Life Sciences Regulation in Israel: Overview

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A Q&A guide to life sciences regulation in Israel.

This Q&A provides a high-level overview of key practical issues, including life sciences clinical trials, manufacturing, marketing, abridged procedure, pharmacovigilance, data privacy, packaging and labelling, biological medicines, medical devices, health care IT, combination products, borderlines, and natural health products.

Pharmaceuticals

1. What are the main legislation and regulatory authorities for pharmaceuticals in your jurisdiction?

Legislation

The main legislation relating to pharmaceuticals in Israel is:

- The Pharmacists Ordinance (New Version) 1981, which regulates the manufacture, marketing, prescribing, importation and registration of medicinal products and also contains provisions relating to data exclusivity.
- The Pharmacist Regulations (Preparations) 1986, which further regulate the marketing, prescribing, importation and registration of medicinal products and also contain provisions relating to pharmacovigilance (PhV) and recall.
- The Pharmacists Regulations (Sale of a Non-Prescription Preparation not in a Pharmacy or not by a Pharmacist) 2004, which regulates the sale of GSL medicines.
- The Pharmacist Regulations (Good Manufacturing Practice) 2008, which further regulates the manufacture, importation and recall of medicinal products.
- Supervision of Prices of Goods and Services Act 5756-1996.
- Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations) 5761-2001.
- Order for the Supervision of Prices of Goods and Services (Application of the Act to Preparations) 5761-2001.

Regulatory Authorities

The regulatory authority entrusted with pharmaceuticals in Israel is the Ministry of Health (MOH) Pharmaceutical Division, which consists of the following units:

- The Institute for Standardisation and Control of Pharmaceuticals, which is responsible for the quality of medicinal products.
- The Medical Preparations Registration Department, which is responsible for the registration of medicinal products.
- The Import of Pharmaceuticals and Drugs Department, which is responsible for the importation of medicinal products.
- The Pharmaceutical Monitoring Section, which is responsible for the approval of labels and packages for medicinal products.
- The Pharmacovigilance and Drug Information Department, which is responsible for the safety of drug treatment.
- The Pharmaceutical Division is responsible, among other things, for:
- Pharmaceutical services in Israel.
- Licensing and inspecting pharmaceutical products.
- Supervising human clinical tests.
- Preventing pharmaceutical crimes.

The Pharmaceutical Division's main goal is to ensure that all medical preparations marketed in Israel comply with the appropriate standards of safety, quality and efficacy. The Pharmaceutical Division is also responsible for enforcing the procedures related to its activities.

Definition of Medicinal Product

The terms "preparation" and "therapeutic drug" are defined in section 1 of the Pharmacists Ordinance as any form of a substance or combination of substances which is one of the following (except for blood, or blood component, obtained from a human being which is intended to be used in its original physiological form and has not undergone substantial processing):

- It has properties for curing or preventing a disease in a human being or animal, or for treating that disease, or it is presented as having said properties.
- It causes (or administered to a human being or animal for the purpose of causing) restoration, replacement, reparation or a change of a physiological action in the body by exerting a pharmacological, immunological or metabolic action.
- It is administered or can be administered to a human being or animal for medical diagnosis.

Clinical Trials

2. Outline the regulation of clinical trials.

Legislation and Regulatory Authorities

Clinical trials are conducted in Israel in accordance with the Public Health Regulations (Clinical Trials in Humans) 1980, and the MOH Clinical Trials Procedure No. 14/02 (effective 1 May 2020) (MOH Procedure). The preamble to the MOH Procedure states that every clinical trial, including its design, approval, performance, documentation and method of reporting, must be carried out in strict compliance with the following Israeli legislation:

- The Public Health Regulations (Clinical Trials in Humans) 1980, as amended.
- The Genetic Information Act 2000.
- The Privacy Protection Act 1981.
- The provisions of the MOH Procedure.
- MOH Guidelines and Procedures, as published from time to time.

In addition, every clinical trial must be carried out in strict compliance with the following international procedures, in as much as they do not contradict the MOH Procedure:

- The principles of the Declaration of Helsinki.
- The Harmonised Guideline for Good Clinical Practice (ICH-GCP E6).
- ISO 14155: Clinical Investigation of Medical Devices for Human Subjects.

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

Authorisations

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

- Clinical trials that are defined as "special" under the Public Health Regulations require the approval of the Helsinki Committee at the hospital in which the trial is set to take place, and the approval of the director of the hospital.
- Clinical trials that are defined as "non-special" under the Public Health Regulations require the approval of the Director General of the MOH, which can be granted by the MOH Department of Clinical Trials on his behalf.
- Clinical trials involving genetic research in human subjects or unnatural female fertilisation must be approved by the Israeli Supreme Helsinki Committee for Clinical Trials in Human Subjects.
- An application to approve the conduct of a clinical trial in human subjects can be submitted only by the investigating physician to the institutional Helsinki Committee.
- A clinical trial can be conducted in more than one medical centre in Israel (multicentre trial). A multicentre trial should be approved by the Ethics Committee in at least one of the medical centres planned to participate in the trial and

subsequently by the MOH. Any clinical trial in human subjects must receive prior authorisation (not only clinical trials conducted in conjunction with or contemplation of a product application).

Consent

Subject to few exceptions, trial subjects must give "informed consent" to their participation in a clinical trial.

Consent must be given in writing, on an informed consent form, approved for that particular clinical trial by the Helsinki Committee.

The principal investigator or sub-investigator must provide the participant with an adequate oral explanation and the participant must read the informed consent form prior to giving consent.

Trial Pre-Conditions

The following conditions must be met before the trial can start:

- The sponsor of the trial must provide adequate insurance coverage and insure its legal responsibility under Israeli laws from claims that may be brought by participants in the clinical trial and/or third-party claims.
- The insurance must cover the legal responsibility of the hospital, medical team and investigator, subject to exclusion in case of negligence or breach of the trial protocol.
- A participant must not pay to participate in the trial.
- The trial protocol must include provisions for safeguarding participants' privacy and confidentiality of gathered information.

A sponsor or health care provider cannot limit the scope of liability to study participants, as set out by Israeli law and MOH regulations.

