Chambers
Global Practice
Guides

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

Life Sciences 2022

Serbia: Law & Practice

Bisera Andrijašević and Anja Gligorević
BDK Advokati

practiceguides.chambers.com

SERBIA

Law and Practice

Contributed by:
Bisera Andrijašević and Anja Gligorević
BDK Advokati see p.24

CONTENTS

1. LIFE SCIENCES REGULATORY FRAMEWORK

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Applicable Legislation

Pharmaceutical products in Serbia are regulated in the Medicines and Medical Devices Act of 2010 (as amended) (Medicines Act). The sections of the Medicines Act regulating medical devices have ceased to apply and medical devices are now regulated separately in the Medical Devices Act of 2017. A considerable number of by-laws regulate in more detail different matters governed by the Medicines Act and Medical Devices Act.

Competent Bodies

Competences for implementation and enforcement of pharmaceutical and medical devices legislation are shared between three governmental bodies:

- the Agency for Medicines and Medical Devices (ALIMS), the regulatory body tasked with enforcement of pharmaceutical and medical devices legislation for pharmaceuticals for human and veterinary use. The ALIMS is an independent regulatory body established by law;
- the Ministry of Health has certain competences with respect to the area of pharmaceuticals and medical devices for human use, particularly with respect to licensing and administrative oversight; and
- the Ministry of Agriculture, Forestry and Water Management is competent for matters concerning the pharmaceutical products intended solely for veterinary use.

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

Right to Appeal

Decisions of the ALIMS can be challenged before the competent ministry, ie, the Ministry of Health with regard to medicines and medical devices for human use, and the Ministry of Agriculture, Forestry and Water Management with regard to medicines for veterinary use.

A party to the proceeding before the ALIMS, or any person whose rights, obligations or legal interest may be affected by the outcome of the proceedings, may submit an appeal. An appeal may also be submitted if the ALIMS fails to adopt a decision within the statutory deadline.

Appeal Procedure

A party may submit an appeal against the ALIMS's decision to the competent ministry through the ALIMS. The deadline for submitting an appeal is 15 days from adoption of the first-instance decision, or, in the case of failure to adopt a decision, within a year from the expiry of the statutory deadline. Decisions of the competent ministry upon appeal, as well as first-instance decisions of the ministries in the matters from their competence, are final and may be challenged only before the Administrative Court.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Classification of Pharmaceuticals

Pharmaceuticals are classified into pharmaceuticals for human use and those for veterinary use. Furthermore, pharmaceutical products are classified into (i) prescription-only, and (ii) over-the-counter (OTC) pharmaceuticals. The ALIMS carries out the classification in the process for issuing marketing authorisations. Prescription-only and OTC pharmaceuticals are subject to different regimes with respect to pricing, advertising, dispensing, and sale.

Classification of Medical Devices

Medical devices are classified into (i) general medical devices, (ii) in vitro diagnostic medical devices, and (iii) active implantable medical devices.

General medical devices are classified according to the degree of risk for the users into:

- Class I – medical devices with a low degree of risk for the user;
- Class IIa – a low to medium degree of risk for the user;
- Class IIb – a medium to high degree of risk for the user;
- Class III – medical devices with a high degree of risk for the user.

A notified body carries out the classification of medical devices. As an exception, the manufacturer classifies class I medical devices and others as in vitro medical devices.

2. CLINICAL TRIALS

2.1 Regulation of Clinical Trials

Clinical Trials for Pharmaceuticals

The Medicines Act is the principal piece of legislation regulating clinical trials of pharmaceuticals. Additionally, the Healthcare Act of 2019 and the Rulebook on 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 Medical Devices of 2011, set out detailed rules related to ethics committee approval and performance of clinical trials.

Clinical trials of pharmaceuticals are conducted in accordance with the Ministry of Health's guidelines on Good Manufacturing Practice (2017), Good Laboratory Practice (2008), and Good Clinical Practice (2017).

Clinical Trials for Medical Devices

The Medical Devices Act and the Rulebook on Clinical Trials for Medical Devices of 2018 (as amended) regulate clinical trials for medical devices.

Clinical trials of medical devices are conducted in accordance with the guidelines of the Good Clinical Practice.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Clinical Trials Subject to Approval

Sponsors must request simultaneous authorisations for conducting a clinical trial from the ALIMS and the Ethics Committee of Serbia, a government-appointed expert body that takes care of the provision and implementation of healthcare at the national level, in the case of:

- clinical trials for medicines which do not have a marketing authorisation or for which a different use from the one prescribed in the approved summary of product characteristics is proposed, or medical devices for which a conformity assessment has not been carried out; and
- an interventional post-marketing clinical trial, where the medicinal product is applied in accordance with the conditions prescribed in the marketing authorisation, but requires additional diagnostic procedures, as well as the monitoring procedures defined by the clinical trial protocol, or where a medical device has been subject to conformity assessment, but the clinical trial is conducted for a purpose that is absent from the conformity assessment.

Clinical Trials Subject to Notification only

Sponsors must only notify the commencement of a trial to the ALIMS if they wish to conduct a non-interventional post-marketing clinical

trial of a pharmaceutical or a medical device in accordance with an approved summary of product characteristics of a pharmaceutical for which a marketing authorisation has already been issued, or a clinical trial of a medical device for which a conformity assessment has already been carried out.

2.3 Public Availability of the Conduct of a Clinical Trial

Clinical Trials Database

Basic information on all clinical trials conducted at a given moment in Serbia are publicly available within the database kept by the ALIMS on the E-government Portal. The information includes the date and number of the relevant decision on approval of the clinical trial, the protocol number, the names of the sponsor and the client, and the title of the trial, as well as its basic description.

Publication of Clinical Trial Results

Sponsors of clinical trials do not have an obligation to make the results of clinical trials publicly available. They must submit to the ALIMS, within one year of completion of the clinical trial, the report containing detailed results, both positive and negative, obtained through the trial.

2.4 Restriction for Using Online Tools to Support Clinical Trials

There are no restrictions for using online tools to support clinical trials, either for recruiting or monitoring purposes. Sponsors must, however, undertake all adequate measures to provide information to, and secure the consent of, the subjects and to protect their personal data.

