The Life Sciences Law Review

Fifth Edition

Editor
Richard Kingham

Law Business Research

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CONTENTS

EDITOR'S PREFACE

The fifth edition of *The Life Sciences Law Review* covers a total of 37 jurisdictions, providing an overview of legal requirements of interest to pharmaceutical, biotechnology and medical device companies. The chapters are arranged to describe requirements throughout the life cycle of a regulated product, from discovery to clinical trials, the marketing authorisation process and post-approval controls. Certain other legal matters of special interest to manufacturers of medical products – including administrative remedies, pricing and reimbursement, competition law, special liability regimes and commercial transactions – are also covered. Finally, there is a special chapter on international harmonisation, which is of increasing importance in many of the regulatory systems that are described in the national chapters.

Now, more than ever, it is important for leaders in the pharmaceutical and medical device industries and their advisers to be knowledgeable about the laws and regulations in major jurisdictions around the world. In the past year, there have been significant developments in the regulation of drugs and medical devices, especially in the United States, where a new law – the 21st Century Cures Act – was passed at the end of 2016. There are prospects for further developments in the coming year. The new president and the Republican-controlled Congress will consider legislative measures affecting the pharmaceutical and medical device sectors, including proposed repeal of the Affordable Care Act, continuing inquiries into pricing of medical products and reauthorisation of user fee laws that fund a substantial part of the drug and device approval processes. The United Kingdom will initiate formal proceedings to begin the process of withdrawing from the European Union, with potential consequences for the medical products sectors. Other jurisdictions, including China and India, are considering reforms to their regulatory systems for medicinal products.

Each of the chapters has been written by leading experts within the relevant jurisdiction. They are an impressive group, and it is a pleasure to be associated with them in the preparation of this annual publication.

Richard Kingham
Covington & Burling LLP
Washington, DC
March 2017

Chapter 20

LITHUANIA

Rūta Pumputienė and Ieva Balėnė[1]

I INTRODUCTION

Located in northern Europe, Lithuania is on the eastern shore of the Baltic Sea. Often referred to as 'a bridge between the West and the East', Lithuania, together with Latvia and Estonia (the Baltic States) have always been of interest to potential investors and international businesses owing to their location, available infrastructure and comparatively easy access to their neighbouring territories. Lithuania is the largest of the three Baltic countries, covering an area of 65,300 square kilometres, and it has a population of 2.9 million. Lithuania is an open economy with a small domestic market; the World Bank has placed it in the 'above average' group in terms of the level of income.

Lithuania's life sciences industry has skyrocketed over the past two decades and is now regarded as one of the most advanced in central and eastern Europe. Annual growth within the biotechnology and pharmaceutical research and production sector is 25 per cent, and with 80 per cent of its output exported, the sector's reach is truly global. With a rich scientific heritage that dates back to the 1970s, Lithuania's biotechnology industry is outpacing developments in many larger central and eastern European countries. Utilising state-of-the-art technology and the country's highly skilled talent pool, companies such as Moog, Sicor-Teva group, Biotechfarma and Thermo Fisher with such core competences as restriction enzymes, modification enzymes and PCR-related products, generic drug production, recombinant biopharmaceutical substances, and biochemistry, microbiology, biological engineering, are putting Lithuanian life sciences firmly on the map.[2]

1 Rūta Pumputienė is the managing partner and Ieva Balėnė is a senior associate at Ruta Pumputiene Law Firm.

2 www.investlithuania.com/focus-industries/life-sciences/.

i Organisation and governance

The Lithuanian health system, under which life sciences regulation falls, consists of governance institutions (the government, ministries and municipalities, as well as other specialist governance and control bodies), providers of healthcare services, and health system resources and services. In the late 1990s, Lithuania moved away from a system funded predominantly from local and state budgets to a mixed system, predominantly funded by the National Health Insurance Fund (NHIF) under the Ministry of Health of Lithuania, which also manages the Compulsory Health Insurance Fund that regulates financial flows and purchasing, through the national health insurance scheme and based on compulsory participation.

The Ministry of Health (MoH) has been a major player in health system regulation through setting standards and requirements, licensing and approving capital investments. The role of the MoH on a local level amounts to regulating the basic healthcare budget, providing methodical support, designing the general principles in arranging general medical care by assessing population-based health statistics through comparative analysis. The MoH is also responsible for licensing health personnel and keeping the register of medical professionals. The Ministry allocates money for retraining general practitioners and nurses. However, many health administration functions are decentralised from the MoH to the regional authorities. Municipalities are responsible for organising the provision of primary and social care, and for public health activities at the local level.

The private sector plays a substantial role in dental care, cosmetic surgery, psychotherapy, some outpatient specialities and primary care. Since 2008, the NHIF has increasingly been contracting private providers for specialist outpatient care.

As for medicinal products, the State Medicines Control Agency under the MoH (SMCA) is responsible for the protection of public health through the evaluation and supervision of medicines for human use. The SMCA carries out regulatory and control functions by granting marketing authorisation, classifying prescription status (prescription-only versus over-the-counter drugs), conducting pharmacovigilance, inspecting the pharmaceutical industry and pharmaceutical product distribution companies (including pharmacies), controlling the quality and advertising of pharmaceuticals and supervising clinical trials. The SMCA registers pharmaceuticals and keeps a list of licences of manufacturing (which covers importing) and wholesale pharmaceutical companies, pharmacies and pharmacists. The activities of the SMCA only concern human medicines.

