The Life Sciences Law Review

Fourth Edition

Editor
Richard Kingham

Law Business Research

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EDITOR'S PREFACE

The fourth edition of *The Life Sciences Law Review* provides an overview of legal issues of interest to pharmaceutical, biotechnology and medical device companies in more than 30 jurisdictions. As before, each chapter contains information on legal requirements relating to the key stages in the life cycle of a regulated product, from discovery, through the clinical development process, registration, manufacturing and promotion, plus other issues of special interest, such as pricing and reimbursement, special liability regimes, competition and commercial transactions in the context of the medical products business. Each of the chapters has been prepared by a recognised expert in the relevant jurisdiction, and the resulting work product will assist industry lawyers, regulatory affairs staff and others who need to have an understanding of the issues in each major market.

There is also a chapter on international harmonisation, which plays an increasingly important role in the regulation of pharmaceuticals and medical devices. In particular, the guidelines adopted by the International Conference on Harmonisation have been incorporated into the national requirements for pharmaceuticals in the European Union, United States, Japan and most other developed countries, and are increasingly influential in developing countries. Readers may find it useful to review this chapter before consulting the national chapters, because it is often key to understanding many local requirements.

Once again, I wish to thank all of the lawyers who contributed to this reference work. It is a pleasure to be associated with them.

Richard Kingham
Covington & Burling LLP
Washington, DC
March 2016

Chapter 28

SERBIA

Bogdan Ivanišević and Slobodan Trivić[1]

I INTRODUCTION

The Serbian medicines market is mainly import-oriented, with two-thirds of import compared with one-third of domestic production. According to the World Bank, health-care expenditure in comparison with GDP is 10.6 per cent, amounting to approximately $475 per capita in total, including government spending and out-of-pocket expenditure.

The Medicines and Medical Devices Act of 2010 (the Act) and a series of related by-laws govern importation, production, distribution, marketing authorisation, and advertising of medicines and medical devices. Under the Act, the Medicines and Medical Devices Agency (the Agency) has important powers concerning production, marketing authorisation, importation, advertising, clinical trials, pharmacovigilance and quality control. The Ministry of Health of Republic of Serbia (the Ministry) supervises the work of the Agency and decides on appeals against its decisions, issues and withdraws authorisations to laboratories and manufacturers, sets price ceilings for prescription drugs, and has the authority to proscribe distribution of medicines as well as continuation of clinical trials that are already under way.

II THE REGULATORY REGIME

The laws regulating the market for medicinal products and medical devices rely in good part on the relevant EU Regulations[2] and Directives, most importantly

1 Bogdan Ivanišević is a partner and Slobodan Trivić is an associate at BDK Advokati/Attorneys at Law. The authors would like to thank Milomir Matović and Igor Nikolić for their assistance in the preparation of this chapter.

2 Nos. 726/2004, 507/2006 and 1394/2007.

Directive 2001/83.[3] A comprehensive legislative reform in 2010 introduced significant novelties in the Serbian law concerning definitions of medicinal products, competences of the Agency, eligibility for marketing authorisation, procedures in granting marketing authorisations, pricing of medicinal products, importation of unregistered medicines and medical devices, labelling and marking of medicines and medical devices, and others.

i Classification

General classification under the Act distinguishes between medicines for human use and medicines for veterinary use, and medical devices.

The statutory definition of medicines for the most part corresponds to the definition from Directive 2001/83. Medicines are products placed in the market in specific potency, pharmaceutical form and packaging, and containing a substance or a combination of substances properties for treating or preventing disease in human beings or animals, and a substance or a combination of substances that may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Medical devices are categorised in three groups: (1) general; (2) in vitro; and (3) active implantable medical devices. The definition of 'general medical device' mirrors that of a 'medical device' under Directive 90/385/EEC. The concepts of in vitro device and active implantable medical device have the same meaning as under Directives 90/385/EEC and 98/79/EC. The Act classifies custom-made device and active medical device under the broader category of general medical device.

