PHARMA & MEDICAL DEVICE REGULATION

Israel

LEXOLOGY
Getting The Deal Through

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Pharma & Medical Device Regulation

Consulting editors

Geoffrey Levitt

DLA Piper

Quick reference guide enabling side-by-side comparison of local insights, including into the regulatory framework; clinical practice; marketing authorisation; amending authorisations; recall; promotion; enforcement of advertising rules; pricing and reimbursement; off-label use and unlicensed products; sale and supply; and recent trends.

Generated 11 October 2022

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Israel

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REGULATORY FRAMEWORK

Competent authorities for authorisation

Identify the competent authorities for approval of the marketing of medicinal products and medical devices. What rules apply to deciding whether a product falls into either category or other regulated categories?

The Ministry of Health (MOH) is responsible for healthcare in Israel. Israeli citizens receive healthcare through one of four government-subsidised national healthcare providers. The healthcare providers and other insurers also provide supplemental insurance beyond the basic government-subsidised national insurance.

Medicinal products, medical devices and other regulated products (eg, food and cosmetics) are approved for marketing by the MOH.

If a product can potentially be considered a medicinal product or a medical device, the MOH acts in accordance with sections 9 to 10 of the Medical Device Regulations (2013). The MOH evaluates the primary mode of action (ie, device or medical product) and the expertise needed to use the product. If foreign regulatory bodies have categorised the product or similar products as either a device or medical product, the MOH will usually follow that categorisation. If there are different foreign regulatory categorisations for a given product, the MOH will follow the categorisation given by the US Food and Drug Administration (FDA).

Law stated - 01 September 2022

Approval framework

Describe the general legislative and regulatory framework for approval of marketing of medicinal products and medical devices.

Marketing approval for medicinal products is handled by the pharmaceutical division of the MOH. The main laws are the Pharmacists Ordinance (1981) , the Pharmacists Regulations – Preparations (1986) and the Pharmacists Regulations – Good Manufacturing Practice (2008).

The approval process beings by filing an application with the MOH to register the drug. This starts with a pre-evaluation of the application prior to the main submission. For imported drugs, the applicant (among others) submits a certificate of pharmaceutical product (CPP) issued within the past two years by a recognised jurisdiction (eg, the United States, Canada, countries that have been member states of the European Union since before 2004, Norway, Iceland, Switzerland, Japan, Australia and New Zealand). If a CPP is not available, then applications for new drugs can be preliminarily filed with an FDA letter of approval or a positive opinion from the European Medicines Agency. Generic applications can be filed without a CPP, but a CPP must be provided within 10 months of filing and the agent will not be registered without a CPP (MOH Rule 8/2012 and Rule 46).

The drug master file for a new drug filing must include:

- documentation regarding the manufacturing site;
- a quality control certificate from the manufacturing site;
- details of the drug (eg, name, list of ingredients including excipients, dosing, strength);
- proposed drug leaflets and packaging;
- clinical and preclinical data;
- a list of countries in which the drug was approved and not approved; and
- any relevant scientific publications.

Generic drugs require the submission of documentation regarding the manufacturing site and bioequivalence data.

The MOH can register a drug if the drug has a quality control certificate or if the MOH is convinced that:

- the agent does not cause (or has the potential to cause) harm;
- the agent is effective for the appointed indication;
- the agent's brand or generic name is not misleading;
- the agent is made under good manufacturing practices; and
- the petitioner will undertake satisfactory pharmacovigilance as outlined in section 6 of the Pharmaceutical Regulations – Preparations.

After registration, the applicant must obtain marketing approval for the first batch of the drug from the MOH. Agents that have blood or plasma components and vaccines need to have every batch approved for marketing under sections 14 to 17 of the Pharmaceutical Regulations – Preparations.

The packaging must state, among others:

- the branded and generic name of the product in English and Hebrew;
- the name and address of the registration holder and the importer;
- a list of the active ingredients;
- the amount of the dosage form;
- the date of manufacture;
- the batch number; and
- the expiration date.

The product must also include a patient information leaflet in Hebrew and Arabic under section 20 of the Pharmaceutical Regulations – Preparations.

The approval of medical devices is handled by the Medical Device Division of the MOH. The main medical device laws are the Medical Device Law (2012) and the Medical Device Regulations (2013).