The State Health Care Accreditation Agency under the MoH (SHCAA) is mainly engaged in licensing healthcare providers and professionals (with the exception of dental services) and public health institutions, laboratories and pathology services; it also has a role in the assessment and control of medical devices. Other functions, such as the organisation of health technology assessment (HTA) and participation in the creation of policies related to the quality of services and equipment, have been less developed.

The SHCAA is also involved in the establishment of medical standards and quality control of healthcare providers. According to the existing legislation, the SHCAA, together with the NHIF and its 10 regional branches, can have a strong impact on healthcare institutions, which can even lead to closure. Similarly, the SMCA has a broad range of responsibilities in the regulation of the pharmaceutical (medicinal products) sector.

A key legal act regulating the life sciences sector in Lithuania is the Law on the Health System that describes the structure and the main principles of the national health system. The health system consists of governance institutions, providers of healthcare services and health system resources and services.

The Law on Ethics of Biomedical Research regulates non-clinical studies and clinical trials. Medicines and medical devices are being regulated separately, principally by the Law on Pharmacy, and medical norms.

II THE REGULATORY REGIME

i Classification

The Law on Pharmacy provides the definition of medicine (medicinal products) as any substance or combination of substances manufactured and presented for treating or preventing disease in human beings provided it meets at least one of the following criteria: (1) has properties that make it suitable for treating or preventing human diseases; or (2) owing to pharmacological, immunological or metabolic action may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions or to making a medical diagnosis.

The definition of a medical device is stipulated in medical norms, which describe it as any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

a diagnosis, prevention, monitoring, treatment or alleviation of disease;

b diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

c investigation, replacement or modification of the anatomy or of a physiological process; and

d control of conception that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means.

The definition of a medical device relates also to software, which is necessary to a person to be able to utilise the medical device as intended by the manufacturer. Separate software, pursuant to the qualification of medical devices, is regarded as an active medical device. Whereas software that is used to control a medical device is automatically classified in the same group as the device it is controlling. The software, which is medical software or part of a medical device, must be validated in accordance with the industry's latest developments, taking into account the life cycle development, risk management, validation and approval. In vitro medical devices, including their software, must be developed to ensure consistency of operations of the device and safety and compliance with *in vitro* diagnostics appliance functions.

For borderline products there are no guidelines explaining how the product should be treated in each case. Therefore, the definitions of particular product (medical device, medicinal product, food, cosmetics, etc.) should be followed. In case the SMCA, the State Food and Veterinary Service, responsible for food and food supplements, or Centres of Public Health, responsible for cosmetic products, believe that a particular product is marketed without prior approval, they may initiate the enforcement actions against borderline products. In practice,

most disputes arise between medicinal products and food supplements and cosmetic products and biocides. However, these cases are rarely presented to the court, which means that parties find a solution without litigation.

Another type of product is human origin medicinal products (tissue, blood, plasma). Such products are generally regulated under the applicable regulation towards medicines. However, animal origin medical devices would be covered by the general regulations applicable to medical devices.

ii Non-clinical studies

Non-clinical studies in Lithuania must be conducted in conformity with the Guidelines for Good Laboratory Practice approved by the MoH. The guidelines are in compliance with European Directives 87/18/EEC and 88/320/EEC. The SMCA is also following the European Medicines Agency's (EMA) general scientific guidelines in the area of non-clinical testing of human medicines.

The protection and welfare of animals in Lithuania is an area covered by a wide range of EU legislation. This includes the protection of wildlife, zoo animals, farm animals, animals in transport and animals used for scientific purposes. Animal studies, whether for the development or production of new medicines, for physiological studies, studying environmental effects or testing of chemicals or new food additives, has to be carried out in compliance with EU legislation.

Lithuania also has specific legislation in place that covers the use of animals for scientific purposes, in compliance with Directive 2010/63/EU, adopted by the EU on 22 September 2010 that took full effect on 1 January 2013, which updates and replaces the 1986 Directive 86/609/EEC on the protection of animals used for scientific purposes.

iii Clinical trials

The key competent authority supervising clinical trials in Lithuania is the SMCA and the function of single opinion adoption is given to the Lithuanian Bioethics Committee (LBC) (and regional bioethics committees if clinical research is restricted to a certain region). Clinical trial documents can be submitted simultaneously to both institutions.

Clinical trials may be commenced only after the SMCA has issued its approval and the LBC has expressed its positive opinion. The relevant approvals are issued by the SMCA and LBC in 60 calendar days. Both authorities may request further information and extend the review period by 30 to 90 additional calendar days.

The trial shall be designed, conducted and reported in compliance with the Good Clinical Practice standards. The sponsor or principal investigator must obtain an insurance policy for the clinical trial. The insurance premium shall cover at least €29,000 in case the insured event occurs. The sponsor or legal representative must be established in the EU and must provide all investigational medicinal products, necessary instruments, measures and materials free of charge for the duration of the clinical trial.