Products such as food supplements, cosmetic products and pesticides are separately regulated.[4] Nevertheless, the standards and requirements contained in the relevant guidelines issued by the Ministry, which apply to non-clinical trials of medicines and medical devices, also govern non-clinical trials of those products.

ii Non-clinical studies

The Ministry issues authorisations to laboratories to conduct non-clinical studies (toxicological and pharmacological trials) on behalf of manufacturers or other eligible applicants. A study must be performed in accordance with the Good Laboratory Practices

3 Regulation (EC) of the European Parliament No. 726/2004, Regulation (EC) of the European Commission No. 507/2006 and Regulation (EC) of the European Parliament and the Council 1394/2007; and, Directive of the European Parliament and of the Council on the Community code relating to medicinal products for human use as regards advanced therapy medicinal products (EC) No. 2001/83 (as amended by Directives Nos. 2002/98, 2003/63, 2004/24, 2004/27, 2008/29, 2009/53 and 2009/120).

4 The Food Safety Act (2009), the Consumer Goods Health Safety Act (2011) and the Plant Protection Products Act (2009).

Guidelines issued by the Ministry.[5] When the laboratory submits to the applicant the results of the study, it must enclose a certificate issued by the Ministry confirming adherence to good laboratory practices.

Studies that are performed on animals are regulated separately under the Animal Welfare Act (2009).[6] Laboratories conducting such studies must register before the Ministry of Agriculture and Environmental Protection – Veterinary Administration (the Veterinary Authority). The Veterinary Authority decides about a request for the conduct of a study submitted by an eligible applicant. In order to receive an approval, the applicant must have appointed a qualified person responsible for the welfare of animals during the study and must meet other conditions prescribed by the Veterinary Authority.

iii Clinical trials

The sponsor of a clinical trial can be a manufacturing pharmaceutical company or another legal entity or individual who initiates, finances, and manages the conduct of the trial. The sponsor can be a foreign entity, provided that it has a representative office in Serbia or has authorised a Serbian-based legal entity to perform one or more of the sponsor's trial-related duties and functions.

Commencement of a clinical trial is conditioned upon approval of two bodies: the ethical committee of the medical institution chosen to carry out the trial; and the Agency. The Agency monitors the conduct of the trial in accordance with the Good Clinical Practice Guidelines, devised by the Ministry.[7] The sponsor is obliged to report to the Agency any serious and adverse reaction or event that may occur during the trial. The Agency may propose that the Ministry inspect and eventually suspend or prohibit the clinical trial if the Ministry determines that the procedure does not comply with the good clinical practice standards.

A sponsor is obliged to employ, on a full-time basis and indefinite term, a qualified person responsible for preparing all documentation during the clinical trial authorisation procedure and subsequent amendments to the documents, as well as for pharmacovigilance (i.e., vigilance of devices).

Persons undergoing clinical trials must have been informed about the nature, significance and potential risks of a clinical trial in a comprehensible manner, and sponsors have to obtain their written consent. Participants can withdraw their consent at any time during clinical trials. Sponsors are obliged to insure the participants before commencing clinical trials from damage that they may sustain as a consequence of such trials.

5 Guidelines on Good Laboratory Practices (2008).

6 The Animal Welfare Act (2009).

7 Guidelines on Good Practices in Clinical Trials (2008).

iv Named-patient and compassionate use producers

The Agency may approve importation 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:

a are undergoing an advanced stage (phase three) 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;
b have completed a clinical trial procedure in such a country;
c are subject to a centralised procedure in the EU for issuance of a marketing authorisation; or
d have received a marketing authorisation in the EU centralised procedure.

In 2015, the Ministry of Health introduced an additional ground for importing medicines not registered in Serbia. Such importation is 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.[8]

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.

A health-care institution that has obtained approval for such importation can donate the imported medicine to another health-care institution, provided that the ethical committee of the health-care institution receiving the donation has enacted a decision on the medical justifiability for the application of such medicine.