Procedural Requirements

Procedural requirements for the conduct of the trial include the following:

- Controlled and prospective medical trials, which involve one or more medical intervention and examination of the impact on health, must generally be listed in the MOH website (see *https://my.health.gov.il/CliniTrials/Pages/Home.aspx*). Non-interventional observational trials are exempt from registration.
- Three months before the end of the approved time period for conducting the trial, the principal investigator must file with the institutional Helsinki Committee an interim report that will include interim results of the trial (if available) and a reasoned application to prolong the time period for conducting the trial (if needed).
- After concluding the trial, the principal investigator must file with the institutional Helsinki Committee a concluding report of the trial.
- After the results of the trial have been processed, the sponsor of the trial must file with the MOH a synopsis of the results of the trial or a copy of an article discussing the results (if published).

A trial in progress is usually discontinued due to serious adverse events (SAEs) occurring during the trial.

The study plan must contain instructions for protecting the privacy of the participants and the confidentiality of the information collected. This is one of the substantial conditions for approving the conduct of a clinical trial.

Any information pertinent to a clinical trial in human subjects, which may lead to the disclosure of the identity of trial participants or details of their medical or genetic condition, will be maintained in confidence and the provisions of Article 19 of the Patient's Rights Act 1996 apply, *mutatis mutandis*. In respect of genetic information, the results of genetic tests are not included for study purposes in the medical file, under Article 30 of the Genetic Information Act.

Transparency and Reporting Requirements

Safety reports on serious adverse events (SAEs) occurring during a clinical trial must be reported to the institutional Ethics Committee if the SAE is unexpected and a connection between the SAE and use of the investigational product cannot be excluded. Death of a participant in a clinical trial must be immediately reported to the chairman of the institutional Ethics Committee and to the Director of the medical Institution (and subsequently to the MOH).

Two months before the end of the period approved for a clinical trial, the principal investigator must submit a progress report of the clinical trial to the institutional Ethics Committee.

Upon completion of a clinical trial, the investigator must submit a trial completion report to the institutional Ethics Committee. This report must contain the following details:

- Date of the report.
- Date of approval of the clinical trial by the Director of the medical institution.
- Application number or approval number in the MOH.
- Name and department of the investigator, subject of the clinical trial.
- Number and date of protocol (if available).
- Version and date of informed consent form.
- Number of participants enrolled in the clinical trial.
- Number of participants withdrawn from the clinical trial and reasons for that.
- Number of participants who discontinued from the clinical trial and reasons for that.
- Details of adverse events observed.
- Results of the clinical trial to date (if available).
- Date of completion of the clinical trial.
- Report on the collection/destruction of all investigational products (as applicable).
- Details about the duration and site of trial document retention.

The Director of the medical institution must send an annual report to the MOH describing the completed/ongoing clinical trials conducted at their institution. The Director of the medical institution may be exempt from sending an annual report to the MOH

if the institutional Ethics Committee has sent the full minutes of all the meetings which have taken place throughout the year, as they have occurred. The exemption must be granted by the MOH at the Director's request.

Manufacturing and Distribution

3. What is the authorisation process for manufacturing and distributing medicinal products?

Application

Under Israeli legislation, and in accordance with the EU good manufacturing practices (GMP) legislation, import and approval of batches of medicinal products for marketing are defined as "manufacturing". Therefore, under the relevant MOH Procedure (No. EX-015/02 (2018)), importers are regarded as manufacturers.

An application for a manufacturer's/importer's authorisation (MIA) is filed with the MOH Pharmaceutical Division' Institute for Standardisation and Control of Pharmaceuticals (GMP Oversight Unit). The application must be filed by a quality assurance manager of a licensed business which manufactures, imports or markets medical preparations or raw materials for medical preparations.

Wholesale marketing can only be carried out by a:

- Wholesale pharmaceutical business (that is, an entity used for storing, distributing, transporting and wholesale marketing of medical preparations or pharmaceutical raw materials).
- Recognised institution (that is, a health institution recognised by the MOH under the Pharmacists Ordinance).

Distributing a pharmaceutical preparation at the wholesale level is considered a manufacturing activity and accordingly also requires an MIA.

Retail marketing of medical preparation can only be carried out by a pharmacist in a pharmacy.

Manufacturing, possession or use of controlled substances (narcotics) requires special permit of the MOH.

Conditions

Conformity with EU GMP rules. The conditions for obtaining an MIA are specified in the Pharmacists Regulations (Good Manufacturing Practice) 2008 (Regulations) and MOH Procedure No. EX-015/02 (2018). Generally, the MOH Procedure provides that the application form for a MIA must be filled in accordance with the guidelines in the chapter *Interpretation of the Union Format for Manufacturer/Importer Authorisation* appearing in the current edition of the EMA document *Compilation of Community Procedures on Inspections and Exchange of Information*. The Regulations and the GMP Oversight Unit section on the Israeli MOH website further clarify that the Israeli GMP rules are aimed at conforming with the EU GMP rules as published at the EUDRALEX VOL.4 (see *http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm*) and that it is the

responsibility of manufacturers and importers into Israel to keep up to date with any changes in the current EU guidelines and to conform with any changes.

Key conditions for obtaining authorisation. Under MOH Procedure No. EX-015/02 (2018), a MIA will be granted only if the following conditions are met:

- The business of the manufacturer/importer has been inspected and found to comply with the GMP requirements.
- The manufacturer/importer holds a business licence in accordance with the Licensing of Businesses Act 1968, if required (alternatively, for importers that do not require a business licence, an authorisation from the Israeli Registrar of Companies must be presented).
- The business is run by qualified professionals, with relevant qualifications for their position.
- The medicinal products (manufactured or imported) are manufactured under GMP conditions at their manufacturing sites.
- The active pharmaceutical ingredients (APIs) that are used in the manufacture of the medicinal products (manufactured or imported) are also manufactured under GMP conditions.

Restrictions on Foreign Applicants

There are no specific restrictions on foreign applicants obtaining Israeli MIAs. However, under Israeli legislation, medicinal products can only be registered in the Israeli Drug Registry (and registration is a pre-condition for the grant of a marketing authorisation) under the name of an Israeli resident or a corporation registered in Israel. In addition, the Israeli MOH GMP Oversight Unit only inspects and approves businesses located in Israel.

Fees

The application fee to obtain or renew an MIA is ILS35,556.