In Lithuania, clinical investigations of medical devices can be performed only with the permission of the LBC. Permissions to conduct clinical investigations of medical devices are issued by the recommendation of the SHCAA. Persons wishing to conduct clinical investigations of medical devices must send the SHCAA an application form with the required documents for such notification. Application documents must be in the Lithuanian language, or the original documents along with translated documents must be provided.

iv Named-patient and compassionate use procedures

Currently no special regulations for compassionate use programmes (CUPs) in the Lithuanian jurisdiction exist. The implementation of CUPs at a national level is not harmonised under the EU laws, although Parts 1 and 2 of Article 83 of Regulation No. 726/2004 create a framework for CUPs in the EU.

However, in practice CUPs are quite widely used in Lithuania by various pharmaceutical companies and, to date, companies, healthcare institutions and physicians have not been challenged because of illegal or improper CUP performance. Article 20 of the Law on the Health System foresees the practical possibility for CUPs. In this case, all responsibility lies with the healthcare specialist as he or she has to: (1) ensure that the medicine is used for treatment of the patient and to try to save or prolong the patient's life; (2) obtain the patient's permission and consent; and (3) obtain the consent of the ethics commission of the healthcare institution.

As regards named-patient medicines, the Rules on Acquisition of Medicinal Products on Named-Patient Basis adopted by the Order of the Minister of Health regulate use of unauthorised medicinal products, however, only to the extent that these products are used under a specific named-patient basis (singular case), and only in cases where they are registered in at least one EEA state.

v Pre-market clearance

As regards medical devices, from 1 May 2004, only those medical devices that comply with the requirements of EC Medical Device Directives, can be placed on the Lithuanian market and put into service. All medical devices must fulfil the essential requirements of the medical device legislation, and must bear the CE marking. The only exceptions are: custom-made medical devices; devices intended for clinical investigation; and *in vitro* diagnostic medical devices intended for performance evaluation.

As for medicinal products, only registered medicinal products manufactured industrially or by a method involving an industrial process may be supplied to the Lithuanian market. Medicinal products may be registered either in the Register of Medicinal Products or in the Community Code of Medicinal Products, or entered in the list of Parallel Imported Medicinal Products (hereinafter, medicinal products granted marketing authorisation). However, Article 8 of the Law on Pharmacy provides three exceptions when non-registered medicinal products may be supplied to the Lithuanian market and used for healthcare according to the procedure established by the Minister of Health. The three exceptions apply when:

a the necessary medicinal products have been granted marketing authorisation in any EEA state;

b the doctor prescribing the bearer prescription medicinal products for the use of a single patient assumes direct and personal responsibility; and

c the Minister of Health provisionally grants authorisation to place medicinal products on the market that are necessary when pathogenic or chemical factors, toxins or ionising radiation posing a health hazard are suspected or established, or in case of a natural disaster.

Additionally, no advertising is allowed for non-registered medicinal products. Part 3 of Article 48 of the Law on Pharmacy indicates that only pharmaceutical information can be provided about an unregistered medicinal product. Such information is described as the

pharmaceutical, clinical and pharmacological characteristics of a medicinal product, that can be announced and distributed in any form and by any means. The prices of medicinal products can also be included in trade catalogues and price lists, provided that they contain no statements about the characteristics of medicinal products.

However, it should be noted that in the pre-approval phase only a wholesaler or healthcare professional (HCP) has particular obligations (e.g., the wholesaler has to submit the information regarding bearer prescription medicinal products to the authorities) while the manufacturer does not have any such obligations; it is not required to be established in Lithuania or to make any specific disclosures, filings, submission of data, etc.

Medicinal product marketing authorisation in Lithuania is granted by the SMCA, the authorised institution, and by the European Commission in all EU Member States. Medicinal product marketing authorisation may be granted to persons who have been established in any EEA state that meet the requirements established by the legal acts.

vi Generics and biosimilars

A generic medicinal product that has been granted marketing authorisation may be supplied to the market after a lapse of at least 10 years from the day of granting initial marketing authorisation to the reference medicinal product. The two-year period counted after the period of data exclusivity shall stand for the reference medicinal product market exclusivity period. The 10-year exclusivity period shall be extended by no more than one year if, during the initial eight years of the specified 10 years, the marketing authorisation holder (MAH) registers one or several new therapeutic indications that, according to scientific evaluation performed prior to the granting of marketing authorisation, are considered as affording substantial clinical benefit compared with the present treatment.

If a medicinal product does not correspond to the term 'generic medicinal product' or its bioequivalence cannot be demonstrated by appropriate bioavailability studies, or if an active substance, therapeutic indications, strengths, pharmaceutical form or route of administration has been modified in comparison to the reference medicinal product, results of the appropriate pre-clinical tests or clinical trials must be presented.