2.5 Use of Resulting Data from the Clinical Trials

The Serbian Data Protection Commissioner has long held that data on a patient participating in a clinical trial are personal data, as long as a specific individual can be identified from such data. The same conclusion also applies under the new Data Protection Act (2018), which is an almost verbatim copy of the GDPR.

The Commissioner has yet to express its opinion on the legal basis for the data processing concerning the resulting data, including for disclosing the data, ie, transferring them to third parties or affiliates. The Commissioner might consider that reliance on consent as the legal basis for any type of processing of data in the context of clinical trials is unavailable because consent could not be considered as freely given. Therefore, one or more of the following legal grounds for the processing could be employed:

- processing is necessary for compliance with a legal obligation to which the controller is subject;
- processing is necessary for the performance of a task carried out in the public interest; or
- processing is necessary for the purposes of the legitimate interests pursued by the controller, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.

The resulting data may be transferred abroad, under the conditions similar to those from the GDPR Articles 44 et seq. Importantly, the Data Protection Act does not recognise the model clauses of the European Commission as a transfer tool eliminating the need to seek and obtain transfer authorisation. Instead, the law authorises (in Article 45(11)) the data protection authority to adopt controller-to-processor standard contractual clauses. The authority adopted these clauses in January 2020. Controller-to-controller standard contractual clauses are still missing in Serbia because the Data Protection Act in the current iteration does not authorise the data protection authority to adopt them.

2.6 Databases Containing Personal or Sensitive Data

Creation of a database with the resulting data from the clinical trials would require carrying out a data protection impact assessment, in line with the Decision of the Serbian Data Protection Commissioner on the list of categories of data processing activities for which a data protection impact assessment must be carried out.

3. MARKETING AUTHORISATIONS FOR PHARMACEUTICAL OR MEDICAL DEVICES

3.1 Product Classification: Pharmaceutical or Medical Devices

An assessment of whether a product should be classified as a pharmaceutical or as a medical device is carried out by the ALIMS in the process of issuing of a marketing authorisation for a pharmaceutical product or registration of a medical device. The Medicines Act and the Medical Devices Act contain the criteria for classification.

The main criterion for differentiating between pharmaceuticals and medical devices is the following: pharmaceuticals are applied to humans or animals with the intention to restore, improve, or modify physiological function by pharmacological, immunological or metabolic action, or by setting up a medical diagnosis; however, medical devices do not fulfil their principal intended purpose in or on the human body by pharmacological, immunological or metabolic means, but the medical device may be assisted in its function by such means.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Biological medicinal products must meet the same quality, safety, and efficacy criteria as other medicinal products to receive marketing authorisation. Biosimilars, however, may benefit from the short-form procedure for the granting of marketing authorisation, equivalent to the one available to generic medicinal products.

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

Validity and Renewal of Marketing Authorisation

Marketing authorisation is valid for five years. It may be renewed based on the reassessment of the risk/benefit ratio of the medicine. If, on the basis of the available pharmacovigilance data, the ALIMS determines that a pharmaceutical is safe, it grants a permanent marketing authorisation. In the event that the ALIMS determines that the pharmaceutical product is not safe, it will refuse to grant a permanent authorisation. Instead, the ALIMS will decide on whether to renew an authorisation for an additional period of five years. A marketing authorisation may be renewed for an additional period of five years only once. If the ALIMS still has justified doubts with respect to product safety, it will terminate the already issued marketing authorisation.

Revoking of a Marketing Authorisation

The ALIMS will revoke a marketing authorisation if it determines that the product is not safe for the life and health of humans and animals. The ALIMS will revoke the marketing authorisation if:

- the medicinal product is harmful under normal conditions of use;
- the medicinal product has no therapeutic efficacy;
- the risk-benefit ratio is not favourable under typical application conditions;
- the qualitative and quantitative medicinal product composition does not match the declared composition of the medicinal product;

- the marketing authorisation was issued on the basis of incomplete or false information, or if data is not amended in accordance with the law;
- the marketing authorisation-holder no longer meets the prescribed requirements;
- the medicinal product was not marketed in Serbia for three years from the date of marketing authorisation issuance or was withdrawn from the market in Serbia for three consecutive years.

The ALIMS may vary, suspend, or revoke a marketing authorisation on the basis of data on adverse drug reactions collected within the scope of its pharmacovigilance activities.

Medical Devices

If the Ministry of Health determines that a medical device constitutes an unacceptable risk to public health and/or safety, or does not meet the statutory requirements, the Ministry may order the manufacturer or its authorised representative to take all appropriate and justified preventive or corrective measures. The Ministry may also prohibit or restrict the placing of a medical device on the market, set specific requirements for the placement of a medical device on the market, or order the withdrawal of a medical device from the market.

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

Pharmaceuticals

The Medicines Act and a series of implementing by-laws govern the granting of a marketing authorisation. The ALIMS is the competent authority for issuing marketing authorisations. A medicinal product may be granted a marketing authorisation after undergoing pharmaceutical (pharmaceutical, chemical, and biological), pharmaco-toxicological and clinical trials and provided that it has the required quality, safety, and efficacy. The ALIMS conducts a formal review of an application for marketing authorisation within 30 days. The substantive review must be completed within 210 days. If the ALIMS requests additional documents from the applicant, the deadline is paused until submission of those documents. There is also an accelerated procedure for obtaining a marketing authorisation, for a medicinal product which obtained a marketing authorisation in accordance with the EU centralised procedure, and for medicines for human use of utmost importance for public healthcare. The accelerated procedure may last no longer than 150 days from receipt of a complete application.

