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Israel
Life Sciences

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This country-specific Q&A provides an overview of life sciences laws and regulations applicable in Israel.

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Israel: Life Sciences

1. Please briefly summarize your country's legislative framework for medicinal products (including biologicals), medical devices, food, and food supplements

Legislative framework:

Medicinal Products

• The Pharmacists Ordinance [New Version] 5741-1981 ("Pharmacist Ordinance") and, the Pharmacists Regulations (Preparations) 5746-1986 ("Preparations Regulations") and the Pharmacist Regulations (Good Manufacturing Practice) 5769-2008 ("GMP Regulations"), which are regulating the manufacturing, marketing, importation, exportation, registration, pharmacovigilance and prescribing of medicinal products.

• Public Health Care Ordinance, 1940, and Public Health Regulations (Medical Experiments on Humans) 5741-1980 ("Clinical Trials Regulations") regulating clinical trials.

Medical Device

• Medical Device Law, 5772-2012 ("Medical Device Law") and the Medical Device Regulations (Registration and Renewal of Medical Device in the Register), 5773-2013 ("Medical Device Regulations"), regulating the manufacturing, marketing, importation, and registration of medical devices.

While the Medical Device Law has yet to formally enter into force, the relevant actors are conducting themselves in accordance with it.

Food and food supplements

• The Public Health Protection Law (Food), 5776-2015 ("Public Health Protection Law"), the Public Health Regulations (Food) (Food Supplements), 5761-2001 ("Food Supplements Regulations") and the Public Health Regulations (Food) (Nutritional Supplements), 5757-1997 ("Nutritional Supplements Regulations").

These Law and Regulations govern the production, marketing, importation, quality and safety of food and food/ Nutritional supplements.

"Nutritional supplement" is defined in the Nutritional Supplements Regulations as : A vitamin, mineral, amino acid, plant, or other food substance approved by the director of the MoH ("Director") for consumption as food, including extracts, concentrates, components, breakdown products, derivatives, or mixtures of any of these, excluding the following: (1) A preparation registered under the Preparations Regulations; (2) A medicinal plant as defined in the Pharmacists' Regulations (Opening and Management of Pharmacies and Drug Rooms), 1982, provided it is not presented as conventional food.

Nutritional Supplements are defined in the Public Health Protection Law as "special food" and as "sensitive food" under the Public Health Protection Regulations (Food) (Declaration on Sensitive Food), 2019 and fall within the scope of "food".

For the sake of clarification: "Food supplement" is defined in the Food Supplements Regulations as a substance added to food for a technological purpose, not intended for consumption on its own as food or as an ingredient, excluding processing aids, nutritional supplements, and a flavouring or fragrance substance.

Below, we will address the term "Nutritional Supplement" instead of "Food Supplement".

2. With regards to medicinal products and medical devices, how is the regulatory process structured in your jurisdiction from R&D through market approval until post-marketing vigilance, and what rules does it follow? Please briefly describe.

The regulatory process for medicinal products and medical devices is overseen by the Ministry of Health (MoH), primarily through its Pharmaceutical Division and the Medical Devices Division.

R&D: Regarding clinical trials see Question 7.

Market Approval:

Medicinal products are subject to approval by the MoH's Pharmaceutical Division – Registration Department. Primary legislations include the Pharmacists Ordinance and related Regulations.

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The procedure adheres to MoH Circular No 08_2012 – "Application Submission Guideline for the Registration of Medical Preparations (Including Changes and Renewals)". The circular classifies pharmaceutical preparations into six groups, including new APIs, generics, and biosimilars each with specific requirements.

New products must submit a registration dossier. Applications include inter alia preclinical and clinical data, and relevant scientific publications. Some exceptions exist.

Generics are registered based on bioequivalence studies. Products already approved by leading regulatory agencies (e.g., FDA, EMA) may be eligible for an expedited process.

The rules applicable to chemical generics do not apply to biosimilars and comparative data on quality must be submitted, as well as comparative non-clinical and clinical data regarding efficacy and safety (Procedure PRA-127/04).

Medical devices are regulated under the Medical Devices Law and associated regulations. Devices must be registered with the Medical Devices Division.

For an application to register medical device manufactured in Israel that is not registered or approved for marketing in a recognized country, the applicant shall attach inter alia the following: the results of a risk management survey conducted for the device (Risk Analysis), a clinical evaluation, a dossier summarizing the clinical trials conducted on the device, and two professional opinions from medical experts in the relevant field addressing the safety and efficacy aspects of the medical device.

A medical device that has been registered or approved for marketing in a recognized country may be registered in Israel based on its registration or marketing approval in that recognized country.

