The Life Sciences Law Review

Fifth Edition

Editor
Richard Kingham

Law Business Research

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This article was first published in The Life Sciences Law Review - Edition 5
(published in March 2017 – editor Richard Kingham)

For further information please email
Nick.Barette@lbresearch.com

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Richard Kingham

Law Business Research Ltd

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Published in the United Kingdom
by Law Business Research Ltd, London
87 Lancaster Road, London, W11 1QQ, UK

www.TheLawReviews.co.uk

ISBN 978-1-910813-48-5

Printed in Great Britain by
Encompass Print Solutions, Derbyshire
Tel: 0844 2480 112

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ACKNOWLEDGEMENTS

The publisher acknowledges and thanks the following law firms for their learned assistance throughout the preparation of this book:

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ARTHUR COX

BAE, KIM & LEE LLC

BAHAS, GRAMATIDIS & PARTNERS

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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 25

POLAND

Ewa Skrzydło-Tefelska and Jacek Myszko[1]

I INTRODUCTION

The majority of the activities within the pharmaceutical sector in Poland are regulated by the Pharmaceutical Law of 6 September 2001 (PhL). The PhL is the basis for a number of Polish executive regulations laying down detailed rules on specific issues (such as good distribution practice, good manufacturing practice and advertising of medicinal products). Medical devices are regulated independently under the Act on Medical Devices of 20 May 2010 (AMD). Other important regulations in the pharmaceutical or medical device sector include, besides EU legislation, the Act on Counteracting Drug Addiction of 29 July 2005 (CDA), stipulating rules of manufacturing and marketing of narcotic and psychotropic substances; and the Act on Reimbursement of Medicines, Foodstuffs for Particular Nutritional Uses and Medical Devices of 12 May 2011 (ARM).

The main authorities in charge of the pharmaceutical and medical device sector are the Minister of Health (MoH), the Pharmaceutical Inspectorate (the main pharmaceutical regulator – MPI) and 16 local voivodeship pharmaceutical inspectors. Marketing authorisations (MAs) are issued by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (ORMP). Public funding of healthcare services and products is operated by the National Health Fund (NHF).

II THE REGULATORY REGIME

i Classification

The definitions of 'medicinal product' and 'medical device' under Polish law are essentially the same as those adopted under the EU legislation. Polish law also follows the general EU rule regarding 'borderline products' – if a product falls within the definition of a medicinal

1 Ewa Skrzydło-Tefelska is a partner and Jacek Myszko is a senior counsel at Sołtysiński Kawecki & Szlęzak.

product and, at the same time, of another type of product (in particular, a food supplement, a cosmetic or a medical device), the medicinal product's regime applies. Most of the aforementioned products are regulated in Poland under separate pieces of legislation; for example, cosmetics are regulated under the Act on Cosmetics (which needs to be reconciled with Regulation (EC) No. 1223/2009 on cosmetic products), and dietary supplements and foodstuffs are regulated under the Act on the Safety of Foodstuffs and Nutrition of 25 August 2006 (which needs to be reconciled with Regulation (EU) No. 609/2013 on food intended for infants and food for special medical purposes).

ii Non-clinical studies

Non-clinical (i.e., pharmacological and toxicological) studies should be carried out in accordance with the rules of good laboratory practice (GLP), as regulated under the Act of 25 February 2011 on Chemical Substances and their Mixtures and under the Executive Regulation of the MoH of 22 May 2013 on Good Laboratory Practice and Performing Research in Accordance with the Rules of the GLP. Consequently, such studies should be carried out by the research entities granted the GLP compliance certificate.

The means of protection of animals used in the course of studies is regulated under the Act of 15 January 2015 on Protection of Animals Used for Scientific and Academic Purposes.

Tests on animals may only be carried out by authorised 'users' and only with consent from the local ethics committee. The register of authorised suppliers, breeders and users is kept by the Minister of Science and Higher Education (available online). Records of experimental animals must be kept by the research centres.

iii Clinical trials

Clinical trials are regulated by the provisions of the PhL. All clinical trials (including bioavailability and bioequivalence studies) should be planned, carried out, monitored and reported in accordance with good clinical practice (GCP) as set out in the regulation of the Ministry of Health on Good Clinical Practice dated 2 May 2012. The sponsor of any clinical trials (a person responsible for initiating, conducting and financing a clinical trial) may be a natural person or an entity with the registered office in the territory of the EU or EEA – if the sponsor does not have its registered office in the territory of the EEA state, it may act solely through a legal representative with a registered office in this territory. As a principle, clinical trials may start only after obtaining a positive opinion from the bioethics committee and the authorisation of the president of the ORMP – at this stage, the trials are also entered into the Central Register of Clinical Trials. The president of the ORMP may refuse to authorise a clinical trial when submitted documents are incomplete, the trial constitutes a threat to public order or is contrary to the rules of social conduct, or when the concept of the trial is not compliant with the requirements of GCP.