Medical Devices

Medical devices are not subject to marketing authorisation. Medical devices may be placed on the market or in use if they comply with essential requirements set out in the Medical Devices Act regarding conformity assessment, labelling, and supporting documents, if they are properly procured, installed and maintained, and used in accordance with their purpose. Even though registration is not a condition for placing the medical devices for which a conformity assessment was carried out on the market or putting them to use, a manufacturer or its representative must submit the application for registration to the ALIMS. The Medicines Act contains a limited list of medical devices which do not need to be registered in order to be placed on the market or put to use (ie, medical devices for approved clinical trials or research and development, custom-made devices, devices for the personal use of a patient previously treated abroad, devices imported on a temporary basis for medical fairs, and those manufactured in medical institutions for in-house use).

Variations

A request for a variation is submitted to the ALIMS. Marketing authorisation-holders are obliged to:

- report IA-type variations within 12 months from the moment of application ("do and tell" procedure);
- report IAIN variations without delay following their application for the purpose of continuous monitoring of the medicinal product;
- request the ALIMS's approval for IB-type and type-II variations before their application ("tell, wait and do" procedure); and
- submit a new request for marketing authorisation for variations related to changes of the active ingredient or changes in strength, pharmaceutical form, or manner of application of the medicine, and for variations of veterinary medicines for animals used in human alimentation.

The ALIMS conducts a formal assessment of the application within 15 days from the day the application and the substantive review within 90 days from the day when the application is deemed complete. The pharmaceutical product must be marketed in accordance with the approved variation at the latest within 12 months from the delivery of the ALIMS's act on approval of the variation.

Transfer of a Marketing Authorisation

A marketing authorisation may be transferred to a new marketing authorisation-holder at the request of the existing one submitted to the ALIMS. The ALIMS will assess whether the prospective new holder meets the requirements prescribed by the law. The ALIMS conducts a formal assessment of the application within 15 days from the day of the application and the substantive review within 60 days from the day when the application is deemed complete.

3.5 Access to Pharmaceutical and Medical Devices without Marketing Authorisations

General Conditions

An importer may submit to the ALIMS a request for importation of a pharmaceutical for which a marketing authorisation was not issued in Serbia if:

- there is no registered pharmaceutical of the same international non-proprietary name (INN), strength, pharmaceutical form, and packaging size on the market in Serbia;
- the pharmaceutical is intended for treatment of rare diseases in humans;
- it is necessary to ensure sufficient quantities and types of a pharmaceutical in the case of epidemics, natural disasters, or other emergency situations; or
- there are no sufficient quantities and types of medicines with marketing authorisation on the market in Serbia.

Compassionate Use Programme

In addition to the import of unregistered pharmaceuticals under the general conditions previously described, import is also permitted on the basis of a compassionate use programme. The purpose of such a programme is to treat specific patients or a group of patients who are afflicted by life-threatening diseases such as AIDS, cancer and other malignant or auto-immune diseases. Import is organised as a donation or humanitarian aid to a health institution, provided that such pharmaceuticals are not subject to clinical trial in Serbia at moment of the submission of request for import, and provided that they:

- are undergoing an advanced stage (Phase III) of clinical trial procedure in an EU country or in a country with similar requirements as Serbia regarding issuance of a marketing authorisation;

- have completed a clinical trial procedure in that country;
- are currently subject to a centralised marketing authorisation procedure in the EU; or
- have received a marketing authorisation in the EU centralised procedure.

Exceptionally, a patient or a group of patients who are not eligible to participate in the ongoing clinical trial for that medicinal product in Serbia may receive a donation or humanitarian aid in the form of unregistered pharmaceuticals or registered pharmaceuticals for an unregistered indication, which are at that time subject to clinical trial in Serbia.

Import of Unregistered Medical Devices

The ALIMS may also authorise the import of a medical device not registered in Serbia. This is permissible if that import is intended for a particular patient or group of patients, or comes as a donation or humanitarian aid, or the subject-matter of the import is a medical instrument for scientific research or for emergency situations. In order to be imported, these medical devices must have undergone a conformity assessment.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

Pharmacovigilance of Medicinal Products

In the post-marketing phase, marketing authorisation-holders must ensure continuous monitoring of adverse drug reactions to a pharmaceutical product (pharmacovigilance), namely:

- the continued monitoring of adverse drug reactions (ADRs), and have a full-time employee with adequate qualifications responsible for pharmacovigilance;
- keep records on all suspected ADRs notified in Serbia, EU countries or any third country, and provide the ALIMS with electronic reports;
- keep records of all suspected serious ADRs reported by health or veterinary professionals, or records of ADRs that MAHs can reasonably be expected to be aware of, and to report this information promptly to the ALIMS, no later than 15 days following the receipt of information;
- submit to the ALIMS periodic drug-safety reports at six-month intervals if the marketing authorisation was conditional or under special circumstances; and
- submit periodic drug-safety reports every six months for a period of two years following the placing of the pharmaceutical on the market, then annual reports for another two years and finally submit reports at three-year intervals.

Vigilance of Medical Devices

A manufacturer of medical devices or its authorised representative must employ a person responsible for vigilance and continuously monitor the medical device on the market, with the aim of identifying any need for corrective or preventive measures.

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

The Agency and the competent Ministries must treat as confidential all the data in the documentation enclosed within an application for the issuance of a marketing authorisation, variation, or a renewal. This obligation applies in particular in relation to trade secrets, ie, when the following cumulative conditions are met:

- the data are confidential, ie, not generally known or easily available to persons usually dealing with that kind of information;
- the data have commercial value due to their confidentiality, during the period of confidentiality; and

- an applicant for a marketing authorisation, variation, and/or renewal, under the circumstances, takes reasonable measures to keep that data confidential.

Information from the documentation submitted during the procedure of obtaining a marketing authorisation, as well as in other procedures handled by the Agency and/or relevant Ministries, may only be disclosed to third parties with the consent of the applicant, or if the data are already available to the general or professional public for the purpose of providing information necessary for use or handling of a pharmaceutical or a medical devices, or required for the protection of health in humans and animals.

3.8 Rules against Illegal Medicines and/or Medical Devices

Pursuant to the Medicines Act and Medical Devices Act, it is prohibited to manufacture or sell counterfeit pharmaceuticals and medical devices. If any such products are detected on the market, the competent ministry will prohibit their sale and order recall at the proposal of the ALIMS.