Post-Market Vigilance:

Medicinal products

Regulated by the Preparations Regulations and MoH guidelines. Marketing Authorization Holders (MAHs) are required to maintain a pharmacovigilance system in line with international standards (e.g., EMA or FDA). MoH Guideline No 6 – "Reporting Adverse Events and New Safety Information" details which information should be provided and additional relevant requirements. Adverse Drug Reaction (ADR) reporting is mandatory and is overseen by the MoH's Pharmacovigilance Department. Periodic Safety Update Reports (PSURs) or Periodic Benefit-Risk Evaluation Reports (PBRER), post-marketing spontaneous reporting of individual case safety reports, and follow-up on serious side effects must also be submitted.

The MoH may impose additional conditions on registration or renewal of the preparation, such as requiring regular and ongoing supply of the preparation.

Medical devices

According to Section 11 of the Medical Device Law the device registration holder should conduct audits and evaluations of registered medical device to improve its safety and quality and report these activities to the MoH. Additionally, the registration holder should report specific incidents related to the use of the registered medical device, such as: severe malfunctions that pose health risks; use of device that caused or is suspected to have caused harm (physical or mental), unexpected adverse effects, significant injuries, or death; actions taken by international health authorities, manufacturer notifications, or new safety-related findings from scientific literature.

3. What is the regulatory process for food supplements, from first notification to the competent authorities until post-marketing vigilance in your country, and what regulations are applicable here? Please briefly describe.

The MoH, via its National Food Services (NFS), oversees the regulatory process to ensure that nutrition supplements comply with safety and quality standards and applicable regulations.

The relevant regulations are the Nutritional Supplements Regulations.

The regulations require submission of: A certificate of analysis detailing the supplement's ingredients and quantities; Documentation of testing methods; Stability data for the supplement; Results of microbiological testing; Certification from a competent authority confirming the manufacturing facility is supervised and the supplement complies with local laws. For imported supplements, in addition a certificate of free sale issued by the competent authority, pertaining to the composition of the nutritional supplement intended for import.

Market authorization:

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A nutritional supplement shall not be marketed in Israel unless it satisfies the following requirements:

- The amount of vitamin or mineral in each unit does not exceed the maximum recommended allowance.
- The Director has not determined that the nutritional supplement may pose a health risk, is unsuitable for human consumption, is not recognized as food, or has unknown safety.
- The supplement complies with the provisions of the Nutritional Supplement Regulations.

Post-marketing vigilance:

If the Director finds that a nutritional supplement has been prepared, manufactured, or labeled in violation of the regulations or that advertisements for the nutritional supplement attribute medicinal or disease-preventive properties to it, the Director may order the immediate cessation of its marketing. This shall apply provided a government physician determines that the nutritional supplement endangers or may endanger public health due to regulatory violations or misleading advertisements.

According to the Public Health Protection Law, food business operators in Israel must take immediate action if they become aware that a food product they manufactured, imported, or sold is harmful, including notifying relevant parties, withdrawing the product from the market, and issuing a public recall if necessary. They are required to report their actions to the Head of the Food Service, maintain records of health-related complaints for at least three years.

4. What are the ongoing obligations in your country after a marketing authorization for medicinal products has been obtained or a conformity assessment been carried out for medical devices?

The medicinal product registration owner must maintain a drug monitoring system, for which a physician/pharmacist with at least two years' experience will be responsible.

See Question 2 (sub-section "Post-Market Vigilance") regarding ongoing obligations for medicinal products and medical devices.

5. Which are the competent national authorities having the regulatory oversight over medicinal products, medical devices, food, and food supplements and what are their respective responsibilities?

The MoH is the main regulatory body. The MoH is the government agency responsible for public health policy and regulation in Israel. It oversees and regulates pharmaceuticals and medical devices, food and nutritional supplements, and issues guidelines relating to the various matters for which it is responsible.

The Pharmacy Division of the MoH oversees the regulation of pharmaceuticals. This includes registration and monitoring of pharmaceutical preparations or medicinal drugs, manufacturing plants, importation/exportation, advertisements, and clinical trials.

MoH's Medical Device Division (AMAR) oversees the regulation of medical devices, including registration, granting import permits, issuing documents to facilitate the export of medical devices. Supervision and control over the production, import, and marketing of medical devices.

The MoH, via the NFS is responsible for supervising all aspects of food (including nutritional supplements) in Israel.

The NFS, oversees the regulatory process to ensure that food (including nutritional supplements) comply with safety and quality standards.

The key responsibilities include establishing regulation and standards, supervising the production, importation, marketing, and distribution of food and nutritional supplements, conducting inspections to ensure compliance with health and safety regulations. Taking corrective actions, such as recalls or bans, when products are deemed unsafe. Granting licenses and permits to manufacturers, and importers of food and nutritional supplements.