The inspection fee per day per inspector authorised by the MOH for the grant of a GMP certificate, or for performing a periodic or ad hoc inspection at the business (other than an initial inspection to obtain or renew an MIA) is ILS2,946).

Authorisations, Variations, and Renewals

The validity period of an MIA is five years. Under the Regulations and MOH Procedure, an application to renew an MIA must be filed with the MOH no later than 120 days before its expiry.

The time frame for the MOH to issue a reasoned decision to approve or deny an MIA renewal application is the same as an MIA grant application (90 to 120 days).

The MIA must specify the name of its holder, its full address, the manufacturing site, the name of the medical preparation and its method of administration which was approved by the MOH for its manufacture or importation. The MIA holder must not manufacture or import medical preparations, unless they comply the conditions under which the medical preparations was registered or with conditions under which the MIA was granted.

A substantial change in the manufacturing conditions or in MIA application must be approved by the MOH. The MOH must render its decision in the application to change the MIA within 90 days from the date of the application.

The MOH can suspend or cancel the MIA if it is of the opinion that the MIA holder operates in a manner detrimental to public health or contrary to the GMP Regulations or the MIA conditions.

Monitoring Compliance and Imposing Penalties

To supervise adherence with the GMP Regulations, the MOH Director General (or authorised officials from the MOH GMP Oversight Unit) can conduct ad hoc inspections without prior notice at manufacturing sites. Under the Regulations and the MOH Procedure, where the Director General views that a manufacturing business is operating in a way that is detrimental (or may be detrimental) to public health or in contravention of the Regulations or the conditions of its MIA authorisation, they may do any of the following:

- Prohibit manufacturing or sale of the medicinal products/APIs that require authorisation.
- Seize and destroy the medicinal products/APIs if necessary.
- Cancel the MIA authorisation, suspend it or refuse to renew it.

In addition, in accordance with the Pharmacists Ordinance, manufacturing or importing a medicinal product in contravention of the Regulations or the conditions of the MIA authorisation is a criminal offence, the penalty for which is one year imprisonment or payment of a court-imposed fine not exceeding ILS75,300.

An appeal against a decision to cancel, suspend or not renew an MIA can be submitted to the MOH Director General within 30 days from the notification date of the decision. The MOH Director General must render a reasoned decision in the appeal within the latest of:

- 30 days from the filing date of the appeal.
- 30 days from the date on which appellant's arguments are presented.

Marketing

Authorisation Procedure

4. What is the authorisation process for marketing medicinal products?

Under Israeli legislation, the authorisation process for marketing medicinal products consists of two parts:

- Registration of the medicinal product in the Israeli Drug Registry.

- Grant of marketing approval for the first batch of the product that is marketed in Israel for the first time.

Application

An application to register a medicinal product must be filed with the MOH Drug Registration Department (Pharmaceutical Division).

As part of the registration process, the applicant must obtain a Quality Control Certificate for the medicinal product, confirming that the product is of suitable quality for medical use. An application for the grant of the Certificate must be filed with the Files Assessment Department of the Institute for Standardisation and Control of Pharmaceuticals at the Pharmaceutical Division.

An application to obtain marketing authorisation for the first batch of the registered product must be filed with the Pharmaceutical Control Section at the Pharmaceutical Division and the Institute for Standardisation and Control of Pharmaceuticals.

An application to list a medical preparation in the Israeli Drug Registry must contain data proving the safety, efficacy and quality of the preparation. The data that must be submitted in the registration dossier depends on the type of medical preparation. For example, the registration dossier of a medical preparation comprising a new API must contain complete pre-clinical and clinical data and up-to-date scientific literature, whereas the registration of a generic product mainly involves the submission of data proving bioequivalence to the reference innovative preparation.

Authorisation Conditions

Under the legislation and MOH Procedures, the following are the main conditions that must normally be met to obtain authorisation to enter the Israeli market:

- The registration of the medicinal product must be under the name of an Israeli resident or a corporation registered in Israel (registration holder).
- With respect to imported pharmaceutical products, the product must be authorised for marketing in a recognised country (US, Canada, EU country, UK, Switzerland, Norway, Iceland, Australia, New Zealand and Japan).
- An application for an imported product must be filed together with a Certificate of Pharmaceutical Product (CPP) issued by a recognised country no more than two years before the application date. The CPP must indicate that the pharmaceutical product is authorised for marketing in the recognised country. However, according to a recent MOH Procedure which modifies previous requirements, the CPP need not normally indicate that the pharmaceutical product is actually on the market in the recognised country (unless the application is for a generic product under the 70 days registration track (see *Question 9*), in which case a CPP issued by the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA) must be filed, indicating that the pharmaceutical product is actually on the market).
- The medicinal product has been granted a Quality Control Certificate by the MOH Institute for Standardisation and Control of Pharmaceuticals, confirming that the product is of suitable quality for medical use.
- The MOH must be satisfied that the pharmaceutical product is safe and efficient for its intended purpose. To that end, the applicant (for a "new" (innovative/ethical) pharmaceutical product) must file with the MOH a complete Drug Master File (DMF) containing pre-clinical and clinical data and up-to-date scientific literature.
- The MOH must be satisfied that the name of the pharmaceutical product is not misleading.

- The MOH must be satisfied that the pharmaceutical product is manufactured under GMP conditions. As part of the application for the grant of a Quality Control Certificate for the medicinal product, the applicant must file with the MOH original and valid GMP certificates for all the manufacturing sites of the finished product (bulk, packaging, inspection and release), sterilised active raw material and solvent, unless the site is indicated in the CPP filed by the applicant.
- The MOH must be satisfied that the Registration Holder has in place a PhV system (*see Question 10*).
- The registration of a medical preparation in the Israeli Drug Registry may be subject to various conditions and restrictions (such as post-registration surveillance, limiting the marketing of the preparation to hospitals, determining that the preparation can only be marketed under prescription, and setting requirements related to the type of packaging and labelling).
- A marketing authorisation is always granted for a specific product.

Key Stages and Timing

Under the Pharmacist Regulations (Preparations), the MOH must complete the registration process of a new medicinal product within 270 days (excluding periods of time in which the applicant responds to a MOH letter of deficiencies). Under the MOH Procedures, the MOH strives to shorten this period to 180 days for new medicinal products that are already registered or received a positive opinion by one of the following regulatory agencies:

- FDA.
- EMA.
- Swiss Agency for Therapeutic Products (Swissmedic).