During the application process, certification that the device is registered and has marketing approval in foreign jurisdictions is submitted, if available. In addition, the application must contain information about the device and distributors, the device's indications, proposed labelling, a proposed information leaflet for the device, information on maintenance and customer service support for the device, and certification of appropriate transportation and storage of the device. A risk analysis, a clinical evaluation and a file summarising the clinical trials involving the device must also be submitted for devices without previously approved comparable devices (Medical Device Regulations, section 3). If the device is approved and can be marketed in a recognised foreign jurisdiction, the MOH is expected to approve the device (Medical Device Law, section 6). There are 21 recognised jurisdictions, which include most of western and northern Europe (eg, the United Kingdom, France, Germany, Spain, Italy, Greece, Iceland, Norway, Switzerland), Canada, the United States, Australia and New Zealand.

Section 23 of the Medical Device Regulations states that the packaging or leaflet of a medical device must list, among others:

- the device's name;
- the device's indication;
- the device's date and country of manufacture;

- any warnings; and
- a serial number.

Law stated - 01 September 2022

CLINICAL PRACTICE

Applicable rules

What legislation controls and which rules apply to ethics committee approval and performance of clinical trials in your territory for medicinal products and medical devices?

Clinical trials are conducted in Israel in accordance with the Public Health Regulations (Clinical Trials in Humans) (1980), as amended (the 1980 Regulations) and the Ministry of Health (MOH) Clinical Trials Guideline No. 14 (2020) (the MOH Guidelines). Every aspect of every clinical trial – including its design, approval, performance, documentation and method of reporting – must be carried out while adhering to the following pieces of Israeli legislation:

- the 1980 Regulations;
- the Genetic Information Law 2000;
- the MOH Guidelines;
- the MOH Guidelines for Manufacture and Import of Investigational Products in the State of Israel, EX-012/01 dated 14 April 2013;
- the Israeli Protection of Privacy Law 1981 and the regulations promulgated thereunder;
- the Israeli Patient's Rights Law 1996 and the regulations promulgated thereunder; and
- various other MOH guidelines and procedures, as published from time to time.

In addition, every clinical trial must be carried out while adhering to the following international sources to the extent that they do not contradict the MOH Guidelines:

- the principles of the Declaration of Helsinki;
- the Harmonised Tripartite Guideline for Good Clinical Practice (ICH-GCP E6); and
- the International Organization for Standardization (ISO) standards ISO 14155-1 and ISO 14155-2: Clinical Investigation of Medical Devices for Human Subjects.

The MOH's Department of Clinical Experimentation is responsible for approving and supervising clinical trials with human subjects.

The following authorisations are required for the associated types of clinical trials:

- Clinical trials that are defined as 'special' under the 1980 Regulations require the approval of the Helsinki Committee at the institution in which the trial is set to take place and the approval of the director of the institution. Special clinical trials do not require MOH approval and include, inter alia, trials without a study product, questionnaire studies, studies using a drug or device that is approved in a recognised country (eg, the United States, member states of the European Union, Switzerland, Norway, Iceland, Australia, New Zealand and Japan) at the approved dosage and indication, and sample collections (other than for genetic purposes).
- Clinical trials that are defined as 'non-special' under the 1980 Regulations also require the approval of the Director General of the MOH, which can be granted by the MOH Department of Clinical Experimentation on his or her

behalf. Non-special studies are any studies that are not defined as special, including studies involving cannabis treatments.

- Clinical trials involving genetic research in human subjects or unnatural female fertilisation and other ethical issues determined by the MOH must be approved by the Israeli Supreme Helsinki Committee for Clinical Trials in Human Subjects.
- Applications to approve the conduct of a clinical trial is submitted by the principal investigator on behalf of the study sponsor to the institutional Helsinki Committee.

With effect from January 2020, the MOH established its National Multi-Centre Study Committee for the purpose of approving multi-centre studies (with three sites or more in Israel). A multi-centre study must be approved by the institutional ethics committee (EC) of at least one of the institutions planned to participate in the study, must be submitted to all relevant ECs and must be subsequently approved by the National Multi-Centre Study Committee. This is currently a MOH pilot project under MOH Guideline No. 168 and is available for non-special clinical trials.

Law stated - 01 September 2022

Reporting requirements

What requirements exist for reporting the commencement of a trial and its results to the competent authorities or the public?