No financial encouragement should be offered to participants of clinical trials unless they are healthy adults who may give informed consent. This ban does not preclude reimbursement of the costs of participation.

In order to conduct clinical trials the informed consent of participants is required. The PhL provides for specific requirements in this respect. Additional requirements apply to clinical trials that involve minors or incapacitated individuals.

The sponsor and the investigator are liable for damages caused in connection with clinical trials and are obligated to take out an adequate insurance policy. Specific requirements are set out in the regulation of the Minister of Finance dated 30 April 2004 on compulsory insurance of the sponsor and investigator.

The products used in the trials should be prepared in accordance with good manufacturing practice. The principal documentation of the trials should be kept by the sponsor and investigator for at least five full years following the end of the study and should be made available to the ORMP upon request.

Medical devices and active implantable medical devices should undergo a clinical analysis based on clinical data. The specific rules for such trials are regulated under the AMD. The clinical trials must be authorised by the bioethics committee and the president of the ORMP and conducted according to the protocol for clinical trials. The informed consent of participants is required, who have right to physical and psychological integrity, privacy and personal data protection; they may withdraw from the trials without sustaining damage or injury. The sponsor and investigator are required to obtain a civil liability insurance policy. Restrictions on offering financial incentives apply, similar to those that apply in trials regarding medicinal products.

The national regulation on clinical trials is still in force but eventually it will be replaced by Regulation (EU) No. 536/2014 on Clinical Trials, which is expected to become applicable in October 2018.

iv Named-patient and compassionate use procedures

The PhL allows for importation of medicinal products that have no MA in the territory of Poland, where it is necessary to save the life or health of a patient. Such medicinal product must be authorised in the country from which it is imported (country of origin) and have a valid MA in such country (a targeted import procedure). The basis for a targeted import procedure is the requisition of a hospital or a physician carrying out therapy outside the hospital, confirmed by a national or regional medical consultant qualified in the relevant field of medicine. Detailed rules governing the distribution of medicinal products imported through the targeted import procedure were set out in the MoH regulation dated 21 March 2012 but on 31 December 2016, the regulation was revoked and no new regulation has been enacted.

The following cannot be placed on the market under the targeted import procedure:

a medicinal products in respect of which a decision refusing an MA, non-extension of the validity period of an MA or revocation of an MA was issued in Poland;

b medicinal products containing the same active ingredients, dose and form as products that have already obtained MAs in Poland; and

c products that, owing to the safety of use or the volume of import, should be placed on the market in accordance with the general provisions of the PhL.

Pursuant to Article 39 of the ARM, medicinal products imported under the targeted import procedure may be reimbursed.

Poland has not expressly implemented legislation specific to compassionate use in the meaning set out in Article 83 of the Regulation (EC) No. 726/2004. The possibility of undergoing treatment with the use of not yet registered products was due to be implemented into the law on clinical trials. The progress on this subject was ultimately halted as the the EU Regulation on Clinical Trials was adopted.

The PhL also provides extraordinary procedures for the importation of medicinal products applicable in the event of a natural disaster (or other similar life- or health-threatening events).

The AMD allows for the introduction into the Polish market of single medical devices that have not yet undergone a compliance assessment procedure if they are necessary to achieve required preventive, diagnostic or therapeutic purposes. Such devices may be marketed on the basis of a decision of the president of the ORMP issued when it is necessary to protect the life or health of a patient, or for the protection of public health. Request for such decision may be filed by a healthcare provider, national, regional or military healthcare consultant, the president of the Health Technology Assessment Agency or the president of the NHF.

Moreover, custom-made devices may be distributed without a CE marking provided that the device is accompanied by a statement by the manufacturer or its authorised representative that it fulfils its essential requirements (or indicating which requirements are not fulfilled and why).

v Pre-market clearance

Medicinal products covered by a Polish national MA and products covered by an MA issued by the EU Council or the European Commission are eligible to be marketed in Poland. There are four ways of obtaining an MA that is effective in Poland: through a national procedure, a centralised procedure, a decentralised procedure and a mutual recognition procedure.