If a biological medicinal product, similar to a reference biological medicinal product, does not correspond to the term of generic medicinal product because of the difference in stocks or manufacturing processes, results of the appropriate pre-clinical tests or clinical trials must be presented. Additionally, the presented information must comply with the analytical, pharmaco-toxicological and clinical trials of medicinal products standards, protocols and appropriate guidelines in respect of the testing of proprietary medicinal products established by the Minister of Health. There is no need to present the results of other trials which are listed in the marketing authorisation dossier of referential medicinal product.

vii Admission to trade of medical devices

In order to place a medical device on the Lithuanian market, the device must undergo conformity assessment in one of the notified EU assessment institutions. Generally, medical devices shall bear the CE marking. Some further registration requirements apply to the devices that are not CE certified (i.e., purpose-made devices intended for clinical trials that do not correspond to material requirements).

Clinical data must be submitted to the notified institution (i.e., the institution that any of the Member States has notified as competent to perform the conformity assessment) in order to obtain the EU Declaration of Conformity. Clinical data has to be described, for

example, within the review of the quality assurance system. Therefore, since the conformity declaration is required to put the product into trade, the clinical assessment would be required. Results of the clinical trials can serve as one of the methods to prove that the product meets the essential requirements (incorporated in the Medical Devices Regulations from Annex I of the Directive concerning medical devices). Trial results are also needed in order to register a medical device that does not bear the CE marking. Finally, clinical trials are also foreseen as an element under the quality assurance system that the manufacturer must have in place in order to obtain the EU Declaration of Conformity from the notified institution.

The manufacturer's declaration of conformity is sufficient when the product is marketed, but the manufacturer must also have the EU Declaration of Conformity from one of the notified institutions. Therefore, before the manufacturer can declare the compliance with essential requirements, an external body (notified institution) shall verify that the product complies with all the applicable EU requirements.

Only the products that have either undergone the conformity assessment or bear the CE marking can be launched in the market. The relevant authority shall be notified about the start of the usage of medical devices attributable to Class II a, II b and III in the territory of Lithuania.

viii Regulatory incentives

Bolar provisions

In Lithuania, as in the EU, there is an exemption to the rights conferred by patents. According to the Law on Pharmacy:

> *Conducting the necessary studies and trials in order to file an application of registration of medical product […] and the consequential practical requirements do not infringe the rights provided by the medical product patent or the supplementary protection certificate that are indicated in the Patent Law of the Republic of Lithuania and in other legal acts regulating protection of the industrial property.*

Additionally, the Patent Law provides that 'the owner of the patent shall have no right to prevent third parties from performing acts […], if: […] the act is done for experimental purposes or for scientific research, and this does not conflict with a normal exploitation of the patent and does not unreasonably prejudice the legitimate interests of the patent owner.'

ix Regulatory and data exclusivity provisions

The provisions regarding regulatory and data exclusivity are set out in the Law on Pharmacy and are as follows:

a Without prejudice to the law relating to the protection of industrial property and know-how, the applicant shall not be required to provide the results of pre-clinical and clinical trials if he or she can demonstrate that the medical product for registration of which he or she is applying is a generic of the reference medical product that is or has been authorised for marketing in any Member State of the EEA or in the Community for not less than eight years. This period counts as the period of data exclusivity of the reference medical product.

b A generic medical product may be placed on the market no less than 10 years after the date of the initial authorisation of the referenced product. The period of two years calculated after the period of data exclusivity counts as the period of market

exclusivity of the reference medical product. The 10-year exclusivity period shall be prolonged for an additional period of no more than one year if, during the first eight years of those 10 years, the MA holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies.

c Without prejudice to the law relating to the protection of industrial property and know-how, the applicant shall not be required to provide the results of pre-clinical and clinical trials if he or she can demonstrate that the medical product for registration of which he or she is applying is a generic of the reference medical product that is or has been registered in the Community for not less than 10 years or in any Member State of the EEA for not less than six or 10 years, depending on the data exclusivity period established in that particular country.

d A non-cumulative period of one year of data exclusivity shall be granted where an application is made for a new indication for a well-established substance, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication.

x Orphan incentives

Orphan medicines are not assessed in Lithuania. All designated orphan medicines are assessed for marketing authorisation centrally in the EU. This allows companies to make a single application to the EMA, resulting in a single opinion and a single decision from the EC, valid in all EU Member States. Sponsors may also have access via orphan designation to conditional approval, which is conducted under the centralised procedure.

Lithuania had officially adopted a national strategy for rare diseases. A national rare diseases coordination committee was formed, including delegated experts from university hospitals, universities, non-governmental organisations and state institution representatives, to oversee the plan. The plan aims to establish a common approach to rare diseases, to raise public awareness and to ensure prevention, early diagnosis, efficient treatment, improvement of quality of life and social support for patients suffering from such diseases. It also includes the optimisation of healthcare services and rational allocation of available resources, as well as measures for improving the assessment of medicinal products and medical devices. However, the level of its implementation is highly contentious; it is yet to be detailed in concrete work plans and there will be no specific budget, therefore the various actions that are necessary will have to be financed through the existing health budget.

xi Non-authorised medicines

To ensure availability of all the necessary medicines for patients, the use of non-authorised medicines is permitted under exceptional circumstances. Non-authorised medicines may be used in ambulatory care and at the hospital on the basis of a special application from a doctor with the signed informed consent of the patient. The treating physician is responsible for prescribing, providing information and advising on the safe use of the non-authorised medicines.

xii Post-approval controls

Marketing authorisation of the medicinal product shall be granted for a period of five years. The marketing authorisation of a renewed medicinal product shall be valid for an

indefinite period except where the SMCA, based on well-founded reasons related to the pharmacovigilance, decides that market authorisation must be reviewed after another five-year period.