In 2019, Serbia signed the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME).

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

If certain goods are suspected of infringing intellectual property rights, customs authorities may, upon request or ex officio, suspend the release of goods or retain the goods. Customs authorities will request that the owner of the goods and the right-holder make a declaration about the potential infringement. The right-holder may initiate court proceedings against the alleged infringer, and in that case the goods will remain confiscated until the court renders a decision, or the right-holder may give permission to the customs authorities to destroy the goods, in which case the goods will be destroyed, provided that the owner of the goods consents to, or does not oppose, the destruction.

4. MANUFACTURING OF PHARMACEUTICAL AND MEDICAL DEVICES

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

Manufacturing of Pharmaceuticals

The manufacturing of pharmaceuticals is subject to a licence issued by the Ministry of Health to legal entities. The application for a manufacturing licence must contain information and documents regarding the location and premises of the manufacturing site, equipment, personnel, medicines to be produced, relevant procedures, as well as other information required by the law. The Ministry issues a licence for a particular manufacturing site and certain forms of pharmaceutical manufactured at that site. The licence may include an entire manufacturing process or only a part of the process. The licence is valid for an indefinite period.

Manufacturing of Medical Devices

Manufacturers of medical devices may be both legal entities and individuals. A manufacturing licence is necessary only for class I medical devices (other than Is and Im class), other in vitro diagnostic medical devices, medical devices for which no conformity assessment has been performed, those not covered by the sign of conformity, custom-made devices for a particular patient, and medical devices for clinical trials, as well as a system or a kit. The Ministry of Health issues a manufacturing licence for medical devices, which is valid for five years.

5. DISTRIBUTION OF PHARMACEUTICAL AND MEDICAL DEVICES

5.1 Wholesale of Pharmaceutical and Medical Devices

Wholesale of medicines and medical devices includes purchase, storage, distribution, imports, and export. A wholesale licence is issued by the Ministry of Health for an indefinite period for pharmaceuticals, and for medical devices for a period of five years.

The exception from obtaining of a wholesale licence applies to (i) manufacturers of medicines for products from their production programme, (ii) manufacturers of medical devices with a registered seat in Serbia, who must obtain a manufacturing licence for medical devices from their production programme, and (iii) entities performing only import or export activities on behalf of and for the account of a medicines wholesale licence-holder.

Applicants for a wholesale licence must provide information and documents regarding the legal entity, location and premises, supply territory, products for which the wholesale licence is sought, personnel, equipment, a plan for an urgent withdrawal of products from the market, as well as the other information of relevance for the issuance of the wholesale licence.

5.2 Different Classifications Applicable to Pharmaceuticals

See **1.3 Different Categories of Pharmaceuticals and Medical Devices** relating to different categories of pharmaceuticals.

6. IMPORTATION AND EXPORTATION OF PHARMACEUTICALS AND MEDICAL DEVICES

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

The import and export of pharmaceutical and medical devices in Serbia are governed by the Medicines Act and the Medical Devices Act, respectively. Import and export constitute the wholesale of medicines and medical devices and as such are additionally regulated in the rule books governing the wholesale of medicines and medical devices.

Depending on whether the product is intended for human or veterinary use, the Ministry of Health or the Ministry of Agriculture issues a pharmaceutical wholesale licence. The ALIMS issues (i) opinions on the import of cell or tissue samples for clinical trials' procedures of medicinal products, (ii) approvals for the import of medicines for clinical trials, and (iii) approvals for the import of medicines without a marketing authorisation.

Customs officials check if all the conditions are met in each case.

6.2 Importer of Record of Pharmaceutical and Medical Devices

An importer of record for pharmaceuticals or medical devices may be a legal person with a relevant wholesale licence.

Furthermore, a pharmaceutical or a medical device manufacturer may import products from its production programme, raw materials and substances for production, interim products, and semi-finished products, in accordance with the manufacturing licence, medicinal products

marketing authorisation, or a subcontracting agreement.

Manufacturers of medical devices with a registered seat in Serbia who do not need a manufacturing licence must obtain a wholesale licence for medical devices from their production programme.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

The import and export of pharmaceuticals and medical devices is subject to a prior issuance of a medicinal product wholesale licence, subject to exceptions described under **6.2 Importer of Record of Pharmaceutical and Medical Devices**.

A legal entity that performs only the activities of the import and export may perform these activities without a medicinal product wholesale licence if it conducts the import and customs clearance activities on behalf of and for the account of a wholesale licence-holder to the site of the goods' free marketing, in accordance with the customs regulations.

Generally, only medicinal products with a valid marketing authorisation and medical devices registered in the ALIMS's registry of medical devices may be imported. Exceptionally, the ALIMS may approve import of medicinal products without a marketing authorisation in Serbia or unregistered medical devices under conditions prescribed for compassionate-use programmes, donation or humanitarian aid, or the emergency situations described in **3.5 Access to Pharmaceutical and Medical Devices without Marketing Authorisations**.

Persons entering or leaving Serbia may carry medicinal products in the amount not exceeding their six-month requirement within one calendar year, for their personal usage or for an animal travelling with them, depending on the type and length of the underlying illness. They have to provide to the Customs Authority the approval of a competent Serbian ministry for bringing in or carrying out medicinal products for personal use.

The transfer of medicinal products across the border in the amount not exceeding the 15-day requirement of an individual is not subject to any approval.

6.4 Non-tariff Regulations and Restrictions Imposed upon Importation

Although Serbia is not yet a European Union (EU) member state, nor a member of the World Trade Organization (WTO), Serbia has to a large extent harmonised its legislation with the EU acquis and WTO agreements. Therefore, non-tariff restrictions are rare and imposed only in particularly justified situations, in line with the general principles of the EU and WTO to limit the use of non-tariff restrictions.

Non-tariff regulations and restrictions are imposed based on the Harmonized Tariff Schedule (HTS) Code. The products that are subject to those restrictions (usually quotas) are listed for example in specific international agreements which Serbia has concluded.