The marketing authorisation holder (MAH) may be an entrepreneur in the meaning outlined in the Polish Act on Freedom of Economic Activity or an entrepreneur conducting business activity in the EU or EEA.

The national procedure is regulated under the PhL. The authority competent to issue an authorisation is the president of the ORMP. The authorisation should be issued within 210 days of the submission of the application for a period of five years (it may be subsequently extended). The authorisation may be issued following verification of an application by the ORMP and after preparing an assessment report with a scientific opinion on the medicinal product. The application for authorisation must include extensive documentation, which reflects the requirements provided in Directive 2001/83/EC. The expedited path for generic products also reflects EU legislation (as a rule, eight years' data exclusivity and 10 years' market exclusivity periods apply). The results of non-clinical and clinical studies are not required for products with active substances that have a well-established use or well-established effectiveness and an acceptable level of safety and use in EU or EEA Member States.

The PhL provides for simplified authorisation procedure for traditional herbal medicinal products and homeopathic products.

Some products do not require MAs to be distributed in Poland, including magistral formulae, officinal formulae, selected radiopharmaceutical products, whole blood, plasma and blood cells of human origin, advanced therapy medicinal products (according to Regulation (EC) No. 1394/2007); neither are authorisations required for products used solely for scientific research, products used by manufacturers, products used in registered clinical trials and intermediate products to be used by manufacturers. The PhL also regulates a parallel import procedure.

Medical devices may generally be marketed only if they have a CE marking (see the EU chapter). The essential requirements for devices, as well as the specific procedure for compliance assessment, are set out in a number of executive regulations of the MoH. The manufacturer is responsible for compliance assessment and introduction of medical devices

to the market. The manufacturer must be domiciled or have registered offices in the EU or appoint an authorised representative who is responsible for a given product. When the manufacturer does not appoint a representative, or the manufacturer or representative is not responsible for introducing the product to the market, the entity that places the product on the market bears responsibility for device's compliance with law.

Medical devices should be notified to the ORMP by the manufacturer or its representative, domiciled or with registered offices in Poland, at least 14 days before the product is first put on the Polish market. Distributors and importers with a domicile or registered office in Poland who introduce medical devices to the Polish market must notify the ORMP without delay, certainly no later than seven days following first introduction of such products to the market.

vi Regulatory incentives

Supplementary protection certificates for medicinal products are granted in Poland according to Regulation (EC) No. 469/2009 (executive measures are implemented into the Polish Industrial Property Law).

Article 15 of the PhL implements into Polish law the data exclusivity and market exclusivity periods (eight and 10 years, respectively) provided by the EU law.

vii Post-approval controls

The obligations stemming from the EU pharmacovigilance system apply in Poland. The Polish implementation of the EU Directive on Falsified Medicines for Human Use entered into force on 8 February 2015.

After the lapse of a five-year period of validity of an MA, the authorisation may be indefinitely extended after examination of documents regarding the product's quality, safety and effectiveness, as well as any side effects. At this stage the ORMP may refuse to extend the authorisation or extend it only for a further five years (if, for safety reasons, the ORMP deems prolongation of the authorisation for an indefinite period to be inappropriate).

Any amendments to an MA may be made upon request of the MAH and requires a decision of the president of the ORMP. The procedure varies depending on the type and scope of amendments.

The MA may be withdrawn because of, *inter alia*, serious adverse reactions related with the product, insufficient therapeutic effectiveness, infringement of provisions of the medicinal product's marketing or failure to notify required new information regarding the product. Violations not resulting in a direct threat to public health may result in suspension of the authorisation. Furthermore, the MA expires if the product is not marketed for three years.

The AMD uses the term 'medical incident' for malfunctions, defects, improper labelling or contents of any manuals as well as other technical or medical causes related to medical devices that may result in death or deterioration of the health of a patient. Healthcare providers are obliged to report any such incidents without delay to the device manufacturer or its representative, as well as to send a copy of the notification to the ORMP. The manufacturer (or its representatives) must carry out field safety corrective action. The president of the ORMP may issue a decision prohibiting or suspending the marketing of unsafe medical devices.

viii Manufacturing controls

The manufacturing of medicinal products is understood broadly and requires a permit from the MPI. There are certain exceptions to the obligation to obtain a permit; such exceptions are generally consistent with the EU legislation.