According to national legislation, numerous obligations arise for persons who are authorised as market authorisation holders. In addition to being responsible for ensuring that the information about the medicine will comply with up-to-date scientific knowledge, to carry out the pharmacovigilance system, market authorisation holders are also responsible for marketing the medicinal product.

As regards medical devices, manufacturers or authorised representatives who have a registered place of business in Lithuania (or other persons authorised by a manufacturer) must notify the SHCAA about Incidents and Field Safety Corrective Actions. The incident means any malfunction or deterioration in the characteristics or performance of a device, as well as any inadequacy in the labelling or the instructions for use that might lead to or might have led to the death of a patient or user, or to a serious deterioration in his or her state of health.

xiii Manufacturing controls

A legal person may engage in the manufacture of a medicinal product upon obtaining a manufacturing licence issued in accordance with the procedure established by Lithuanian laws. A legal person may engage in partial manufacturing of medicinal products or in certain manufacturing processes (i.e., dividing of the components, packaging, etc.), yet such activities also require possession of a manufacturing licence. The manufacturing licence also grants the right to distribute medicinal products manufactured by the licence holder.

Medicinal products must be manufactured in enterprises in accordance with the principles and guidelines of the good manufacturing practice (GMP) for medicinal products, approved by the Minister of Health and taking into account the recommendations of the EC, the EMA and other EU institutions. Confirmation on the compliance with GMP standards shall be issued by the SMCA.

xiv Advertising and promotion

Advertising and promotion of medicinal products is regulated by the Law on Pharmacy and the Regulations on Medicinal Products Advertising, approved by the Order of MoH. The majority of the advertising provisions of EU Directive 2001/83/EC have been transposed directly into the Law and the Regulations and only a few amendments have been made to the provisions of the Directive. Although the wording is sometimes different, the meaning of the national provisions remains, in principle, the same as the Directive.

There is also an industry code of ethics – the Code for Pharmaceutical Marketing (the Code of Ethics) – adopted at the will and upon common agreement of the Innovative Pharmaceutical Industry Association (a member of the European Federation of Pharmaceutical Industries and Associations) and the Medicines Manufacturers Association (in principle manufacturers of generics) that also provides rules on the advertising of medicinal products. However, this Code of Ethics is a self-regulation document, not a legal act.

In general, in Lithuania, there is a distinction between the provision of pharmaceutical information on medicinal products and advertising thereof. The main principles for the advertising of medicinal products are: (1) only registered medicinal products may be advertised in Lithuania; and (2) advertising may not be misleading and must be objective.

The advertising of both prescription and non-prescription medicinal products is allowed to HCPs, while advertising of prescription medicinal products and reimbursable medicinal products aimed at the general public is prohibited.

The use of free samples is allowed in order to market products only to HCPs that are able to prescribe medicinal products. It is prohibited to leave free samples of medicinal products for HCPs, distribute them among HCPs and the general public, or use them for healthcare purposes. Special procedures apply with respect to free samples for their importation, storage, distribution, etc.

Inducements to HCPs by giving remuneration whether in money or in kind are prohibited.

Sales promotion events are allowable, however, the Law establishes that the hospitality at such events must have a reasonable purpose and can be extended only to the participating specialists. Payment of travelling, accommodation and other expenses for participants in such events is not allowed. For scientific conferences or events, the registration fee and travel, accommodation and catering expenses can be reimbursed. The MAH (or representative) must accumulate information about the expenses for such events and the HCPs participating therein and submit the information to the SMCA according to the established procedure.

Promotion and advertisement of medical devices is not specifically regulated.

xv Distributors and wholesalers

With the exception of the registration process that the medicinal product must undergo and the fact that the distributor has to possess a wholesale distribution licence (a medical device must have the EU conformity assessment and the CE marking), there are no further requirements for the distribution of medicinal products or medical devices.

A legal person shall have the right to engage in wholesale distribution of medicinal products, active substances and excipients in the list of the EC, used in manufacturing of medicinal products or extemporaneously prepared medicinal products, only holding a wholesale distribution licence. Wholesale distribution shall be performed in compliance with the requirements of good distribution practice regulations approved by the Minister of Health and with a view to the recommendations of the EC, the EMA and other EU institutions. If the holder of the wholesale distribution licence wishes to engage in the manufacture or import of medicinal products from third countries, he or she must acquire a manufacturing licence.

Requirements that are more stringent than those applied to legal persons holding a wholesale distribution licence, which are issued according to the procedure established by the Law on Pharmacy, may not be applied with respect to persons holding a wholesale distribution licence issued by other EEA states and wishing to engage in wholesale distribution in Lithuania.

