TRADE AND DISTRIBUTION OF THERAPEUTIC PRODUCTS (PHARMACEUTICALS/BIOLOGICS AND MEDICAL DEVICES)

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REGULATORY FRAMEWORK AND COMPETENT AUTHORITIES

1. What are the principal statutes, regulations, and competent authorities that govern the import, wholesale distribution, retail sale, and export of therapeutic products (ie, for pharmaceuticals/biologics and medical devices, noting any separate or overlapping regimes)? In the case of a federal state, what is the division of powers between the federal government and the states?

In Israel, the regulation of therapeutic products (pharmaceuticals, biologics, and medical devices) is centralised under the authority of the Ministry of Health (MoH).

Israel is a unitary state and therefore has no federal/regional division of powers. Regulatory oversight is exercised nationally.

Pharmaceuticals and biologics

Pharmaceuticals and biologics are governed by the Pharmacists Ordinance (New Version), 1981, and the Pharmacists Regulations (Preparations), 1986, which establish the framework for registration, labelling, packaging, import, and distribution. Also applicable are the Pharmacists Regulations (Good Manufacturing Practice), 2008, and the Pharmacists Regulations (Sale of Preparations Without a Prescription, Outside a Pharmacy, and Not by a Pharmacist), 2004.

The MoH's Pharmaceutical Division approves and registers medicinal products, licences manufacturers and importers, supervises wholesale distribution and storage, enforces pharmacovigilance obligations, and regulates advertising and promotion.

Medical devices

Medical devices are regulated under the Medical Device Law, 2012, and the Medical Device Regulations, 2013, which include classification, registration, and licensing requirements.

The MoH Medical Device Division (AMAR) oversees device registration and import licensing, manufacturing compliance and quality compliance (such as ISO 13485 standards), vigilance reporting, recall management, and enforcement of advertising and promotional controls.

Import, distribution, and export

Manufacture and import of medicinal products require a manufacturer's or importer's authorisation, most of which are valid for five years (but can vary), subject to good manufacturing practice and business licensing requirements. Wholesale distribution and storage require MoH approval and compliance with good distribution practices. Importation of medical

devices is authorised under sections 17–18 of the MoH's Medical Device Regulations, with manufacturing and storage subject to international standards such as ISO 13485 and ISO 9001 standards.

Competent authorities:

Israel's competent authorities are: (1) the Ministry of Health – Pharmaceutical Division for pharmaceuticals and biologics; and (2) the Ministry of Health – Medical Device Division (AMAR) for medical devices.

2. How are therapeutic products classified for regulatory purposes (eg, prescription-only, over-the-counter, hospital-use, risk classes for devices, etc.) and what legal consequences attach to each classification with respect to trade and distribution? In particular, is premarket review and approval required by a competent authority?

The Pharmacists Ordinance (1981), the Pharmacists Regulations (Preparations) (1986), and the Medical Device Law (2012) define the classification of medicinal products and medical devices, the regulatory obligations attached to each category. Premarket approval processes administered by the Ministry of Health (MoH).

Medicinal products are classified as registered or non-registered. Registered products are further divided by supply category: prescription-only (Rx) medicines may only be dispensed by a certified pharmacist in a licensed pharmacy on a valid prescription, and retail dispensing outside a pharmacy is generally prohibited; pharmacist-only OTC (P) products may be sold only in pharmacies; and over-the-counter general sale list (GSL) preparations may be sold in authorised non-pharmacy outlets subject to MoH permit and conditions.

Non-registered pharmaceuticals generally cannot be marketed domestically, although they may permit limited import/manufacture/marketing for specific purposes. Medical devices are classified by risk and must be registered with AMAR before marketing. Foreign approvals from recognised jurisdictions may support registration, and AMAR may impose supply and maintenance conditions. Premarket review is required for both medicines and devices: medicines are registered via the Pharmaceutical Division under MoH Circular No. 08_2012 (including quality and pre-clinical/clinical data, with generics based on bioequivalence and biosimilars on comparability); and medical devices require AMAR registration (often expedited based on recognised foreign approvals).

