

THE LIFE SCIENCES  
LAW REVIEW

SIXTH EDITION

Editor  
Richard Kingham

THE LAWREVIEWS

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# PREFACE

The sixth edition of *The Life Sciences Law Review* covers a total of 34 jurisdictions, providing an overview of legal requirements of interest to pharmaceutical, biotechnology and medical device companies. The chapters are arranged so as 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.

It is vitally important that lawyers who advise companies in the life sciences sector, and the business executives whom they serve, have a working knowledge of the regulations and policies that govern drugs, biologics and medical devices. It is equally important to keep current with developments in the regulatory systems, which govern access to the market, pricing and reimbursement, advertising and promotion and numerous other matters that are essential to success. It is our hope that this annual publication will be helpful in this respect.

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 2018

# POLAND

*Ewa Skrzydło-Tefelska and Jacek Myszko<sup>1</sup>*

## 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 Ministry of Health (MoH), the Pharmaceutical Inspectorate (the main pharmaceutical regulator – MPI) and 16 local voivodship 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 still operated by the National Health Fund (NHF); however, the Polish government is planning to liquidate the 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 EU legislation. Polish law also follows the general EU rule regarding ‘borderline products’ – if a product falls within the definition of a medicinal 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).

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

## **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 GLP. Consequently, non-clinical studies should be carried out by research entities that have been granted a 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 Ministry 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 European Union or the European Economic Area (EEA) – if the sponsor does not have its registered office in the territory of a 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 policy 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.

Before conducting a clinical trial, 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 Ministry 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. 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. They also have the 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. The draft amendment of the PhL should be made available in the first quarter of 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. A medicinal product must be authorised in the country from which it is imported (country of origin) and have a valid MA in that 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 Regulation (EC) No. 726/2004. Currently, the proposal of specific regulations is included in the bill amending the ARM. This draft is at the stage of governmental work and it is difficult to assess when the new regulation will enter into force.

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. 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. A request for a 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 European Union or the 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 submission of the application for a period of five years (which 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 a 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 European Union 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 European Union 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 its 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, and certainly no later than seven days following the first introduction of the products on 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 EU law.

The Polish Ministry of Economic Development is planning to begin a new programme of rewarding pharmaceuticals entrepreneurs who conduct their economic activity and run the research and development centres in Poland and employ Polish nationals. The companies that are the 'Friends of Polish Industry' could rely on the easier reimbursement negotiations.

## **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 by the president of the ORMP. The procedure varies depending on the type and scope of the amendments.

The MA may be withdrawn because of, *inter alia*, serious adverse reactions related to 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, and to send a copy of that 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; these exceptions are generally consistent with EU legislation.

Manufacturers of medicinal products must comply with provisions of 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 a manufacturer to undertake any of the activities expressly mentioned in the permit and with respect to the products listed in the permit. If the manufacturer wishes to expand the list of



medicinal products or the scope of its activities, it must apply for the relevant amendment of the permit. The processing of controlled substances requires additional authorisation (see Section II.xiii).

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, which is 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 with the facility (e.g., in the event of a merger). 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 form of lending, tied transactions, facilitations, acquisitions or sponsored services, vouchers, coupons or other benefits not expressly named. Various sanctions apply for violation of this 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 and 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 the 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. Also the findings of pharmaceutical inspectors prove that the interpretation of law is not consistent and changes quite often. Under the new supervision system, periodic inspections are carried out in each wholesale premises at least once during a three-year period. There is also rather limited understanding of the pharmaceutical authorities for the more advanced business models (e.g., logistic operators running wholesale premises or transporting medicinal products for third parties); in most cases they tailor their expectations based on the 'regular' buy-sell business model. As a result, the standard for running a pharmaceutical wholesale business in Poland is set much higher than in most other EU countries.

Retail trade may be undertaken by pharmacies (the PhL distinguishes between generally accessible pharmacies and hospital pharmacies) and pharmacy outlets. Some over-the-counter 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 categories of dispensing 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. This authorisation is valid 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 a 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, with the identification number of a notified body, are included in the 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 a CE marking 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, the importation and exporting (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. These authorisations are issued by the MPI. As a general rule, the importation and exporting 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 these products (which 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, and so on.

