# 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?**

Japan regulates the import, wholesale distribution, retail sale, and export of pharmaceuticals (including biologics), medical devices, and regenerative medicine products (*saisei iryo-to seihin*) (collectively, 'therapeutic products') under a unified national framework established by the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices. This is commonly known as the Pharmaceuticals and Medical Devices Act, or PMD Act. This statute serves as the principal legal foundation for all commercial stages of therapeutic product handling and is supplemented by cabinet orders, ministerial ordinances, and administrative guidelines, together with fair competition codes and voluntary rules issued by relevant industry organisations.

Several other laws may apply in addition to the PMD Act, depending on the characteristics of the product or the nature of the business. These include: (1) the Pharmacists Act, which governs the licensing and duties of pharmacists and the establishment of pharmacies; (2) the Poisonous and Deleterious Substances Control Act; and (3) the Narcotics and Psychotropics Control Act.

Japan is a unitary state and does not have a federal system. National regulatory authority resides with the Ministry of Health, Labour and Welfare (MHLW), which is responsible for policy-making, regulatory oversight, and the issuing of licences and marketing authorisations under the PMD Act. The Pharmaceuticals and Medical Devices Agency (PMDA), established under the Act on Pharmaceuticals and Medical Devices Agency, Independent Administrative Agency, operates under MHLW's supervision and is entrusted with technical tasks related to import, export, distribution, and post-marketing regulation. Prefectural bodies are also delegated administrative responsibilities, including the licensing of wholesalers, retailers, and pharmacies, and conducting local inspections, under Article 1-3 of the PMD Act. Unless otherwise noted, all article references below are to the PMD Act.

**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?**

Under the PMD Act, pharmaceuticals (including biologics) are classified into three main types: (1) pharmacy-only pharmaceuticals (*yakkyoku iyakuhin*, Art 4(5)(ii)); (2) pharmaceuticals requiring guidance (*yo-shido iyakuhin*, Art 4(1)(iii)); and (3) over-the-counter (OTC) pharmaceuticals (*ippan-yo iyakuhin*, Art 4(5)(iv)). Pharmaceuticals that must be sold by a pharmacist include pharmacy-only pharmaceuticals, pharmaceuticals requiring guidance, and Category 1 OTC pharmaceuticals. Among these, a face-to-face explanation by a pharmacist at the time of sale is specifically required for pharmacy-only pharmaceuticals and pharmaceuticals requiring guidance (Arts 9-3, 36-4, 36-6 and 36-9).

There are two types of pharmacy-only pharmaceuticals: (1) ethical drugs, which are prescription medicines supplied through pharmacies or medical institutions; and (2) pharmacy-made pharmaceuticals (*yakkyoku seizo hanbai iyakuhin*, Arts 2(17)(3) and 80(7), and Art 3 of the Order for Enforcement of the PMD Act), which are prepared and sold by pharmacies for individual patients. Ethical drugs are further categorised into prescription-only drugs and generic drugs.

Pharmaceuticals requiring guidance include: (1) products designated as poisonous or deleterious substances under separate legislation; (2) newly reclassified drugs switching to OTC immediately after their transition from prescription status; and (3) newly introduced direct OTC drugs with limited clinical experience or safety data.

OTC pharmaceuticals are divided into three categories according to risk levels: (1) Category 1, which includes the highest-risk products and requires pharmacist involvement during sale; (2) Category 2; and (3) Category 3, which includes the lowest-risk products (Art 36-7).

under Japanese law, in vitro diagnostics are also regulated as pharmaceuticals – not medical devices, and are defined separately as pharmaceuticals not intended for direct application to the human body (*taigai shindan-yo iyakuhin*, Art 2(14)). Nevertheless, they are regulated in practice in a manner similar to medical devices, particularly in terms of classification and quality standards. Therefore, for the purposes of this survey, in vitro diagnostics are treated as distinct from pharmaceuticals.

Medical devices are similarly classified into three types based on risk levels and intended use: (1) general medical devices (*ippan iryo kiki*, Art 2(7)), corresponding to Class I; (2) controlled medical devices (*kanri iryo kiki*, Art 2(6)), corresponding to Class II; and (3) specially controlled medical devices (*kodo kanri iryo kiki*, Art 2(5)), corresponding to Class III and IV, with Class IV, representing the highest risk.