Manufacturers of medicinal products must comply with provisions of the good manufacturing practices (set out in the MoH regulation, reflecting the respective EC guidelines). Manufacturing permits may cover the manufacturers' own products and any products manufactured for third parties (as a contractor). A manufacturing permit allows manufacturers to undertake any of the activities expressly mentioned in the permit and with respect to the products listed in the permit. If manufacturer wishes to expand the list of medicinal products or the scope of activities, it must apply for the relevant amendment of the permit. The processing of controlled substances requires additional authorisation (see Section II.xiii, *infra*).

Manufacturing permits are issued for an unspecified period of time. The MPI also issues a separate certificate confirming compliance of the manufacturing facility with the GMP requirements, valid for three years from the date of the latest inspection carried out by the MPI (the date of the inspection is stated on the certificate).

Depending on the legal form of the transfer of ownership of a manufacturing facility, manufacturing permits may be transferred along with the facility (e.g., in the event of a merger) or new permits may be required in the event of the sale of the facility to another entrepreneur.

ix Advertising and promotion

Advertising of medicinal products is regulated under the PhL and under the MoH executive regulation dated 21 November 2008. Applicable restrictions for advertising and promotion are generally consistent with the applicable EU legislation. Only the MAH (or a parallel importer) and any entity authorised by the MAH may undertake advertising of medicinal products (in practice written authorisation is required by the MPI). Reimbursed medicinal products cannot be publicly advertised. Violation of the applicable rules may trigger various sanctions, including criminal sanctions or a fine.

The regulations regarding advertising of medical devices are very limited. Under the AMD, promotional materials, presentations and information on devices may not be misleading as to the properties and operation of devices by:

a attributing properties, functions and operations to a device that are non-existent;

b giving the impression that treatment or diagnosis with the device is guaranteed to be successful;

c failing to inform of the expected risks connected with using the device in accordance with its intended use or for a period longer than intended; and

d suggesting use or properties other than those declared during the conformity assessment.

The ARM prohibits manufacturers and distributors of reimbursed products (including medicinal products, medical devices and reimbursed foodstuffs) to offer any encouragement regarding such products to patients or healthcare professionals authorised to issue prescriptions. In particular it is prohibited to offer conditional sale, rebates and bonuses,

packages, loyalty programmes, donations, prizes, small gifts, trips, lotteries, any forms of lending, tied transactions, facilitations, acquisitions or sponsored services, vouchers, coupons or other benefits not expressly named. Various sanctions apply for violation of such ban.

Pharmacies in Poland may not advertise. This prohibition includes a broad range of promotional activities such as loyalty programmes and the publication of price lists.

x Distributors and wholesalers

Wholesale is defined in accordance with EU legislation. Wholesale trade may be undertaken by pharmaceutical wholesalers as well as pharmaceutical manufacturers (in the latter case, limited to their products). Before 8 February 2015 (when the amendments to the PhL entered into force) customs and consignment warehouses had also been authorised to carry on a wholesale trade in medicinal products. However, by operation of the new amendment to PhL, such entities were automatically transformed into pharmaceutical wholesalers. Wholesalers must obtain an authorisation issued by the MPI, except for manufacturers (a manufacturing permit already encompasses authorisation for sale of manufactured products). All wholesalers are required to follow the rules of good distribution practice (as regulated under the MoH Regulation dated 13 March 2015). The regulation implements EC Guidelines of 2013, but the Polish implementation is more strict than the requirements stemming directly from the Guidelines.

Retail trade may be undertaken by pharmacies (the PhL distinguishes generally accessible pharmacies and hospital pharmacies) and pharmacy outlets. Some OTC products may also be sold in herbal medicine stores, medical supplies stores and general stores.

Distribution of medical devices does not require any specific authorisation and may be undertaken by any entrepreneur (provided they comply with the requirements of the AMD).

xi Classification of products

Under the PhL there are the following dispensing categories of medicinal products:

a those dispensed over-the-counter without a physician's prescription (OTCs);
b those dispensed on a physician's prescription;
c those dispensed on a physician's prescription for restricted use;
d those dispensed on a physician's prescription, containing narcotic agents or psychotropic substances defined in separate regulations; and
e those for hospital use only.

