The Life Sciences Law Review

Fifth Edition

Editor
Richard Kingham

Law Business Research

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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 16

ISRAEL

Dovev Apel[1]

I INTRODUCTION

The life sciences industry in Israel is a dynamic and ever-growing industry that evolves in tandem with developments in the respective fields of science and technology. The Israeli life sciences industry consists of various disciplines, such as medicinal preparations, medical devices, biotechnology, etc., and includes, *inter alia*, leading international companies (e.g., the world's largest generic pharmaceutical company and one of the 10 largest pharmaceutical companies in the world).

The life sciences industry in Israel is highly regulated. Medicinal preparations ('preparations') are mainly regulated by the Pharmacists Ordinance,[2] corresponding regulations,[3] procedures and guidelines issued by the Ministry of Health (MOH).

The Pharmacists Ordinance recently underwent extensive amendment.[4] The initial and main object of the amendment was to introduce punitive sanctions against the phenomenon of pharmaceutical crime and, particularly, counterfeit, theft and use of defective preparations. In addition, a specific provision was incorporated to define activities that may amount to consumers being misled within the context of the Pharmacists Ordinance (and that may also serve as a basis for civil and criminal liability). During the legislative process, the scope of the amendment was extended to incorporate provisions and requirements previously included in regulations or MOH guidelines. As a consequence of the amendment, the Pharmacists Ordinance now includes not only a comprehensive punitive chapter, but also additional chapters catering for the imposition of administrative sanctions and the regulation of supervisory authorities.

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1 Dovev Apel is a partner at S Horowitz & Co.

2 The Pharmacists Ordinance (New Version) 1981.

3 The Pharmacists Regulations (Preparations) 1986; the Pharmacists Regulations (Good Manufacturing Practice) 2008.

4 The amendment entered into force in October 2016.

The Israeli regulatory regime of medical devices ('devices') is currently under development. The Medical Devices Law was enacted in 2012, and the MOH is still in the process of drafting various regulations and guidelines.[5]

The regulatory authorities for preparations and devices are the Pharmacy Department and the Medical Devices Department, within the MOH.

II THE REGULATORY REGIME

i Classification

Generally, the distinction between preparations, devices and other products (e.g., biological preparations and food supplements) is based on their respective definitions, as outlined in the applicable legislation.

For products constituting combinations of preparations and devices, or whose classification is unclear or disputed, the MOH's guideline provides that classification would be based on the product's primary mode of action. If a product is registered in more than one 'recognised country',[6] including the United States, the preference will generally be the classification of the US Food and Drug Administration.

For preparations, the guidelines also distinguish between generic and innovative products. The registration of a generic preparation is an abbreviated procedure, mainly involving proof of bioequivalence to the reference innovative preparation.

Israel is a 'second-line' country (i.e., the registration and marketing authorisation as granted by a recognised country[7] would be a condition for the registration and marketing in Israel).

Additional categories of preparations include 'biological preparations' and their follow-on versions called 'biosimilars'. Biosimilars are distinguished from standard generic preparations, mainly owing to the complexity of the biological active substances that render their follow-on versions as similar, albeit not identical. The registration of biosimilars thus requires experimental data (including *in vitro*, clinical and non-clinical data) proving their similarity to reference preparations, from the perspective of quality, safety and efficacy. Furthermore, biosimilars and their reference preparations are not interchangeable, unless decided otherwise at the time of registration. Following registration, the interchangeability will be reviewed periodically and at the registration holder's request, *ad hoc*, by an advisory committee to the MOH.

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5 The Medical Devices Law 2012. The Law will enter into force only after the relevant regulations are enacted. At this stage, only a portion of the regulations has been enacted (i.e., the Medical Device Regulations (Registration of a Medical Device and the Renewal Thereof), 2013). Nonetheless, in February 2014 the MOH published a Circular advising on the implementation of the principles of the Medical Devices Law as of April 2014.

6 The recognised countries under the Medical Devices Law are: Austria; Belgium; Britain; Canada; Denmark; Finland; France; Germany; Greece; Iceland; Ireland; Italy; the Netherlands; Norway; Portugal; Spain; Sweden; Switzerland; and the US.

7 A 'recognised country' is defined in the Pharmacists Regulations as any one of the following: Australia; Canada; each member of the EU; Iceland; Israel; Japan; New Zealand; Norway; Switzerland; and the US.

ii Non-clinical studies

The regulation of non-clinical studies in Israel focuses on experimental testing carried out on animals.[8]

In general, animal testing is approved, provided that the goals of the experiment cannot be met by reasonable alternatives. Additionally, experiments may not be performed for cosmetic testing purposes. Experiments on animals must be conducted by a qualified investigator, approved by the Council for Animal Experiments. The Council also issues permits to institutes performing studies. Institutes carrying out studies are required to report to the Council annually, and upon discovery of failures or problems with the experiment.

The Council is further required to appoint an audit committee to investigate claimed violations of the original experiment permit. Punitive sanctions may be imposed, for example, where an experiment is performed without the proper permits.

Furthermore, non-clinical studies must be carried out in an authorised accredited laboratory in compliance with the OECD's Principles of GLP.[9]

iii Clinical trials

Clinical trials are largely regulated by regulations and guidelines,[10] which outline the procedure for filing applications for the conduct of clinical trials and their approval process.