Reviewing and approving new food products and nutritional supplements before they enter the market.

6. Please briefly describe the procedure of challenging regulatory decisions (e.g., denial of marketing authorization) made by the competent regulatory authority in relation to medicinal products, medical devices, and food

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supplements.

Decisions made by Israeli regulatory bodies may be subject to legal and administrative challenges.

The applicable law provides procedures to challenge decisions (administrative procedures) in certain instances. By way of example, a registered pharmaceutical preparation owner may object to the MoH's decision not to renew the registration therefor before the Director (or an authorized official). Another example is individuals seeking funding for treatments not covered by the standard healthcare package (e.g., for off-label or compassionate use), who may apply to their Health Maintenance Organisation's (HMO's) special committee. Decisions made by these committees can be appealed before the labour courts.

In addition, any Israeli citizen has the right to file an administrative appeal with the administrative courts against the decision of any authority, provided that the decision pertains to matters outlined in the Administrative Matters Courts Law of 2000. In the healthcare sector, this includes, decisions made under the Pharmacists Ordinance, the National Health Insurance Regulations of 2012, the Organ Transplantation Law of 2008, the Public Health Protection (Food) Law of 2015, and any authority's decision concerning importation under any law, including specific decisions regarding importation licences.

Moreover, governmental decisions can be challenged before the Supreme Court. The Supreme Court also hears appeals and applications for leave to appeal lodged against decisions of the district courts serving as administrative matters courts.

7. Please briefly describe the legal framework and the relevant regulatory procedure (e.g., application process, requirements, approval, denial) that applies in your jurisdiction to clinical trials for medicinal products and medical devices.

The Clinical Trials Regulations, which implement the Declaration of Helsinki, constitutes the main legal act overseeing clinical trials in Israel. Additionally, several MoH guidelines and circulars apply. The main guideline is Guideline 14 on Medical Experiments on Humans (2020), which governs the submission and approval of clinical trials.

The guideline includes the requirement that every trial, including its planning, approval, execution, documentation, and reporting, must strictly adhere to the following laws, regulations and procedures:

- the principles of the Declaration of Helsinki;
- the Clinical Trials Regulations;
- the Genetic Information Law, 2000;
- the Privacy Protection Law, 1981;
- the guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH-GCP E6);
- ISO 14155: Clinical Investigation of Medical Devices for Human Subjects;
- Directives, circulars and procedures issued by the MoH from time to time.

In addition, legislation relevant to the realm of the specific research may apply, such as the Physicians Ordinance, the Patients' Rights Law, the Medical Device Law, the Prohibition of Genetic Intervention Law (Human Cloning and Genetic Modification of Reproductive Cells), the Dangerous Drugs Ordinance and various standards.

For "Non-special medical trials" as defined in the Clinical Trials Regulations the approval process entails a dual scrutiny mechanism involving assessment by both the medical institution's Helsinki Committee and the MoH.

Generally, for "specialised medical trials", as defined in the regulations (e.g., trials on registered preparations and medical devices), approval by the institution's Helsinki Committee and institution's director is sufficient.

Trials relating to human genetics, non-natural female fertilisation, and others determined by the MoH, require the opinion of the Supreme Helsinki Committee. This committee may also approve urgent medical cases where the informed consent of a trial participant cannot be given.

Multi-centre trials are evaluated by a dedicated national committee, according to the MoH's Guideline 168 (2023).

8. Is there a public database for clinical trials in your country, and what are the rules for publication?

According to the MoH's Guideline 14, the initiation of a clinical trial is contingent upon its registration within the MoH website MyTrial.

The website will list controlled and prospective studies that involve one or more medical interventions and

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assess their effects on health outcomes (excluding healthy volunteers).

The information presented on the MyTrial website includes details on the disease/medical condition, the intervention being tested, the manner the trial is conducted, criteria for inclusion and exclusion, a list of the centres where the trial is conducted, and contact details for obtaining further information.

Exemptions to registration on the MyTrial website can be requested from the Helsinki Committee. They can be based on reasons of IP in feasibility trials, provided the trial was not registered on the USA's National Institutes of Health (NIH) website.

9. Please briefly summarize the rules that must be observed in your jurisdiction when using data from clinical trials?

The informed consent forms outlined in the MoH's Guideline 14 specify that consent to participate in a clinical trial also includes permission to transfer medical and personal data collected during the trial to external parties for processing. This information must be transferred in encoded form, without identifying details, while the link between the code and personal identifiers remains securely maintained by the principal investigator in Israel. Any modifications to these forms require approval from the Helsinki Committee.