As regards medical devices, there are no specific regulations with respect to the business model of medical device distributors; however, any commercial activity (i.e., establishing a company or opening a branch) in the territory of Lithuania must be registered in the public registry. Generally, the medical devices regulations derive from the relevant EU directives; hence it must be relatively similar throughout the EU. Pursuant to the principle of free movement of goods, any product that can be legitimately placed on the market in another EU Member state can also be placed on the Lithuanian market, although some formalities may be applied (e.g., notification, registration of the product, conformity assessment).

xvi Classification of products

Though the Law on Pharmacy does not specifically define classification of medicinal products, in practice there are separate definitions of medicinal products for human use: over-the-counter (OTC) medicines, hospital medicines and prescription-only medicines (POM). POM are being included in the List of Reimbursable Medicines in Lithuania and hospital medicines are being purchased either centrally (via NHIF central public tenders) or locally (via separate hospital tenders). OTC products are not reimbursable in Lithuania but can be sold only in pharmacies. The obligation to classify a medicinal product and define it as OTC or to prescription only is the responsibility of the SMCA.

xvii Imports and exports

A legal person may engage in import from third countries of medicinal products or investigational medicinal products if they have received a manufacturing licence. A legal person may engage in total and partial manufacture of medicinal products, investigational medicinal products or in the various processes of dividing up, packaging or presentation only subject to holding an authorisation. He or she must also acquire the authorisation for the import of medicinal products and investigational medicinal products intended for export.

Medicinal products and investigational medicinal products imported from third countries must be manufactured in enterprises authorised by an authorised institution of the country to engage in the manufacturing of medicinal products, investigational medicinal products and must uphold standards of good medicinal practice, which are at least equivalent to those laid down in the Community.

Only legal persons who have received a wholesale distribution licence may import bearer prescription medicinal products from a third country. A natural person shall have the right to import to or export from Lithuania for his or her own needs, and to receive or send by post medicinal products according to the procedure established by the Minister of Health.

Medicinal products can be parallel imported to Lithuania if they are registered in the List of Parallel Imported Medicinal Products and in respect of which a permit for parallel import has been issued. The SMCA administers the List of Parallel Imported Medicinal Products, as well as marketing authorisation of the parallel imported medicinal products, approval of the terms of variation of the permits for parallel import, suspension of the permit validity and revoking the suspension of validity and the permit validity.

xviii Controlled substances

The Law on the Control of Narcotic Drugs and Psychotropic Substances establishes the principles of the classification of narcotic drugs and psychotropic substances, legitimate circulation of these drugs and substances when they are used for healthcare, veterinary and scientific purposes and the control of their circulation in accordance with the requirements of international treaties.

Narcotic drugs and psychotropic substances are classified in Lithuania according to their harmful effect upon human health, when they are being abused, and according to whether they can be used for healthcare purposes. Pursuant to international treaties of Lithuania, the MoH classifies and includes narcotic drugs and psychotropic substances in the Schedules according to the control regime applied to them.

xix Enforcement

The state control of activities with pharmaceutical products is executed by the SMCA. Control is exercised in compliance with legal acts and with regard to the Compilation of Community Procedures on Inspections and Exchange of Information adopted on behalf of the EC by the EMA.

The SMCA inspects and evaluates the manufacturing or commercial establishments of the manufacturers, importers of medicinal products, investigational medicinal products or active substances used as starting materials, as well as laboratories entrusted by the manufacturing licence holder with the task of carrying out checks, whether the manufacturing processes used in the manufacture of immunological products are properly validated and whether the batch-to-batch consistency is attained. The manufacturer or importer are required, as necessary, to submit copies of the control reports signed by the relevant qualified person. It must be established whether the manufacturing and purifying processes used in the preparation of medicinal products derived from human blood or human plasma are properly validated, batch-to-batch consistency must be ensured and the absence of specific viral contamination guaranteed. The performance of clinical tests or trials, other activities involving medicinal products and the entities related to the activities are included within the competence established by the Regulations of the SMCA.

The SMCA is entitled to impose administrative penalties for non-compliance with particular requirements related to activities with medicinal products while in exceptional cases criminal liability might be imposed by the court (e.g., in clinical trial cases or other).

As for medical devices, the SHCAA is the competent authority that has to ensure that the medical devices are placed on the Lithuanian market under the requirements of the Medical Device Directives. In case any non-compliance arises, the SHCAA is entitled to impose administrative penalties.

III PRICING AND REIMBURSEMENT

i Medicinal products

The structure of the Lithuanian reimbursement system is as follows:

a medicinal products are compensated for on the basis of the diagnosis;
b reimbursement rates are divided according to the severity of the disease;
c there are positive lists of the products;
d for certain patient groups additional discounts are provided, for example, children and the elderly; and
e medicinal products are compensated for according to the reference prices.

The MoH has the most important role as it decides both on strategic planning and on whether a product will be reimbursed and at what price. The Pharmaceuticals Reimbursement Committee (the Reimbursement Committee), consisting of representatives from the MoH, Ministry of Finance, Ministry of Social Security and Labour, and representatives from NGOs and associations, advises the Minister of Health on reimbursement decisions. The NHIF is in charge of contracting pharmacies and reimbursing medicine costs, as well as for procuring high-cost pharmaceuticals via public tenders. The Reimbursement Committee is in charge of deciding which medicinal products will be reimbursed.