The criteria for classifying medicinal products into one of the categories are specified in the MoH executive regulation dated 14 November 2008. The dispensing category must be indicated in the MA and may only be changed by an amendment of the MA. The main consequences of classification are limitations on the allowed channels of distribution (only OTCs may be sold in general stores) and limitations on the advertising of products other than OTCs directed to patients.

Medical devices are classified as Class I, IIa, IIb or III depending on the risk connected with their use. The factors relevant to classification are the time of contact of the device with an organism, the place of contact, the level of invasiveness, local and systemic effects, and the function and technologies used. Medical devices for *in vitro* diagnostics are classified as Class A or B in accordance with Directive 98/79/EC.

xii Imports and exports

The import of a medicinal product from third countries (non-EEA) requires an import authorisation that is issued in a procedure similar to the granting of a manufacturing authorisation by the MPI.

The parallel import of products authorised to be marketed in Poland requires the importer to obtain an authorisation for the import of each specific product. Such authorisation is issued for five years and may be renewed for subsequent five-year periods.

In order to remedy problems with shortages of state-reimbursed medicines Poland has introduced new restrictions on the export of some products listed as being in danger of shortages (the list is compiled on the basis of product availability data gathered from the market by the MPI and is published by the MoH). A parallel exporter must file a notification to the MPI 30 days prior to the export of any listed products. The MPI may then issue a decision banning the export. If such decision is issued the wholesaler is obliged to sell the products in Poland.

There are no general limitations of import and export of medical devices. However, reimbursed medical devices are subject to the same parallel export procedure as medicinal products (see above). Importers of medical devices are obligated to ensure that the compliance assessment for the device was performed, that the manufacturer has appointed an authorised representative and that the CE marking, along with identification number of a notified body, are included in product's labelling (if required). An importer domiciled or with a registered office in Poland is also obliged to keep a declaration of conformity or required statements and certificates regarding the device. The president of the ORMP, at the request of a manufacturer or authorised representative domiciled or with a registered office in Poland, may issue a certificate of free sale to facilitate the export of devices with CE markings or custom-made devices.

xiii Controlled substances

The marketing of narcotic drugs and psychotropic substances (controlled substances) is governed by the CDA. Drug precursors are additionally governed by EU regulations.

Under the CDA, import and export (from or to EU and non-EU Member States) of controlled substances may be carried out only by businesses with authorisation to manufacture or wholesale trade. Such authorisations are issued by the MPI. As a general rule, import and export of controlled substances require consent from the MPI and the competent authorities in the country of export. When the controlled substances are in transit through Poland, they must be accompanied by an export authorisation granted by the authorities in the country of origin and they cannot be stored in customs warehouses. There are exceptions to these rules with regard to controlled substances imported for personal medicinal needs.

The wholesale trade in controlled substances and drug precursors also requires authorisation granted by the MPI. The retail trade in such products (that are also medicinal products) may be undertaken by pharmacies and pharmacy outlets.

There are further specific requirements regarding storage, handling and issuance of controlled substances, keeping pertinent records and documentation, etc.

xiv Enforcement

The MPI supervises manufacturing, import, quality and distribution of medicinal products and marketing of medical devices. When an instance of non-compliance is detected, the

MPI generally issues a decision ordering the contravener to remedy the breach. If there is a direct threat to life and health of the population, the MPI may immediately close the manufacturer's or distributor's operations.

The president of the ORMP is the competent inspection authority for medical devices manufactured, marketed, used and assessed in Poland. The president of the ORMP may issue decisions prohibiting, suspending or restricting marketing and use of devices for reasons regarding patients' safety, public health, safety and order, etc.

The PhL and the AMD provide for criminal liability for infringement of some rules regarding labelling, compliance assessment, marketing or failure to perform some duties by the entities responsible for product compliance. In such a situation, enforcement is carried out by the police, public prosecutors and courts.

III PRICING AND REIMBURSEMENT

Under the ARM, medicinal products listed in the Register of Reimbursed Products (the Register) are reimbursed. Under certain conditions, medicines without an MA and medicines for use exceeding the scope described in the characteristics of the medicinal product may also be reimbursed.

Reimbursement of a medicinal product already entered into the Register cannot be automatically extended to the equivalent generic or medicinal product or parallel imported medicinal products (they need to be separately entered into the Register).