As of 2015, a medicinal product may be imported into Serbia under this regime in several types of packaging. Including:

a packaging in which the medicine has undergone a clinical trial abroad;
b packaging for a medicine imported as a donation or humanitarian aid, which contains a marking such as 'named-patient programme', 'compassionate use' or similar; or
c packaging that has been approved in the foreign country in the procedure for issuance of a marketing authorisation in that country.[9]

v Pre-market clearance

In order for a medicine to be placed on the market in Serbia, the Agency has to issue a marketing authorisation. Persons belonging to one of the following categories may be eligible for such authorisation:

a manufacturers of a medicinal product who have manufacturing authorisations issued in Serbia;

8 Rulebook on the Conditions for Import of Medicines and Medical Devices Which Do Not Have Market Authorisation, or Which Are Not Registered in the Registry of Medical Devices (2014, amended in 2015).

9 Ibid.

b representative offices or authorised representatives of foreign manufacturers, based in Serbia;

c authorised Serbian-based representatives of foreign non-manufacturing entities that hold marketing authorisations for medicinal products, issued by competent bodies in the EU or in another country in which regulations provide for the same requirements for issuing authorisations for medicinal products as in Serbia; or

d Serbian-based legal entities to which manufacturers with manufacturing authorisations issued in Serbia have transferred their marketing authorisations or granted the right to be the marketing authorisation holder (MAH) for the production portfolios.

Applicants from any of these four categories have to have qualified persons employed on a full-time basis and for an indefinite term, responsible for pharmacovigilance and, additionally, persons responsible for handling the administrative procedures before the Agency.

The Agency has 30 days to carry out a formal review of an application, and 210 days for a substantive review, the latter centring on the issues of quality, efficacy and safety of the medicinal product.

The Agency may issue a marketing authorisation in a procedure with complete documentation, a simplified authorisation procedure or under special conditions if the medicinal product has received marketing authorisation in the EU. The simplified procedure applies to generics, generic hybrid medicines and biosimilars.

The Agency may also issue a marketing authorisation in an accelerated procedure within 150 (instead of 210) days of receipt of a duly prepared application for medicinal products that have been issued a marketing authorisation in accordance with a centralised procedure in the EU and for medicinal products for human use and of utmost importance for public health care (primarily therapeutic innovations).

The Agency can issue a conditional marketing authorisation under a special agreement between the Agency and the applicant. The Agency then monitors 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 the following categories:

a medicines used in the treatment, prevention or diagnosing of life-threatening diseases;

b medicines used in emergency cases or for treatment of rare diseases;

c medicines that have received a marketing authorisation under centralised procedure in the EU; or

d other medicines of particular public health interest.

Conditional marketing authorisation can also be issued in the accelerated procedure.

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

Traditional herbal and homeopathic medicines are normally not subject to marketing authorisation procedures. Instead, the Agency simply registers such medicines

if they meet certain conditions concerning labelling, potency and the mode of use as prescribed in a Ministry rulebook.[10] If, however, the herbal or homeopathic medicine does not meet the conditions, it becomes subject to a marketing authorisation procedure.

A separate rulebook governs registration of medical devices.[11] Those who may apply for registration of medical devices are manufacturers to whom the Ministry has issued a manufacturing authorisation or an authorised representative of a foreign manufacturer. The rulebook differentiates between applicants for registration of medical devices carrying a CE mark[12] and applicants for registration of devices lacking such mark. The latter group must submit more detailed application documentation to the Agency.

Custom-made medical devices can be lawfully manufactured on the basis of an order by a qualified professional for an individually named patient. They are not subject to registration before the Agency and require a special 'custom-made' marking. Devices modified for professional use by a medic do not fall within the scope of custom-made medical devices to which the above rules apply.

vi Regulatory incentives

Under the Patent Act (2011), the Intellectual Property Office may grant a supplementary patent certificate with respect to a particular medicinal product, which confers the same rights as conferred by the basic patent. The application for a certificate may be lodged within six months of the date on which the first marketing authorisation was issued, or, where the marketing authorisation is granted before the basic patent is granted, within six months of the date on which the patent is granted. The certificate is granted for a period equal to the period that elapsed between the date on which the application for a basic patent was lodged and the date of the first marketing authorisation, reduced by a period of five years, provided that the duration of the certificate does not exceed five years.