Under the PMD Act, a regenerative medicine product (*saisei iryo-to seihin*) refers to a product used in human or veterinary healthcare, that is: (1) derived from processed human or animal cells – such as those cultured or otherwise modified – for the purpose of reconstructing, repairing, or forming bodily structures or functions, or treating or preventing disease; or (2) intended for the treatment of disease through the introduction of genes into human or animal cells for expression within the body (Art 2(9)).

A business licence is required to engage in the manufacture, import, or sale of therapeutic products, and an approval, certification, or notification – either by or to PMDA or MHLW, depending on the product classification – is required for each product falling within the aforementioned categories. Selling such a product without the required business licences or product authorisation may result in imprisonment or other statutory penalties.

## 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?**

To engage in the business of marketing therapeutic products, a person is required to obtain an appropriate licence from the MHLW (Art 12(1) for pharmaceuticals, Art 23-2(1) for medical devices and in-vitro diagnostics, and Art 23-20(1) for regenerative medicine products). To obtain such a licence, the applicant must comply with orders of the MHLW concerning: (1) the standards of quality control specified in the Ministerial Ordinance on Standards for Quality Assurance for Pharmaceuticals, Quasi-drugs, Cosmetics and Regenerative Medicine Products (GQP Ordinance) for pharmaceuticals and regenerative medicine products, and in the Ministerial Ordinance on the Standards for the System for Conducting Operations Relating to the Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Drugs (QMS Ordinance) for medical devices and in-vitro diagnostics; and (2) the standards of post-marketing safety control specified in the Ministerial Ordinance on the Standards for Post-marketing Safety Control of Pharmaceuticals, Quasi-drugs, Cosmetics, Medical Devices and Regenerative Medicine Products (GVP Ordinance) (Art 12-2(1), etc.). In addition, a marketing authorisation holder must appoint individuals who satisfy the qualifications or experience requirements prescribed by ministerial ordinances, including marketing directors (Art 17 for pharmaceuticals, Art 23-2-14 for medical devices and in-vitro diagnostics, Art 23-34 for regenerative medicine products, etc.).

To engage in wholesale distribution business of selling pharmaceuticals, in vitro diagnostics or regenerative medicine products to non-end consumers (eg, medical institutions, pharmacies or other required licence holders), a person is required to obtain a wholesale distribution licence from the prefectural governor for the place where a business office is located (Arts 25(iii), 34(1) and 40-5(1), etc.). To obtain the licence, the structure and equipment of the business must comply with applicable regulatory standards, including cleanliness, minimum floor space, adequate lighting, and appropriate storage (Arts 3 and 5-2 of the Regulations for Buildings and Facilities for Pharmacies ('Regulations for Buildings and Facilities')). Generally, wholesale distributors are required to place a pharmacist at each business office and have them manage the business office (Art 35(1)).

Moreover, the Good Distribution Practice Guidelines outline the distribution management practices for marketing authorisation holders and wholesale distributors from when pharmaceuticals are shipped to the market until they reach medical institutions, pharmacies or store-based distributors.

There is no concept of a wholesale distribution licence or notification for medical devices. The same licences or notifications apply regardless of whether the business is conducted on a wholesale or retail. The requirement to obtain a licence or make a notification depends on the classification of the medical device (Art 39(1) and Art 39-3(1)).

**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?**

For pharmaceuticals and in vitro diagnostics, to end users, a pharmacy may sell any pharmaceuticals, including: pharmacy-only pharmaceuticals; a person with a store-based distribution licence (ie, drugstore) may sell pharmaceuticals requiring guidance and OTC pharmaceuticals; and a person with a household distribution licence may sell OTC pharmaceuticals only. A person may obtain a licence from the governor of the territory in which the business is located (Arts 4, 25(i) and (ii),26 and 30). Household distribution refers to a sales method in which pharmaceuticals are placed in advance at the consumer's residence, and payment is collected for the quantities actually used by the consumer.