### **xiv Enforcement**

The MPI supervises the manufacture, importation, quality and distribution of medicinal products and the 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 the 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 of the 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 (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 (or EAN) 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),<sup>2</sup> the level of payment (whether the patient receives the product for free or against some payment),<sup>3</sup> the regulated (fixed) price of sale and the specification of the limit group to which the particular product belongs.

There is also the possibility of reimbursing medicinal products under the emergency access to the drugs technologies procedure. Namely, a patient may obtain an extraordinary reimbursement of a medicinal product that is not on the reimbursement list, provided that use of that particular medicinal product is necessary because of the inefficiency of a standard therapy. Contrary to compassionate use, emergency access to the drugs technologies does not apply to medicinal products that do not have an MA.

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2 The specific categories are listed in the ARM.

3 Different levels of payment are possible.

#### IV ADMINISTRATIVE AND JUDICIAL REMEDIES

In general, decisions made by administrative bodies in Poland are subject to appeal. The appeal may be examined by the supervisory body or by the same body (the latter 're-examination procedure' applies to decisions issued by ministries, 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: the basic complaint is adjudicated by the voivodeship administrative courts, whereas a 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 during the period 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.<sup>4</sup> The infringement of this provision may result in criminal liability. It is also prohibited to accept any advantages or 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. People in these professional positions 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 for companies.

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<sup>4</sup> The supply, offer or promise 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. A patient may apply to the regional commission for evaluation of a medical event. When the commission rules that a medical event has occurred, the ruling is binding for the hospital’s civil liability insurer, which is obliged to offer a sum of proposed damages within 30 days (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.

There are also plans to introduce a special regime for obligatory vaccines. Currently, the Polish government is working on the bill of amendment of the Act of 5 December 2008 on preventing and combating infections and infectious diseases among people. One of the aims of this bill is to create a special fund for adverse post-vaccinal reactions.

## **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 of Competition and Consumer Protection. Since the pharmaceutical market is already thoroughly regulated, there have been no significant antitrust decisions issued in this field during the past year.

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 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

The most controversial idea from the Polish government at the moment is the draft Act on openness in public life. Many entrepreneurs have expressed concerns relating to the possibility of their trade secrets being disclosed as a result of the application of this Act. The most sensitive issue is the possibility of disclosure of the data exchanged during the course of reimbursement price negotiations with MoH, the reimbursement decision itself and the appendix thereof relating to the risk-sharing schemes or the content of agreements between pharmaceutical companies and its contractors. Recently the MoH promised to exclude the aforementioned from the application of the draft law; however, the draft is still changing and its final shape is still uncertain.

The big challenge for the Polish legislator, but also for the pharmaceutical companies, could be the application of Regulation (EU) No. 536/2014 on Clinical Trials in October 2018. This Regulation brings in a series of amendments to the existing system. The essential issue is the proper preparation of sponsors for clinical trials, the pharmaceutical companies, the investigators and the institutions to perform clinical trials under the new regulations. Currently, the PhL is not in line with Regulation (EU) No. 536/2014, and must therefore be significantly amended.

There is also a very vivid discussion regarding biosimilar medicines in Poland. Since the patent protection for certain biological medicinal products is due to expire in Poland in the near future, manufacturers of the biological (reference) medicinal products are taking various steps to *de facto* ensure continuation of the previous market share and of the therapy with the up-to-date patented products, despite expiry of the patents. The most controversial part of the discussion is in regard to the bioequivalence and interchangeability of reference products and biosimilar products during the course of a therapy that has already been initiated. The Polish reimbursement regime encourages the introduction of cheaper, biosimilar products, thus creating price pressure on both the reference biological products and the new biosimilar products.

## 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 as 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 intellectual department at SKS, with a strong emphasis on life sciences, she advises numerous clients from the 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 the 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 & SZŁĘZAK**

ul. Jasna 26

00-054 Warsaw

Poland

Tel: +48 22 608 7000

Fax: +48 22 608 7070

[ewa.tefelska@skslegal.pl](mailto:ewa.tefelska@skslegal.pl)

[jacek.myszko@skslegal.pl](mailto:jacek.myszko@skslegal.pl)

[www.skslegal.pl](http://www.skslegal.pl)



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