If a marketing authorisation for a medicine was issued in Serbia or in the EU or another country with similar requirements for the issuance of authorisation, other persons cannot apply for marketing authorisation for a corresponding generic product, generic hybrid medicine or biosimilar for a period of eight years from the issuance of the authorisation for the reference medicine. Authorisation to market a generic product, generic hybrid medicine or biosimilar may not be granted before the expiration of 10 years after the issuance of the authorisation for the reference medicine. This period can be extended to another year if, during the first eight years, the MAH has obtained an authorisation for one or more new indications amounting to a substantial therapeutic improvement.

10 Rulebook on the Detailed Conditions and Method of Registration of a Medicine into the Registry of Traditionally Herbal and Homoeopathic Medicines (2011).

11 Rulebook on Method of Registration of Medical Devices in the Registry of Medical Devices and Content of Registration Application for Medical Device in the Registry of Medical Devices (2010).

12 The mark confirming that the product meets the requirements of the relevant EU medical device directives.

vii Post-approval controls

The MAH is obliged to monitor, keep records of, and report in a timely manner to the Agency any adverse effects caused or believed to be caused by the use of the medicinal product. The Agency also receives input from 'regional pharmacovigilance centres' designated by the Ministry, which are duty-bound to collect, process and deliver to the Agency any information that they identify concerning adverse effects of a medicine.

The Agency is authorised to change, on the basis of the data obtained, the terms under which the marketing authorisation was initially issued, to withdraw the authorisation or to suspend it temporarily for the medicine at issue. The Agency is obliged to notify the Ministry no later than one business day after the issuance of the decision, and it may propose to the Ministry to suspend or proscribe the distribution of the medicine or to order its withdrawal from the market.

If an MAH wishes to transfer the marketing authorisation to another company, it must apply for approval with the Agency. The Agency may approve the transaction if the transferee would otherwise be eligible to receive a marketing authorisation. Upon expiration of a 12-month period after the Agency's approval of transfer, the new MAH may place the medicine on the market only in accordance with the approved variation.

viii Manufacturing controls

Medicinal products can be manufactured by companies that have obtained an authorisation from the Ministry, regardless of whether the products are intended for distribution in the internal market or for export. The manufacturer is authorised separately for each series of medicinal products for one or more manufacturing facilities.

Under the Guidelines on Good Manufacturing Practices, the manufacturer must have a person supervising the aspects of the manufacturing process that critically affect the resulting quality of the medicine, including selection and use of the substances and the packaging materials, and testing of the final product.[13] The Guidelines also mandate involvement of a qualified pharmacist in charge of verifying that the medicinal products being placed on the market have been produced in accordance with the Act and the implementing regulations. The manufacturer must act in accordance with good medicines distribution practices, which are set out in guidelines issued by the Ministry.[14] If the manufacturer also has a quality control laboratory, it must have a qualified pharmacist for quality control and it must comply with standards of good laboratory practices. The Ministry is authorised to control the manufacturer's compliance with the said rules and standards.

The Act and a rulebook, the latter enacted by the Ministry, regulate the manufacturing of medical devices.[15] The by-laws additionally provide for mandatory application of SRPS EN ISO 13485:2008 standards governing quality requirements for medical devices.

13 Guidelines on Good Manufacturing Practices (2010).

14 Guidelines on Good Medicines Distribution Practices (2008).

15 Rulebook on the Requirements for Production of Medical Devices (2012).

ix Advertising and promotion

Under the Act and an implementing rulebook,[16] advertising of medicinal products and medical devices means any form of communication of truthful information about a medicinal product to the general and professional public with a view to encouraging prescription, supply, sale or consumption of medicinal products.

The law contemplates the following modes of advertising of medicinal products and medical devices:

a advertisement through the media, including the internet, advertisement in public places and forms of advertising by other means (mail, visits, or similar);

b promotion of medicines to health-care and veterinary professionals who are qualified to prescribe medicines, by means of providing information at professional conferences or in professional journals, or through other forms of promotion;

c giving of free samples to the professional public; and

d sponsorship of scientific and promotional events attended by the professional public.

