

**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?

The principal statutes and regulations are Law No. 29459 (Law of Pharmaceutical Products, Medical Devices and Sanitary Products) and its regulations, namely the Regulation for the Registration, Control and Sanitary Surveillance of Pharmaceutical Products, Medical Devices and Sanitary Products (Supreme Decree No. 016-2011-SA) that regulates the quality and efficacy of such products and the Regulation for Pharmaceutical Establishments (Supreme Decree No. 014-2011-SA) that regulates the activities carried out by the relevant laboratories/manufacturers, importers, warehouses, wholesalers and pharmacies.

The competent authority responsible for authorising and overseeing the commercialisation of all types of therapeutic products, as well as the authorisation of pharmaceutical laboratories at the national level, as well as wholesalers located in Lima, is the General Directorate of Medicines, Supplies and Drugs (*Dirección General de Medicamentos, Insumos y Drogas* or DIGEMID), which is part of the Ministry of Health (*Ministerio de Salud* or MINSA).

The authorisation and supervision of wholesalers (at the regional level) and pharmacies (at the national level) involved in these activities falls under the purview of regional health authorities, which coordinate their oversight through DIGEMID.

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 the conclusion of a premarket review and approval process required by a competent authority?

Pharmaceuticals/biologics are classified as prescription-only or over-the-counter (OTC) products. Specifically, (1) special numbered prescription products, (2) prescription-only products, (3) OTC but pharmacy-only products and (4) OTC products that are allowed to be sold by non-pharmacy commercial establishments. The specific classification determines the sale conditions for the different types of products. Products falling into categories (1) to (3) may only be sold by authorised pharmaceutical establishments, with products falling into categories (1) and (2) requiring a prescription (and category (1) products being subject to stricter controls and traceability requirements), while category (4) products benefit from an exceptional sales channel limited to very low-risk products that are expressly authorised for sale in non-pharmacy commercial establishments.

Medical devices are classified according to the level of risk posed to the consumer in order to determine the applicable authorisation pathway: Risk 1 (low) to Risk 4 (high). However, the level of risk doesn't necessarily determine the sale conditions. The risk class mainly affects the premarket review and compliance burden. Medical devices are also classified by their sale conditions: (1) hospital use, (2) prescription only and (3) OTC. Medical devices falling into category (1) are only allowed to be supplied to health institutions and professionals, category (2) devices can only be sold when a valid prescription is presented and category (3) devices are allowed to be sold directly to consumers. Some OTC devices, which must be expressly authorised, may be sold by non-pharmacy commercial establishments.

All therapeutic products, notwithstanding their classification, require marketing authorisation (ie, premarket review and approval by DIGEMID) to enable their manufacture, import, storage, distribution, commercialisation, promotion, dispensing, retail sale and use in Peru.

LICENSING, AUTHORISATIONS AND DISTRIBUTION CHANNELS

3. Which licences, authorisations, registrations or other official permissions are required for businesses to engage in the wholesale distribution of therapeutic products, and what key conditions (such as good distribution practices, facility standards, personnel-related requirements and insurance or financial guarantees) are attached to them?

The wholesale distribution of therapeutic products requires a wholesaler (*Droguería*) pharmaceutical establishment authorisation. In order to secure such an authorisation, the corporation must be established in Peru and a registered professional pharmaceutical chemist must be retained by the company. Also, the authorised establishment needs to secure a certificate from DIGEMID in regard to their compliance with the relevant good practices pertaining to their business activities. For wholesalers, they must secure certificates confirming their compliance with good storage practices (BPA), good distribution and transport practices (BPDT) and good pharmacovigilance practices (BPF). The good pharmacovigilance practices (BPF) certificate is only necessary if the wholesaler is the holder of the relevant marketing authorisation of therapeutic products.

4. Are there any 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 are attached to them?

To provide therapeutic products directly to consumers, a business requires a pharmacy (*Farmacia* or *Botica*) authorisation. In order to secure such an authorisation, the business must be established in Peru and a registered professional pharmaceutical chemist must be retained. Also, the authorised establishment must secure a certificate from DIGEMID confirming its compliance with the applicable good practices: a good pharmaceutical office practices (BPOF) certificate, which covers storage, dispensing and pharmacovigilance and, if applicable, distribution, transportation and pharmacotherapy.

Exceptionally, non-pharmacy commercial establishments may sell medicinal products whose sale conditions expressly allow it. These establishments do not require a specific licence or certificate but must comply with the applicable parts of good storage practices.

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

All authorised pharmacies are allowed to sell therapeutic products to consumers over the internet. The prerequisite is that such pharmacies must notify the applicable regional health authority in order to conduct such sales.

IMPORT

6. What requirements are set as part of 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)?

Therapeutic products are restricted imports. The importer must be an authorised wholesaler (*Droguería*) and must hold BPA certification when importing pharmaceuticals or medical devices. Also, the importer can be an authorised laboratory that manufactures such products under contract and must hold BPM certification. The product to be imported must have a marketing authorisation (ie, premarket review and approval by DIGEMID).

An exceptional import authorisation is possible for the use of therapeutic products without marketing authorisation for specific purposes like a declared public emergency, exclusive research, training purposes or the personal treatment of a patient.

