its implementing legislation represent a step forward towards harmonisation with the EU legislation in the area of medical devices. A new Law on Medicines is also in the pipeline; however, no official draft has been published at this time.

whose INN is not on the list or generic medicines whose INN is on the list but in a different pharmaceutical form; and
- 120 days for original or innovative medicines.

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

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

26 Are manufacturers or distributors of medicinal products statutorily obliged to give a discount?

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

Medicine quality and access to information

27 What rules are in place to counter the counterfeiting and illegal distribution of medicines?

Production or sale of a counterfeit medicine in Serbia is prohibited. The Ministry is obliged to prohibit and order withdrawal from the market of a counterfeit medicine. The production and sale of a counterfeit medicine is a commercial offence, for which a fine may be imposed in the range between 1 million and 3 million Serbian dinars for legal entities. A fine of between 100,000 and 200,000 Serbian dinars may be imposed on a responsible person in a legal entity. In addition to the fine, commercial activities may be forbidden for three to 10 years.

The relevant rules are enforced by the Ministry and its inspection department, in cooperation with the Ministry of Internal Affairs/Police, Customs Administration, Prosecutor's Office, Intellectual Property Office and the ALIMS. If there is any suspicion that a medicine is a counterfeit, a complaint may be submitted to the Ministry by a patient, healthcare professional, manufacturer, or a MAH, in line with the Rulebook on the Manner of Quality Control of Medicines and Medicinal Devices of 2011 (as amended). In the case of suspicion of a counterfeit medicine, the competent health inspector may request from the ALIMS to conduct extraordinary control of medicine.

Serbian authorities also rely on international cooperation in order to fight against counterfeit medicines. Serbia has not yet signed the Council of Europe's MEDICRIME Convention.

28 What recent measures have been taken to facilitate the general public's access to information about prescription-only medicines?

As advertising of prescription-only medicines to the general public is prohibited, all the relevant information is provided by the ALIMS and other competent authorities. The ALIMS organises and monitors the collection and assessment of adverse reactions to a medicinal product, as well as the processing and evaluation of the obtained data and, in order to protect public health, makes the relevant information available to health and veterinary professionals and, if necessary, to the general public. The ALIMS publishes on its website the information for patients and the general public, including information on clinical trials, adverse effects of medicines and withdrawals of medicines from the market.

Furthermore, the ALIMS has adopted the concept of 'open data'. Since 2015, the ALIMS has made available several sets of data on the e-government portal, including the registers of human and veterinary medicines and medical devices, approved clinical trials, import authorisations for non-registered medicines and generic names of medical devices.

The medicines database may also be publicly accessed through a mobile phone app available for Android and iOS, and contains all the information from the summary of product characteristics.

29 Outline major developments to the regime relating to safety monitoring of medicines.

The MMDA and the Rulebook on the Method of Reporting, Collecting and Monitoring Adverse Reactions to Medicines of 2011 (as amended) govern pharmacovigilance in Serbia. The main stakeholders in pharmacovigilance are the ALIMS, the Inspection Department within the Ministry, MAHs, HCPs and patients. In 2005, the National Pharmacovigilance Centre was established within the ALIMS. The Ministry determines regional pharmacovigilance centres for specific parts of the national territory. The ALIMS also cooperates with the competent pharmacovigilance centre of the World Health Organization, and other relevant international institutions.

In the pre-marketing phase, safety of a medicines is assessed in clinical trials and the procedure for issuing of marketing authorisation, and in the post-marketing phase the pharmacovigilance is carried out continuously.

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 the ALIMS with electronic reports;
- keep records of all suspected serious ADRs reported by health or veterinary professionals, or records of ADRs that MAHs can reasonably be expected to be aware of, and to 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.

The ALIMS organises and monitors the collection and assessment of adverse reactions to a medicinal product, as well as the processing and evaluation of the obtained data, and on that basis may:
- determine a list of medicines that are marked with a symbol for additional monitoring of their safety profile after obtaining marketing authorisation;
- modify, terminate, or temporarily revoke a marketing authorisation; and
- suggest the competent ministry stop or prohibit the marketing, or withdraw a medicinal product from the market.

Every healthcare institution in Serbia is obliged to appoint its pharmacovigilance coordinator as the contact person in the domain of pharmacovigilance. HCPs and patients may report suspected ADRs on a dedicated form and submit the reports via email, post or fax. Online reporting of ADRs is also available on the ALIMS's website, through an eReporting module released and maintained by the Uppsala Monitoring Centre of the World Health Organisation. Online reporting allows national pharmacovigilance centres to capture individual safety case reports directly from patients and HCPs into the VigiFlowTM database.

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Vaccination

30 Outline your jurisdiction's vaccination regime for humans.

Serbia has a mandatory vaccination system. Vaccination is mandatory with regard to:

- active immunisation of persons of certain age against 11 diseases: tuberculosis, diphtheria, tetanus, poliomyelitis, pertussis, measles, rubella, mumps, hepatitis B, haemophilus influenzae type B, pneumococcus vaccine (starting from March 2018);
- active immunisation of persons in international travel against yellow fever and other diseases as requested by the host country; and
- active and passive immunisation of persons exposed to certain infectious diseases, persons in special risk, and persons employed in healthcare institutions.

The HPV vaccine has not yet been made mandatory.

Primary healthcare physicians are tasked with administering vaccines and keeping immunisation records. Vaccination costs are recoverable for the vaccines included on the Positive List. Parents who choose not to vaccinate their children may be fined from 30,000 to 150,000 Serbian dinars for each refusal and are sometimes threatened with jail sentences.

Immunisation coverage of all vaccines in Serbia has, until recently, been above 95 per cent for all types of vaccines. The anti-vaccination lobby for the measles, mumps, and rubella (MMR) vaccine has been active in the country since 2012, blaming the MMR vaccine for autism and opposing mandatory MMR vaccination. Until 2011, MMR vaccination coverage in Serbia was above 95 per cent, which is the targeted level for eliminating measles and rubella adopted in the European Vaccine Action Plan 2015–2020. In 2011, the coverage was 98 per cent for two-year-olds and 96.5 per cent for six-to-seven-year-olds, while in 2013 it started to decrease and in 2014 it fell to 85.6 per cent and 89.2 per cent, respectively. An outbreak of measles occurred at the end of 2014, with 721 reported cases in 2017, according to the World Health Organization.

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