Stating only the name of a medicinal product, international nonproprietary name or trademark, if it is intended solely as a reminder of the product, is not considered as advertising of a medicinal product.

Over-the-counter (OTC) medicines can be advertised in the media or in other ways. Information about the medicinal product or medical device must be presented objectively and may not be misleading. Only medicinal products with valid marketing authorisations can be advertised. Information about the effects of the products may be provided only in accordance with the summary of product characteristics, which makes an integral part of the marketing authorisation.

Advertisement of prescription-only medicines to the general public is explicitly forbidden in any form. As an exception, the Ministry or the Veterinary Authority may authorise provision of information on the usage of certain prescription-only medicines to the general public via the media, in situations of disease of epidemic or epizootic proportions.

Promotion of a medicinal product to the professional public must include the basic information about the product contained in the marketing authorisation (i.e., information corresponding to the summary of product characteristics, as well as the information about the rules governing supply of the product).

x Distributors and wholesalers

Wholesale of medicines and medical devices is used in the Act as a generic term for their distribution, import, export, supply and storage. The Ministry is competent to authorise

16 Rulebook on the Modes of Advertising of Medicines and Medical Devices (2010).

such activities and keep a registry of the authorised wholesalers. A company applying for wholesale authorisation must comply with requirements regarding the qualified pharmacist, facilities, equipment and staff.[17]

xi Classification of products

The Agency has the authority in the marketing authorisation procedure to classify medicines as prescription-only or OTC. The factors determining the categorisation are as follows:

a potential health hazards if the medicine is used without medical supervision;
b whether the medicine presents a health hazard because the practice has demonstrated its frequent and widespread incorrect use;
c whether the medicine contains substances or preparations whose effects or side effects demand further research; and
d whether the medicine is prescribed for parenteral administration.

Classification must be marked on the outer packaging of a medicinal product.

xii Imports and exports

As mentioned in Section II.x, *supra*, the Act considers import or export of medicines as types of wholesale. Importers or exporters, as the case may be, must comply with the general requirements applying to wholesalers regarding the engagement of a qualified pharmacist, adequate facilities, equipment and staff. In the clearance procedures before the customs authorities, the importer or exporter (as the case may be) must present an agreement with the MAH, a copy of the MAH's marketing authorisation and an invoice obtained from the foreign supplier (i.e., from the foreign purchaser in the case of export from Serbia).

xiii Controlled substances

The Law on Substances Used in the Prohibited Production of Narcotic Drugs and Psychotropic Substances (2005) provides the statutory framework for production and wholesale of narcotics and psychotropic substances in Serbia. The Ministry is competent to classify controlled substances, control and monitor their placement and movement on the Serbian market, and authorise the manufacturing of substances, their import or export, distribution, transportation and other related activities. Only the controlled substances that appear on a list managed by the Ministry may be lawfully marketed in Serbia, with an authorisation also issued by the Ministry.

17 Rulebook on the Requirements for Wholesale of Medicines and Medical Devices, the Data Entered into the Registry of Authorisations for the Wholesale of Medicines and Medical Devices, and the Modes of Registration (2012).

xiv Enforcement

The Ministry and the Veterinary Authority are in charge of verifying the compliance of legal entities and individuals with the relevant laws and regulations. They monitor compliance with the varied good practice guidelines and, when considered necessary, prohibit production, wholesale, laboratory testing or advertisement of medicinal products. These authorities are also authorised to order withdrawal or destruction of medicines and certain medical devices that have been found to be defective.

III PRICING AND REIMBURSMENT

The pricing regime varies depending on whether the medicine is classified as prescription-only or OTC. Prices of prescription-only medicines are fixed 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. MAHs freely determine the prices of OTC medicines. They must notify the Ministry before 31 March of the current year of the price for the previous year.