<p>Import duties are applied <i>ad valorem</i>. The duty levels are zero per cent, four per cent, six per cent or 11 per cent, depending on the classification of the imported product. Imports are subject to risk-based border inspections.</p>
<p>7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by post), and what quantitative limits, prescription requirements, customs declarations, duties or other restrictions apply?</p>
<p>For personal use, DIGEMID expressly provides an exceptional import authorisation for natural persons to import and use therapeutic products for disease prevention and individual treatment. To obtain this authorisation, the natural person needs a medical justification and a prescription issued by a licensed health professional. There is no fixed numeric cap set by DIGEMID on the amount of products allowed via this exceptional pathway. The prescriber defines the dose, duration and total quantity needed, which must correspond to the indicated treatment duration.</p>
<p>8. Are foreign suppliers allowed to 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?</p>
<p>A foreign supplier that wants to sell medicinal products in Peru must do so through a local authorised pharmaceutical establishment. The products must comply with Peruvian regulations and a marketing authorization must be secured (ie, premarket review and approval by DIGEMID). A foreign shipment that is exempt from these requirements needs to secure an exceptional import authorisation for personal use.</p>
<p>9. How is the 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 the product's original quality, safety and traceability?</p>
<p>Trademark and patent rights are internationally exhausted once a product has been introduced commercially in any country by the rightsholder. Therefore, a rightsholder cannot stop the parallel importation of a product based on trademark or patent rights once the first legitimate instance of marketing has occurred in another country.</p> <p>However, regarding trademark rights, exhaustion applies only where a product and the immediate packaging have not been modified, altered or deteriorated. Therefore, re-labelling or re-packaging may enable the rightsholder to enforce their trademark rights.</p> <p>Even if the relevant intellectual property rights have been exhausted, a parallel importer must comply with the sanitary regulations and must operate through an authorised pharmaceutical establishment and must import the product by obtaining an import certificate, provided the imported product has the same characteristics as the product already authorised in Peru. The import certificate tracks the original authorisation's validity, and the import certificate holder assumes the same obligations and responsibilities as the authorisation holder, including being bound by changes made to the underlying authorisation.</p>
<p>EXPORT</p>
<p>10. Are there quantitative quotas, permits or other measures that restrict or condition the export of therapeutic products (for example, to mitigate shortages or address public health emergencies), and how are such measures administered and enforced?</p>
<p>Therapeutic products manufactured in Peru exclusively for export are exempt from the Peruvian marketing authorisation requirement. If the product is also commercialised in Peru, marketing authorisation is required.</p> <p>There are no export quotas or restrictions that apply to address public health matters.</p> <p>The manufacturer or exporter must comply with the pharmaceutical establishment regulations.</p>

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?

Therapeutic products manufactured in Peru exclusively for export are exempt from the Peruvian marketing authorisation requirement.

The manufacturer or exporter must comply with the pharmaceutical establishment regulations, ie, the relevant good storage practices (BPA) or good manufacturing practices (BPM).

LABELLING, TRACEABILITY 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?

Therapeutic product labels must be in Spanish. Information in other languages may only appear if it was approved in the marketing authorisation dossier.

For pharmaceuticals/biologics sold by prescription, the label must not include dosing information. For OTC pharmaceuticals/biologics, the outer label must include specific patient information (dosing information). If such information does not fit on the label, it must be placed on an insert. In regard to medical devices labelling, instructions for use must be included (exception for certain Class I devices).

The traceability requirements in regard to product labelling are the sanitary registration number (marketing authorisation), batch/lot number, (when applicable) expiry date and (for devices) the serial number.

Labels in therapeutic products must always be indelible and must match the approved label featured in the marketing authorisation dossier.

PRICING, REIMBURSEMENT AND MARKET ACCESS

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

There is no price control regime for therapeutic products in Peru.

There is a reimbursement regime for therapeutic products: Law No. 29344, the Framework Law on Universal Health Insurance.

There is a public procurement regime for therapeutic products: Law No. 30225, the State Procurement Law.

There is a stock obligation regime for generic medicines in pharmacies: Law No. 32033, the law that guarantees and promotes access to and use of generic medicines under the International Non-proprietary Names (INN) system and strengthens the regulation of pharmaceutical products and medical devices for the benefit of patients and users.

There are no supply-related obligations for therapeutic products.

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?

DIGEMID and the regional health authorities control and survey the trade and distribution of therapeutic products and the establishments that manufacture, import, export, store, distribute, dispense, sell and use them. These authorities can carry out onsite inspections, impose fines and sanitary safety measures to prevent harm to public health and prevent further infringements (eg, market recall, the cancellation of marketing authorisations, the closure of establishments, the destruction of products, etc).

Without prejudice to the relevant regulatory measures, Peru’s Penal Code includes specific offences related to the falsification, adulteration, contamination and marketing of expired products, including aggravated outcomes (serious injury or death), among others.

DIGEMID and the regional health authorities may conduct joint operations with the police and the Prosecutor’s Office, and the case may proceed in parallel with a criminal investigation.

15. Is there any 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?

- The Executive publicly presented to Congress, in April 2025, an institutional reform bill to replace DIGEMID with an autonomous national authority. Congress is currently debating as to whether to grant its approval. The bill is explicitly framed as a response to DIGEMID’s institutional weaknesses.
- Law No. 32319 is a fast-track law that accelerates marketing authorisations for pharmaceuticals/biologics approved in certain ‘high sanitary vigilance countries’, which was enacted and published in May 2025.
- Ongoing GMP-certification enforcement: DIGEMID publicly announced the suspension of 176 marketing authorisations for products linked to missing or insufficient GMP certification.
- DIGEMID launched a formal consultation by publishing a draft regulation on the potential to operationalise quality controls for initial and subsequent batches of therapeutic products.
- There is an ongoing regulatory effort in Peru aimed at ensuring that certain medicines can be safely substituted for one another. The Ministry of Health has introduced mandatory lists of products that must be complemented by studies proving their therapeutic equivalence, with a second list approved in August 2025.