The Life Sciences Law Review

Third Edition

Editor
Richard Kingham

Law Business Research

The Life Sciences Law Review

The Life Sciences Law Review
Reproduced with permission from Law Business Research Ltd.

This article was first published in The Life Sciences Law Review - Edition 3
(published in March 2015 – editor Richard Kingham).

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

The Life Sciences Law Review

Third Edition

Editor
Richard Kingham

Law Business Research Ltd

THE LAW REVIEWS

THE MERGERS AND ACQUISITIONS REVIEW

THE RESTRUCTURING REVIEW

THE PRIVATE COMPETITION ENFORCEMENT REVIEW

THE DISPUTE RESOLUTION REVIEW

THE EMPLOYMENT LAW REVIEW

THE PUBLIC COMPETITION ENFORCEMENT REVIEW

THE BANKING REGULATION REVIEW

THE INTERNATIONAL ARBITRATION REVIEW

THE MERGER CONTROL REVIEW

THE TECHNOLOGY, MEDIA AND
TELECOMMUNICATIONS REVIEW

THE INWARD INVESTMENT AND
INTERNATIONAL TAXATION REVIEW

THE CORPORATE GOVERNANCE REVIEW

THE CORPORATE IMMIGRATION REVIEW

THE INTERNATIONAL INVESTIGATIONS REVIEW

THE PROJECTS AND CONSTRUCTION REVIEW

THE INTERNATIONAL CAPITAL MARKETS REVIEW

THE REAL ESTATE LAW REVIEW

THE PRIVATE EQUITY REVIEW

THE ENERGY REGULATION AND MARKETS REVIEW

THE INTELLECTUAL PROPERTY REVIEW

THE ASSET MANAGEMENT REVIEW

THE PRIVATE WEALTH AND PRIVATE CLIENT REVIEW

THE MINING LAW REVIEW

THE EXECUTIVE REMUNERATION REVIEW

THE ANTI-BRIBERY AND ANTI-CORRUPTION REVIEW

THE CARTELS AND LENIENCY REVIEW

THE TAX DISPUTES AND LITIGATION REVIEW

THE LIFE SCIENCES LAW REVIEW

THE INSURANCE AND REINSURANCE LAW REVIEW

THE GOVERNMENT PROCUREMENT REVIEW

THE DOMINANCE AND MONOPOLIES REVIEW

THE AVIATION LAW REVIEW

THE FOREIGN INVESTMENT REGULATION REVIEW

THE ASSET TRACING AND RECOVERY REVIEW

THE INTERNATIONAL INSOLVENCY REVIEW

THE OIL AND GAS LAW REVIEW

THE FRANCHISE LAW REVIEW

THE PRODUCT REGULATION AND LIABILITY REVIEW

THE SHIPPING LAW REVIEW

THE ACQUISITION AND LEVERAGED FINANCE REVIEW

THE PRIVACY, DATA PROTECTION AND CYBERSECURITY LAW REVIEW

www.TheLawReviews.co.uk

PUBLISHER
Gideon Roberton

BUSINESS DEVELOPMENT MANAGER
Nick Barette

SENIOR ACCOUNT MANAGERS
Katherine Jablonowska, Thomas Lee

ACCOUNT MANAGER
Felicity Bown

PUBLISHING COORDINATOR
Lucy Brewer

MARKETING ASSISTANT
Dominique Destrée

EDITORIAL COORDINATOR
Shani Bans

HEAD OF PRODUCTION
Adam Myers

PRODUCTION EDITORS
Tim Beaver, Robbie Kelly, Joanne Morley

SUBEDITOR
Janina Godowska

MANAGING DIRECTOR
Richard Davey

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

www.TheLawReviews.co.uk

ISBN 978-1-909830-40-0

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

ACKNOWLEDGEMENTS

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

ADVOKATFIRMAET BA-HR DA

ANAND AND ANAND

AXON LAWYERS

BAE, KIM & LEE LLC

BÄR & KARRER AG

BDK ADVOKATI/ATTORNEYS AT LAW

CASTRÉN & SNELLMAN ATTORNEYS LTD

COVINGTON & BURLING LLP

DIERKS + BOHLE

FAUS & MOLINER

FIEBINGER POLAK LEON & PARTNER RECHTSANWÄLTE GMBH

GORODISSKY & PARTNERS LAW FIRM

LEE AND LI, ATTORNEYS-AT-LAW

MAPLES AND CALDER

MATTOS MURIEL KESTENER ADVOGADOS

NAGASHIMA OHNO & TSUNEMATSU

NORTON ROSE FULBRIGHT

NSN LAW FIRM

PLESNER LAW FIRM

SÁNCHEZ DEVANNY

S. HOROWITZ & CO

SOŁTYSIŃSKI KAWECKI & SZLĘZAK

STUDIO LEGALE BIRD & BIRD

TAY & PARTNERS

TOBAR & BUSTAMANTE

TOMPKINS WAKE LAWYERS

VIEIRA DE ALMEIDA & ASSOCIADOS

VILAF

WONGPARTNERSHIP LLP

CONTENTS

EDITOR'S PREFACE

The third edition of *The Life Sciences Law Review* extends coverage to a total of 36 jurisdictions, providing an overview of legal requirements of interest to pharmaceutical, biotechnology and medical device companies. As before, 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.