Serbia has a mandatory health insurance system administered by the National Health Insurance Fund (NHIF). The NHIF publishes a list of medicines that are provided to insurers as prescription-only and reimbursed by the government insurance programme. The managing board of the NHIF decides on inclusion of a medicine in the list of medicines. A medicine may be included in the List on the basis of a recommendation from NHIF's expert commission for the relevant group or type of medicines or a recommendation from the Ministry of Health. The MAH may itself submit a formal request to the NHIF to include the medicine on the list.

Certain medical devices contained in a list of devices are also reimbursed by the NHIF. The NHIF sets maximum prices of medical devices included in the list.

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

Persons demonstrating a substantial interest in the matter may appeal any administrative decision issued by the Agency, Ministry or Veterinary Authority, under the rules of the general administrative law. The appeal is submitted to the Ministry, which issues a final and binding decision, with no possibility of further decision-making. Against such decision of the Ministry the authorised person can initiate a dispute before an administrative court.

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYORS

According to the Rulebook on the Modes of Advertising of Medicines and Medical Devices,[18] an MAH is obliged to keep records of its advertising agents and their employees, including fees paid for the advertising services, and to provide the relevant data to the competent authority (the Ministry or the Veterinary Authority) at its request.

Promotional gifts made to health-care professionals, in order not to amount to a breach of the Rulebook, have to be of a symbolic value and relate strictly to the pharmaceutical, medical, dental or veterinary profession. Strict requirements are also provided for giving gifts in the form of medicines. The relevant rules oblige a promoter to mark the medicine with the phrase 'free sample, not for sale' and to limit the number of free samples that may be given as a gift to 15 one-off usage medicines per year, or to one medicine for repeated use.

The Act prohibits advertisements aimed at encouraging prescription or provision of medicines by means of conferring or promising to confer financial, material or other benefits. The Rulebook also expressly extends such prohibition to promotional activities.

After 1 January 2015, control is also exercised among the industry members themselves. Leading pharmaceutical companies associated in INOVIA[19] have enacted a Code regulating the promotion of medicines to health-care professionals and their administrative staff. The Code addresses the use of promotional products, distribution of free samples of medicines, organisation of meetings and provision of medical and educational services.[20] According to the Code, a compliance committee will control observance of the Code's rules by the members. If the committee finds that a member has breached the Code, it may impose sanctions including exclusion from membership or, should the breach amount to violation of a statute, reporting to the authorities.

VI SPECIAL LIABILITY OR COMPENSATION SCHEMES

There is no special legal regime governing compensation for damages caused by the use of medicines or medical devices. Damages resulting from the use of any type of product are regulated by the ordinary product liability legislation. There are two competing schemes, set out in the Obligations Act and the Consumer Protection Act, respectively. The statutory schemes still remain to be tested in practice, as the case law in Serbia regarding damages caused by the use of medicines or medical devices is remarkably scarce.

The Obligations Act does not expressly refer to compensation for damages caused by the use of a medicine or medical device, but such compensation is available if the medicine or device proved to operate as a 'dangerous object', either *per se* or because of a defect. The injured person may claim material and non-material damage. The time limit

18 See footnote 16, *supra*.

19 The Association of the Manufacturers of Innovative Drugs.

20 Code on Promotion of Prescription-Only Medicines to, and Interactions with, Health-Care Professionals.

for filing a lawsuit is three years from the moment the injured person became aware of the damage and of the manufacturer's identity, cumulatively. In any event, the statute of limitations expires five years after the date the damage was caused.

Under the Obligations Act, liability attaches irrespective of fault (if any) of the manufacturer. A causal link between the damage and the object is presumed. The manufacturer may be exempted from liability by proving that the medicine (or device) was either produced or placed on the market by a third person. When the medicine (or device) is dangerous *per se*, the manufacturer may defend by proving to have taken all necessary measures to prevent occurrence of the damage by such appropriate means as a warning, safe packaging or other.