6.5 Trade Blocs and Free Trade Agreements

Serbia is a party to the Stabilisation and Association Agreement with the EU, the Central European Free Trade Agreement, and the Agreement with EFTA, as well as a number of bilateral free-trade agreements.

7. PHARMACEUTICAL AND MEDICAL DEVICE PRICING AND REIMBURSEMENT

7.1 Price Control for Pharmaceuticals and Medical Devices

The prices of pharmaceuticals are controlled by the government only with respect to prescription-only pharmaceuticals. The government determines the criteria for the pricing of pharmaceuticals, and calculates their maximum prices at the joint proposal of the ministries competent for health and trade. The Ministry of Health calculates the maximum wholesale price for prescription-only pharmaceuticals.

The pricing of prescription-only medicines is governed by the Medicines Act, the Decree on Criteria for Forming of Prices of Prescription-Only Pharmaceuticals for Human Use, and the Decision on Maximum Prices of Prescription-Only Pharmaceuticals for Human Use. Prescription-only pharmaceuticals for which the government did not determine the maximum wholesale price may not be placed on the market.

Once the government decides on the maximum permitted wholesale price of the pharmaceutical, marketing authorisation-holders may apply to include the pharmaceutical into the positive reimbursement list of medicines ("Positive List"), to be prescribed and issued at the expense of the compulsory health insurance. Wholesalers of pharmaceuticals as well as pharmacies must align the prices of pharmaceuticals that they have in stock with the maximum prices determined by the government on the same day as the relevant decision on maximum prices enters into force.

However, marketing authorisation-holders are free to determine the prices of over-the-counter medicines and must only notify the Ministry before March 31st of the current year of the price for the previous year.

7.2 Price Levels of Pharmaceutical or Medical Devices

The Ministry of Health calculates the maximum wholesale price for prescription-only pharmaceuticals based on a number of criteria. One of these criteria is price parity, ie, the comparable wholesale prices of pharmaceuticals in reference countries, namely, Slovenia, Croatia and Italy and the current wholesale price in Serbia.

7.3 Pharmaceuticals and Medical Devices: Reimbursement from Public Funds

For the cost of a pharmaceutical to be reimbursed, the product must be included in the Positive List. The general criteria for adding a pharmaceutical to the List are, as follows:

- pharmaco-therapeutic justification of the pharmaceutical;
- pharmaco-economic justification of the pharmaceutical; and
- financial resources provided by the annual financial plan of the National Health Insurance Fund.

In cases when there are not sufficient resources to include in the Positive List all pharmaceuticals which comply with the general criteria, the National Health Insurance Fund further considers two special factors: (i) the existence, if any, of a managed entry agreement, and (ii) the priority for adding the pharmaceutical to the list according to the following criteria:

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

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Within the scope of the process for inclusion of pharmaceuticals into the Positive List of pharmaceuticals to be reimbursed from the national health insurance, the Central Medicines Commission established by the National Health Insurance Fund conducts the health technology assessment of medicines when reviewing the applications for inclusion of pharmaceuticals on the List.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Dispensing and sale of pharmaceuticals is regulated only with respect to prescription-only medicines. The ALIMS decides whether a medicine is to be dispensed only on prescription in a marketing authorisation procedure. Prescriptions and dispensing of pharmaceuticals are regulated in the Rulebook on Form and Content of Medical Prescription, Manner of Issuing and Prescription of Pharmaceuticals. Healthcare professionals are obliged to observe the recommendations from Good Practice in Prescribing of Pharmaceuticals.

A pharmacy may replace the prescribed brand-name medicine with its generic equivalent only if the patient consents after being adequately informed by the pharmacist, and under the condition that the physician did not prohibit replacement on the prescription.

8. DIGITAL HEALTHCARE

8.1 Rules for Medical Apps

There are no special rules governing medical apps in Serbia. Medical devices are defined in the Medical Devices Act as any instrument, apparatus, appliance, software, implant, reagent, material and other product used alone or in combination, including software provided by the manufacturer for diagnostic or therapeutic purposes and which is software support that is necessary for its proper use in people intended by the manufacturer, and is used for:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation or compensation of injury or disability;
- investigation, replacement or modification of the anatomy or physiological or pathological process and state;
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations;
- control or support of conception; and
- products intended for cleaning, disinfection or sterilisation of medical devices.

Therefore, a medical app may be classified as a medical device, depending on its intended use. The ALIMS has the authority to determine if a medical app is a medical device, on a case-by-case basis.

8.2 Rules for Telemedicine

Telemedicine is not regulated in Serbia. In the context of the coronavirus health crisis, the Ministry of Health introduced an E-health portal, where patients can fill out a questionnaire with regard to their symptoms and receive instructions on the steps to take, and can enter their contact information to be contacted by a physician for an appointment.

Conditions for the introduction of a wider variety of telemedicine services should be fulfilled through the implementation of a proposed Programme of Digitalisation of the Health System of the Republic of Serbia for 2022-2026.

8.3 Promoting and/or Advertising on an Online Platform

There are no special rules applicable to online advertising. Advertising of medicines and medical devices is regulated in the Medicines Act and Medical Devices Act, respectively, while the relevant by-laws provide detailed rules.

In addition, the Serbian Association of Manufacturers of Innovative Drugs (INOVIA) adopted in 2014 the Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (the INOVIA Code).

8.4 Electronic Prescriptions

Electronic prescriptions in Serbia are regulated in the Rulebook on Form and Content of Medical Prescription, Manner of Issuing and Prescription of Pharmaceuticals. Prescription of medicines is conducted through an integrated health information system in electronic form, and prescriptions in paper form may still be issued exceptionally.

8.5 Online Sales of Medicines and Medical Devices

Online sales of medicines and medical devices are prohibited in Serbia.

8.6 Electronic Health Records

According to the Health Documentation and Health Records Act (2014, as amended) (HDHRA), health institutions, private practices, and other legal entities are obliged to keep health records (Article 2, para 2). The records may be kept either in paper or electronic format. Where not all the requirements for keeping the records in electronic format are met, the competent healthcare professional is obliged to keep a printed and signed copy of the electronic records in paper format.