Overall, product classification determines market access and distribution restrictions in Israel.

LICENSING, AUTHORISATIONS, AND DISTRIBUTION CHANNELS

3. Which licences, authorisations, registrations, or other official permissions are required for businesses to engage in wholesale distribution of therapeutic products, and what key conditions (such as Good Distribution Practice, facility standards, personnel, insurance, or financial guarantees) attach to them?

Wholesale distribution of therapeutic products in Israel is governed by the Pharmacists Ordinance (1981), the Pharmacists Regulations (Preparations) (1986), and the Medical Device Law (2012), together with MoH guidelines.

A pharmaceutical trading house is authorised for the storage, distribution, transport, and wholesale marketing of medicinal preparations or raw materials, and must be managed by an MoH approved pharmacist, in accordance with MoH Guideline 139. The wholesale distribution of medicinal products is subject to Good Distribution Practice (GDP) standards, including MoH Guideline 130 and MoH Guideline 126, and the MoH's Pharmaceutical Division supervises adherence, and may conduct ad hoc inspections without prior notice. If the MoH Director General or authorised inspectors determine that a distributor is operating in a manner which may endanger public health or is in breach of GDP regulations, they may impose enforcement measures, as detailed below in section 14.

The Pharmacists Ordinance also requires that businesses engaged in the importation or manufacture of medicinal products obtain a manufacturer's or importer's authorisation, submitted by the quality assurance manager and completed in accordance with the European Commission's Compilation of Community Procedures on Inspections and Exchange of Information – Interpretation of the Union Format for Manufacturer/Importer Authorisation, supported by evidence of Good Manufacturing Practice (GMP) compliance and a valid business licence.

For medical devices, AMAR grants the required importation and distribution authorisation under the Medical Device Regulations (2013). Manufacturing and distribution are subject to ISO 13485 standards, storage and transport must comply with ISO 9001 standards, and businesses must hold the appropriate valid business licence for these activities.

Businesses engaging in wholesale distribution of therapeutic products in Israel must obtain the relevant MoH authorisations and operate in compliance with GDP, GMP, and ISO standards.

4. Are there distinct licensing or notification requirements for businesses that provide therapeutic products directly to consumers (including community pharmacies, internet pharmacies, or other retailers), and what key conditions attach to them?

Retail distribution of therapeutic products in Israel is regulated under the regulatory framework described in the response to Question 1, above; and the Pharmacists Regulations (Sale of a Product Not in a Pharmacy or Not by a Pharmacist) 2004, together with MoH guidelines.

Prescription medicines and non-prescription medicines not listed in the general sale list for over may only be dispensed by a pharmacist in a licensed pharmacy under the Pharmacists Regulations (2004). GSL (over the counter) products may be sold by non-pharmacists or in non-pharmacy businesses with a permit issued by the MoH.

Community pharmacies must be MoH licensed and operated by certified pharmacists, subject to MoH inspection and compliance with professional and facility standards. Internet pharmacies including the online sale and delivery of medicines are regulated under MoH Procedure No. 128 (2014), as further detailed in the response to Question 5, below.

5. What rules govern the sale of therapeutic products to consumers over the internet (including social-media and marketplace platforms)?

Online sale of therapeutic products in Israel, is strictly regulated under MoH Guideline 128. Pharmacies may allow patients to order prescription medicines online and may display the price

of a medicine and provide a link to the official patient information leaflet on the MoH website. However, the promotion and advertisement of prescription drugs is prohibited, including through social media or marketplace platforms. The purpose of such restrictions is to maintain controlled extension of licensed pharmacy operations and is subject to the same consumer protection and public health standards that apply to in-person sales.

Online pharmacy must maintain a physical premises and comply with all applicable professional, technical, and data-protection standards. This is to ensure that online sales meet the same regulatory, safety, and quality requirements as traditional pharmacy operations.