Before filing an application for registration of a new medicinal product and the start of the 270/180 days period, the applicant must file with the MOH an application for a preliminary assessment of the product, and obtain approval to file the main application. Under the MOH Procedures, the MOH strives to complete the preliminary assessment within five business days. However, it is possible to file the application for a preliminary assessment with the MOH only on one specific day per month (as of 2019).

Fee

The main fees are as follows:

- The fee to obtain a Quality Control Certificate for the medicinal product is ILS16,458 and the renewal fee is ILS6,705.
- The fee for registering a pharmaceutical product on the Israel Drug Register is ILS 6,071 and the renewal fee is ILS 1,890.

Authorisations, Variations, and Renewals

Pharmaceutical products are registered in Israel for an initial period which does not exceed five years and are then renewable for an unlimited period of time, unless the Director General of the MOH is of the opinion that this period should be limited for reasons related to quality, efficiency and safety. An application for renewal must be filed with the MOH by the appointed

pharmacist of the Israeli registration holder no later than 30 days prior to the expiry of each registration. Each renewal is subject to MOH discretion (which, of course, must be reasonable).

An application to renew an MIA authorisation must be filed with the MOH no later than 120 days before its expiry.

The transfer of a marketing authorization is subject to prior approval by the MOH. If the manufacture's agent in respect of a registered product has been changed, the appointed pharmacist of the new agent must file a petition to change the registration holder. The petition must be accompanied by the manufacturer's:

- Notification that the holder of the registration is no longer its agent.
- Declaration about the appointment of a new registration holder.
- Declaration that it allows the new registration holder free access to all of the confidential information in the product dossier.

The MOH can revoke a registration of a medical preparation in one of the following cases:

- Preparation may cause harm or is found to be inefficient.
- Preparation is manufactured, imported and marketed contrary to the registration conditions.
- Registration holder does not maintain a medicine PhV system under the Pharmacist Regulations (Preparations).

The MOH can also suspend or cancel an MIA if the MOH is of the opinion that the MIA holder operates in a manner detrimental to public health, or contrary to the GMP Regulations or the MIA conditions. In such a case, The MOH must allow the registration/ MIA holder to present arguments before rendering its final decision.

Protection of Confidential Information

Confidential information and documents in the registration dossier of a medical preparation cannot be inspected by third parties but the MOH can rely on such information and documents for the purpose of approving the marketing of a generic substitute, unless the innovative product is protected by a marketing exclusivity.

Exceptions

5. Are there additional or alternative regulations for special types of medicines or medicines intended for particular types of patients or diseases?

In special circumstances, a medicine may be exempt from registration in Israel if it falls within one of the exemptions listed in Regulation 29(a) of the Pharmacists Regulations (Preparations), as implemented by the MOH's Director General. This includes where:

- The medicine is to be used as part of a compassionate use programme.
- The medicine is intended for the treatment of a serious disease or medical condition and no alternative medicines for treating the same disease or medical condition are registered and marketed in Israel.
- The medicine is designated for the medical treatment of Israeli residents in relation to an epidemic or other contagious disease.
- The medicine concerns protection from chemical or radioactive substances.

The marketing of vaccines, blood products or plasma derivatives that have been manufactured in Israel requires an official batch release certificate from the MOH's Institute for Standardisation and Control of Pharmaceuticals.

The MOH follows the EU regulatory requirements relating to the safety, quality and efficiency of cellular and tissue-based products and advanced therapy medicinal products (ATMPs). Import of "simple" cells and tissues must comply with the guidelines of the MOH's Institute for Standardisation and Control of Pharmaceuticals. ATMPs are classified as medical preparations and their registration in the IL Drug Registry must conform to the relevant EU directives and regulations, the provisions of the Pharmacists Ordinance and the Pharmacist Regulations (Preparations).

The manufacturing, importing, exporting, distributing and marketing of dangerous drugs and/or psychotropic substances in Israel requires special permits and licences.

6. Can products be marketed without a marketing authorisation in certain circumstances?

In general, a medical preparation can only be marketed in Israel if listed in the Israeli Drug Registry. However, the MOH can, in certain circumstances, approve the marketing of a medical preparation in Israel which is not listed in the Israeli Drug Registry if the preparation is exempt under Regulation 29(a) of the Pharmacists Regulations (Medical Preparations) and is unlikely to harm public health. The exemptions include:

- Where the importation of the preparation is for the personal use of a specific patient.
- Where the preparations are to be imported by a pharmacy or manufactured in Israel in small quantities.
- Where the preparations are intended for essential medical treatment and compassionate use.
- Where the preparations are designated for medical treatment of Israeli residents in the cases of an epidemic or contagious disease, or in relation to the protection from chemical or radioactive substances.

Monitoring Compliance and Penalties

7. What powers does the regulator have to monitor compliance with marketing authorisations and impose penalties for a breach?

Where the Director General of the MOH determines that a registered pharmaceutical product is detrimental or may be detrimental to public health, or is inappropriate or inefficient for its approved indication, or is manufactured, imported and marketed in contravention of the conditions of its registration, or the registration holder does not maintain a PhV system as required under the Regulations, they can:

- Prohibit the manufacturing, import and marketing of the product.
- Order a product recall from the market.
- Publish a notice to the public announcing the prohibition on marketing of the drug.
- Take any measure required to guarantee public health.
- Revoke the registration of the product in the Israel Drug Register or refuse to renew it.

(Section 12(a), Pharmacists Regulations (Preparations).)

In addition, under the Pharmacist Ordinance, manufacturing or marketing a medicinal product or ordering its use contrary to the conditions of its registration or MIA or GMP requirements is a criminal offence the penalty for which is a one-year imprisonment or payment of a court-imposed fine of up to ILS75,300.

Furthermore, under the Pharmacist Ordinance, marketing a medicinal product contrary to the conditions of its registration is subject to monetary administrative sanction of ILS150,000 and if the infringer is a corporation, ILS300,000.

Instead of imposing monetary administrative sanctions, the MOH can send advance warnings or require the provision of binding undertakings not to further violate certain provisions of the Pharmacists Ordinance.