Generally, an application must be approved by the managers of the Institute, the Helsinki committee of the institute (the Israeli term for the Institutional Review Board, the IRB) and the MOH, prior to the clinical trial. 'Special clinical trials', in which the level of risk to the subjects is limited and which give rise to no exceptional ethical issues concerning the risks-benefits balance, generally do not require the MOH's approval. The classification of a clinical trial as special or non-special should be determined by the IRB within 48 hours from the receipt of the full application. Applications of non-special trials are transferred immediately to the MOH.

An application can be submitted only by a licensed physician. Additionally, the application requires the submission of the sponsor's undertaking form and the sponsor's response to a questionnaire, which serves as a recommendation as to the classification of the trial as well as the submission of other ancillary documents (e.g., the informed consent form, the study protocol).

Furthermore, the engagement between the sponsor and the lead investigator requires the approval of a committee established and operated under the supervision of the MOH.[11]

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8 The Animal Welfare (Experiments on Animals) Law 1994; The Animal Welfare (Experiments on Animals) Rules 2001.

9 Under the Laboratory Accreditation Authority Law 1997, laboratories in Israel are accredited in accordance with the OECD's Principles of Good Laboratory Practice (GLP), including non-clinical *in vitro* experiments.

10 Including the Public Health Regulations (Medical Trials in Human Beings) 1980; the MOH Guidelines for Medical Trials in Humans, as updated in 2016. MOH Circular 7/05, which lays down the framework for the supervision of clinical trials in humans (either by the MOH or by the relevant institutional bodies), will be replaced by new guidelines (No. 144/01), which will enter into force in February 2017.

11 Circular No. 4/10, 'Rules for the engagement of MOH Institutes with commercial companies' (Circular 4/10).

The investigator is required to obtain the participant's informed consent in writing, following a clear, verbal, non-pressuring explanation. The Investigator is further required to inform the participants of any new information that could affect their decision to participate.

The lead investigator and the sponsor are required to report to the MOH of the clinical trial's progress and conclusion, including serious adverse events.

iv Named-patient and compassionate use procedures

Preparations

Generally, a preparation may be marketed in Israel only if it is registered in the registry of preparations, by the MOH. Nonetheless, the MOH is authorised, under corresponding regulations and guidelines, to approve the marketing of a preparation even if it is not registered, or not in accordance with its registration, provided that the preparation falls within the specified exemptions, and provided further that it does not harm public health. These exemptions include, *inter alia*, preparations imported by a pharmacy or sick fund or manufactured in Israel in small quantities.[12]

Said exemption may be applied for the importation of a preparation for the personal use of a specific patient ('a named patient'). It further applies to 'essential medical treatment' and 'compassionate use'.[13]

Devices

A device may also be marketed in Israel only if it is registered with the MOH, unless it falls within the products listed in the Second Addendum to the Law.

Furthermore, the MOH is authorised, under corresponding regulations, to approve the manufacturing and marketing of devices that are unregistered or not in accordance with their registration, *inter alia*, for 'essential medical treatment' and 'compassionate use'.

v Pre-market clearance

Preparations

As noted in subsection iv, *supra*, a preparation may be marketed in Israel only if it is registered with the MOH, unless it falls within the specified exceptions and provided that it will not harm public health.

An application to register a preparation may only be filed by an Israeli resident or a company registered in Israel.

A preparation will be accepted for registration upon the following principle conditions:

a the preparation satisfies the quality requirements, and is found to be appropriate for medical use;

b the preparation is found to be safe and efficient for its intended use and its name is not misleading;

c the preparation is manufactured in accordance with good manufacturing practices (GMP); and

d the registration holder maintains a pharmacovigilance (PV) system.

12 Section 29(a)(3) of the Pharmacists Regulations.

13 Circular No. 19/07, 'Approval of medicinal preparation according to Section 29 of the Pharmacists Regulations (Preparations), 1986, and the attached Notice concerning the Manager Consent according to the Pharmacists Regulations (Preparations), 1986'.

For imported preparations, a certificate of pharmaceutical product (CPP), indicating the approval and marketing of the preparation in a recognised country, is further required.[14]

The MOH may further register the preparation subject to certain conditions, for post-registration control purposes.

A manufacturer or an importer of preparations is required to obtain GMP approval from the MOH, in order to ensure the quality and safety of such preparations.

According to the GMP Regulations, the manufacturer of a preparation will verify manufacture of the active pharmaceutical ingredients (API) in accordance with GMP, by carrying out audits at their manufacturing sites. Where such audits cannot be carried out, other means of verification may apply.

For generics, the Registration Guideline provides an abbreviated registration procedure.

For biological preparations and biosimilars, the MOH guideline generally adopts the policy of the European Medicines Agency (EMA).[15]

Under the MOH's policy,[16] homeopathic products are not registered as preparations, since their therapeutic efficiency has neither been proven to, nor considered by, the MOH. Homeopathic products are approved for importation and marketing, provided their safety is proven.

Attribution of medical indications or therapeutic characteristics on packaging and on any advertising material is prohibited, unless approved by the MOH in advance, based on clinical data.[17] Homeopathic products are stored in pharmacies behind the counter, separated from preparations and sold by a pharmacist. The holder of the marketing authorisation is required to report any complaint or suspected adverse event to the MOH.

Devices

As noted in subsection iv, *supra*, a device may be marketed in Israel only if it has been registered with the MOH, unless listed in the Second Addendum to the Devices Law, and save for the aforementioned exemptions.

An application to register a device with the MOH may only be filed by an Israeli resident or by a company registered in Israel.