IMPORT

6. What is the import-control framework for therapeutic products (eg, import licences, product registration or listing prerequisites, customs classification, tariff rates, national or regional exemptions, and routine or risk-based border inspections)?

The importation of therapeutic products into Israel is regulated under the regulatory framework described in the response to Question 1, above; together with MoH procedures governing import authorisations and quality assurance.

Under Israeli law and EU Good Manufacturing Practice principles, the import and approval of medicinal product batches for marketing are defined as manufacturing activities. Therefore, importers are treated as manufacturers and must obtain MoH a Manufacturer/Importer Authorisation (MIA) prior to importation.

A medical preparation being imported into Israel must be registered in the Israeli Drug Registry, unless it qualifies for an exemption under section 29(a) of the Pharmacists Regulations (Preparations) 1986.

The importation of a medical preparation requires MoH authorisation which must be supported by specific documentation demonstrating the product's quality, safety, and regulatory status. The application for import authorisation must include:

- a certificate confirming that the product was stored and transported under appropriate conditions;
- a Certificate of Pharmaceutical Product (CPP) issued within the past two years by a recognised country-such as United States, Canada, EU Member States, Switzerland, Norway, Iceland, Australia, New Zealand, or Japan-confirming that the product is authorised for marketing in that jurisdiction;
- the label and patient leaflet of the product; and
- confirmation that the product is registered in the Israeli Drug Registry.

The MoH will not issue an import authorisation unless the medicinal product has been transported and stored exclusively by authorised dealers in recognised countries. These requirements ensure that imported products maintain their integrity and traceability throughout the supply chain.

Imported therapeutic products are also subject to MoH oversight and inspection. The MoH may conduct ad hoc inspections to verify compliance with GDP and GMP requirements. Products which fail to meet regulatory standards may be seized, destroyed, or denied entry into the market.

7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by mail), and what quantitative limits, prescription requirements, customs declarations, duties, or other restrictions apply?

Israeli law permits consumers to import therapeutic products for personal use without registration under Regulation 29(a)(1) of the Pharmacists (Preparations) Regulations 1986, provided that imports are non-commercial and in small packages for individual use. MoH has shifted from a pre-approval system to a declaration-based process, requiring importers to sign a declaration (Form 1) confirming the product is for personal use, does not contain controlled substances, is accompanied by a valid prescription if needed, and that the importer assumes full responsibility for its use, waiving claims against the MoH.

Personal import is only permitted if five conditions are met. These are: (1) the quantity does not exceed a 90-day supply for one person; (2) the product is registered and marketed in the country of origin; (3) it is not a dangerous drug or psychotropic substance under Israeli law; (4) it is purchased from a licensed pharmacy abroad; and (5) the recipient signs Form 1 – declaration of import. For travellers, the 90-day limit applies, except for narcotic and psychotropic drugs, which are limited to 31-days and may require additional documentation, (eg, a medical certificate).

Dangerous drugs and preparations containing psychotropic substances, are strictly prohibited from personal import unless the traveller is a tourist with a valid 'Certificate for Carrying Dangerous Drugs for Travellers' from their home country, along with a prescription and original packaging. Travellers are responsible for ensuring compliance with Israeli law, as definitions of controlled substances may differ from other countries. Commonly restricted psychotropic substances include alprazolam, clonazepam, and zolpidem, while narcotics include methylphenidate, amphetamine, and morphine. Products not considered medications abroad may still be regulated as medications in Israel if they have medical properties.

8. May foreign suppliers ship therapeutic products directly to consumers via e-commerce or mail order, and what local presence, platform registration, verification, or labelling obligations – if any – must they satisfy?

Noting the above personal use exception, foreign suppliers are not permitted to sell or ship therapeutic products directly to Israeli consumers through e-commerce or mail-order channels. Only licensed Israeli importers, manufacturers, and pharmacies may engage in the sale or distribution of therapeutic products.