The MOH inspectors can check medical preparations or raw material for those preparations, their manufacture processes and the implementation of the GMP Regulations at the premises where the preparations or raw materials are manufactured or stored or offered for sale. The MOH inspectors can:

- Demand the submission of information or documents relating to medical preparations or raw materials.
- Take samples of medical preparations or raw materials.
- Seize the preparations and raw materials.
- Destroy preparations and raw materials, if they are likely to harm public health.
- Carry out inspections without prior notice at the manufacturing sites.

Data and Marketing Exclusivity Protections

8. What exclusivity does a marketing authorisation holder benefit from?

Medical preparations containing a new chemical entity (NCE) may qualify for marketing exclusivity (ME) of up to six and a half years, counted from the first registration of the medical preparation in recognised countries (the US, EU member states, the UK and several other countries).

The Israeli ME protection is not entirely equivalent to a full data exclusivity protection. During the ME period in Israel, generic companies can still file applications to register their products based on bioequivalence studies and the MOH will review the applications. The grant of marketing approvals for such generic pharmaceuticals will be delayed until the expiry of the ME period. In addition, during the ME period, the MOH can rely on the data in the registration dossier of the innovative product for the purpose of approving the export of generic products.

Biological products and new therapeutic indications are not entitled to ME protection in Israel and there is no special protection for orphan medicines.

The data in the registration dossier remains confidential even after the expiry of the ME period and third parties are not allowed to inspect it. However, once the ME period expires, the MOH can rely on the data in the registration dossier of the innovative product for the purpose of approving the marketing of the generic product.

Abridged Procedure for Marketing Authorisation

9. Outline the abridged procedure for marketing authorisation.

Under the MOH Procedures, generic versions of chemical or small molecule medicines are generally registrable based on bioequivalence studies and are generally exempt from producing pre-clinical and clinical data. An applicant for the registration of a generic product is not privy to any information contained in the Drug Master File of the innovative product and relies only on the fact that the innovative product is listed in the Israel Drug Registry.

In general, a generic product is registrable in Israel only if its innovative version is registered and marketed in Israel. However, under the MOH Procedures, the MOH can approve the registration of a generic product based on its innovative version where the registration of the innovative product has expired or the marketing of the innovative product has been discontinued in Israel. In addition, where the marketing of the innovative product has been discontinued in all of the recognised countries, the MOH can approve the registration of a generic product based on another generic version that is marketed in Israel.

The MOH will consider a small molecule product as generic if it comprises the same API as the innovative product (with the same strength and dosage form), even if the generic API is in a different form (different salt, ester, ether, isomer or mixture of

isomers) from the innovative product. However, if there is a material difference in characteristics that impact safety or efficacy, the applicant for the registration of the generic product must establish to the MOH that the difference does not in fact prejudice the safety or efficacy of the product.

Small molecule generic products applied for registration in Israel after receiving marketing authorisation from the FDA or the EMA, must be registered by the MOH within 70 days (as opposed to the standard examination period which is 270 days) (section 47A(a2)(2), Pharmacists Ordinance).

The expedited procedure for registering a standard (small molecule) generic product in Israel is not applicable to biosimilars. The party applying for the registration of a biosimilar in Israel must submit experimental data, including *in-vitro*, pre-clinical and clinical data proving its similarity to the reference product in terms of quality, safety and efficacy. The Israeli MOH guidelines addressing the registration of biosimilars in Israel generally follow EMA's policy.

Pharmacovigilance and Other Commitments

10. What pharmacovigilance obligations and other commitments apply after a company has obtained marketing authorisation? Are there further conditions on how the medicinal product is distributed and made accessible to patients?

Pharmacovigilance (PhV) System

Under the Pharmacists Regulations (Preparations) and MOH Procedures, the registration holder must have in place a PhV system administered by a Qualified Person Responsible for Pharmacovigilance (QPPV). The Regulations and MOH Procedures set out in detail the PhV obligations that the QPPV must perform, including duties to collect, document, save, investigate and analyse information and reports with respect to adverse reactions, and reach conclusions and recommendations that must be reported to the MOH on measures that should be taken to ensure the safety and efficacy of the medicinal product.

In addition, the registration holder must obtain a contractual commitment from the manufacturer of the medicinal product to forward to it any information required to maintain its PhV obligations under the Regulations.

The Regulations and MOH Procedures set out detailed time frames for reporting to the MOH Risk Management and Drug Information Department adverse reactions and new safety information, based on the seriousness of the event/information and other criteria. In addition, the registration holder must file periodic benefit-risk evaluation reports (PBRERs) in accordance with the up-to-date EU regulatory framework.

In addition, MOH Procedure No. 142 (March 2016) sets out instances in which the registration holder must maintain a risk management system with respect to the medicinal product and sets out the necessary features of a risk management plan. The MOH Procedure provides that it is based on the EU risk management plan (RMP) procedure and that, as a default and when available, the Israeli risk management system will be based on the EU RMP that was approved for the medicinal product. In the absence of an approved EU RMP, the Israeli risk management system will in principle be based on the risk evaluation and mitigation strategies plan that was approved for the product in the US or on a risk management plan that was approved for the product in a specific EU country or another recognised country, if available. The risk management plan will be adapted to

Israel in accordance with the demands of the MOH Risk Management and Drug Information Department and the provisions of the MOH Procedure.

Other Commitments

Under the Pharmacists Regulations (Preparations), the Director General of the MOH can prescribe any of the following as a condition for the registration or renewal of the registration of a medicinal product and, if the drug is registered, to add or change any of them at any time:

- Post-registration surveillance, according to terms set out by the Director General.
- Limiting the marketing of a product to hospitals only.
- Limiting the dispensing of the product to a physician's prescription.
- Determination of the type, quality, labelling, form and safety of packaging of the product.
- Any other condition relating to the correct and safe use of the product.
- Regular and continuous supply of the product.

Foreign Marketing Authorisations

11. Are foreign marketing authorisations recognised in your jurisdiction?

Foreign marketing authorisations are not recognised in Israel. However, marketing authorisations granted in selected foreign countries (recognised countries) are relevant and can be relied upon (in certain circumstances) in the Israeli registration process (see *Question 9*).