Controlled and prospective clinical trials that involve one or more medical interventions and an examination of the impact on health must generally be registered on the MOH website . Non-interventional observational studies are exempt from registration. Registration should be made by the sponsor after receipt of EC approval for the study (Form 6) and is required to receive the relevant institution's approval for the conduct of the study (Form 7). The information on the site is required to be reviewed and updated by the sponsor at least once each quarter or as required.

One year after study completion and after the final analysis of the study results, the sponsor is required to file a clinical safety report with the MOH.

Any publication of the study results must be made in full and in the correct context.

Law stated - 01 September 2022

Consent and insurance

Are there mandatory rules for obtaining trial subjects' consent to participate? Must sponsors arrange personal injury insurance to a particular limit?

The sponsors use the MOH informed consent form (ICF) for the study. Hebrew, English, Russian and Arabic versions of the general adult ICF format are published on the MOH website. The MOH recently issued guidance to sponsors, contract research organisations and institutions that includes additional rules for the submission of ICFs. In this guidance, the MOH emphasised that certain provisions of the ICF cannot be altered, including section 3 (General Information), section 4 (Data Protection) and section 5 (Withdrawal from the Study). If a sponsor wants to add additional relevant and material information that is important for the participant when considering participation in the study, such an addition should be short and concise, formatted in a method that indicates what changes have been made, and should be justified in the study's application form for the EC's consideration. A sponsor or institution cannot limit their liability to study participants.

The sponsor is required to submit to the institution an insurance certificate with evidence of the insurance maintained

for the study in accordance with the requirements of the MOH Guidelines. The sponsor is required to maintain clinical trials insurance with a limit of US$3 million per occurrence and in aggregate for the period of the study and seven years thereafter (including by way of an extended reporting period, consistent with Israel's statute of limitations period). The hospital, medical staff and investigator should be included as additional insured persons, except where liability is due to their negligence, recklessness or deviation from the study protocol.

Law stated - 01 September 2022

MARKETING AUTHORISATION

Time frame

How long does it take, in general, to obtain an authorisation from application to grant, what fees are payable and what is the normal period of validity of the authorisation?

The Ministry of Health (MOH) notifies the applicant of its registration decision within 270 days of filing, excluding any delays due to the submission of supplementary information (Pharmaceutical Regulations – Preparations, section 5). The MOH tries to shorten the period to no more than 180 days if the drug already has US Food and Drug Administration (FDA), European Medicines Agency (EMA) or SwissMedic approval if a full approval package is provided. Generic approval can be shortened to 70 days if the same generic drug has already been approved by the FDA or EMA. The initial registration period is five years.

The fee for registering a new drug is 6,071 shekels.

The fee for a quality control evaluation is 16,458 shekels.

The time frame for approval of a device is 120 days and the initial registration period is generally five years. The filing fee is 1,212 shekels.

Law stated - 01 September 2022

Marketing exclusivity

What protections or exclusivities apply to the marketing period of an approved medicinal product or variation?

Israel offers marketing exclusivity for new chemical entities for six years and six months from the first registration of the drug in a recognised jurisdiction (Pharmacists Ordinance, section 47d). There is no similar protection for biologics, although the MOH will not approve biosimilars unless they have already been approved by the FDA or EMA and are marketed in a recognised jurisdiction.

Law stated - 01 September 2022

Protecting research data

What protections or exclusivities apply to the data submitted by originators to gain initial approval and, on variation or new application, to add indications or pharmaceutical forms?

Israel offers marketing exclusivity for new chemical entities for six years and six months from the first registration of the drug in a recognised jurisdiction (Pharmacists Ordinance, section 47d). There is no similar protection for biologics, although the MOH will not approve biosimilars unless they have already been approved by the FDA or EMA and are marketed in a recognised jurisdiction.

Law stated - 01 September 2022

Freedom of information

To what extent and when can third parties make freedom of information applications for copies of research data submitted by applicants for authorisation to market medicinal products or medical devices?

Research data remains confidential and cannot be obtained by third parties. The data can only be used by the MOH, without being supplied to a third party, after the expiration of the market exclusivity period to approve a generic formulation.

Law stated - 01 September 2022

Regulation of specific medicinal products

What are the specific requirements and processes for marketing approval of the major categories of regulated products?

The MOH will not approve biosimilars unless they have already been approved by the FDA or EMA and are marketed in a recognised jurisdiction. Homeopathic products are more leniently regulated under MOH Rule 10.