Online sales are limited to licensed Israeli pharmacies operating under MoH supervision. According to MoH Guideline 128, as detailed in the response to Question 5, above.

All therapeutic products marketed in Israel must comply with local labelling and packaging requirements, as detailed in the response to Question 12, below.

In practice, foreign suppliers must partner with a local licensed importer or pharmacy to access the Israeli market and must adhere to Israel's stringent authorisation, verification, and labelling obligations.

9. How is parallel importation (i.e., of products licensed and sold in other jurisdictions) of therapeutic products by businesses regulated, particularly with respect to intellectual-property rights, product re-labelling or re-packaging, and requirements to maintain original quality, safety, and traceability?

Parallel importation of therapeutic products in Israel is regulated under the Pharmacists Ordinance (1981) and supervised by the MoH. It permits import of medicinal products licensed and sold abroad, subject to strict quality, safety, and traceability conditions.

From a regulatory perspective, the parallel import of 'matching preparations' (a drug identical to the Israeli-registered product and manufactured by the same manufacturer, even if produced at a different facility) is explicitly allowed under the Pharmacists Ordinance. Parallel importation requires marketing authorisation but is exempt from full drug registration. Importers must obtain an import permit from the MoH Parallel Import Department before engaging in such trade.

To maintain integrity and traceability, imported preparations must be transported and stored exclusively by authorised dealers in recognised countries. Documentation must confirm that the product was stored and transported under appropriate conditions and that it is equivalent in quality and composition to the Israeli-registered version.

Parallel importation of patented goods may in certain cases constitute patent infringement in Israel and as a result, parallel importation typically focuses on non-patented or off-patent products to avoid infringement risks.

The regulations do not specify separate rules for relabelling or repackaging parallel-imported products. Nevertheless, imported goods must retain all mandatory labelling information – manufacturer details, batch number, expiry date, and other identifiers – consistent with the Pharmacists Regulations (Preparations) (1986). Any modification must preserve the product's traceability and quality.

EXPORT

10. Are there quantitative quotas, permits, or other measures that restrict or condition the export of therapeutic products (eg, to mitigate shortages or address public-health emergencies), and how are such measures administered and enforced?

Israel's regulatory framework allows the export of therapeutic products under specific authorisations issued by the MoH but does not establish general export quotas or numerical limits. However, the MoH retains authority to impose export-related conditions or restrictions when necessary to protect public health or ensure the continuous domestic supply of essential medicines and medical devices.

Under the Pharmacists Regulations (Preparations) 1986, certain medical products may be manufactured or imported for export purposes without full domestic registration. These 'export-only' authorisations allow companies to produce therapeutic products exclusively for foreign markets, provided the activity is approved by the MoH and does not endanger public health. Similarly, the Medical Device Law empowers the Minister to issue regulations granting exceptions to registration for export-only devices.

Although no formal export quotas are specified, the MoH may impose conditions on the registration or renewal of medicinal products to ensure regular and ongoing domestic supply. The Director of the MoH may amend these conditions at any time to prevent shortages or maintain the availability of essential medicines. This authority effectively enables the MoH to restrict or delay exports when necessary to protect domestic supply during public-health emergencies or shortages.

The Medical Device Law provides a similar mechanism for medical devices, allowing the MoH to impose or modify conditions on registration to ensure regular supply, service, and maintenance in Israel.

Enforcement is carried out through MoH inspections of manufacturers and distributors to verify compliance with registration conditions and supply obligations. In cases of non-compliance, the MoH may suspend or revoke authorisations, ban export, or seize and destroy non-compliant goods.

11. Is there any form of 'export-only' or 'dual-labelling' authorisation that permits the manufacture and export of therapeutic products not approved for domestic marketing, and if so, what standards, labelling, or record-keeping obligations apply?