There are three criteria for reimbursement of medicinal products: (1) the medical benefits provided by the pharmaceutical; (2) results of pharmacoeconomic evaluation; and (3) the impact of reimbursement of that pharmaceutical on the budget of the NHIF.

Since introducing price negotiation, prices of reimbursed pharmaceuticals are regulated through a reference pricing system; the reference manufacturing price should not exceed 95 per cent of the average manufacturer's price in the eight reference EU countries (Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Poland, Romania and Slovakia). Pharmaceuticals are also grouped on the basis of the international non-proprietary name method of use, form, purpose and length of action and the reference price that is being reimbursed for the group is the cheapest priced product in the group. When the product's final pharmaceutical price is higher than the reference price, the patient pays the difference as a co-payment.

The government reimburses only the base price of the medicinal product and only certain compensation levels of such base price (100 per cent, 90 per cent, 80 per cent or 50 per cent). The base price is calculated using a certain formula and, in principle, is part of the lowest retail price of the medicinal product within a specific group of medicines. Accordingly, patients buying reimbursable medicinal products still have to make a co-payment, since, in general, the selling price of a medicinal product in the whole distribution chain is not statutorily fixed in Lithuania. Wholesale and retail prices are set by the wholesalers (distributors) and the retailers (pharmacies) respectively. However, certain highest price thresholds that cannot be exceeded while selling medicines in the distribution chain (wholesaler, retailer, final customer or patient) are statutorily fixed. The MoH approves the base, the highest retail prices and the highest wholesale and retail mark-ups of reimbursable medicinal products, and the highest wholesale and retail mark-ups of non-reimbursable medicine.

The MAH and parallel importers have to declare to the MoH the price at which a non-reimbursed medicinal product will be distributed in Lithuania and submit the prices of this product in the eight reference countries.

ii Medical devices

Reimbursement of medical devices (medical aid device) in Lithuania is organised under the same system as with medicinal products. The MoH has approved a list of conditions for which medical treatment would be compensated from compulsory health insurance funds. Base prices and the highest retail prices of reimbursable medical devices are approved only for those medical devices that have been included in the List of Diseases and Reimbursable Medical Devices for their Treatment (the 'C-List') approved by the MoH.

The assessment criteria for including medical devices in the C-list are whether the medical device: (1) compensates the functionality that patient has lost; (2) helps the patient to improve working capacities; or (3) decreases the need for hospital care.

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

All disputes that arise before the final decision of the competent authority may be resolved internally; however, no particular rules are stipulated or applied. Such dispute resolution is mostly non-official (i.e., authorities are not obliged to negotiate or discuss the question with the applicant); however, they have to respect one of the most important principles of public administration – the right to be heard, which means that authorities have to accept the explanations of the applicant.

When the final decision is adopted, it may be challenged in the administrative court within 30 days. After the administrative court of first instance adopts its decision, it can be appealed to the Supreme Administrative Court within 14 days of the receipt of the decision. The decision of the Supreme Administrative Court is final and binding.

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYERS

The relationships between prescribers (HCPs) and pharmaceutical companies are highly specific and sensitive owing to the frequent conflicts of interest and transparency issues. However, it is essential that these two parties collaborate and work together for the proper treatment of the patient. The boundaries of this specific communication are established mainly in the Law on Pharmacy, which stipulates that:

a healthcare or pharmaceutical professionals providing healthcare and pharmaceutical services have no right to advertise medicinal products;

b these professionals may be given advertisement of POM products in accordance with particular advertising rules;

c visits of medicinal representatives of the company are allowed only outside of working hours and not at the time that is dedicated for consultation or treatment of the patients;

d special rules are applied to promotional events; and

e special rules are applied to scientific and professional events.

Additionally, the self-regulatory mechanism – Code of Ethics – stipulates more stringent rules and disclosure requirements that are mainly based on the EFPIA Code of Ethics. Accordingly, as of mid-2016, companies have to disclose all transfers of value that are provided to HCPs and healthcare organisations.

The pharma industry also has the opportunity to provide sponsorship to healthcare organisations, including associations of HCPs. Such sponsorship is subject to the provisions of the Law on Charity and Sponsorship of the Republic of Lithuania and allows legal entities to provide sponsorship to: (1) monetary funds; (2) any other assets, including manufactured or purchased goods (e.g., medicinal products); and (3) services provided or rendered by sponsorship providers. However, the institution that is willing to obtain sponsorship has to be granted the status of a recipient of sponsorship in accordance with the procedure laid down in the laws.

Another important issue related to financial relationships is anti-bribery regulation in Lithuania. Criminal liability arises from passive and active corruption. Both the giver and the recipient of a bribe in the public or private sector can be held liable for violations of anti-bribery provisions in the Criminal Code. Legal persons are also liable for corruption-related violations under the Criminal Code.