Law stated - 01 September 2022

Rewards and incentives

What rewards or incentives for approval are applicable to the major product categories, including orphan drugs, drugs for paediatric use, generic drugs and biosimilars?

None, except for an abridged regulatory period for generic drugs.

Law stated - 01 September 2022

Post-marketing surveillance of safety

What pharmacovigilance or device vigilance obligations apply to the holder of a relevant authorisation once the product is placed on the market?

Holders of authorisations must have a pharmacovigilance programme with a qualified person responsible for pharmacovigilance (QPPV) in charge of the programme. The QPPV must be vigilant with regard to the safety and efficacy profile of the product, gather and report information regarding adverse effects, and investigate any information regarding adverse effects. Periodic risk–benefit evaluation reports are filed by the QPPV. The MOH can also require the maintenance of a risk management system under section 26 of the Pharmaceutical Regulations – Preparations and MOH Rule 142.

Under section 11 of the Medical Device Law, device authorisation holders must also:

- undertake vigilance programmes;
- provide periodic reports to the MOH; and
- notify the MOH of:

- any significant deficiencies with the device that can impact the health of patients;
- any usage of the device that damaged a patient's health;
- any action taken by a foreign health authority;
- any notifications issued by the manufacturer; and
- any new information regarding the safety of the device published in scientific journals.

Law stated - 01 September 2022

Other authorisations

What authorisations are required to manufacture, import, export or conduct wholesale distribution and storage of medicinal products and medical devices? What type of information needs to be provided to the authorities with an application, what are the fees, and what is the normal period of validity?

Importation and manufacture of medical products require a manufacturer's or importer's authorisation. The application is submitted by the quality assurance manager. The application is completed in accordance with the European Commission's Compilation of Community Procedures on Inspections and Exchange of Information – Interpretation of the Union Format for Manufacturer/Importer Authorisation. The information required is listed MOH Rule EX-015/02; in particular, good manufacturing practice compliance and an appropriate business licence are required. The fee for such an authorisation is 35,556 shekels and it is valid for five years.

Conducting wholesale distribution and storage of medical products requires MOH approval, which is predicated on the appointment of a head pharmacist and acting in accordance with good distribution practice, among other factors.

The Medical Device Division of the MOH provides an importation authorisation for the holder of a device registration as outlined in sections 17 to 18 of the Medical Device Regulations. All manufacturing of devices is undertaken in accordance with International Organization for Standardization (ISO) standard ISO 13485 and authorised manufacturers must have an appropriate business licence for the manufacture of medical devices (see Business Licence Order (2013) and section 19 of the Medical Device Regulations). All storage and transportation of medical devices must be undertaken in accordance with ISO 9001 and businesses need an appropriate business licence for devices (see Business License Order (2013) and section 20 of the Medical Device Regulations).

Law stated - 01 September 2022

Sanctions

What civil, administrative or criminal sanctions can authorities impose on entities or their directors and officers for breach of the requirements concerning controlled activities?

Violations related to the manufacturing, importation and wholesale of medical products is punishable by up to one year of imprisonment or a fine of 75,300 shekels and an administrative fine of up to 75,000 shekels under section 60 of the Pharmacists Ordinance. Directors and officers in companies can be fined up to 29,200 shekels. Similar sanctions are provided for violations related to medical devices. However, fines under the Medical Device Law can be as high as 226,000 shekels and are doubled for corporations, but there are no provisions for administrative fines, as detailed in section 15 of the Medical Device Law.

Law stated - 01 September 2022

Exemptions

What, if any, manufacture and supply of medicinal products is exempt from the requirement to obtain an approval to market?

Under section 29 of the Pharmaceutical Regulations – Preparations, the following medical products are exempt:

- products imported in non-commercial amounts for personal use;
- products imported by pharmacies or manufactured in Israel in small amounts;
- preparation of a medicine using approved products by a pharmacist for a patient based on a doctor's prescription; and
- products for investigational purposes.

Specific rules were published on 23 August 2016 in a MOH notice related to the Pharmaceutical Regulations – Preparations.

Law stated - 01 September 2022

Parallel trade

Are imports allowed into your jurisdiction of finished products already authorised in another jurisdiction, without the importer having to provide the full particulars normally required to obtain an authorisation to market? What are the requirements?

A comparable product can be imported into Israel under section 47c of the Pharmacists Ordinance. In practice, to obtain authorisation for the product without the full registration of the drug being required, the drug must be imported from the same manufacturer as the product registered in Israel under MOH Rule 35.