Israel's regulatory framework provides an 'export-only' authorisation that permits the manufacture and the export of therapeutic products not approved for domestic marketing.

The MoH may allow specific preparations to be imported or manufactured for export purposes without full domestic registration. Similarly, the Medical Device Law allows the Minister to issue regulations that exclude certain types of medical devices from the registration requirement for purposes such as export.

Key standards and obligations

Good Manufacturing and Distribution Practices (GMP/GDP)

Products intended for export must be manufactured under Good Manufacturing Practice (GMP) standards. Export activities must be conducted under Good Distribution Practice (GDP) standards.

Prevention of diversion

For medicinal products intended for export that are not registered in Israel, appropriate measures must be taken to prevent their distribution in the Israeli market.

Labelling and packaging

The provided regulations do not specify rules for 'dual-labelling' or unique record-keeping obligations specifically for export-only products. The general requirements for documentation under the GDP framework apply, which include maintaining procedures, instructions, contracts, and records.

LABELLING, TRACEBILITY, AND PRODUCT INFORMATION

12. What local language labelling, patient information, unique device identification, serialisation, anti-counterfeiting, or traceability requirements must be met before imported therapeutic products may circulate domestically or before therapeutic products may be exported?

Labelling, patient information, and traceability for therapeutic products in Israel are governed by the MoH under the Pharmacists Regulations (Preparations) (1986) and the Medical Device Regulations (2013). These requirements must be met before imported medicinal products or medical devices may circulate domestically or be exported.

Labelling and patient information for medicinal products

Imported medicinal products must comply with local language and content requirements to ensure accessibility and transparency for patients and healthcare professionals. Packaging must include:

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

Each product must also include a patient information leaflet in Hebrew and Arabic, as required under section 20 of the Pharmacists Regulations (Preparations). These multilingual requirements ensure that patients receive clear and accurate information regarding the safe and effective use of medicinal products.

Labelling and identification for medical devices

The Medical Device Regulations (2013) sets out mandatory labelling and identification obligations for medical devices. The packaging or leaflet must specify:

- the device's name and indication;
- the date and country of manufacture;
- any warnings relevant to the device's use; and
- a serial or batch number for traceability.

These requirements form the foundation of Israel's traceability system for medical devices, enabling regulators and manufacturers to identify and track products throughout their lifecycle.

Import documentation and authorisation requirements

Before a therapeutic product can be imported into Israel, the importer must obtain MoH authorisation and provide documentation confirming compliance with quality and safety standards, including the documentation listed in the response to Question 6, above.

The MoH will not issue an import authorisation unless the product has been transported and stored exclusively by authorised dealers in recognised countries. These measures ensure that imported products meet international standards for quality and integrity before entering the Israeli market.

Traceability and anti-counterfeiting measures

While Israel does not currently operate a dedicated serialisation or anti-counterfeiting system, traceability is ensured through batch and serial number requirements for both medicinal products and medical devices, combined with MoH oversight of import authorisations, quality certificates, and distribution practices. Together, these mechanisms provide a robust safeguard against counterfeiting and enable effective product tracking throughout the supply chain.

Export requirements

For export, AMAR issues documentation confirming compliance with registration and quality standards to facilitate the export of medical devices. Similarly, the export of medicinal products requires that the product be registered and authorised under the Pharmacists Regulations and supported by the relevant MoH certification.

PRICING, REIMBURSEMENT, AND MARKET ACCESS

13. Are there any price-control, reimbursement, public procurement, or stock/supply-obligation regimes that (while not trade measures per se) materially influence the distribution channels or availability of therapeutic products?

Price control regime for medicinal products

The prices of prescription medicinal products in Israel are regulated under the Supervision of Prices of Goods and Services Act 5756-1996, the Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations) 5761-2001, and the Order for the Supervision of Prices of Goods and Services (Application of the Act to Preparations) 5761-2001. Under these instruments: (1) for innovative products without generic equivalents, the maximum price is set as the average of the three lowest prices among Hungary, Spain, France, Belgium, the UK, Germany, and the Netherlands; (2) for innovative products with generic equivalents and for generic products, any increase in the maximum price requires a petition and MoH approval.