The Register is compiled on the basis of reimbursement decisions issued by the MoH and is updated every two months. The application for reimbursement may be filed by the MAH, its representative or holder of parallel import authorisation. The medicinal product covered by an application must meet the following requirements at the moment the application for reimbursement is filed:

a it must have a valid MA or remain on the market as specified in the PhL;

b it must actually be available on the market (the evidence thereof must be attached to the application); and

c it must be granted an international article number (EAN) code or another code equivalent to an EAN.

Prices (sale price, wholesale price and retail price) of reimbursed products are regulated (either by way of fixing the actual sale price or fixing the maximum price margin that may be added to the fixed sale price at a given stage). Prices are negotiated by the applicant and the MoH and only when a consensus has been reached may the product be subject to reimbursement.

The decision on reimbursement encompasses the category of reimbursement availability (i.e., under which category the medicine is reimbursed),[2] the level of payment (whether the patient receives the product for free or against some payment),[3] the regulated (fixed) price of sale and the specification of the limit group the particular product belongs to.

2 The specific categories are listed in the ARM.

3 Different levels of payment are possible.

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

In general, decisions of administrative bodies are subject to appeal in Poland. The appeal may be examined by the supervisory body or by the same body (the latter 're-examination procedure' applies to decisions issued by ministers, such as the MoH, and heads of central governmental bodies, such as the MPI and the ORMP). After completion of the appeal procedure, the decision may still be subject to judicial (administrative court) review. The judicial review procedure has two stages, so the basic complaint is adjudicated by the voivodeship administrative courts, while the cassation complaint against the decision of such court is adjudicated by the Supreme Administrative Court. If the Supreme Administrative Court finds that the decision is inconsistent with the law, in most cases it will quash the decision and state that it must be re-examined. Parties may request a stay of enforcement of the administrative decision for the time of the judicial review.

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYERS

Under the PhL it is forbidden to address the advertising of medicinal products to persons qualified to prescribe and to persons trading in medicinal products involving inducements.[4] The infringement of this provision may result in criminal liability. It is also prohibited to accept any advantages and benefits. An exception is made for gifts of small value (not exceeding 100 zlotys) related to a medical or pharmaceutical practice, bearing advertising or branding for the specific company or medicinal product.

The ARM provides for administrative and criminal sanctions for certain marketing practices. In general, it is prohibited to provide any benefit tied with reimbursed products, addressed in particular to patients, entrepreneurs or authorised persons (in particular physicians authorised to issue prescriptions), particularly by way of conditional sale, rebates and bonuses, packages, loyalty programmes, donations, prizes, small gifts, trips, lotteries, any form of lending, tied transactions, facilitations, acquisitions or sponsored services, vouchers, coupons or other benefits not expressly named.

Financial relations between companies and healthcare professionals is a very sensitive subject in Poland and a careful approach to the subject is generally recommended. Special care should be exercised in relation to healthcare professionals who perform administrative functions at hospitals and other entities, who also place orders for medicinal products and medical devices. Such professionals should not be offered any incentives or gifts as it may trigger various types of liability for both the healthcare professional and the person or entity offering the incentive (criminal sanctions may also apply). Such actions may also be perceived as bribery or violation of public tenders, which may result in criminal liability for individuals and trigger significant fines to the companies.

4 The supply, offering or promising of pecuniary advantages, gifts and various types of facilitation, prizes, trips, and organising and financing medicinal products' promotional meetings at which hospitality manifestations are not limited to the main purpose of the meeting.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

There is no specific liability regime relating to the use of medicinal products or medical devices. The general principles apply – in particular, principles on the liability for the use of defective products (mirroring EU legislation in this respect).

Apart from the general possibility of seeking compensation in court, there is a special system of compensating personal injuries introduced by the Act on Patient Rights and the Patient Ombudsman. The Act introduces the term 'medical event', which is an infection of a patient with a biological pathogen, bodily injury or health disorder, or the patient's death following: (1) a diagnosis, if it led to improper treatment or delayed appropriate treatment, contributing to the development of the disease; (2) treatment, including surgery; or (3) use of a medicinal product or a medical device that did not follow current medical knowledge. The term 'medical event' only applies to hospital healthcare services. The patient may apply to the regional commission for the evaluation of medical events. When the commission rules that a medical event has occurred, the ruling is binding for the hospital's civil liability insurer, who is obliged to offer a sum of proposed damages within 30 days, amounting to 300,000 zlotys for death and 100,000 zlotys for other injuries, which may be accepted or rejected by the applicant. This system, however, deals with medical incidents and not directly with defective medicinal products or medical devices.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

Competition law in the life sciences sector is regulated and enforced in accordance with EU law. The body responsible for supervision of practices restricting competition is the Office for the Competition and Consumer Protection. Since the pharmaceutical market is already thoroughly regulated, in the past year there have been no significant antitrust decisions issued in this field.