Additionally, the HDHRA prescribes the keeping of a so-called electronic medical dossier. According to the law, the dossier is kept within the Integrated Health Information System of the Republic of Serbia (Article 49) and it contains the assembled data important for the patient's long-term health status which derive from the patient's health records and health insurance records kept in electronic format. Only competent healthcare professionals may access the dossier, immediately prior to the provision of healthcare services. Patients are entitled to opt for their electronic medical dossiers not to be kept. Patients are also entitled to access their data from the dossier. They may exercise the right to access either online or by addressing the competent healthcare professional or other authorised individual. In practice, there has been little use of electronic medical dossiers.

The Serbian Data Protection Act considers health-related information as sensitive data (Article 17 of the Act). The processing of sensitive data is permissible if the data controller may rely on a legal basis for processing of any category of personal data, sensitive or not, and additionally on a statutory exception from the general prohibition of the processing of sensitive data.

It is permitted to transfer and store sensitive data of patients on cloud platforms. The Serbian Data Protection Commissioner would typically consider a cloud platform to be a data processor. Therefore, exporters of health-related sensitive data may use as the transfer instrument the controller-to-processor standard contractual clauses which the Data Protection Commissioner issued in January 2020.

9. PATENTS RELATING TO PHARMACEUTICALS AND MEDICAL DEVICES

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

In Serbia, the Patent Act (Official Gazette of the Republic of Serbia, No 99/2011, 113/2017 – other act, 95/2018, 66/2019 and 123/2021) (Patent Act) applies to all patents.

Under the Patent Act, the general patentability requirements of novelty, inventive step, and industrial application apply to all inventions, including pharmaceutical and medical device inventions.

However, there are certain exceptions to patentability of pharmaceutical inventions. A patent will not be granted in respect of methods for treatment by surgery or diagnostic methods or therapy practised directly on the human or animal body (Methods). This exception does not apply to products, in particular substances or compositions, for use in any of these methods.

9.2 Second and Subsequent Medical Uses

The Patent Act allows for the patentability of a second or subsequent medical use of a known substance or composition.

The patentability requirement of novelty does not exclude patentability of any substance or composition, comprised in the state of the art, for use in a Method, provided that its application in any Method is not comprised in the state of the art. The requirement of novelty also does not exclude patentability of that substance or composition, for any specific use in a Method, provided that such use is not comprised in the state of the art.

Provisions of the Patent Act that regulate the issue of second and subsequent medical uses are in line with the corresponding provisions of the European Patent Convention (EPC). The European Patent Office's (EPO) interpretation of these provisions is that they also apply to patent claims for treatments that draw their novelty from new dosage regimes, methods of administration, or new classes of patients (the interpretation expressed in the EPO Enlarged Board of Appeal's decision G2/08). Since the corresponding provisions of the Patent Act are modelled after the EPC, it can reasonably be expected that the Serbian Intellectual Property Office (IP Office) and courts would also allow patent claims in relation to new dosage regimes, methods of administration, or new classes of patients.

The activities that constitute infringement of second and subsequent patents of pharmaceutical products are described in **9.4 Pharmaceutical or Medical Device Patent Infringement**.

9.3 Patent Term Extension for Pharmaceuticals

The owner of a pharmaceutical patent can apply for a supplementary protection certificate (SPC).

A patent-owner can submit an SPC request to the IP Office within six months from obtaining marketing authorisation for the patented product. The SPC is valid for the period equal to the period from the date of submission of the patent application to the date of the first marketing authorisation, minus five years. The maximum duration of an SPC is five years. An SPC can be extended for six additional months if all necessary tests are completed in the European Union in accordance with an approved paediatric research plan.

SPCs obtained as of 2 July 2022 will not confer protection against the acts of (i) making of a product protected by an SPC for the purpose of

export, and (ii) making, no earlier than six months before the expiry of the SPC, of a product, for the purpose of storing the product in Serbia, in order to place that product on the Serbian market after the expiry of the SPC.

Third parties can request that the IP Office declare an SPC invalid under the same conditions prescribed for declaration of patent invalidity.

9.4 Pharmaceutical or Medical Device Patent Infringement

The following activities constitute patent infringement:

- manufacturing, offering, placing on the market, using, and importing or storing for those purposes, a patented product or a product directly obtained through a patented process;
- using or offering a patented process; and
- offering or supplying products that constitute essential elements of a protected invention to parties unauthorised to use the invention, provided that the products are offered or supplied in bad faith.

An applicant, owner, or licensor of a patent may submit a lawsuit to the competent court for patent infringement or a serious threat of infringement. Applying for marketing authorisation before a patent expires does not amount to patent infringement, since it falls within the scope of exemption mentioned in **9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices**.

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

Defences to patent infringement include:

- use in personal and non-commercial purposes;
- research and development activities, including activities that are necessary for obtaining an authorisation for placing medicinal products on the market (a Bolar exemption); and
- direct, individual preparation of a medicine in a pharmacy in accordance with a prescription, and placement of that medicine on the market.

Compulsory licences are available on request.

Requirements for obtaining a compulsory licence depend on the grounds on which the licence is sought (eg, insufficient use of the protected invention, inability to use another invention commercially, etc). Usually, the following will apply:

- a request for a compulsory licence can be submitted after the expiry of a period of four years from the date of filing of the patent application, or three years from the grant of the patent, whichever period expires later;
- In order to obtain the licence, the requestor must prove that he or she has previously unsuccessfully attempted to conclude a licensing agreement with the patent-owner.

These requirements will not apply if a compulsory licence is being issued because of a public emergency (eg, in the fields of health, defence, and ecology) which jeopardises the survival of the state or its citizens, or in cases of public non-commercial use.

9.6 Proceedings for Patent Infringement

An applicant, patent-owner, SPC-owner, and patent licensor may submit a lawsuit to the competent court for patent infringement or a serious threat of infringement.

Available remedies include, among others:

- determination of infringement or serious threat of infringement;

- prohibition of acts that constitute infringement or serious threat of infringement;
- compensation of damages; and
- seizure, removal from the market, or destruction of infringing products.