Law stated - 01 September 2022

AMENDING AUTHORISATIONS

Variation

What are the main requirements relating to variation of authorisations for medicinal products and medical devices?

Variations in authorisations are submitted by the appointed pharmacist and approved by the Ministry of Health (MOH). To obtain an approval of a variation – such as adding an additional indication, changing age limitations or a change in the dosage regiment of a medicinal product – the applicant submits a European Medicines Agency or US Food and Drug Administration approval, or a certificate of pharmaceutical product (CPP) detailing the variation, draft drug leaflets, relevant clinical and preclinical data, and a summary of foreign countries in which the variation was approved or not approved (MOH Regulation 08/2012).

For devices, variations involve the submission of information similar to the initial filing as relevant to the variation.

Law stated - 01 September 2022

Renewal

What are the main requirements relating to renewal of authorisations for medicinal products and medical devices?

The main requirements are the submission of a CPP, a quality control certificate for the product, periodic safety update reports and updated leaflets (MOH Regulation 08/2012). For devices, renewals involve the submission of information similar to the initial filing and information regarding vigilance.

Law stated - 01 September 2022

Transfer

How easy is it to transfer the existing approvals or rights to market medicines and medical devices? How long does this take in general?

Transfer of rights in the registration is approved by the MOH and involves submitting affidavits relating to the transfer under MOH Rule 36). Unopposed transfers can be completed within several weeks. For devices, transfers involve the submission of information similar to the initial filing that is relevant to the transfer.

Law stated - 01 September 2022

RECALL

Defective and unsafe products

What are the normal requirements for handling cases of defective or possibly unsafe products, including approvals required for recall and communication with health professionals?

Any limitations or warnings by a foreign regulatory authority, severe adverse events or other significant safety-related information should be reported by the registration holder within 15 days of receiving the information under Ministry of Health (MOH) Rule 6. The registration holder is supposed to report any deficiency in a medicinal product as soon as possible and an investigative report with a risk assessment must be submitted 48 hours after the initial notification. The recall of the product from the market includes locating the product, preparing a notice, collecting the product, and notifying the district pharmacist and the good manufacturing practice department. Depending on the severity of the deficiency, a decision on a recall must be made within 24 to 72 hours under MOH Rule Pub-003/08. Section 13 of the Medical Device Regulations requires the registration holder to take any necessary steps to recall a defective device.

Law stated - 01 September 2022

ADVERTISING AND PROMOTION

Regulation

Summarise the rules relating to advertising and promotion of medicinal products and medical devices, explaining when the provision of information will be treated as promotional. Do special rules apply to online advertising?

The Pharmacists Regulations – Preparations and the Pharmacists Regulations – Sale of Preparations Without a Prescription, Outside a Pharmacy, and Not by a Pharmacist (2004) (the 2004 Regulations) are the laws that specifically

regulate pharmaceutical advertising in Israel. The general Consumer Protection Law (1981) and its related regulations are also relevant.

There are also several Ministry of Health (MOH) rules. The main rules are:

- Rule 24/04 – Advertising Preparations (last updated in March 2020);
- Rule 134 – Raising Disease Awareness;
- Rule 137 – Rules for Improving the Use and Compliance with Prescribed Medicinal Treatment Using Non-Commercial Information;
- Rule 49 – Distribution of Leaflets to Doctors/Consumers and Special Information on Preparations; and
- Rule 13/2018 – Commercial Engagements by Medical Institutions.

There are also advertising rules enacted by the National Second Authority for Television and Radio.

Finally, the 2014 Joint Code of Ethics between the Israeli Medical Association and the Representative Organisations of the Pharmaceutical Companies Active in Israel (the Joint Ethics Code) regulates pharmaceutical advertising. The main representative organisation party to the Joint Ethics Code is Pharma Israel.

In section 1 of the Pharmacists Regulations – Preparations, advertising is defined as 'providing information in writing, through the media or by any other means'. In section 1 of the 2004 Regulations, an advertisement is defined as 'publication by speech, in writing, in print, or by means of other media that an interested party makes in the marketing of a non-prescription medicine or made on its behalf, and directed to either all or part of the public'. These general definitions of advertisement apply to all potential forms of advertisement. The definition is general and applies to all target audiences. However, disease awareness campaigns and other information can be provided to patients and doctors.