Mergers and acquisitions within the pharmaceutical and medical devices sector are subject to notification to the antimonopoly authorities (standard provisions apply).

ii Transactional issues

There is a specific procedure for a change of MAH, in which the agreement on the transfer of rights and obligations of the MAH must be submitted to the ORMP together with a statement that only a change of MAH has occurred (i.e., the MAH is the only element of the authorisation or documentation that has changed).

Most other authorisations under the PhL (e.g., MAs, wholesaler and pharmacy authorisations, licences to trade in controlled substances) cannot be transferred by agreement. However, according to the general rules of the commercial companies code, administrative authorisations and licences may be transferred, via an acquisition or a merger by or with another company.

VIII CURRENT DEVELOPMENTS

Major changes to the retail distribution of medicinal products were proposed and discussed in 2016. The government proposed full separation of retail sale of medicinal products and

other products. This would include banning the OTC drugs sale from general stores and allowing them to be sold only in pharmacies. In turn, the pharmacies would potentially lose the right to sell products other than medicinal products (most importantly, cosmetics).

The government also expressed the intention to adopt a very strict approach on the subject of concentration of pharmacies. It has proposed major changes to the regime for granting pharmacy licences; under the new regime, obtaining a licence would only be possible if the applicant was a pharmacist or a company composed solely of pharmacists. Further, obtaining new licence would be impossible if the applicant (or companies in which he or she is a partner or shareholder) already owned at least four pharmacies. The possibility of transferring an existing licence to the new company in case of reorganisation or if the company was acquired would be prohibited.

Although, ultimately, the government may adopt a more lenient approach to the pharmacy market in Poland, business owners should bear in mind that the above-mentioned changes are quite likely and, if confirmed, may be implemented soon.

Appendix 1

ABOUT THE AUTHORS

EWA SKRZYDŁO-TEFELSKA

Sołtysiński Kawecki & Szlęzak

Ewa Skrzydło-Tefelska joined SK&S in 1999 and became a partner in 2006. She combines practice with academic work being a lecturer of EU law at the university in Lublin, where she received her PhD in 1987 and title of habilitated doctor in 2013. She studied for several years in France, the United States and at the Hague Academy of International Law. Dr Skrzydło-Tefelska's practice focuses on advice and litigation in patent and trademark protection matters, including unfair competition and advertising. As a co-head of the IP Department at SKS, with strong emphasis on life sciences, she advises numerous clients from pharmaceutical and medical devices sector, foodstuff producers and manufacturers of cosmetics both in regulatory matters and in the litigations involving their IP rights. She is an author of books and articles on various aspects of EU and Polish law, especially involving issues of industrial property protection, pharmaceutical law and advertising. She is a frequent speaker at national and international conferences in the area of industrial property law, advertising law and pharmaceutical law.

JACEK MYSZKO

Sołtysiński Kawecki & Szlęzak

Jacek Myszko is a senior counsel at Sołtysiński, Kawecki & Szlęzak. He focuses his practice on IP-related issues and pharmaceutical law in its various aspects.

Mr Myszko graduated with a law degree from the Nicolaus Copernicus University in Torun, Poland and with a diploma in EU studies from the J Monnet European Studies Centre. He also completed an IP law programme at the Jagiellonian University in Cracow, Poland and various international courses organised by, *inter alia*, the University of Cambridge (English and EU law), the Catholic University of America and Columbus School of Law (business and trade law). He has advised Polish and foreign clients in many cases on all aspects of trademark and biotechnical patent protection; various aspects of medicinal products distributions schemes, including direct distribution, distribution via public tenders and application of reimbursement procedures; restructuring and acquisition (including audits) of

pharmaceutical companies and pharmacies; and issues related to contacts of pharmaceutical companies and medical devices companies with healthcare professionals (training, scientific conferences, etc.).

SOŁTYSIŃSKI KAWECKI & SZLĘZAK
26 Jasna St
00-054 Warsaw
Poland
Tel: +48 22 608 7000
Fax: +48 22 608 7070
ewa.tefelska@skslegal.pl
jacek.myszko@skslegal.pl
www.skslegal.pl