The basic requirements for the registration of devices are: (1) the benefit outweighs the risks; (2) the device has been found to be efficient and of appropriate quality for its intended use; (3) the device has been manufactured according to GMP; and (4) the device's name is not misleading.

However, if the device is registered or approved for marketing in one of the countries listed as a recognised country and is being marketed in said country, the MOH will register the device for the same period as approved in such recognised country.

14 Guideline REG 08_2012, 'Procedure for Filing Applications for the Registration of Medicinal Preparations (including Amendments and Renewals)' ('the Registration Guideline').

15 Guideline No. 127, 'Registration Conditions and Use Policy for Biosimilar Preparations' ('Guideline No. 127').

16 Guideline No. 10, 'Homeopathic Products'.

17 Additional restrictions concerning the advertisement and labelling of homeopathic product are detailed in the said MOH guideline.

vi Regulatory incentives

Patent term extension

The Israeli Patents Law[18] empowers the Registrar of Patents to extend the term of certain patents for an additional term not exceeding five years beyond the 20-year period of protection. Such extension order may be granted only with respect to 'basic patents', protecting a preparation, a substance (an API), a process for the manufacture of such substance or preparation or the use thereof, or a device for which licensing is required.

An extension order will be granted only if the following conditions are met:

a the substance, the process for its manufacture or use or a preparation that contains the substance or the process for its manufacture, or the device, has been claimed in the basic patent that is in force;

b a preparation containing the substance is registered in the Registry of Pharmaceutical Preparations;

c the registration according to Paragraph (2) is the first registration allowing for use of the substance in Israel for medicinal purposes;

d no prior extension order has been granted in respect of the basic patent or the substance;

e the application for the extension order has been filed in good faith;

f the scope of protection to be granted under the extension order will not exceed the protection granted under the basic patent;

g an extension of the patent term protecting such preparation or device (the reference patent) has been granted in the US; and

h an extension to the reference patent has been granted and has not yet expired in one or more of the following EU Member States: France, Germany, Italy, Spain and the UK.

In the event that marketing authorisation has not been obtained in the countries designated in points (g) and (h) above (commonly known as the 'two-states requirement'), the conditions set out in those paragraphs shall not apply.

Subject to the following, an extension order shall remain valid for a period equal to the shortest extension afforded to the reference patent in a recognised country.[19] Reference patent term extensions granted after an Israeli extension order has been granted must also be considered.[20] In any event, the extension term will not exceed five years. The extension order further provides that the overall period of the basic patent and the extension order shall terminate no later than 14 years from the date the first marketing authorisation in a recognised country. Moreover, the extension order shall expire no later than the first date of expiry of the extension period granted in a recognised country, in which marketing authorisation has been obtained, or revocation of any reference patent.

The extension term will also expire, *inter alia*, if: (1) the registration of the preparation containing the substance is cancelled; or (2) the basic patent is revoked or amended in such

18 The Patents Law 1967 (the Patents Law).

19 A 'recognised country' is defined, for this purpose only, to mean France, Germany, Italy, Spain , the UK and the US.

20 LCA 8127/15, 8263/15 *The Manufacturers Association of Israel v. Merck Sharp & Dohme Corp. et al.* (15 June 2016).

a way that the substance, the process for its manufacture, the use of the substance, the preparation incorporating the substance or the process for its preparation, or the device, is no longer protected under the patent.

An application for an extension order should be filed 90 days following the grant of a marketing authorisation by the MOH. This period is not extendable.

Market exclusivity for originator products

Israeli law provides, under certain circumstances, protection to confidential data submitted as part of a marketing authorisation application, provided that its origination entailed considerable effort. New chemical entities (NCE) registered in Israel are therefore entitled to a period of market exclusivity, during which the MOH will not issue a marketing authorisation for a new medicinal product containing said NCE. No regulatory exclusivity period is granted for a new indication.

The market exclusivity period will be capped by the earlier of the following:

a six years from the registration date of the preparation that contains NCE in Israel; or

b six years and six months from the registration date of the preparation that contains NCE in a recognised country.[21]

Other provisions aimed to encourage the furtherance and development of products for rare diseases, diseases that are prevalent in developing countries and for pediatric use are not available in Israel.

vii Post-approval controls

Preparations

The Pharmacists Ordinance provides that the manufacturing, storage and distribution of preparations complies with GMP and GDP requirements.

The registration holder of a preparation is required to manufacture[22] or import preparations only in accordance with the registration conditions, including validated infrastructure and facilities.

In addition, the MOH is authorised to conduct periodic inspections of the plant, in accordance with the EMA Guidelines.[23]

A registration holder may engage subcontractors to carry out the manufacturing and importation activities. However, the parties' respective responsibilities should be clearly defined in the contract.

The manufacturing department of the registration holder is required to control the manufacturing process, in accordance with written and approved standard operating procedures, perform validation of new processes or major changes, and periodic revalidation of key stages of the manufacturing processes.

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21 Including Australia, Canada, members of the EU, Iceland, Japan, New Zealand, Norway, Switzerland and the US.

22 Under the Pharmacists Ordinance, the term 'manufacturing' is defined broadly as including 'mergence, blending, assembly, refining, processing, transformation and activation of any chemical or physical process for the preparation of a product or the packaging of a product'.