These pricing controls directly affect the commercial terms under which products are distributed and sold, ensuring affordability while limiting pricing flexibility for manufacturers and distributors.

Reimbursement and the national health basket

The National Health Insurance Law (1994) establishes Israel's National Health Basket, which defines the medicines, medical devices, and technologies that must be provided by the four statutory Health Maintenance Organisations (HMOs). Key features include:

- products included in the Health Basket are state-subsidised and supplied through the HMOs' own or affiliated pharmacies;
- patients may request reimbursement for products not included in the Basket, with each request assessed individually based on medical necessity, alternative treatments, and clinical justification; and
- the Health Basket is updated annually following cost-benefit analyses and recommendations by a public committee, subject to government approval.

The reimbursement structure shapes distribution channels by concentrating supply through the HMOs and influencing which products achieve broad market penetration.

Public procurement and price negotiation

Pharmaceutical companies typically negotiate prices with the MoH as part of the process of introducing new drugs or technologies into the Health Basket. These negotiations, combined with the annual Health Basket review, function as a de facto public procurement mechanism, determining which products are widely distributed through the national healthcare system.

Supply obligations

The MoH may impose conditions on the registration or renewal of medicinal products to ensure their regular and ongoing supply. The MoH Director may amend these conditions at any time to prevent shortages and maintain continuous availability of essential medicines. Similarly, the Medical Device Law, authorises the MoH to impose conditions on the registration of medical devices to ensure their regular supply, service, and maintenance. These obligations ensure that both medicinal products and medical devices remain consistently available in the domestic market, even when commercial incentives might otherwise limit supply.

Impact on distribution and availability

Together, these regimes – price control, reimbursement through the Health Basket, public procurement negotiations, and mandatory supply obligations – create a tightly regulated environment that directly influences how therapeutic products are priced, distributed, and accessed in Israel.

While not trade measures per se, they determine market entry conditions, distribution priorities, and availability levels across the healthcare system, ensuring affordability and continuity of supply for patients nationwide.

ENFORCEMENT, COMPLIANCE, AND RECENT DEVELOPMENTS

14. What investigative powers, sanctions, and remedial measures (administrative, civil, or criminal) are available to regulators when they detect non-compliance with trade and distribution rules for therapeutic products, and how are these powers used in practice?

The Israeli regulatory framework provides the MoH and other competent authorities with extensive powers to investigate, sanction, and remedy non-compliance in the trade and distribution of therapeutic products.

Investigative and supervisory powers

The MoH's Pharmaceutical Division is the primary body supervising the distribution of medicines. Under the GDP Regulations and MoH Procedure No. 130, the Director General of the MoH and authorised officials from the GMP Oversight Unit may conduct ad hoc inspections without prior notice at the premises of distributors to verify compliance with GDP standards.

If a distributor is found to be operating in a manner that endangers public health or violates GDP requirements, the MoH is empowered to:

- ban the sale of the relevant medicinal products or active ingredients;
- seize and destroy the products; and
- cancel, suspend, or refuse to renew the manufacturer/importer authorisation (MIA).

These measures are designed to ensure that the quality and safety of medicinal products are maintained throughout the supply chain.

Administrative and criminal sanctions

Violations of the Pharmacists Ordinance relating to the manufacturing, importation, and wholesale distribution of medicinal products are subject to both criminal and administrative penalties. These include:

- imprisonment of up to one year; or
- fines of up to NIS 75,300 (approx. US$26,000); and
- administrative fines of up to NIS 75,000 for certain breaches.

In addition, directors and officers of companies may be fined up to NIS 29,200 (approx. US$10,000).