Additionally, if trial data forms a database containing identifying information (e.g., health status), it qualifies as “sensitive data” under the Protection of Privacy Law of 1981. The use of such databases is governed by the provisions specified in the law and regulations, including:

• If an external service provider requires database access for providing a service, the agreement must comply with the Protection of Privacy Regulations (Data Security) of 2017, addressing data security implementation, confidentiality, and reporting requirements.

• Transferring data outside Israel is governed by the Protection of Privacy Regulations (Transfer of Data to Databases Outside State Borders) of 2001. These include inter alia situations where the transferee is a corporate entity controlled by the database owner, and the owner is required to ensure the protection of privacy after the transfer; where a transferee has contracted the database owner, it should commit to adhering to the conditions for maintaining and using the information applicable to a database in Israel.

In addition, MoH circulars from 2018 (1/2018, 2/2018) address secondary uses of health data and collaborations based on such data, mandating measures like de-identification, requirements for approvals, and security measures.

10. Are there any trends and/or legislative proposals in your country on digitizing the process of conducting clinical trials (e.g., digitalization of the application process, decentralization of clinical trials)?

A significant development in digitizing the process of conducting clinical trials is the launch of the MyTrial registry website by the MoH in 2017. This platform centralizes information on clinical studies conducted across various medical centers in Israel, enhancing transparency and accessibility.

Additionally, Israel is applying decentralized clinical trial methodologies, such as Direct-to-Patient (DtP) approaches. These methods aim to reduce the need for patient visits to clinical sites, thereby increasing participation and adherence.

11. What are your country's legal requirements for the authorization of manufacturing plants for medicinal products, medical devices, food, and food supplements? Please briefly describe.

According to the GMP Regulations, among other things:

- The plant should be operated by skilled professionals, including a QA manager, a responsible pharmacist, and a business manager;
- The preparations should be manufactured according to GMP and the principles of EU Directives 2003/94/EC for human preparations;
- The APIs used in manufacturing the preparation should be manufactured according to GMP and the principles of EU Directive EC/2001/83 for medicinal products for human use;
- The MoH must audit the business according to the EMA's “Compilation of Community Procedures on Inspections and Exchange of Information"; and
- The plant must have a business licence pursuant to the Business Licensing Law.

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According to the Medical Device regulations the manufacturing plant's GMP should meet the requirements of ISO 13485 and have a business licence.

According to the Public Health Regulations (Food) (Good Manufacturing Practices), 1993 among other things the plant must have a food manufacturer license, must comply with GMP standards and have a business license.

12. Please briefly describe the typical process of distributing medicinal products, medical devices, and food supplements in your country, encompassing, if applicable, the wholesale distribution of products.

Wholesale marketing of medical products can be done only by "pharmaceutical trading houses" – an entity used for storage, distribution, transportation, and wholesale marketing of preparations or raw materials. The pharmaceutical trading houses should be managed by a pharmacist approved by the MoH according to Guideline 139.

Wholesale is also allowed by institutions that were acknowledged by the Minister of Health. The Minister of Health is also authorised to allow wholesale by other entities for necessary treatment, research or registration, provided it does not harm public health.

Distribution should comply with Good Distribution Practice (GDP) according to MoH's Guideline 130 of the MoH. Storage and transportation should comply with Guideline 126 of the MoH.

Retail sale of medicinal products (prescription drugs) is allowed solely by a pharmacist in a pharmacy.

A non-prescription medicinal product that has been approved for marketing outside a pharmacy or without a pharmacist may only be sold in another business that has received approval by the district pharmacist, according to the Pharmacist Regulations (sale of medicine without a prescription not in a pharmacy or not by a pharmacist) 2004.

MoH's Guideline 56 regulates the sale of non-prescription drugs for general marketing, not dispensed by a pharmacist in a pharmacy.

A Medical device marketed in Israel shall be transported and stored by an entity holding certification from a body recognized by the Director h, confirming that its transportation conditions comply with the requirements of the ISO 9001 standard, as well as a business license for the storage and transportation of medical device in accordance with the Business Licensing law of 1968.

Retail sales of nutritional supplements include pharmacies, health stores, and online platforms.

13. Please briefly describe the pricing and reimbursement rules, if any, for medicinal products, medical devices, and food supplements in your jurisdiction?

Price Levels:

The prices of medical devices and nutritional supplements are not controlled.

Regarding pharmaceuticals, the relevant legislations are: The Order for Supervision of Prices of Commodities and Services (Maximum Prices for Prescription Preparations), 2001 and Order for the Supervision of Prices of Commodities and Services (Application of Law on Preparations), 2001. These laws stipulate as follows:

The maximum price of prescription preparations is to be determined based on pricing in several European counties.