23 EMA/572454/2014 'Compilation of Community Procedures on Inspection and Exchange'.

Furthermore, the manufacturer or importer must maintain an independent quality assurance department (QA). The QA is required, *inter alia*, to deal with complaints concerning the quality of the preparation and to investigate recalls from the market.

The first batch of a registered preparation must be approved by the MOH prior to being marketed in Israel for the first time.

The registration holder is also required to establish and maintain a PV system and to appoint a qualified person for pharmacovigilance.[24]

The registration holder is required to inform the MOH of any relevant change to the registration conditions. The manufacturer may not make material changes unless approved in advance by the MOH.[25]

Unauthorised changes could constitute grounds for the revocation of a registration. The MOH might also revoke a registration if the product may cause harm or is found to be inefficient, or if its registration requirements are not met. The MOH is required to allow the registration holder to submit arguments prior to rendering its final decision in this regard.

The Pharmacists Ordinance specifies a requirement to report a defect in a preparation and authorises the MOH to take action in order to safeguard public health. The corresponding MOH guideline[26] contains requirements concerning, *inter alia*, the time frame for, and manner of, reporting a defect and its investigation, as well as the decision-making process concerning the handling of the defect, including the option to order a recall for the removal of defective preparations from the market.

Following notification by the manufacturer, the MOH will delete an agent's status as registration holder. The MOH may, in accordance with the manufacturer's notification, approve a new agent as the registration holder. The previous registration holder may continue marketing his or her inventory for a period of one year.

As noted in subsection v, *supra*, the MOH may subject the registration of preparations to certain conditions for post-approval control purposes. One such condition – the existence of a regular and ongoing supply – was recently addressed by the MOH, by directing the registration holders to hold, at any point in time, an inventory sufficient for at least 30 days of consumption (beyond the ongoing inventory available in pharmacies and clinics). In exceptional cases (e.g., preparations with a short shelf life), an exemption must be approved in advance.

Furthermore, a registration holder is required to inform the MOH of marketing cessation (temporary or permanent) or of its decision not to renew its registration at least six months before the contemplated permanent cessation and at least three months before the contemplated temporary cessation, or – in the case of sudden and unexpected cessation – as soon as the registration holder becomes aware thereof. Accordingly, it is mandatory that the registration holder maintain an inventory of preparations intended to be marketed in Israel for a minimum period of six months.

24 Guideline No. 6, 'Reporting on Adverse Events and New Safety Information'.

25 Guideline No. EX-009/01, 'Guideline for Filing an Application for Change in a Medicinal Preparation from the Quality Aspect'.

26 Guideline No. PUB-003/07, 'Notification of Defect in Preparations and Active Raw Material'.

In cases where a registration has expired and not been renewed, or where the registration has been revoked, the registration holder may continue marketing his or her inventory for a period of one year, unless the MOH instructs otherwise in writing.

Biosimilars require univalent labelling, strict monitoring and proactive reporting of adverse reactions as well as the submission of a risk management plan, risk evaluation and mitigation strategy.[27]

Devices

The registration holder is required to inform the MOH of any change in the data submitted at the time of registration of the device.

The Minister of Health is authorised to enact regulations pursuant to which the registration holder will be required to perform follow-up operations and inspect the registered device. Regulations of this nature have not yet been drafted.

The Minister of Health is also authorised to enact regulations regarding post-marketing surveillance, including a duty to report to the MOH of any known 'special event' arising in connection with registered devices. Such special events include:

a a serious malfunction in the device that may endanger the patient's health;

b use of the device that caused or was suspected of causing unexpected damage to the patient's physical or mental health, or that caused significant damage or death; and

c action taken by any health authority or an announcement published by the manufacturer, the registration holder or any health authority concerning the device, its marketing and use, or any new safety data published in the main scientific literature in the field.

Regulations of this nature have not yet been drafted. However, a MOH guideline is currently being drafted based on the corresponding American and European guidelines.

The Minister of Health is authorised to enact regulations for the recycling of disposable devices. At this stage, said regulations have not yet been drafted.

viii Manufacturing controls

Preparations

As noted in subsection vii, *supra*, the GMP Regulations largely include conditions under which a manufacturer or an importer can obtain GMP approval from the MOH, and the basic requirements for manufacturing and testing preparations, in order to ensure their quality and safety.

The responsible pharmacist is required to notify the MOH of any transfer of ownership of the relevant manufacturing facilities.

Devices

One of the basic requirements for the registration of a device is that it is manufactured in compliance with the GMP requirements.

Marketing a device in Israel requires a certificate from the health authority or equivalent regulatory body of the country in which the device was manufactured, certifying that the manufacturer's GMP standards accord with the requirements of ISO 13485.

27 Guideline No. 127.

Here too, the registration holder must notify the MOH of any transfer of ownership of the relevant manufacturing facilities.

ix Advertising and promotion

Preparations

The term 'advertising' is defined in the Pharmacists Regulations as an act of disseminating information, in writing, through the media or by any other means.

The Pharmacists Regulations distinguish between advertisements directed at healthcare professionals and those directed at the general public and advertisement of prescription and non-prescription preparations. As a general rule, advertising a preparation cannot contradict its registration, nor can it attribute indications which were not specifically approved.

Advertisements for healthcare professionals, of prescription and non-prescription preparations, are permitted, provided they emphasise the approved indications.

Online advertising for healthcare professionals is permitted, subject to certain limitations, such as applying mandatory means to identify users prior to them gaining access to said information.