Infringement proceedings are initiated with a lawsuit. The defendant then submits a response to the lawsuit, after which the court schedules hearings. The defendant may at any time submit a request for determination of invalidity to the IP Office. The court would consider the invalidity proceedings a preliminary issue, and may decide to rule on this issue itself, or, more likely, to discontinue the court proceedings and wait for the IP Office's decision on invalidity.

Before, during or after the proceedings, the court may order provisional measures on request, provided that the requestor presents evidence reasonably supporting his or her claim that his or her rights have been infringed or are about to be infringed. Such provisional measures include, for example, seizure or removal from the market of infringing products, and prohibition of acts that represent infringement or serious threat of infringement.

9.7 Procedures Available to a Generic Entrant

A generic entrant has no obligation to "clear the way". However, by not "clearing the way", a generic entrant exposes itself to possible infringement proceedings, in the event that its activities amount to a serious threat of patent infringement.

The authorisation procedure for pharmaceuticals and medical devices does not take account of patent protection.

10. IP OTHER THAN PATENTS

10.1 Counterfeit Pharmaceuticals and Medical Devices

Intellectual property right-holders may initiate civil proceedings in the case of counterfeiting. Moreover, counterfeiting is a criminal offence. Anyone can submit a criminal complaint to a public prosecutor, based on which the public prosecutor will decide whether to conduct an investigation, file an indictment, or reject the criminal complaint. Counterfeiting may also trigger misdemeanour proceedings. Customs authorities may prevent counterfeited goods from entering Serbian territory, as explained in **3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices**.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

The IP Office will reject an application for a descriptive trade mark. According to the IP Office's Methodology in the Procedure for Trademark Registration and Procedures for Registered Trade marks (Methodology), a mark used for pharmaceuticals will be considered descriptive if:

- the mark consists exclusively of the name of the chemical substance used for production of that pharmaceutical; or
- the mark slightly deviates from the generic name of the chemical substance.

According to the Methodology, the IP Office will consult the World Health Organization's (WHO's) list of international non-proprietary names (INNs). In trade-mark registration proceedings, the IP Office considers the WHO's recommendation that a verbal trade mark for a pharmaceutical should differ in at least three letters from the generic name.

The new Trademark Act, enacted in 2020, lifted the prohibition on parallel imports. According to the Trademark Act, a trade-mark proprietor who has placed, or consented to placing, on the market anywhere in the world goods protected by the trade mark, cannot prohibit further circulation of such goods.

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

It is possible to protect a 3D shape as a trade mark. Therefore, pharmaceuticals, medical devices and their packaging may be protected, provided that they meet the requirements for trade-mark protection. However, if a mark consists exclusively of the shape or another characteristic which results from the nature of the goods, or is necessary to obtain a certain technical result, or gives substantial value to the goods, trade-mark protection cannot be granted. This restriction may be especially significant when seeking protection for 3D trade marks that relate to medical devices, tablets, etc.

A shape can also be protected as industrial design if it meets the requirements of novelty and individual character. However, protection will not be granted if the design is determined solely by the function of the product in question.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Data Exclusivity for Foreign Manufacturers

Different rules on data exclusivity apply to manufacturers with and without a seat in Serbia. Originators without a seat in Serbia may benefit from a ten-year exclusivity period from the issuance of the marketing authorisation for the data submitted to obtain that marketing authorisation. Originators may not extend the exclusivity period on account of amendments to the marketing authorisation in terms of medicinal product strength, pharmaceutical form, methods of administration, packaging, or variations and claims for extension of the scope of the marketing authorisation.

Therefore, an applicant for a marketing authorisation issuance in a short-form procedure (for a generic medicinal product, generic hybrid medicinal product, or biologically similar medicinal product) may obtain a marketing authorisation after ten years from the date of issuance of the marketing authorisation for the reference product, but may apply for that marketing authorisation earlier, after at least eight years have elapsed from the date when the initial marketing authorisation had been issued in Serbia, in the European Union or in countries that have the same or similar requirements for the issuance of the authorisation.

If, during the eight years from the issuance of the marketing authorisation for the reference medicinal product, the marketing authorisation-holder for the reference medicinal product obtains a new marketing authorisation for one or more new indications that show a significant improvement in that reference medicinal product therapy, the period of ten years may be extended (cumulatively) for one more year.

Data Exclusivity for Manufacturers with a Seat in Serbia

These rules will also apply to manufacturers with a seat in Serbia from the moment of accession of Serbia in the European Union. Currently, the ten-year protection period applies only to biotechnological medicines, while for the other medicinal products the protection period is six years from the date of receiving the first marketing authorisation for the reference pharmaceutical.

11. COVID-19 AND LIFE SCIENCES

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

In March 2020, the Customs Administration announced that legal entities, regardless of the business activity they perform, may import masks and gloves in order for their employees' personal protection. However, masks and gloves imported for these purposes may not be distributed, ie, sold to third parties.

During March, April and May of 2020, the Regulation on Special Technical Requirements, Standards and Application of Medical Devices During the Emergency Condition Due to COVID-19 Disease Caused by SARS-CoV-2 (Regulation) was in force. The Regulation allowed the procurement, putting into use and application in treatment of medicines and medical devices that were not manufactured in accordance with all prescribed standards. This relaxation applied only during the state of emergency.

11.2 Special Measures Relating to Clinical Trials

On 24 March 2021, the ALIMS issued Instructions for Clinical Trial Sponsors During the COVID-19 Pandemic. The instructions cover, among others, the following topics:

- handling the medicine in a clinical trial;
- changes in visits/transfer of respondents from one centre to another;
- informed consent of the respondents;
- revising the monitoring plan, etc.