OCT Preparations (which are dispensed by a pharmacist) require prior approval for price raising.

Regarding General Sale List (GSL) preparations (sold not by a pharmacist), it is required to provide reports regarding prices and profitability from the sales thereof.

Reimbursement from public funds:

The National Health Insurance Law, 1994 provides a lengthy list of all the healthcare services to which all residents of Israel are entitled, known as the "Health Service Basket" ("Health Basket").

Once a pharmaceutical or medical device is included in the Health Basket, it is state-subsidized and provided by HMOs. In particular cases, patients may request reimbursement for items not included in the Health Basket. Healthcare providers assess these requests individually, considering medical necessity, alternative treatments, and clinical justification.

The Health Basket is updated yearly based on cost-benefit analyses, according to the recommendations of a public committee, which are then assessed by the government before a decision is made.

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14. What legislative framework applies to the advertising for medicinal products, medical devices, and food supplements in your country?

The advertising of medicinal products and medical devices (through any means of communication) is governed by the Preparations Regulations, Pharmacist Regulations (sale of medicine without a prescription not in a pharmacy or not by a pharmacist) 2004 and Medical Device Law as well as the MoH's guidelines, including inter alia the following:

- Guideline PRA-024/04, relating to the advertisement of preparations;
- Guideline 137, relating to "Rules for improved educated use and compliance to medical treatment of prescribed medicine, through non-commercial information"; and
- Guideline 134, relating to "Raising diseases awareness rules for accessibility of information to the public, funded by the registration owner directly or by third parties".

Advertising of prescription medicinal preparations to the general public is not allowable.

Advertising of non-prescription medicinal preparations requires approval in advance from the MoH (unless it is in a professional/scientific journal).

Regarding medical devices, the MoH has the authority to set terms and restrictions on the method and content of advertising of a medical device within the framework of its registration.

The MoH can regulate advertisement of a medical device if it poses a risk to public health, imposing restrictions as needed.

Regarding nutrition supplements, according to the Public Health Protection Law, no person shall attribute to food any properties of strengthening or healing the body, any of its organs or systems, or the prevention, cure, relief, or assistance in coping with a disease or its symptoms whether through labelling or advertising.

15. What laws apply to patents and trademarks for medicinal products, medical devices, and food supplements in your country?

The main legislation relating to patents:

- Patents Law, 1967, which stipulates patent granting procedures, enforcement and protection of patents.
- The Patent Regulations (Authority Practice, Rules of Procedure, Documents, and Fees) 1968.
- The Israeli Patent Registrar circulars, and the Examination Guidelines of the Israeli Patent Office.

The Patents Law includes provisions for extending the term of pharmaceutical and medical device patents ("PTE").

Under the Patents Law, methods for therapeutic treatment of the human body are excluded from patentability.

While the Patents Law does not impose specific patentability requirements for pharmaceuticals, medical devices or nutritional supplements, the Examination Guidelines and circulars provide specific guidelines on life science-related inventions.

Israel follows a patent pre-grant opposition system, allowing third parties to oppose the grant of a patent within three months from the publication of its allowance. Generic companies and other competitors regularly monitor patent allowances to be able to submit a pre-grant opposition and by that at least delay the grant of a patent, if not prevent it or reach a settlement with the patent applicant.

Typical issues encountered in the Israeli Patent Office and courts under Israeli patent law relate to questions of the novelty and inventive step embodied in inventions such as formulations, salt forms, polymorphs, dosage regimes, and second medical uses, which are often challenged by opponents and parties seeking revocation.

The main legislation relating to trademarks:

- The Trademarks Ordinance (New Version), 5732-1972, which regulates the registration, protection, and enforcement of trademarks.
- The Trademarks Regulation, 1940.

16. Please briefly describe how patent infringements in relation to medicinal products and medical devices are addressed in your jurisdiction, including possible defense strategies and legal proceedings against patent infringements.

Patent infringement occurs when an unauthorised party exploits the invention as defined in the claims (literal

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infringement) or exploits the “essence of the invention in light of the claims" (non-literal infringements, which may be compared to the doctrine of equivalents). These principles apply equally to pharmaceutical and medical device patents.

The most common defences are non-infringement or invalidity. In addition, the unauthorised exploitation of a patented invention would not be considered infringing if it includes: Non-commercial use of the invention; Experimental use for improving the invention or developing another invention; An experimental use for obtaining regulatory licences after the expiration of the patent (a Bolar-type exception).

Additional defences may be prior use of the invention by the defendant, exhaustion of rights, and a licence having been granted.