In contrast, advertising of prescription preparations directed at the general public is prohibited. However, under special approval, explanatory information may be handed personally to a patient by the attending physician.[28]

MOH guidelines concerning the improvement of compliance in patients who were prescribed preparations and raising the public awareness of various diseases,[29] may also allow registration holders to provide patients with a broader range of information. Subject to the prior approval of the MOH, such information can also be transmitted to a wide array of therapists, including therapists who are not authorised to prescribe prescription preparations, if the information is required as part of their professional services and for treating patients. In any event, said information cannot include advertising content or encourage the consumption of preparations. In this context, it is noteworthy that, as of recently, Guideline No. 137 allows, in large part, for such information to be provided to patients, subject to the MOH being notified thereof, as opposed to obtaining the MOH's prior approval as was previously the case.

Advertising of non-prescription preparations is permitted, subject to its preliminary approval by the MOH. Such advertising must be accurate, clear and consistent with the registered indications. The regulation sets forth mandatory data that must be included in such advertising, as well as data that must be excluded. Restrictions are also imposed on advertisements including a comparison between products. An unapproved advertisement may result in a clarification notice, cancellation or prohibition of the advertisement and cessation of future marketing or cancellation of the product's registration certificate.[30]

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28 Guideline No. 24, 'Advertising of Medicinal Preparations in accordance with Regulation 28' (Guideline No. 24).

29 Guideline No. 137, 'Rules for the Improvement of Educated Use and Medicinal Treatment Compliance in Patients who were Prescribed with Prescription Medicinal Preparations, via Noncommercial Information' ('Guideline No. 137'); Guideline No. 134, 'Raising Diseases Awareness - Rules for the Accessibility of Information to the General Public, Funded or Conducted under the Auspices of a Registration Owner or a Third Party'.

30 Guideline No. 24, Section 3.7; a letter from the MOH to responsible pharmacists, manufacturers, importers, and owners of registered preparations.

Promotion of preparations is also prohibited, specifically, raffles, handing out sample products or promising an additional preparation.

The rules of the Broadcasting Authority and the Second Authority for Television and Radio further regulate broadcasted commercials and the concession owner's liability with regard to misleading health-related advertisements or the unauthorised advertisement of medicines.[31] While the former prohibits almost all forms of advertisement of preparations, the latter allows commercials for non-prescription preparations, under various circumstances.

Devices

The MOH is authorised to supervise the advertising of devices but, currently, no regulation to this effect has been drafted.

x Distributors and wholesalers

Preparations

The Pharmacists Ordinance distinguishes between wholesale and retail marketing. While wholesale marketing may only be carried out by a wholesale pharmaceutical business[32] or a health institution, retail marketing may only be carried out by a pharmacist in a pharmacy.

Under the Pharmacists Ordinance and the GMP Regulations, preparations and APIs must be stored, transported or distributed under good distribution practices (GDP). In this context, Israeli law adopted the principles of the EU regulatory regime.[33]

The MOH is authorised to conduct periodic audits of such businesses, in accordance with risk management and a list of priorities, at least every three years, following which a GDP certificate may be granted.

Devices

Transportation and storage of devices can be performed only by a licensed business that possesses a certificate from an entity recognised by the MOH, certifying its compliance with the requirements of ISO 9001.

xi Classification of products

Preparations

The Israeli legislation distinguishes between distribution of prescription (Rx) and over-the-counter (OTC) preparations, which can only be performed by a pharmacist, and distribution of general sales list (GSL) preparations, which may not necessarily be carried out in a pharmacy or by a pharmacist.

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31 The Rules of the Israeli Broadcasting Authority (Commercials and Radio Announcements) 1993; the Rules of the Second Authority for Television and Radio (Ethics in Television Commercials) 1994; and the Rules of the Second Authority for Television and Radio (Ethics in Television Commercials) 1999.

32 A 'wholesale pharmaceutical business' is defined in the Pharmacists Ordinance as a business used for storage, distribution, transportation and wholesale marketing of medicinal preparations or pharmaceutical raw materials. A wholesale pharmaceutical business can be operated, subject to the professional management of a responsible pharmacist.

33 Guideline No. 130, 'Good Distribution Practice of Preparations'.

The classification of the relevant preparations is determined by the MOH, at the time of registration. The registration holder may apply to reclassify an Rx preparation as OTC.

Devices

The MOH is authorised to register a device, subject to certain conditions and restrictions, including restricting its use to professionally qualified personnel or only in accordance with a physician's order.

Furthermore, the MOH is authorised to prescribe technical specifications for devices on the basis of which regulations were enacted for the licensing of special devices used by medical institutions, such as MRIs and CT scanners.[34]

xii Imports and exports

Preparations

Under the Pharmacists Ordinance, the term 'marketing' is broadly defined to include 'importing'. The following are required in order to obtain an approval to import a preparation into Israel:[35]

a a CPP indicating the approval and marketing of the preparation in a recognised country;

b importation may only be performed by a pharmaceutical company, a wholesale pharmaceutical business or a storage facility of a health institute;

c an application for an import certificate may be filed only by a pharmacist appointed by the applicant and approved by the MOH; and

d the preparation must be registered in the Registry of Preparations, or fall within the specified exemptions of preparations that may be manufactured, marketed and used even if unregistered, or not in accordance with its registration.[36]

The MOH will not issue an import certificate, unless the following conditions are met: (1) the preparation was transported into Israel by licensed dealers in recognised countries; and (2) en route to Israel, the preparation was stored only in recognised countries.