Under the Medical Device Law, similar sanctions apply to violations involving medical devices. Fines can reach NIS 226,000 (or double for corporations), and imprisonment of up to one year may be imposed. The Medical Device Law, however, does not provide for administrative fines but allows for criminal prosecution and suspension or revocation of authorisations.

The Public Health Protection (Food) Law (2015) also establishes criminal penalties, including imprisonment or fines, for breaches in the manufacturing, importation, or sale of food and nutritional supplements. Employers and corporate officers must ensure compliance, and the Director of the Food Service may issue administrative warnings instead of fines in certain cases.

Civil liability and remedies

In addition to administrative and criminal enforcement, civil liability may arise under the Tort Ordinance (1968) or the Consumer Protection Law (1981). Liability may result from negligence, breach of statutory duty, product defects, misleading representation, or breach of warranty, potentially leading to compensation claims or class actions. In some cases, courts may award punitive damages.

Enforcement practice

The MoH enforces compliance through inspections, audits, product recalls, administrative orders, fines, and criminal prosecutions. These enforcement tools are applied across the entire supply chain – from manufacturers and importers to distributors and retailers – to safeguard public health and ensure adherence to regulatory standards.

Additionally, the Israel Competition Authority (ICA) plays a complementary role in enforcement where anti-competitive conduct intersects with the pharmaceutical sector. The ICA has the

authority to impose substantial administrative fines, initiate criminal proceedings, and conduct its own investigations into abuses of monopoly power or unfair pricing practices.

15. Is there recent case law, legislative or policy developments, noteworthy enforcement trends, or anticipated reforms that may significantly alter the regulation of trade, distribution, or cross-border movement of therapeutic products in the future?

Several recent legislative, regulatory, and policy developments are expected to influence the regulation of trade, distribution, and cross-border movement of therapeutic products in Israel. These are outlined below.

Amendment to the Pharmacists Ordinance (Amendment No. 37) – 2024 Israel's

'What is Good for Europe is Good for Israel' reform allows importers registered as 'proper importers' to bring in cosmetic products legally marketed in EU member states, Switzerland, or the UK through a streamlined import process. The reform aims to facilitate imports, increase competition, and reduce consumer prices while maintaining product safety standards.

Healthcare Services Quality Assurance Law (2025 Draft Bill)

Published by the MoH in January 2025, this draft bill seeks to enhance compliance and enforcement powers, expand the MoH's authority over healthcare institutions and HMOs, and introduce financial penalties for non-compliance. If enacted, it will strengthen regulatory oversight across the supply and distribution chain of medicinal products.

Forthcoming Pharmacy Infrastructure and Non-Prescription Sales Reforms

Under the 2023 'Enabling Regulation' framework, the MoH announced plans to update pharmacy infrastructure regulations and expand the sale of GSL (over the counter) medicines outside pharmacies. These anticipated reforms, outlined by the Director of the Pharmaceutical Division on 3 February 2025, are expected to reshape domestic distribution channels and modernise retail access to non-prescription medicinal products.

Amendment to the Controlled Substances Regulations (1980, approved January 2025)

In January 2025, the Knesset Health Committee approved a major amendment to the Controlled Substances Regulations (1980), tightening oversight of opioid prescriptions and mandating electronic prescriptions via HMOs. The amendment also introduces limited flexibility for certain medications (eg, ADHD, narcolepsy, and eating-disorder treatments). While primarily domestic in scope, the reform reflects a broader policy trend toward stricter monitoring and control of therapeutic substances, which may indirectly affect importation and distribution practices.

New Expedited Medicinal Product Registration Pathways (2025 pilot programme)

Effective March 2025, the MoH introduced a pilot programme establishing three reliance-based registration routes for innovative, biosimilar, and generic medicinal products. These routes rely on prior approvals from leading international regulators such as the FDA, EMA, MHRA, HC, SMC, and TGA, aiming to streamline cross-border regulatory reliance and accelerate market

entry for imported medicinal products. The programme reduces duplicative review processes while maintaining public-health safeguards.