An infringement action must be pursued by the patent owner or their registered exclusive licensee. Patent infringement actions are initiated through the plaintiff's filing of a statement of claims to the relevant district court following which, the defendant files a statement of defence, with the plaintiff allowed to file a short statement in response thereto. Discovery proceedings follow after which, the parties submit evidence, cross-examinations are held, summary briefs are submitted, and a judgment is issued. Motions for temporary remedies may be sought.

17. Does your jurisdiction provide for restrictions on the use of trademarks for medicinal products, medical devices, food, and food supplements?

Under Israeli trademark law, marks that may cause confusion with an earlier registered trademark or foster unfair competition are ineligible for protection. Additionally, descriptive trademarks and those lacking a distinctive acquired character must remain available for general industry use. Consequently, descriptive names in the food and food supplement industry, as well as international non-proprietary names (INNs) for pharmaceutical substances, cannot be registered as trademarks. In the pharmaceutical sector, trademarks undergo a stricter examination process to mitigate the risk of misleading consumers and healthcare professionals, and to ensure that the list of goods is confined solely to the intended use of the pharmaceutical product.

In the food and dietary supplements sector, the MoH enforces stringent regulations under the Nutritional Supplements Regulations to prevent trademarks from falsely implying health benefits or suggesting the presence of specific ingredients. Furthermore, the Pharmacists Ordinance and related regulations require that product packaging and labeling, including the trademarks associated with a product, provide accurate information, with restrictions on certain terms to avoid misrepresentation.

18. Please briefly describe the product liability regime for medicinal products, medical devices, and food supplements in your country.

In Israel, liability for medicinal products, medical devices, and food supplements can arise under different legal doctrines, including strict liability, negligence, and breach of statutory duties. The main relevant laws governing these forms of liability are:

Defective Products Liability Law, 1980 imposes strict liability on manufacturers if a defective product causes harm, regardless of fault or negligence.

Torts Ordinance (New Version), 1968 applies in other cases and more generally, for example when harm is caused due to negligence, e.g. a breach of the duty of care, such as inadequate safety testing, poor manufacturing practices, or inadequate warnings. The Torts Ordinance also establishes liability for breach of statutory duties, and failure to comply with legislation (e.g. see question 1).

19. Please provide a short overview of risks of liability (criminal liability, serious administrative / civil liability) and enforcement practice with regards to medicinal products (including biologicals), medical devices, foods, and food supplements.

The Pharmacist Ordinance imposes criminal liability, including one to three year imprisonment or fines, for violations of various obligations under the Ordinance. Corporate officers must supervise and take necessary measures to prevent offenses, or they face the fine prescribed for an individual for the same offense.

The MoH may also impose administrative fines for violations, such as sourcing medicinal products or raw materials from unauthorized suppliers or marketing unregistered drugs.

Similarly, the Medical Device Law provides criminal sanctions (imprisonment or fines) for registration holders, manufacturers, or marketers violating the law. However, it

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does not include stipulations regarding administrative fines. A corporate officer must supervise and take all necessary measures to prevent offenses under Section 15 by the corporation or its employees. Failure to do so may result in a fine.

The Public Health Protection Law mandates criminal penalties, including imprisonment or fines, for breaches in manufacturing, importing, and selling food. Employers and corporate officers must ensure compliance. The director of the Food Service or authorized officials may, under certain circumstances, issue administrative warnings instead of a notice of intent to impose a fine.

Civil liability may arise e.g from negligence, breach of duty, product defects, misleading representation, or warranty violations, leading to lawsuits under e.g. the Tort Ordinance (1968) or Consumer Protection Law, including class action suits for large-scale harm.

The MoH enforces regulations through e.g. inspections, audits, recalls of non-compliant products, administrative orders, fines, criminal prosecution.

20. Does your jurisdiction provide for a specific legislative and regulatory framework for digital health applications (e.g., medical apps)? If yes, please briefly describe the relevant framework.

Digital health applications are not regulated by specific legislation. However, the definition of medical device includes inter alia a device used for medical treatment, as well as a device or computer program required to operate such a device.

MoH has issued guidelines/circulars pertaining to specific aspects of digital health.

MoH Guideline 128 entitled: “Delivery and transport services for pharmaceutical products from a pharmacy through online sales or courier services", allows pharmacies to provide online ordering services for medicinal products, including prescription drugs, under certain conditions. The guideline is designed to improve patient access to medications while maintaining safety and adherence to regulatory requirements.

MoH Circular 8/2019 entitled: “Providing access to personal health data for patients – “Health in the Palm of Your Hand." Is aimed at establishing guidelines and regulations for expanding the information accessible to patients through electronic personal medical records in HMOs. The circular relates to aspects such as the obligation to provide information to the patient through an online personal health record (PHR) in the HMO, the required technical capabilities for the online personal health record in the HMO.