Special permits are required for importation and exportation of narcotics. Importation permits are valid for one year, while exportation permits are valid for only three months, with the possibility of three months' extension. Special permits are also required for importation of psychotropics and dangerous drugs.

Devices

The term 'marketing' in the Devices Law is similarly defined broadly to include 'importation' of devices. Therefore, identical principal requirements applicable to the importation of preparations, apply to devices.

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34 The Public Health Ordinance, 1940; the Public Health Regulations (Special Medical Devices) 1994.

35 The Pharmacists Regulations; the GMP Regulations; the Registration Guideline; MOH Guideline No. 33, 'Importation and Marketing of Medicinal Preparations and Pharmaceutical Materials'; and MOH Circular 19/07.

36 Section 29 of the Pharmacists Regulations.

The registration holder is required to identify the importer in the registration application, and the MOH will include the importer's details in the registration certificate, on the basis of which the importer can then apply for an import permit.

Marketing an imported device requires a certificate from the health authority or any other regulatory body of the country in which the device was manufactured, certifying that the manufacturer's GMP standards satisfy the requirements of ISO 13485. Furthermore, carriers of devices must possess a certificate from an entity recognised by the MOH, certifying that their storage and transportation conditions meet the requirements of ISO 9001.

xiii Controlled substances

Narcotics may be supplied in Israel only by a licensed pharmacist to hospitals, doctors, licensed pharmacists, a person who has been prescribed a narcotic or a person who holds a permit to buy narcotics. A permit for the manufacturing, possession or use of narcotics may be granted by the MOH, subject to specific disclosure requirements.[37]

A manufacturer or a wholesaler of psychotropics may only sell drugs listed in the First Addendum to the Pharmacists Ordinance to doctors, licensed pharmacists, dentists, veterinarians or permit holders. In addition, a manufacturer or a wholesaler may not engage in the retail of psychotropic drugs, unless it is separate from the wholesale business.

xiv Enforcement

Preparations

The Pharmacists Ordinance[38] imposes punitive measures, in the form of imprisonment or a fine, based on the type and nature of the offence.

In general, the punitive measures are imposed according to three levels of criteria, subject to the severity of the offence.

Under the first level, six months' imprisonment or a fine not exceeding 29,200 shekels will be imposed for misdemeanours committed at the level of retail marketing.

Under the second level, one year's imprisonment or a fine not exceeding 75,300 shekels will be imposed for offences committed at the level of manufacturing and wholesale distribution. Offences of this nature include, *inter alia*, wholesale marketing of preparations not by a wholesale pharmaceutical business or a health institution; running a wholesale pharmaceutical business without delegating the professional management to a responsible pharmacist; marketing a preparation with quality inappropriate for medical use, or a preparation subject to a recall; manufacturing or importing a preparation without registration or not in accordance with its registration conditions, or not in compliance with the GMP requirements; and storage of preparations not in conformance with the GDP requirements.

The third level of punitive measures was established in order to tackle the phenomenon of pharmaceutical crime and, particularly, counterfeit, theft and use of defective preparations,

37 The Dangerous Drugs Ordinance (New Version) 1973; and the Dangerous Drugs Regulations 1979; MOH Guideline No. 155, 'Prescriptions for Dangerous Drugs – Clarifications' (August 2016).

38 As noted in Section I, *supra*, effective as of October 2016, an extensive amendment of the Pharmacists Ordinance entered into force, encompassing, in particular, punitive measures, administrative enforcement and supervisory authorities.

and imposes three years' imprisonment or a fine of 226,000 shekels on the manufacturing, marketing and possession of a preparation (or a raw material) that is contrary to the registration requirements, and that may mislead customers with regard to an 'essential detail' of the preparation. In this context, an 'essential detail' is restricted to the preparation's name, dosage form, labelling, indication, its classification as a preparation, composition, strength, batch number, expiry date, origin and marketing or release documentation.

In addition to criminal sanctions, which are intended to cater for situations giving rise to criminal liability, the Pharmacists Ordinance also allows for the imposition of monetary administrative sanctions. Based on the experience gained from the imposition of this type of penalty in other legislative fields, monetary administrative sanctions are the main tool relied upon as a means of enforcement of the regulatory regimen on legitimate 'players' in the market.

The monetary administrative sanctions are imposed in the event of breach of provisions of the Pharmacists Ordinance (a PO breach) according to five levels of criteria, subject to the severity of the relevant breach.

Under the first level, a monetary administrative sanction of 7,000 shekels will be imposed for a PO breach committed at the level of pharmacy management (e.g., failure to provide employee training, failure to conduct a yearly inspection).

Under the second level, a monetary administrative sanction of 10,000 shekels will be imposed for a PO breach committed at the level of retail marketing, for marketing a preparation that is not registered or for holding or marketing a preparation labelled as a 'physician sample'.

Under the third level, a monetary administrative sanction of 20,000 shekels will likewise be imposed for a PO breach committed at the level of retail marketing, for holding preparations or raw materials intended for sale that were not obtained from a wholesale pharmaceutical business or a recognised institute, for storage not in compliance with the GDP requirements or for marketing an expired preparation.

The fourth level imposes a monetary administrative sanction of 50,000 shekels on a registration holder, a manufacturer or an importer who marketed an inappropriately labelled preparation and on a pharmacy owner who fails to delegate the professional management of the pharmacy to a responsible pharmacist.