For medical devices, a person must obtain a sales business licence to sell highly specially controlled medical devices, or file a sales business notification to sell controlled medical devices, to end users (Arts 39 and 39-3).

To obtain such licences, the business must meet regulatory standards concerning its structure and equipment (eg, appropriate access and layout, minimum floor space, adequate lighting and ventilation, and secure and hygienic storage of products) as well as its business operation system (eg, staffing, business hours coverage, and safety management) (Regulations for Buildings and Facilities; Ministerial Ordinance Prescribing the System for Conducting Operations in Pharmacies, Shop Sales Businesses, and Household Distribution Businesses).

Regenerative medicine products may not be sold directly to general consumers (Art 40-5(7)).

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

Proprietors of pharmacies or store-based distributors who have notified the relevant prefectural governors, at the time of obtaining their licences, of their intention to conduct internet sales are permitted to sell OTC pharmaceuticals via the internet (Arts 4(3)(iv)(b) and 26(3)(v)). However, pharmaceuticals requiring face-to-face provision of information and instructions may not be sold online.

When pharmacies or store-based distributors intend to sell OTC pharmaceuticals via the internet, they need to comply with additional requirements regarding the structure and equipment of their premises to ensure proper regulatory oversight (Arts 1(1)(xvi) and 2 (xiii) of the Regulations for Buildings and Facilities).

There are no specific regulations regarding sales of medical devices over the internet.

Platformers offering sales platforms are generally not considered as 'sellers' under the PMD Act. However, depending on the actual distribution flow, where a platformer is assessed as acting beyond a mere platform provider, it may be regarded as a seller, and the distribution of therapeutic products without the required licences may be deemed illegal.

## 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)?**

In principle, the commercial importation of therapeutic products in Japan requires the appropriate licences under the PMD Act. While limited imports for non-commercial purposes, such as the importer's own use, are treated differently (see response to Question 7, below), a person importing therapeutic products for sale must obtain a marketing authorisation holder licence for each product category. In addition, if the importer performs final packaging, Japanese-language labelling, storage, or testing and inspection, a manufacturing licence is required, or, in the case of medical devices and in vitro diagnostics, registration is required instead. Furthermore, the sale, lease, or provision of therapeutic products constitutes the marketing of therapeutic products (Art 2(13)). Accordingly, imported therapeutic products are subject to the same product-specific authorisation requirements as domestically manufactured products and may not be imported for sale or provision in Japan without the required authorisation.

If therapeutic products marketed in Japan are manufactured at facilities outside Japan, each such facility must obtain foreign manufacturer certification (for pharmaceuticals and regenerative medicine products) or registration (for medical devices and in vitro diagnostics). (Art 13-3, 23-2-4 and 23-24).

From a humanitarian perspective, customs duties on therapeutic products are often exempted or set at a low rate, with tariff classification and codes determined under the Customs Act. At import customs clearance, the importer must demonstrate compliance with the PMD Act, including holding the required licences and having obtained the necessary product authorisations.

**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?**

Importing therapeutic products solely for non-commercial purposes, such as the importer's own use, and not for sale or provision to a third party, falls outside the scope of regulation under the PMD Act.

To prevent the importation of therapeutic products that have not been authorised in Japan for distribution purposes, Japan has established an Import Confirmation System under which the regulatory authorities confirm in advance that the purpose of importation is not sale or provision within Japan (Arts 56-2, 64, and 65-4). Under the Import Confirmation System, importers of unauthorised therapeutic products are, in principle, required to obtain confirmation from the MHLW (Art 56-2(1)). If the authority determines that there is a risk that the importation is intended for sale or provision, such an importation is not permitted. (Art 56-2(2)) Where the purpose of importation is categorically recognised as being other than sale or provision, such as where the products are imported in small quantities for personal use, the products may be imported without obtaining import confirmation. (Art 56-2(3))

With respect to the customs clearance of therapeutic products for products subject to the Import Confirmation System, customs verifies that the required confirmation from the MHLW has been obtained. If such confirmation has not been obtained, customs clearance of the relevant therapeutic products will not be permitted. Customs declarations, tariff classification, and customs duties and VAT are governed by the general rules of the Customs Act.