Data Privacy

12. Do privacy and data protection laws impact on pharmaceutical regulation in your jurisdiction?

The duty to maintain a person's privacy is prevalent in Israeli legislation. With respect to a patient's privacy, the Patient Rights Act 1996 imposes a general duty on medical practitioners (and other therapists) and employees of health institutions to maintain the confidentiality of any information concerning a patient, that they received in the course of performing their duties or in the

course of their employment. The Act also provides that a medical practitioner/therapist or the director in a health institution will take measures necessary to ensure that employees under their authority maintain the confidentiality of patient information. In addition, the Privacy Protection Act 1981 imposes a general duty (which also applies to commercial companies) not to publish information concerning a person's health.

Under the Privacy Protection Regulations (Information Security) 2017, databases containing personal medical information or genetic information must comply with strict security procedures.

The transfer of personal data from a database in Israel to a database abroad is permitted under strict conditions specified in the Privacy Protection Regulations (Transfer of Data to Databases Outside the State Borders) 2001.

The duty to maintain a patient's privacy is also provided in various MOH Procedures, including:

- MOH Procedure (No. 14 (2016)), which provides that the Helsinki Committee will not approve a clinical trial in human subjects unless it is satisfied that the trial programme includes provisions on ways to maintain the privacy of the participants in the trial and the confidentiality of the collected information.
- MOH Procedure (No. 6 (2013)), which provides that reports on adverse reactions will not include identifying details of the patient and that information included in follow-up reports must not breach the patient's privacy.

Packaging, Labelling, and Tracking

13. Outline the regulation of the packaging and labelling of medicinal products.

Legislation and Regulatory Authority

The legislation that applies to the packaging and labelling of medicinal products includes the:

- Pharmacists Ordinance.
- Pharmacists Regulations (Preparations).
- Pharmacists Regulations (Sale of a product not in a pharmacy or not by a pharmacist), 2004.
- MOH Procedures.

The MOH is the regulatory authority responsible for enforcing the rules relating to packaging and labelling of medicinal products.

Information Requirements

Under the Preparations Regulations, the package of a medicinal product must include the following information:

- Trade name of the product and the generic name of the product (and where there is no generic name, the chemical name).
- Name and address of the registration holder of the product, or of the authorisation holder to import the product, as appropriate, and if the product is imported, the name and address of the importer.
- Specifications of the API and the quantities per unit dose of the product, in their generic name, and where there is no generic name, the chemical name.
- Date of manufacture of the product, batch number and expiration date.
- A leaflet, stating the directions for use of the product, the active ingredients and their quantities, the inactive ingredients, the properties of the product and its contraindications.
- The package of every medicinal product marketed to a patient in Israel must be marked with a barcode.

The Pharmacist Ordinance and MOH Procedure No. 43 also provide that instructions to review the leaflet prior to administration of the medicine must appear on the packaging. In addition, for over-the-counter products, the purpose of use of the product must appear on the packaging.

Serialisation

The package of every medicinal product marketed to a patient in Israel must be marked with a barcode (see above, *Information requirements*). The appointed pharmacist of the registration holder is responsible for the implementation of this requirement. Under local regulations and procedures, there is no general obligation to apply an anti-tampering device on the packaging of a medicinal product.

Other Conditions

The name and address of the importer (if the product is imported) must appear in Hebrew. In addition, under MOH Procedure No. 43, the trade name of the medicinal product and instructions to review the patient leaflet prior to consuming the medicine must be indicated in English, Hebrew, Arabic and Russian. The purpose of the product (for over-the-counter products only) must be indicated in Hebrew. For prescription and over-the-counter products, the leaflet must appear in English, Hebrew and Arabic. For general sale list products, the leaflet must also appear in Russian.

Prescription preparations, general sale list (GSL) preparations and other preparations comprising specific active substances (such as paracetamol, dipyrone and NSAIDs) must be packaged in child-resistant packaging if they are marketed in the form of liquid preparations, tablets in bulk or powders for human use.

Medical toxins must be packed in pressure packages or special containers, and the packaging must be marked by special signs and labels (Pharmacists Regulations (packaging and marketing of drugs, toxins and harmful chemicals) 1969; Pharmacists Order (classification of poisons, their registration and handling)).

Biological Medicines

14. What is the definition of biological medicines in your jurisdiction? Are there any additional or alternative regulations that apply specifically to them?

There is no separate legislation regulating biologicals, including gene therapy medicinal products (GTMPs) or combination products. However, internal guidelines published by the MOH have adopted the regulatory requirements under relevant EU directives and regulations with respect to the safety, quality and efficiency of biological products including GTMPs. Any relevant EMA Guidelines and/or FDA procedures may also be considered by the MOH when making decisions relating to the regulation of biological products.

Medical Devices

Legislation and Regulatory Authorities

15. What are the main legislation and regulatory authorities for medical devices in your jurisdiction?

The main legislation regulating the manufacture, marketing and licensing of medical devices in Israel is the:

- Medical Device Act 2012 (MDA).
- Medical Device Regulations (Registration of a Medical Device in the Register and its Renewal) 2013 (MD Regulations).

So far, the MDA and the MD Regulations have not entered into force and will only do so after the enactment of additional regulations relating to the manufacture, marketing and use of non-registered medical devices. However, although the MDA and MD Regulations have not yet entered into force, the government and quasi-government health institutions in Israel are still required by the MOH to purchase medical devices that conform to the policy outlined in the MDA. In practice, sick funds (that is, mandatory, government-funded health care scheme provided by health insurers) and non-governmental hospitals in Israel also condition the purchase of medical devices on their registration with the IL Registry of Medical Devices (AMAR Registry).

The MOH's Medical Device Division (AMAR unit) is responsible for the registration of medical devices in Israel, for granting import and export permits and for monitoring and supervising the manufacture, import and marketing of medical devices in Israel.

Medical Devices Definition

16. What is the definition of a medical device (or equivalent) in your jurisdiction?

According to the MDA, a medical device can be any of the following (excluding a preparation as defined in the Pharmacists Ordinance):

- A device used for medical treatment, or other device or computer software required to operate such a device. In this regard, the device could include any accessory, chemical material, biological product or biotechnological product.
- Contact lenses.
- An electrical device emitting ionic or non-ionic radiation used for cosmetic treatment.

The main difference between a "medical device" and a "medicine" is that a medicine is defined in the Pharmacists Ordinance as any form of a substance or combination of substance which are excluded from the statutory definition of medical device.