Under the fifth level, the MOH is authorised to impose a monetary administrative sanction of 150,000 shekels (300,000 shekels for a corporation) for a PO breach committed at the wholesale level, including running a wholesale pharmaceutical business without delegating the professional management to a responsible pharmacist. The fifth level may also apply for a PO breach committed at the registration holder, manufacturer and importer levels, where any of the above manufactured or marketed an unregistered preparation or contrary to its registration conditions, etc. In this context, both regulations and a corresponding MOH guideline were recently published[39] that set out the circumstances and considerations under which the scope of the monetary administrative sanctions detailed above may be reduced. Apart from the above, the MOH has very little discretion as to the implementation of monetary administrative sanctions.

39 The Pharmacists Regulations (Reduction in Amount of Monetary Sanction) 2016; Guideline No. 145, 'Administrative Enforcement – Provisions Regarding the Imposition of Monetary Sanctions Under the Pharmacists Ordinance'.

As an alternative to monetary sanctions, the Pharmacists Ordinance authorises the MOH to implement administrative measures in the form of advance warnings or binding undertakings, based on criteria as outlined in MOH guidelines. Accordingly, a guideline addressing such alternative punitive measures was recently issued by the MOH.[40]

The Pharmacists Ordinance also authorises the Minister of Health to appoint inspectors, who will have the authority to:

a demand identification;
b demand information or documents;
c enter a place where there exists a reasonable basis to assume that supervised preparations are being manufactured, stored or marketed; and
d take measurements or take samples of preparations.

Devices

The Minister of Health is authorised to appoint inspectors to supervise the implementation of the provisions of the Devices Law.

If a device ceases to comply with its registration conditions or any of the restrictions prescribed by the MOH, its registration in a recognised country has been revoked, or the MOH suspects that it may harm public health, the MOH is authorised to impose administrative sanctions including discontinuation or restriction of manufacture or marketing of a device or deletion of its registration, restriction on the advertisement and recall from the market.

Furthermore, breach of the following provisions of the Devices Law is considered a criminal offence: (1) manufacturing or marketing unregistered devices, not for personal use or not in accordance with their registration conditions; (2) instructing the use of, or using, unregistered devices; and (3) instructing the use of, or using, devices not in accordance with the MOH's instructions or restrictions. It will also be deemed a criminal offence if a registration holder fails to carry out follow-up activities, inspect registered devices or fails to report special incidents.

In such events, the court has the authority to impose criminal sanctions, including imprisonment and fines. Where the breach is committed by a company, the fines are doubled. Furthermore, office holders may be found liable for offences committed by the company or any of its employees.

III PRICING AND REIMBURSEMENT

The Israeli sick funds are required to provide to all Israeli citizens and residents a basic basket of medications and medical services (the Health Basket),[41] for which the patient pays the deductible price only.[42] The Health Basket is updated annually by the MOH's general manager, based on the recommendations of the Public Committee.

40 Guideline No. 146, 'Administrative Enforcement – Advance Warnings or Binding Undertakings in Prevention of a Breach Under the Pharmacists Ordinance (in Lieu of Monetary Sanctions)'.

41 The National Insurance Law 1994 (the NIH Law).

42 The deductible price is currently set at 16 shekels. If the price exceeds 118 shekels or 126 shekels, depending on the sick fund, the deductible price will be 15 per cent of the consumer price (if a generic alternative exists, the deductible price will be 10 per cent of the consumer price or 16 shekels, whichever is lower).

The Ministers of Health and Finance are authorised to regulate the prices of services and products by issuing a relevant order.[43]

Three means of price regulation are applied in the field of preparations:[44]

a price-fixing by the regulator is applied with regard to Rx preparations.[45] Under this regulation, the price list is periodically updated. However, owing to continued erosion in preparations' prices in Israel, a price freeze was recently imposed with respect to low-cost preparations (under 16 shekels). Moreover, a professional committee was established in order to review the present model of price-fixing that is used for Rx preparations and to present its recommendations to the Inter-Ministerial Pricing Committee of the Ministry of Health and the Treasury. To date, the professional committee has published its preliminary recommendations for public review, and has also held hearings on the subject;

b submission of an application prior to increasing prices above the fixed price is applied with regard to OTC preparations;[46] and

c report of prices and profits is applied with regard to GSL preparations.

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

MOH policy, procedures and guidelines are subject to judicial review, within the framework of a petition filed with the Israeli Supreme Court.

Concrete decisions, relating to specific preparations or technologies, are initially dealt with by appeal procedures within the MOH.[47] According to the MOH guidelines, a decision given by the MOH in the appeal process will be considered final. However, in practice, such decision is subject to judicial review, through a petition filed with the Israeli Supreme Court.

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYERS

Financial relationships between companies that market preparations and devices, and healthcare professionals and health institutions and personnel, are subject to general restrictions set out in the Israeli Penal Law 1977 and the Civil Service Rules, to which civil servants are subject, with regard to, *inter alia*, private practice and employment as well as the acceptance of benefits.

43 The Supervision of Prices on Services and Products Law 1996.

44 The Order for the Supervision on Prices of Products and Services (Application of the Law on Preparations) 2001 and the amendment thereto enacted in 2006.

45 The Order for the Supervision on Prices of Products and Services (Maximum Prices for Rx Preparations) 2001, outlines the pricing method by referencing prices from several European countries.