MoH Circular 6/2019 entitled: “Standards for Operating Remote Health Services (Telehealth-Telemedicine)" is aimed at establishing standards for providing remote health services to ensure high-quality, accessible, and readily available healthcare for patients.

The circular relates inter-alia to the following aspects: the responsibility of healthcare organizations and principles for operating remote health services, roles in the service – responsibilities and required training, the healthcare provider's responsibility in remote health services is equivalent to their responsibility during an in-person consultation.

21. Does your jurisdiction provide for laws or certain legal measures to ensure the supply of medicinal products and medical devices, or are such rules envisaged in the future? If yes, please briefly describe those rules.

The Pharmacists Regulations (Preparations) allow the Director to impose conditions to ensure the continuous supply of a pharmaceutical product as a requirement for its registration or renewal. If a product is already registered, the Director may amend these conditions at any time.

Under the Patents Law, the Israeli government has the authority to permit the use of a patent-protected invention if it is necessary for the defense of the state or for ensuring essential supply or services. This power was first exercised in the beginning of the Covid-19 epidemic in March 2020 when approval was given to exploit three Israeli patents owned by AbbVie in order to import to Israel generic versions of KALETRA (an antiretroviral drug), due to its potential effectiveness against COVID-19.

Under the Patents Law, if the government exercises its authority over a patent, the patent owner must be notified and is entitled to royalties for the authorized use of their patent.

In addition, if a patent owner abuses its monopoly, the Registrar of Patents may grant a compulsory license to an applicant seeking to exploit the patented invention, provided it is filed after three years from the patent grant or four years from the patent application date, whichever is later. This license will primarily serve the needs of the local market.

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Under the Medical Device Law, the Director may impose conditions on the registration of medical devices to ensure their regular supply to consumers. Additionally, conditions may include service and maintenance obligations. The conditions can be modified or added at any time with a reasoned decision.

22. Are there any specific compliance standards in your jurisdiction for the marketing of medicinal products and medical devices (e.g., codes of conducts of industry associations, etc.)? If yes, please give a brief overview of the relevant standards.

Israel has specific compliance standards, for example, Pharma Israel, along with its member companies, the Israel Medical Association, the Federation of Israeli Chambers of Commerce, and the Manufacturers' Association of Israel, has signed a joint ethics covenant.

This covenant governs areas such as conferences, continuing education, clinical research, financial support and donations, service provision, and the promotion of medicinal products, the roles of medical representatives, and more.

The covenant prohibits improper incentives, such as gifts or benefits that could influence clinical judgment; include rules on pharmaceutical samples, prohibiting their commercial quantities and ensuring they are not sold to patients; And states that pharmaceutical companies cannot organize a conference whose content is not medical-professional or include entertainment beyond modest and marginal cultural activities.

Post-marketing surveillance (Phase IV) studies must be scientifically or professionally justified and not used solely for marketing purposes. Promotional materials must specify the brand and generic names, active ingredients, and company/agent details responsible for marketing.

Pharmaceutical companies cannot conduct marketing activity regarding unregistered products in Israel but may share scientific information, without promotional aspects, provided they disclose the regulatory status subject to the current regulatory rules.

23. Please state 3-5 key decisions by courts or regulatory authorities that have been issued recently and that are relevant for the life sciences sector.

A. Patent Term Extension (PTE) –

In a decision of the Israeli Patent Office in Unipharm v. BMS, the relationship between the conditions for granting a PTE order, and the conditions leading to the expiry of a PTE order were examined.

Israeli PTE law includes a unique mechanism. This mechanism includes, among others, a condition commonly referred to as the "Two-State Condition". This condition requires that marketing authorization and PTEs have been granted in the USA and in at least one recognized European state, in respect of the corresponding pharmaceutical and patent, and have not yet expired.

In addition, according to the PTE law, the term of a PTE order shall lapse no later than the first date on which the extension period in respect of the reference patent lapses or any reference patent has been revoked in one of the recognized states.

In Unipharm v. BMS case, a corresponding patent in the UK was revoked and Unipharm requested that the Israeli PTE be revoked. BMS argued that even following the revocation in the UK, the conditions for grant of the PTE order continued to be satisfied, since in PTEs existed both in the USA and an additional recognized European state.

The Israeli Patent Office did not accept BMS' position, emphasizing the word "any" in the law, namely any revoked corresponding patent. No appeal was filed against this decision, and it is therefore not binding in future cases. However, it reflects the position of the Israeli Patent Office in similar cases that may come and it will probably be required to take the issue to the appellate court to change that position.