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 2015

Chapter 25

POLAND

Ewa Skrzydło-Tefelska and Jacek Myszko[1]

I INTRODUCTION

The majority of the activities within the pharmaceutical sector are regulated in Poland by the Pharmaceutical Law of 6 September 2001 (PhL). The PhL creates grounds for a number of Polish executive regulations laying down detailed measures for 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 devices sector include 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 devices 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 health-care 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

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

rule that in the event the 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 regime regulating medicinal products applies. Most of the aforementioned products are regulated in Poland under separate pieces of legislation: for example, cosmetics, under the Act on Cosmetics (which needs to be reconciled with EU Regulation 1223/2009 on cosmetic products), and dietary supplements and foodstuffs as such under Act on the Safety of Foodstuffs and Nutrition of 25 August 2006.

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, such studies should be carried out by the research entities granted a GLP compliance certificate.

Protection of animals used in the course of studies is regulated under the Act of 21 January 2005 on Studies on Animals.

Tests on animals may only be carried out by specific research centres (experimental units) and only with consent from the competent ethics committee and authorisation from the head of the research centre. The register of authorised experimental units is kept by the Minister of Science and Higher Education (available online). Records of experimental animals must be kept by the research centres.

At the time of writing, the law is being amended to implement EU Directive 2010/63/EU on the Protection of Animals Used for Scientific Purposes. The Act on Protection of Animals Used for Scientific and Academic Purposes, intended to replace the current law, is currently under deliberation of the Polish Parliament.

iii Clinical trials

Clinical trials are regulated in the PhL. All clinical trials (including bioavailability and bioequivalence studies) should be planned, carried out, monitored and reported in accordance with good clinical practice, as set out in the regulation of the Ministry of Health on Good Clinical Practice (GCP) dated 2 May 2012. The sponsor of any clinical trials (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; when the sponsor does not have its registered office in the territory of an EEA state, it may act solely through a legal representative with a registered office in this territory. As a principle, the clinical trials may start only after obtaining a positive opinion from the bioethics committee and the authorisation of the President of the ORMP, at which point the trials are entered into the Central Register of Clinical Trials. The President of the ORMP may refuse to authorise the clinical trials in the event that submitted documents are incomplete, that the rationale for the study constitutes a threat to public order or is contrary to the rules of social coexistence, or that the rationale of the trials is not compliant with the requirements of GCP.

No financial encouragement should be offered to participants of clinical trials unless they are adults who may give informed consent and are healthy participants in clinical trials. 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 acquire civil liability insurance in connection with the clinical trials. 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 five full years following the end of the study (unless the agreement between them requires the documents to be kept longer) and it should be made available to the ORMP upon request.

Also, medical devices and active medical devices for implementation should undergo a clinical analysis, which is 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 following 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 civil liability insurance policy. Restrictions on offering financial incentives apply, similarly to those applying in trials regarding medicinal products.

On 16 July 2014 the new EU Clinical Trials Regulation No. 536/2014 entered into force, which would replace national provisions in this matter. The new regulation will become applicable no earlier than 28 May 2016.

iv Named-patient and compassionate use procedures

The PhL allows for importation of medicinal products with no MA in force in the territory of Poland, where it is necessary to save 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 are set out in the MoH regulation dated 21 March 2012.

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, due 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 products not yet registered after clinical trials was due to be implemented into the law on clinical trials; the preparatory work was, however, halted due to pending works on the EU regulations on this subject.

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 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 at the request of a health-care provider, national, regional or military health-care consultant, the President of the Health Technology Assessment Agency or the President of the NHF – when it is necessary to protect the life or health of a patient, or for the protection of public health.

Moreover, custom-made devices may be distributed without any 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

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

The marketing authorisation holder (MAH) may be an entrepreneur in the meaning of the Polish freedom of economic activity law or an entrepreneur carrying out business activity in the EU or EEA.

The national procedure is regulated under the PhL and 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 requires extensive documentation, which reflects the requirements stipulated in EU 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 well-established use or well-established effectiveness and an acceptable level of safety and use in the EU or EEA states.

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

Some products do not require marketing authorisations 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 EU Regulation 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 be marketed, strictly speaking, only if they have 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. It may 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 first introducing the product into 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 EU Regulation 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 for in 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 scope of amendments.