46 Guideline for handling a request for the approval of an OTC preparation.

47 Guideline No. 73, 'Objection to the manager's decision to reject a request for the registration of a preparation in the register, or to a decision to reject a request for an additional indication, or to a decision to restrict a preparation within its registration'.

Said relationship is further subject to the restrictions in Circular 4/10,[48] which requires engagements funded by commercial companies to be approved in advance by the MOH committee.[49]

Donations made by certain entities to health institutions should be reported annually to the MOH.[50] A donor who made a donation to an entity in the health field must report annually to the MOH. Furthermore, donations to physicians, pharmacists and investigators, in an amount exceeding the aggregate of 2,500 shekels per year, must also be reported.

The Physicians Association in Israel and representatives of the pharmaceutical companies in Israel published in 2004 a Joint Ethical Convention as a self-regulatory act. The Convention allows for the existence of a professional relationship between the two parties for the purpose of advancing medicine and science, while ensuring the physicians' independence and professional integrity.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

No specific compensation regulations have been enacted with respect to preparations or devices in Israel. The Damaged Products Liability Law 1980 (the DPL Law) defines a 'damaged product' as a product that may cause bodily injury because of a flaw or as a result of disregarding the warnings included in the patients' leaflet or use instructions. The DPL Law sets out the manufacture's liability for compensating a person who suffered bodily injury as a result of a damaged product, regardless of whether the manufacturer was guilty for the damaged product; this compensation is subject to a cap. Alternatively, said person can claim negligence on the part of the manufacturer.[51] In such event, the manufacturer's guilt must be established; however, the damage is not limited to bodily injury or to a compensation cap.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

Patent disputes and, in particular, pharmaceutical patents, are of special relevance to the life sciences sector in Israel.

The Restrictive Trade Practices Law 1988 (the RTP Law) excludes arrangements in which the owner of a patent registered in Israel dictates restrictions relating to the use of its patent. Notwithstanding this, the Restrictive Trade Practices Tribunal has held that this exclusion does not apply to actions of a patent owner who abuses his or her position as a monopoly. Therefore, ownership of a patent does not necessarily establish immunity from supervision under the Law, if the patent owner has a dominant position in the market.

48 Originally, Circular 4/10 applied to the MOH (including its various units) and the Clalit Sick Fund employees; in practice, it is implemented by additional health institutions.

49 For example, trials; holding conferences, seminars and advanced training; publication of a trial's results; donation of medicinal products and equipment; financing of staff salary; and travels abroad, including the participation in conventions.

50 The NIH Law.

51 The Civil Wrongs Ordinance (New Version).

The settlement of patent disputes may also be subject to the RTP Law. Nonetheless, thus far, the Restrictive Trade Practices Authority's involvement in the pharmaceutical market has been very limited.

Furthermore, under the Patents Law, the Registrar may grant a compulsory licence if the patent owner abuses his or her position as a dominant firm (i.e., a monopoly). However, in practice, very few applications for a compulsory licence have been filed.

ii Transactional issues

Transactions are subject to the provisions of the RTP Law. Restrictive arrangements are prohibited, unless approved in advance or deemed exempt under the RTP Law. Furthermore, mergers that meet any of the thresholds prescribed in the RTP Law may be carried out only if approved in advance by the Controller of Restrictive Trade Practices, provided there is no reasonable suspicion that competition in the relevant market will be significantly harmed, or that the public will be harmed as a result. Granting exclusive licences for long-term periods (or for indefinite periods) may be considered as a merger, and, thus, subject to approval by the Controller of Restrictive Trade Practices.

Furthermore, as noted in Section II.vii, *supra*, transfer of a marketing authorisation is subject to the MOH's prior approval.

Transactional issues in Israel relevant to preparations and devices alike also involve patent transactions, such as patent assignment and licensing. The assignment of an invention and patent rights requires a written agreement, and must also be recorded in the Registry of Patents in order to be valid against third parties. A patent owner may grant exclusive or non-exclusive licences to use the patented invention. A licence so granted must similarly be recorded in the Registry of Patents to ensure its validity against third parties. Only an exclusive licence entitles the licensee to initiate infringement proceedings or apply for patent term extension.

Appendix 1

ABOUT THE AUTHORS

DOVEV APEL

S Horowitz & Co

Dovev is a partner at S Horowitz & Co, an Israeli premier full-service law firm, offering a full range of dispute resolution, corporate and commercial services to the international and Israeli business, industrial and financial communities. Its 90-year legacy of excellence in practising law and more than 160 legal professionals makes S Horowitz & Co one of the first and largest law firms in Israel.

Dovev specialises in intellectual property, life sciences and health law. Dovev advises and represents clients in connection with the full gamut of the regulatory aspects pertaining to various life science products, including pharmaceuticals, medical devices, food supplements, genetic tests, etc.

Dovev advises a number of major companies engaging in pharmaceuticals, medical devices and other life sciences products on a wide range of contentious and non-contentious issues focusing on life sciences and the health industry. Dovev also acts as external legal counsel to the Israeli Manufacturers Association and, in this capacity, is actively and continuously involved in, and contributes to, the drafting by the MOH of the relevant regulatory procedures, as well as the legislative process, applicable to various matters pertaining to the life sciences industry. Dovev also represents local and multinational clients in administrative and legal proceedings, including in proceedings before the Israeli Supreme Court (sitting as the highest court of justice) and also represents clients in a wide range of tort actions and class actions, touching on life sciences and health-related issues, before the various courts.

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