B. MoH's new framework for "enabling regulation" in pharmaceutical registration (March 23, 2025) –

The framework is designed to substantially reduce drug approval timelines in Israel and increase availability, while preserving safety and quality standards.

Key aspects of the proposed changes, include:

• Fast-track approval routes for originator and biosimilar drugs already registered by leading regulatory authorities (e.g. the FDA or EMA), reducing the timeline to a maximum of 70 or 120 days.

• A dedicated pathway for the first-time registration in Israel of generic drugs (generics that have not yet been

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registered elsewhere worldwide).

C. MoH's prioritization mechanism in pharmaceutical registration (Guideline No. 86/02, effective April 1, 2025) –

Priority may be given, for example, based on unmet medical needs, costs savings for HMOs, and for other considerations.

D. New food import regulations –

The Public Health Protection (Food) Regulations (Import of Dietary Supplements by a Proper Importer), 5785–2025, were published in late July 2025. The regulations introduce a new dedicated track for qualified "proper"importers, allowing them to efficiently obtain a prior import approval online.

24. What, if any, are the key legal and regulatory trends in your jurisdiction with regards to the digitalization of the local healthcare system and with regards to the use of artificial intelligence in the life sciences sector? Please briefly describe.

Digitalization of Healthcare system:

Israeli MoH and HMOs are regularly advancing digitalization of many aspects of the healthcare system – see the issues covered under question 19 above (MoH guidelines regarding online pharmaceutical services, patient access to personal health data, and telehealth standards).

In July 2024, Israel enacted the Medical Information Mobilization Law, 5784-2024.

The objective of the law is to establish the right of every individual to transfer their medical information, aiming to improve their healthcare and overall well-being. This includes access to innovative treatments, preventive care, and personalized, proactive medicine, while safeguarding privacy and ensuring informed consent. The substantive provisions of this law are set to take effect in July 2027.

Use of artificial intelligence:

In February 2026, the Israeli MoH published guiding principles for the evaluation of prospective interventional clinical trials involving AI tools. The document is intended to assist Helsinki Committees in conducting responsible ethical, scientific, and risk-aware assessments, while upholding core values of patient safety, privacy protection, transparency, accountability, fairness, and appropriate human oversight, alongside enabling innovation that may improve healthcare quality.

Concerning AI and patent law, in December 2025 the District Court determined that no patent applications where AI is the sole inventor and not a human inventor capable of legal acts will be registered. This decision is part of Dr Stephen Thaler's global campaign seeking recognition of an AI system (DABUS) as the sole inventor across multiple jurisdictions. The decision explicitly left open the separate question of what level of human contribution is required where AI is merely an assisting tool.

In September 2025 the Government of Israel passed a resolution establishing a National Artificial Intelligence Headquarters within the Prime Minister's Office, intended to serve as the central governmental body for accelerating and coordinating Israel's AI strategy. The decision aims to maintain and strengthen Israel's global position in AI, promote innovation, and consolidate earlier government resolutions in this field, while ensuring compliance with human rights and Israel's international commitments, including alignment with the OECD AI Principles.

25. Please briefly highlight 3-5 key developments or trends in your jurisdiction with regards to the life sciences sector as you consider them relevant. This may include legislative proposals, market activity, etc.

Patents law

The Israeli Patent Office and MoJ published in the end of 2025 the Patents Bill (Amendment No. 15), 5786–2025. The bill is the most comprehensive overhaul of Israel's patent system in decades, and include many main provisions of the proposed amendment include: examination of patent applications upon request, a new track for filing a provisional patent application, expansion of the cases in which a grace period applies, authorization of the Minister of Justice to prescribe conditions and limitations regarding divisional applications, the right to continue exploiting an invention after the reopening of the examination file, and additional remedies with respect to infringing products. More details can be find in our website here.

In addition, there is currently pending a proposal for an amendment to the Patents Law (Patents Bill (Amendment No. 14) (Increasing Competition), 5782–2022). This is a proposal that is supported by the generic industry, and which is inspired by the EU regulation 2019/933, allowing manufacture of an otherwise infringing product during

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the period of a PTE, provided that the exploitation of the invention is made for export purposes; or for marketing and stockpiling for sale in Israel, during the last six months of the period of the patent term extension, provided that any delivery of the product in Israel will be made after the expiration of the extension period.

Guidelines for Examination of patent applications – During 2025 the Israeli Patent Office conducted a round-table discussion inviting members of the public to discuss aspects related to the examination of antibodies and personalized medicine, with the aim of updating the Guidelines for Examination. Suggested Guidelines relating to personalized medicine were subsequently published and are expected to come into effect in the coming months.

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