Contrary to "regular" medical devices, the registration of a none-sterile, low-risk medical device can be renewed by submitting a notice of continued marketing of the medical device (there is no need to file a renewal application). The registration of a "regular" medical device is valid for up to five years, while registration of an implant is valid for three years. Medical devices used only in hospitals and medical centers may be exempt under the MD Regulations from various regulatory requirements relating to the marking of packages and leaflets.

Classification of Medical Devices

17. Briefly outline any classification system and the main classifications of regulated medical devices.

There is no classification system for medical devices in Israel.

Under the MDA, various categories of low-risk medical devices, listed in the MDA's Second Addendum (for example, swabs, elastic bandages, dental floss, non-sterile dressing materials, condoms, feminine hygiene products, cotton wool products and weight scales for people) do not need to be registered as a prerequisite for their marketing.

Requirements to Manufacture and Market Medical Devices

18. What are the requirements to manufacture and market medical devices?

According to the MDA, which has not entered into force but is already being followed by Israeli government/quasi government hospitals and Sick Funds (see *Question 15*), registration of a medical device in the AMAR Registry is a prerequisite for its manufacture and marketing in Israel, unless the medical device is listed in the MDA's Second Addendum.

If the medical device has already been registered or approved for marketing in a recognised country (the US, Canada, EU member states, the UK, Switzerland, Norway, Iceland, Australia, New Zealand and Japan) and is actually marketed there, the Medical Device Division will register the device for a period that will not exceed the MA period in the same recognised country. If the registration of the device is subject to certain conditions in the recognised country, these will also constitute part of the Israeli registration of the medical device.

An application to register a medical device, which is already registered and marketed in a recognised country, should be accompanied by either (among other things):

- A document proving that the device has been approved for marketing in the recognised country (for example, a US FDA 510(k) pre-market notification or other recognised pre-market approval).
- The manufacturer's Declaration of Conformity and CE Mark certificate issued by a European Notified Body.

If the medical device has not already been registered in one of the recognised countries, the applicant must submit:

- The results of risk analysis.
- A clinical evaluation
- A summary of the clinical trials.
- Two expert opinions addressing the safety and efficacy of the medical device.

An application to register a medical device in Israel must be submitted by an Israeli resident or a corporation registered in Israel.

Labelling is one of the conditions for registering a medical device in Israel. Under the MD Regulations and the guidelines of the MOH's Medical Device Division, the external packaging and leaflet of a medical device intended for home use must include various details, including:

- The commercial name of the device.
- The name and address of the manufacturer.
- The name and address of the registration holder.
- The registration number of the device.
- The necessary storage conditions.
- Any use/maintenance instructions and safety measures.

19. Are there exceptions to the requirements (for example, for clinical studies, special individual patient use, custom devices, and compassionate use)?

According to the MDA, the MOH Director General can approve the manufacturing, marketing or use of unregistered medical devices, or can approve the off-label use of registered medical devices when their approval is necessary for one of the following uses and provided that these medical devices are unlikely to cause harm to public health:

- Where it concerns essential medical treatment.
- Where it concerns research activities.
- For the development and manufacturing of the medical device (other than its marketing).
- In preparation for an emergency or for the use of the medical device in an emergency situation.
- Where the medical device is intended for export purposes only.
- Where the medical device is to be used by a medical institution but the registration for the device has been cancelled or not renewed.
- The off-label use of a registered medical device.
- Where the medical device is to be used by a health institution, which has been approved for marketing in a recognised country and is the subject of a pending registration application in Israel, for the purposes of conducting clinical assessment in a limited number of patients.
- Personal use.

Draft regulations, setting out the rules and terms under which the MOH Director General will be authorised to exempt a medical device from registration, were published in December 2021 but have not yet been brought into effect.

20. Are there fewer or different requirements for medical devices that have already been licensed or approved in another jurisdiction?

If a medical device has been registered or approved for marketing in a recognised country and is actually marketed there, the medical device can be registered in Israel based on its registration/marketing approval in the same recognised country (see *Question 18*). In such a case, the registration process in Israel is relatively straightforward and there is no need to conduct further testing or to provide clinical data.

21. What are the main requirements to import medical devices from or export medical devices to other jurisdictions?

Imports

Importing medical devices from other jurisdictions into Israel requires a permit from the MOH.

If the medical device is imported for the purpose of its marketing in Israel, it must be listed in the AMAR Registry. However, if the medical device is imported for other purposes such as personal use or for use by a physician in their private clinic, the device does not need to be listed in the AMAR Registry.

The MOH's Medical Device Division issues two types of import permits:

- Periodic import permit.
- One-time import permit.

A one-time import permit refers to a specific shipment of medical devices and may be issued in cases such as when:

- The medical device is not being imported to be marketed in Israel.
- The application to register the device in Israel is still under examination and the importer wishes to conduct a clinical assessment of the device.

Exports

If the medical device is listed in the AMAR Registry and has been approved for marketing in Israel, the MOH's Medical Device Division will issue a certificate of free sale (CFS) to exporters.

A medical device intended for export purposes only may be exempt from registration.

The parallel import of medical devices in not regulated under Israeli law.

Health Care IT

22. Is there any specific regulation of medical software, health care IT, or e-health products (such as mobile health apps)?

Israel does not have specific regulation for health care IT issues or mobile medical applications. However, the broad definition of the term "medical device" in the MDA does cover the computer software required for activating the medical device.

Combination Products and Borderlines

23. Does your jurisdiction recognise combination products? Are there any additional or alternative regulations that apply specifically to them?

Products combining a medical device and a medical preparation are regulated under the laws and guidelines applicable to medical devices or medical preparations, depending on their primary mode of action. A combination product cannot be registered both as a medical device and a medical preparation.

Borderlines

24. What product type determinations are relevant and are there specific mechanisms for determining which regulatory regime applies to a borderline product?

In cases where a medical device is combined with a medicine, its classification as a medicine or a medical device is determined according to its primary mode of action and the required expertise of the party applying for the registration of the product. If the combination product is also registered in the US, the Israeli MOH will adopt the classification used by the FDA.

A request for designation of a combination product as a medical device or a medical preparation can be submitted to the MOH's Medical Device Division or the Medical Preparations Registration Department. The request must be decided within 30 business days. The decision can be appealed to the Deputy Director General of the MOH.