The MOH regulates the advertisement of devices and, if an advertisement causes harm (or has the potential to harm) to the public, the MOH can order the registration holder to stop selling the device, condition sale on compliance with conditions or limit the type and form of advertisement set by the MOH under section 12 of the Medical Device Law. The MOH uses this standard, although further regulations need to be enacted for the Medical Device Law to come into force. The Israeli Consumer Protection Law also prohibits misleading advertisements.

The Physicians Ethics Code prohibits doctors from advertising in a manner that causes undue pressure on patients in clinics. Healthcare professionals that work at medical government institutions (which comprise most medical institutions), governmental clinics, and private entities that act under an MOH licence and their employees are restricted in their ability to have promotional material in their offices unless pre-authorised (MOH Rule 13-2018).

Finally, the MOH has limited pharmacists' ability to engage in the promotion of drugs and medical devices.

Law stated - 01 September 2022

Inducement

What regulations exist to discourage the provision of inducements to healthcare professionals to prescribe, sell, supply or recommend use of a particular medicinal product or medical device?

Healthcare professionals that work at medical institutions cannot accept any gifts under MOH Rule 13-2018, section 14.6. According to section 50 of the Joint Ethics Code, doctors can accept nominal gifts.

Law stated - 01 September 2022

Reporting transfers of value

What requirements apply to recording and publishing details of transfers of value to healthcare professionals and organisations by companies marketing medicinal products or medical devices?

There is a disclosure requirement for foreign and domestic companies. If the yearly total provided by the company is greater than 2,500 shekels, the company must report donations to the MOH once annually under the provisions of section 40a of the National Insurance Law.

Law stated - 01 September 2022

Enforcers

Describe the bodies involved in monitoring and ensuring compliance with advertising controls for medicinal products and medical devices, distinguishing between any self-regulatory framework and control by the authorities.

The MOH can act to order the advertisement's removal and order the publication of a clarification. Actions that can lead to fines or imprisonment can be initiated by the MOH under section 5.8 of MOH Rule 04/24.

There are also enforcement capabilities under the Joint Ethics Code that create a joint enforcement forum by combining members of industry and doctors.

Law stated - 01 September 2022

Sanctions

What are the possible financial or other sanctions for breach of advertising and promotional controls for medicinal products or medical devices?

Courts can impose sanctions of up to 150,000 shekels for a violation of the rules on advertisements by an individual and 300,000 shekels for a violation by a company. Under a temporary article of the Pharmacists Ordinance, violators of the Pharmacists Regulations – Sale of Preparations Without a Prescription, Outside a Pharmacy, and Not by a Pharmacist are subject to up to six months in prison.

The potential sanctions for violations of an order related to the advertisement of a medical device are one year of imprisonment. Fines can be as high as 226,000 shekels and are doubled for corporations. Similar sanctions are possible under consumer protection law.

Inducements can be handled under anti-bribery legislation. The punishment for bribing a public official is up to seven years of imprisonment, a fine of up to 1 million shekels for individuals, a fine of up to 2.2 million shekels for companies or four times the amount of the bribe, or a combination thereof. Gifts in an amount greater than a nominal value given to healthcare professionals also can violate the Civil Service (Gifts) Law (1979). This law allows for civil servants to be fined an amount of up to three times the value of the gift.

Law stated - 01 September 2022

OFF-LABEL USE AND UNLICENSED PRODUCTS

Off-label use

May health professionals prescribe or use products for 'off-label' indications? May pharmaceutical companies draw health professionals' attention to potential off-label uses?

Yes, in accordance with section 29 of the Pharmaceutical Regulations and the specific rules published in a Ministry of Health (MOH) notice relating to the Pharmaceutical Regulations.

Advertisement of unauthorised medicines or indications is not allowed.

However, additional updated information substantiated in professional literature that does not contradict the product information leaflet can be provided to medical professionals (doctors, nurses, pharmacists). The information cannot be intended to influence or encourage a type of use that is not in accordance with the drug's MOH registration. Providing this information on a website is only allowed if the website requires medical professionals to register and log in with a password (MOH Rule 137, section 3.1.2).

The information in the provided medical literature cannot relate to unapproved indications. The information provided must state the approved indications and reference the product's patient or doctor information leaflet under section 28a.b of the Pharmacists Regulations – Preparations. However, information regarding a drug for which an approval application has been submitted but has not been approved – or an applied for but as yet unapproved indication – can also be provided to medical professionals in the above manners (MOH Rule 24/04, section 5.2.3).