Through the process of harmonisation with the EU law, Serbia enacted a new Consumer Protection Act in 2014. The Act transposes numerous provisions from the EU Product Liability Directive[21] into national law. In contrast with the rules under the Obligations Act, the injured person must prove that there existed a causal link between the damage (death, personal injury, or destruction of any item of property other than the defective product itself) and the defect. Only compensation of material damage may be claimed under the Consumer Protection Act. The injured person may bring a lawsuit within three years of learning of the damage, the defect and the identity of the producer. In any event, the right to bring an action expires 10 years from the date the manufacturer put the product that caused the damage into circulation.

The manufacturer may avoid liability by proving one or more of the following:

a it did not put the product into circulation;

b the defect did not exist at the time the product was put into circulation;

c the product was neither manufactured by it for sale or any form of distribution, nor manufactured by it in the course of its business; or

d the defect is owing to the product's compliance with mandatory regulations enacted by a competent body. The manufacturer may be absolved of responsibility, fully or in part, if faulty conduct of the injured person, or any person under its responsibility, contributed to the damage.

Unlike the Product Liability Directive, the Consumers Protection Act does not recognise the development risks defence. Some authoritative legal writing has suggested that such defence might be available under the Obligations Act. In another provision protective of the consumer, the Consumers Protection Act stipulates that liability of the manufacturer for damage caused by defective products may not be limited or excluded by a contract.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

Serbian competition law is modelled on EU competition law. The Commission for the Protection of Competition (CPC) is responsible for competition law enforcement.

21 Directive 85/374/EEC.

The CPC has not shied away from intervening in the pharmaceutical sector. In 2008 it found that pharmaceutical companies fixed selling terms of their products. In 2013 it opened an investigation against Actavis for the alleged abuse of a dominant position owing to its refusal to issue certain documents to the wholesaler, thus denying the latter the possibility of participating in a public procurement procedure. The proceedings are still pending.

Further, the CPC has issued opinions on the compatibility of pharmaceutical legislation or agreements with competition law. The latest opinion was issued in 2013 when it assessed the compatibility of a protocol on cooperation in the supply of medicines concluded between the NHIF and pharmaceutical companies obliging the pharmaceutical companies to lower the price of medicines by 10 per cent owing to the effects of the economic crisis. The CPC found that the protocol was compatible with the competition legislation provided that the non-signing of the protocol would not entail any sanction and that signing the protocol would not confer additional benefits on the respective pharmaceutical companies.

VIII CURRENT DEVELOPMENTS

In October 2014, the Ministry established a working group to draft a new Medicines and Medical Devices Act, with the aim of bringing the law further in line with EU regulations and directives. Enactment of a new Act would also entail changes in the numerous implementing by-laws accompanying the Act that is currently in force.

Appendix 1

ABOUT THE AUTHORS

BOGDAN IVANIŠEVIĆ

BDK Advokati/Attorneys at Law

Bogdan Ivanišević joined BDK Advokati in 2012 to head the firm's intellectual property practice. In that time, he has also established sectors for media and entertainment. He co-leads the data protection and privacy team, as well as the life sciences and health-care sector group. Mr Ivanišević has a specialisation in intellectual property law and an LLM in international legal studies from the American University Washington College of Law. He obtained his LLB at the University of Belgrade School of Law. He is a member of INTA and the Serbian Bar Association. Mr Ivanišević is also an editor and major contributor to BDK's data protection and intellectual property blogs. He has contributed to leading intellectual property law blogs and magazines, such as *IP Kat*, *The 1709 Blog* and *IPPro The Internet*. Prior to launching a career in intellectual property law, Mr Ivanišević spent 12 years working as a human rights researcher and lawyer for Human Rights Watch and the International Centre for Transitional Justice.

SLOBODAN TRIVIĆ

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Slobodan Trivić joined BDK Advokati in 2014 as a junior associate. He specialises in commercial, pharmaceutical, environment and product liability law. Mr Trivić earned his LLB in 2013 from the University of Belgrade and is currently an LLM student at the same university. He is a member of the Health Care Committee of the American Chamber of Commerce in Serbia. Mr Trivić contributes to the *Students Economic Law Review* published by the Law Faculty of the University of Belgrade.

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