Natural Health Products

25. Is there a separate regulatory regime for natural health products (or equivalent) (for example, traditional medicines, homeopathic medicines, supplements, vitamins, and minerals)?

Homeopathic Products

Homeopathic products are subject to a separate regulatory regime set out in MOH Guideline No. 10. The regulatory regime for these products is based on the MOH's approach that treatment using homeopathic products is not a substitute for conventional medical treatment. Therefore, a homeopathic product cannot be registered as a medical preparation and must be marketed without a medical indication. Despite the medical efficacy of such products remaining unproved, their quality and safety must be ensured and Guideline No. 10 was issued for this purpose.

Nutritional Supplements

The manufacturing and marketing of nutritional supplements in Israel is regulated under the Public Health Regulations (Food) (Nutritional Supplements) 1997 (Nutritional Supplement Regulations). According to the Regulations, the term "nutritional supplement" covers vitamins, minerals, amino acids, and plants (among others) but excludes any medical preparation registered under the Pharmacists' Regulations (Preparations) and any medicinal plant as defined in the Pharmacists' Regulations (Opening and Management Conditions of Pharmacies and Drug Rooms) 1982. The purpose of the Regulations is to ensure the safety and quality of nutritional supplements which are manufactured or marketed in Israel.

Medicinal Plants

The marketing of medicinal plants in Israel is regulated under the Pharmacists' Regulations (Opening and Management Conditions of Pharmacies and Drug Rooms) 1982. Medicinal plants listed in the latest European, British, US or French pharmacopeia can be marketed in pharmacies (with the exception of specific plants for which marketing is strictly forbidden). Therefore, certain pharmacopeial plants can be marketed only in pharmacies while others cannot be marketed at all, to prevent harm to public health.

26. Which authorities regulate the manufacture and marketing of natural health products?

The MOH's Pharmaceutical Division regulates the manufacture and marketing of homeopathic products.

The MOH's National Food Service (NFS) regulates the manufacture and marketing of nutritional supplements.

27. What notifications, registrations, approvals, and licences are required to manufacture and market natural health products?

Manufacturing

Homeopathic raw materials or products can be manufactured in Israel in plants maintaining good manufacturing practices (GMP) which received a GMP certificate from the MOH's Institute for Standardisation and Control of Pharmaceuticals. One of the conditions for importing homeopathic products into Israel is the compliance of the manufacturer in the recognised countries with GMP requirements.

A nutritional supplement, manufactured in Israel or abroad, must also be manufactured under GMP conditions.

Marketing

Homeopathic products. The marketing of homeopathic products in Israel must be approved by the MOH's Pharmaceutical Division. Marketing approval will only be given if the product's safety has been proved. In certain cases, the applicant will be required to submit toxicological data in relation to the product. A homeopathic product intended for patients under six years of age will only be approved on the basis of pediatric clinical and safety data.

An application to approve the marketing of a homeopathic product in Israel must be accompanied with (among other things):

- A GMP certificate for the manufacturing site.
- A copy of a monograph relating to each raw material/homeopathic product.
- Specifications and a certificate of analysis in relation to the final product.
- A CFS issued by the competent authority of the manufacturing country or country where the final homeopathic product is to be marketed.

Marketing approval for a homeopathic product is valid for up to five years.

Nutritional supplements. The marketing of nutritional supplements in Israel must be approved by the NFS. A nutritional supplement will not be marketed in Israel unless the following conditions are met:

- The amount of vitamin or mineral in each dosage unit does not exceed the maximum intake level specified in the Second Addendum to the Nutritional Supplement Regulations.
- The nutritional supplement is edible, safe and unlikely to harm health.
- The nutritional supplement complies with the Nutritional Supplement Regulations.

The following documents must be submitted to the MOH in order to obtain marketing approval for a nutritional supplement in Israel:

- A certificate of analysis specifying the ingredients of the nutritional supplement and their quantities.
- A document specifying the methods of analysis of the nutritional supplement.
- A document specifying the stability data of the nutritional supplement.
- The results of a microbiological analysis of the nutritional supplement.
- A document from a competent authority certifying that the manufacturer's plant is subject to its supervision and that the nutritional supplement complies with all of its requirements.

28. Are there fewer or different requirements for natural health products that have already been licensed or approved in another jurisdiction?

A homeopathic product intended for oral or external use, which has been authorised for marketing in one of the recognised countries, may be exempt from registration in Israel if it is imported into Israel in small quantities for patients of a specific pharmacy and subject to the fulfillment of the additional terms set out in MOH Guideline No. 10.

29. Is it possible to sell natural health products to or buy natural health products from other jurisdictions?

Homeopathic products can only be imported into Israel from recognised countries. The marketing of imported homeopathic products in Israel requires marketing and import authorisations (see *Question 27, Marketing*). The manufacturers of the imported homeopathic products must comply with GMP requirements.

The regulatory requirements applicable to the marketing of nutritional supplements in Israel also apply to their import (see *Question 27, Marketing*). If the nutritional supplement is imported, a CFS must be submitted to the NFS in addition to the documents mentioned in *Question 27*. These documents must be submitted for the approval of each batch of the imported supplements.

No specific restrictions are imposed on the export of homeopathic products or nutritional supplements into other jurisdictions.

Recent Developments and Reform Proposals

30. Have there been any significant recent developments or proposals for reform?

In August 2022 the Knesset (Israeli Parliament), at first reading, approved a bill to amend the Patents Act, which would introduce manufacturing and stockpiling waivers during the post-termination exercise period. The bill is still pending at the Knesset

In December 2021, the MOH published draft regulations, setting out the rules and conditions under which the Director General of the MOH will be authorised to exempt a medical device from registration. Once these regulations are enacted, the MDA will come into force (even though the MDA is already being followed by government/quasi-government hospitals and the Sick Funds.

In addition, major reforms are presently underway in relation to the medicinal cannabis industry in Israel, which will expand its ease of access.

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Publications

- *IP in Life Sciences* (Globe Business Publishing, 2015).

- *Global Patent Litigation* (Kluwer Law International, 2015).
- *Patent Transactions in the Life Sciences* (Globe Business Publishing, 2014).
- *E-Discovery and Data Privacy: A Practical Guide* (Wolters Kluwer, 2010).
- *Copyright: Global Law and Practice* (Sweet and Maxwell, 2003).

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