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

The AMD uses the term 'medical incident' for malfunctions and defects, as well as improper labelling or contents of any manuals, or other technical or medical causes connected with the properties or effectiveness of the medical device, that may result in death or deterioration of the health of a patient. Health-care providers are obliged to report any such incidents without delay to the device manufacturer or its representative, as well as sending 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. Exceptions to the obligation to obtain permit generally follow EU legislation in this respect.

Manufacturers of medicinal products must also 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 in respect of the products listed in the permit. In the event that 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 exact legal form of the transfer of ownership of a manufacturing facility, any 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 straightforward 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 generally resemble 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 failure 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 encouragements regarding such products to patients or health-care 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 procedures of good distribution practice (as regulated under the MoH Regulation dated 26 July 2002; the new regulation implementing new EC Guidelines is expected in 2015).

Retail trade may be undertaken by pharmacies (the PhL distinguishes generally accessible pharmacies and hospital pharmacies) and pharmacy outlets. 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 foregoing categories are specified in the MoH executive regulation dated 14 November 2008. The dispensing category is 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 requires an import authorisation, which 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.

The import and export of medical devices may be undertaken freely by entities abiding by the requirements set out in the AMD. 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 (where 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 registered office in Poland, may issue a certificate of free sale to facilitate the export of devices with 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 the 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 such substances or to trade in them wholesale; such authorisations are issued by the MPI. Each instance of import of controlled substances into Poland requires consent from the MPI and the competent authorities in the country of export. Export from Poland also requires the consent of the MPI granted on the same basis as that granted by the authorities of the country of destination. 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 Exceptions are made to these rules for 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 (being at the same time medicinal products) may be undertaken by pharmacies and pharmacy outlets.

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

xiv Enforcement

Supervision of manufacturing, import, quality and distribution of medicinal products and marketing of medical devices is carried out by the MPI. When an instance of non-compliance is detected, it will generally issue a decision ordering the contravener to remedy the breach; where a direct threat to life and health of the population occurs, it 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 action assessed in Poland. The president of the ORMP is competent to issue decisions regarding the establishment of any special requirement prohibiting, suspending or restricting marketing, 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 situation, enforcement is carried out by the police, public prosecutors and courts.

III PRICING AND REIMBURSEMENT

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

Reimbursement of a medicinal product already entered into the Register cannot be automatically extended to the equivalent generic or medicinal product, or medicinal products originating from parallel import (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 several requirements at the moment of the filing of the application for its reimbursement:

a it must have a valid MA or remain on the market in the meaning of 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.

In Poland, prices (i.e., 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 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.

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

Decisions of administrative bodies are, as a principle, 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 is two-stage, 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 return it for re-examination. Parties may request a stay of enforcement of the administrative decision for the time of the judicial review.

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYORS

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 such advantages and benefits. An exception is made for the offer and acceptance of 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 connected with certain marketing practices. In general, it is prohibited to provide any benefit tied with reimbursed products, addressed in particular to any benefit recipients, entrepreneurs or

2 The specific categories are listed in the ARM.

3 Different levels of payment are possible.

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.

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.

Particularly sensitive are relations with health-care professionals who at the same time perform administrative functions at hospitals and other entities, placing orders for medicinal products or medical devices. Such professionals should strictly not be the target of any incentive or gifts, etc., since it may trigger various types of liability for both the health professional and offering person or entity (also, criminal sanctions may apply). In particular, such actions may be perceived as bribery or violation of public tenders. Criminal acts of individuals acting for or on behalf of companies may additionally trigger significant fines to be imposed on the companies.

Financial relations between companies and health-care professionals constitute a very sensitive subject in Poland since they have been the source of various past irregularities.

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).

There is a special system of compensation for personal injuries (independent of the courts) 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; (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 health-care services. The patient may make an application 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 up 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, 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 set out 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 highly regulated, in the past year there have been no significant antitrust decisions issued in this field.

As in other sectors, 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 one must submit to the ORMP the agreement on the transfer of rights and obligations of the MAH, as well as a statement that only a change of MAH has occurred (i.e., the holder is the only element of the authorisation or documentation that has changed).

Most other authorisations under the PhL (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, along with a company who holds them, via an acquisition or a merger by or with another company.

VIII CURRENT DEVELOPMENTS

Due to the very competitive pricing of state-reimbursed medicines, Poland has become a significant exporter of medicinal products within the parallel import procedure. This caused problems regarding the availability of some products, since distributors prefer to export medicines abroad rather than sell them in Poland for lower prices and with fixed distributors' margins. At the time of writing, the Polish parliament is working on an amendment to the PhL that allows restricting the parallel export of reimbursed products where there is a danger of a market shortage of those products.

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, 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 health-care 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