No special measures were issued in relation to COVID-19 treatments or vaccines.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

In accordance with the provisions of Medicines Act, pre-dating COVID-19, the ALIMS can issue a temporary marketing authorisation for the duration of an epidemic, natural disaster or state of emergency and only for a certain type and quantity of a medicine. On that basis, the Government has adopted the Regulation on Temporary Marketing Authorisation for Medicine – Vaccine for Immunisation of the Population Against Infectious Disease COVID-19 (Official Gazette of the Republic of Serbia, Nos 17/2021 and 97/2021) (Regulation), providing that the ALIMS may issue a temporary marketing authorisation for a COVID-19 vaccine if one of the following applies:

- the vaccine is on the World Health Organisation's (WHO) list of COVID-19 vaccines (in accordance with the WHO's Emergency Use Assessment and Listing mechanism);
- there is a bilateral agreement signed by Serbia, the applicant is a medicine manufacturer that has a manufacturing licence in Serbia, and the vaccine is not yet on the WHO's list of COVID-19 vaccines (but the listing procedure has been initiated); or
- the vaccine is registered in the country of origin, the EU, or in countries that have identical or similar requirements for the issuance of a marketing authorisation as in the countries of the EU.

Under the Regulation, the ALIMS may only issue a temporary marketing authorisation if an epidemic has been declared, the Ministry of Health has issued an order on emergency immunisation, and the relevant national bodies have determined that it is necessary to obtain a certain amount of COVID-19 vaccine urgently.

Other possible pathways applicable for emergency approvals of pharmaceuticals under the Medicines Act are for the ALIMS to issue:

- a marketing authorisation in an expedited procedure for a medicine of the greatest interest for protection of population health, primarily relating to innovation of treatment, as well as for a medicine that has already been approved by the European Medical Evaluation Agency;
- a provisional marketing authorisation for medicines used in an emergency, or for other medicines of a greater public health interest; in a state of emergency where public health is in jeopardy, the applicant can obtain a provisional marketing authorisation without providing to the ALIMS the clinical, pharmaceutical, biological, toxicological, and other types of data that are generally required;
- a "marketing authorisation under special circumstances" for a medicine of a particular public health interest.

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

No new measures were introduced due to COVID-19 to facilitate obtaining the manufacturing certifications.

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

During March, April and May of 2020, the export and re-export of medicines was prohibited, except in the case where:

- medicines were manufactured in Serbia, but were not registered in Serbia, ie, the medicines were manufactured exclusively for foreign markets; and
- a foreign person shipped medicines in the transit procedure from the Serbian customs territory.

Exceptionally, the export and re-export of medicines was allowed upon the approval of the government.

11.6 Drivers for Digital Health Innovation Due to COVID-19

The ALIMS announced during the COVID-19 crisis that, as of 20 August 2020, its activities that were previously performed in direct contact with parties were to be performed exclusively by e-mail, registered mail, or telephone. The ALIMS provided dedicated e-portal and email addresses for communication with parties.

In the context of the coronavirus health crisis, the Ministry of Health introduced an E-health portal, where patients can fill out a questionnaire regarding their symptoms and receive instructions on the steps to take. The patients can enter their contact information to be contacted by a physician for an appointment.

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

The government has not announced an intention to issue compulsory licences for COVID-19-related treatments or vaccines.

The general rules for issuing compulsory licences, described in **9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices**, would also be applicable to COVID-19-related patents.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

No liability exemptions were introduced regarding COVID-19 vaccines or treatments.

In accordance with the regular liability regime, the marketing authorisation-holder is responsible for the quality, safety, and efficacy of the medicine.

The manufacturer of a medicine is responsible for the process of manufacturing. If that manufacturer places a product batch on the market, he or she is also responsible for the quality, safety and efficacy of the medicine.

11.9 Requisition or Conversion of Manufacturing Sites

Existing provisions of the Rulebook on the Conditions, Content of Documentation and Manner of Approval of Amendments to the Marketing Authorisation (2012) regulates requisition or conversion of manufacturing sites. The marketing authorisation-holder must notify the ALIMS of suspension on any manufacturing site ("Do and Tell" procedure). In the case of a modification of a manufacturing site of biological medicine active substance, the marketing authorisation-holder must apply for a new authorisation.

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

No changes to the system of public procurement were introduced due to COVID-19.

BDK Advokati is a full-service commercial law firm for corporate, institutional and high net worth (HNW) clients with multiple specialisations and with offices in Serbia, Montenegro, and Bosnia and Herzegovina. The firm advises clients on deals and support and represents them in contentious situations and provides legal advice in support of their business. The firm's focus is on prime expert work and complex cross-border deals, but it is also able to work on bread-and-butter matters in an efficient manner due to institutionalised know-how and organised processes. BDK Advokati's Life Sciences and Healthcare Group has assembled lawyers with different areas of expertise of relevance to these industry sectors, and has advised leading multinational companies on commercial, competition, data protection, disputes, employment, M&A and industry regulations. Present and former clients from the industry include Aspen Pharma, Biotest AG, GlaxoSmith-Kline, Hoffmann-La Roche, Mylan, Hemofarm and Farmalogist.

AUTHORS

Bisera Andrijašević is head of BDK Advokati's life sciences and healthcare sector, with a particular focus on regulatory issues. Although she is based in the firm's Montenegrin office, she participates in work across all of the firm's three jurisdictions. She also has extensive experience in competition law matters. Bisera is a member of the AmCham Healthcare Committee. She is a frequent contributor to BDK Advokati's Competition Law Blog. She obtained LLM degrees from the University of Hamburg and the Erasmus University in Rotterdam and an MA from the University of Bologna. Bisera also completed studies at the European Pharma Law Academy 2017 at Downing College, Cambridge. She is fluent in English, conversant in French and reads Italian.

Anja Gligorević is a junior associate in the intellectual property and data protection departments. She obtained her LLB from the University of Belgrade in 2019 and is currently pursuing an LLM in intellectual property law. Anja is fluent in English and possesses intermediate knowledge in German.

BDK Advokati

Bulevar kralja Aleksandra 28
11000
Belgrade
Serbia

Tel: +381 11 3284 212
Email: office@bdkadvokati.com
Web: www.bdkadvokati.com

Chambers Guides to the Legal Profession

Chambers Directories are research-based, assessing law firms and individuals through thousands of interviews with clients and lawyers. The guides are objective and independent.

practiceguides.chambers.com