Law stated - 01 September 2022

Unlicensed products

What rules apply to the manufacture and importation and supply to healthcare providers of unlicensed medicines or medical devices?

Under section 29 of the Pharmaceutical Regulations – Preparations, the following medical products are exempt:

- products imported in non-commercial amounts for personal use;
- products imported by pharmacies or manufactured in Israel in small amounts;
- preparation of a medicine using approved products by a pharmacist for a patient based on a doctor's prescription; and
- products for investigational purposes.

Specific rules were published on 23 August 2016 in a MOH notice related to the Pharmaceutical Regulations – Preparations.

Law stated - 01 September 2022

Compassionate use

What rules apply to the establishment of compassionate use programmes for unlicensed products?

Yes, under section 29 of the Pharmaceutical Regulations – Preparations. Specific rules related to these regulations were published on 23 August 2016.

Law stated - 01 September 2022

SALE AND SUPPLY

Regulation

Are there special rules governing the dispensing or sale of particular types of medicinal products or medical devices?

The list of controlled substances can be found in the Controlled Substances Ordinance (1973). The special rules governing the dispensing or sale of such products are regulated under Ministry of Health (MOH) Rule 08/2018.

Law stated - 01 September 2022

Online supply

What laws and guidelines govern online dispensing, sale and supply of medicinal products and medical devices?

Pharmacies can allow patients with prescriptions to order online in accordance with MOH Guideline 128. Promotion and advertisement of prescription drugs are prohibited in Israel. However, the price of the medicine and a link to its patient leaflet on the MOH website can be shown on the pharmacy's website.

Law stated - 01 September 2022

Pricing and reimbursement

What are the controls imposed on pricing of medicines and medical devices and reimbursement by national social security systems that are applicable to manufacturers, distributors and pharmacists?

New drugs and devices are approved and added to the national medical basket based on recommendations by a public committee on an annual basis. The additional budget for new drugs and devices is usually approved in advance and the committee decides which drugs or devices to recommend for inclusion. The basket relates to drugs and devices that the sick funds, under Israeli nationalised medicine, must provide to their members. The cost of drugs is negotiated by the Ministry of Health and, at times, by the sick funds. The committee's recommendations regarding new drugs and devices are based on the cost of the treatment and other factors.

The maximum price of branded drugs without a generic competitor is determined by the average of the three lowest costs in Belgium, Hungary, France, the United Kingdom, Germany and the Netherlands. The price of a branded drug with a generic competitor or a generic drug is under the supervision of a governmental committee and a petition needs to be filed to have the price raised. This is provided for in the Supervision of Prices of Goods and Services Law 1996, the Order Supervising Prices and Goods (Maximum Price of Prescription Medicines) 2001, and the Order Supervising Prices and Goods (Implementing the Law on Medicines) 2001.

There are four sick funds in Israel. Israeli citizens must join one of the funds, which provide healthcare under the Israeli national healthcare system.

Law stated - 01 September 2022

UPDATE AND TRENDS

Forthcoming legislation and regulation

Is there any current or foreseeable draft legislation or other rules that will affect the regulation of pharmaceuticals and medical devices? What is likely to change, and what steps need to be taken in preparation?

There have recently been several proposals for additions and amendments to the laws and regulations that affect medical devices. However, due to the upcoming elections in November 2022, no changes appear imminent in Israel.

Law stated - 01 September 2022

Jurisdictions

Australia	Clayton Utz
Austria	Preslmayr Attorneys at Law
Brazil	Kasznar Leonardos
China	East & Concord Partners
Colombia	OlarteMoure
Denmark	Accura Advokatpartnerselskab
European Union	DLA Piper
France	Intuity
India	ANA Law Group
Israel	Pearl Cohen Zedek Latzer Baratz
Italy	Avvocati Associati Franzosi Dal Negro Setti
Japan	Atsumi & Sakai
Malaysia	Raja, Darryl & Loh
Mexico	OLIVARES
South Korea	Lee & Ko
Spain	Faus & Moliner
Sweden	Advokatfirman Hammarskiöld
Switzerland	Wenger Vieli Ltd
Taiwan	Formosa Transnational Attorneys at Law
Thailand	Baker McKenzie
USA	DLA Piper