**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?**

Where a foreign company without a place of business in Japan intends to sell therapeutic products manufactured abroad, the foreign company itself may obtain marketing authorisation for such products (Arts 19-2, 23-2-17, 23-2-23, and 23-24). In such cases, however, the foreign company is required to designate a business operator located in Japan to act as its marketing authorisation holder (a 'Designated Marketing Authorisation Holder' or D-MAH). As a general rule, the D-MAH, rather than the foreign company that obtained the marketing authorisation, assumes the responsibilities imposed on a marketing authorisation holder under the PMD Act.

Notwithstanding the above, in the case of medical devices or in vitro diagnostics, a foreign company that has obtained marketing authorisation is responsible for establishing and operating the quality management system (Art 114-58 of the Regulation for Enforcement of the PMD Act, Art 2(1) of QMS Ordinance). Within this framework, the D-MAH is responsible for carrying out operations within Japan, but the foreign company which obtained the marketing authorisation remains responsible for ensuring that the D-MAH properly performs such operations (Art 72-3 of the QMS Ordinance).

**9. How is parallel importation (ie, 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?**

In Japan, parallel importation of therapeutic products for commercial sale is only permissible if the importer is a marketing authorisation holder (see response to Question 6, above) and complies with all regulatory obligations applicable under the PMD Act, including those relating to labelling, package inserts, quality, safety, and traceability.

**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?**

There are no export quotas, permits, or other measures restricting or conditioning the export of therapeutic products even in case of shortages or public health emergencies. For provisions concerning the securing of supply in the event of a shipment suspension, see response to Question 13, below.

However, exporting certain active pharmaceutical ingredients – particularly those used as raw materials for narcotics or psychotropic drugs – requires prior approval from the Minister of Economy, Trade and Industry under Japan's export control laws.

**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?**

No additional licences or authorisations are required where an appropriately licensed manufacturer exports a product with the requisite marketing authorisation in Japan. However, if an export product differs from the domestically distributed product in terms of the approved items or manufacturing site, an export notification for the relevant product must be submitted to the PMDA no later than three months before commencement of manufacture or import. In addition, an export notification is also required where the export product is otherwise identical to the domestically distributed product but differs in labelling (foreign language) or packaging configuration (Arts 74 through 74-3 of the Order for Enforcement of the PMD Act).

Because export activities require compliance with the regulatory requirements of the destination country, and therefore cannot be regulated under the same standards applicable to domestically distributed products, to the extent activities are conducted in accordance with the such relevant export notification, certain labelling and distribution regulations – such as requirements to publish information on dosage, administration, and other precautions for use and handling, to establish systems for providing such information, and to make related notifications – do not apply to: (1) the manufacture or import of therapeutic products conducted for export as a business; or (2) the sale, provision, storage, or display for export of therapeutic products manufactured or imported as a business.

Manufacturers exporting certain therapeutic products must undergo a written or on-site inspection every five years to confirm compliance with applicable manufacturing and quality control standards. This applies to: (1) pharmaceuticals; and (2) medical devices and in-vitro diagnostics where certification has been requested by a foreign government or an international organisation, and to all regenerative medicine products intended for export, regardless of any such request (Art 80).

## 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?**

It is necessary to provide labelling which provides users of therapeutic products with information sufficient to identify and distinguish the products for their proper use, including: the name and address of the marketing authorisation holder; the name of the therapeutic products; the manufacturing lot number; indications identifying the category of the therapeutic products; and the expiry date (collectively, 'Statutory Labelling') (Art 50). Statutory Labelling must be fixed to the immediate container or immediate packaging of the therapeutic products (Arts 50, 63, and 65-2).

In addition, marketing authorisation holders are required to prepare information on precautions and other matters (collectively, 'Precautionary Information') to be provided to users to ensure the proper use of therapeutic products. Such Precautionary Information includes: information on dosage and administration; warnings, including cases in which fatal or extremely serious adverse reactions may occur; contraindications identifying patients to whom the product must not be administered; information requiring special caution in use that does not fall under contraindications; interactions with concomitantly used pharmaceuticals; adverse reactions; and other information relating to precautions for use and handling (Arts 52(1)). Such information is publicly available on the PMDA's website.