In practice, a court shall generally impose a non-custodial sentence upon a person prosecuted for the first time for a minor or less serious premeditated crime (the gravity depends on the purpose of the corruption, legal or illegal actions and the value of the bribe taken by the official). In the event of the imposition of a custodial sentence, the court must justify its decision.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

Lithuania does not have any special liability or compensation systems intended to compensate persons injured by medicines or medical devices, therefore general rules regarding liability for all injuries apply.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

In Lithuania, the authority responsible for the protection and enforcement of competition law is the Competition Council. The Council also coordinates matters related to state aid and performs expert examination of state aid projects, as well as maintaining the state aid register. The Council also carries out functions assigned by other laws, such as the Law on Prices, Law on Prohibition of Unfair Practices of Retail Undertakings, Law on Advertising and Law on Prohibition of Unfair Business-to-Consumer Commercial Practices. The Council investigates competition restrictions both on its own initiative and on the basis of notifications and complaints. It should be also noted that the Council has extensive investigatory powers. It may:

a request information from undertakings under investigation;
b search any premises with or without notice;
c inspect and copy documents;
d seize evidence;
e seal the premises used by undertakings;
f obtain oral and written explanations; and
g require individuals to appear at the offices of the Council.

In addition, the Law on Competition entitles the Council to obtain information and documents from other economic entities – non-subjects – and also from public and local authorities. Investigators of the Council may enlist police assistance. Before entering and searching the premises, and reviewing or removing documents, however, a court order must be obtained.[3]

Lithuania does not have an extensive court case practice in competition issues related to the life sciences sector, therefore national courts would follow the case law of the European Court of Justice. One of the reasons for the lack of such practice could be that no innovative drug manufacturers pursue manufacturing activities in Lithuania. In addition, owing to strict regulation of clinical trials, many companies decide to perform the trials (and establish centres of clinical trials) in other countries. However, Lithuania has strong potential and highly qualified human resources for the creation of innovations in the life sciences sector.

ii Transactional issues

As Lithuania is a rapidly developing country, many transactional activities are being performed. However, they mostly relate to the activities that arise in other countries (e.g.,

3 http://kt.gov.lt/en/index.php?show=contacts&con_meniu=compet.

when a parent company established in the United States decides to separate part of its business (e.g., neurology) or sell it to another company and, consequently, its subsidiary established in Lithuania has to do the same).

Most transactional issues are harmonised within the EU, therefore Lithuania does not have any specific features of its legislation that relate to licence agreements, collaborations or other transactions in the life sciences industry.

VIII CURRENT DEVELOPMENTS

The main developments are described in the strategy plan of Ministry of Health for 2016–2018. Among numerous other initiatives and priorities it is worth highlighting these priorities: improving the quality of and access to the healthcare service by continuing hospital network consolidation; widening the scope of newly established e-health infrastructure; creating anti-corruption programmes; improving healthcare funding and spending efficiencies; and improving the health of children and mothers.

Appendix 1

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Ms Rūta Pumputienė is an attorney at law, founder and managing partner of Ruta Pumputiene Law Firm, with over 12 years' legal experience, mainly in life sciences sector. Rūta continues her practice after working for 10 years as an associate partner in the biggest business law firm in the Baltics. She works with life science companies in Lithuania within the pharmaceutical, food and other regulated industries sectors. Rūta specialises in strategic consulting for both national and international companies. She is widely considered one of the most experienced life sciences law and intellectual property experts in the Baltic States. Ms Pumputienė graduated from Vilnius University Faculty of Law in 2004, and further continued postgraduate studies at the University of London, obtaining a Master of Laws (LLM) degree in International Intellectual Property Law in 2010. Since 2013, Ms Pumputienė has been heading the Local American Working Group (LAWG), a standing committee established by the American Chamber of Commerce in Lithuania to tackle issues concerning the healthcare system and pharmaceutical industry in Lithuania. LAWG is a well-known name defining an informal pharmaceutical industry platform representing the voice and opinion of innovative pharmaceutical companies on various issues in the sector, and acts as a lead authoritative body dedicated to transparent dialogue on healthcare issues between public and private players. Ms Pumputienė also has three years' experience as a university lecturer on intellectual property in e-space and is a frequent speaker in national and international conferences on medical law, intellectual property, EU and domestic trade law spheres and has authored and co-authored dozens of publications on medical law, pharmaceutical law, intellectual property and related law matters.

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Ms Ieva Balėnė is a senior associate in Ruta Pumputienė Law Firm where she continues her practice after working as an associate in the biggest business law firm in the Baltics. Her main area of specialisation is life sciences, particularly advising clients on pharmacy, biotechnology

law and health policy matters. Ms Balėnė's interest in life sciences began at Vilnius University where she completed a master's degree in law in 2012 with the thesis entitled 'Ensuring the protection of human rights envisaged in ECHR Articles 5 and 8 when treating individuals suffering from infectious diseases'. Currently, Ms Balėnė is studying at King's College London in the postgraduate EU Competition Law programme. Ieva also did her internship at one of the world's premier university-based institutions for the study and promotion of human rights and humanitarian law – the Irish Centre for Human Rights at the National University of Ireland. At present, along with her legal practice in Ruta Pumputienė Law Firm, Ms Balėnė is a speaker at local and international conferences such as the EU experience sharing programme, as well as seminars and other events.

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