To prevent product mix-ups, ensure traceability, and improve distribution efficiency, barcode labelling has been made mandatory in Japan for prescription pharmaceuticals, in vitro diagnostics, medical devices, and regenerative medicine products. Depending on the product type and packaging unit, barcodes are required to include the product code, expiry date, manufacturing lot number or symbol, and quantity (Art 68-2-5).

The sale of therapeutic products without the required information or prescribed barcode labelling is prohibited (Arts 55(1), 64 and 65-4).

## 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?

The prices of those therapeutic products covered by public health insurance are listed under the insurance price list. Marketing authorisation holders have no pricing discretion other than submitting relevant supporting materials in the price listing process. The prices are determined by the MHLW based on advice from the Central Social Insurance Medical Council *(chuikyo).*

Marketing authorisation holders of 'specified pharmaceuticals' (pharmaceuticals designated by the MHLW as requiring a particularly stable supply due to their medical importance; Art 2(17)) must promptly report to the MHLW if they decide to suspend or restrict shipments within the following six months, or if there is a risk that such suspension or restriction may occur (Art 18-3). When shipments are actually suspended or restricted, the marketing authorisation holder must promptly notify the MHLW, and the MHLW will publicly disclose the information contained in such notifications (Art 18-4). On receiving a report or notification, or where otherwise necessary for public health purposes, the MHLW may request additional information from relevant parties regarding the manufacturing, importation, or sale of the specified pharmaceuticals or substitutable products (Art 18-5).

The MHLW may also request marketing authorisation holders, manufacturers, wholesale distributors or other relevant parties to cooperate in ensuring the supply of the specified pharmaceuticals or substitute pharmaceuticals where it determines that a shortage of specified pharmaceuticals exists or is likely to occur, and may make it difficult to provide appropriate medical care, thereby posing a risk to life and public health. (Art 36(1) of the Medical Care Act).

Under the Japan's National Health Insurance drug pricing framework, marketing authorisation holders of prescription pharmaceuticals that wish to discontinue the supply and have the products delisted from the insurance listing are expected to obtain prior written consent from substitute suppliers agreeing to supply substitute pharmaceuticals, as well as written consent from academic societies in the clinical fields in which the pharmaceuticals are used.

Recently, attention has been focused on the impact on Japanese pharmaceutical companies and the Japanese market stemming from drug pricing pressures driven by the Most-Favored Nation (MFN) policy enacted in the United States. Attention has also been drawn to domestic policy discussions concerning generic competition and the expansion of switch OTC drugs.

## 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?**

Therapeutic products lacking the required approval, certification or notification (Arts 55(2), 64 and 65-4), or failing to meet applicable quality standards, may not be sold (Arts 56(1), 65 and 65-5). Moreover, no person other than a pharmacy proprietor or a person holding the requisite licence to sell therapeutic products may sell such therapeutic products (Arts 24, 39 and 40-5).

Where a violation of the PMD Act is found, the MHLW or the relevant prefectural governor may require reports, conduct on-site inspections, and order necessary measures, including disposal or recall, to prevent risks to public health (Arts 69(1) and 70(1)). The MHLW may further order improvements to quality control or post-marketing safety control, and in serious cases, may suspend business operations or revoke licences (Arts 72, 72-2, 75 and 75-2).

A person who sells unauthorised therapeutic products, or who sells therapeutic products without the required licence, is subject to imprisonment or a fine (Arts 84 to 88). A corporation may also be fined where such violation is committed by its employee in the course of business (Art 90).

**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?**

Recent amendments to the PMD Act and related laws have introduced measures to secure a stable supply of pharmaceuticals. In addition to what is mentioned in the response to Question 13, the amendments empower the MHLW to instruct marketing authorisation holders or manufacturers to prepare and submit supply-shortage prevention plans for certain critical pharmaceuticals where a potential shortage could affect the provision of appropriate medical care and public health.

Increasing concerns over the stable supply of pharmaceuticals, including from an economic security perspective, mean that future developments warrant close monitoring.