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

Authors: Sofía Quezada, Delmer Rodríguez and Luis Vega

Firm: BLP Legal

squezada@blplegal.com, d.rodriguez@blplegal.com, lvega@blplegal.com

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 regulatory framework governing the import, distribution, sale and export of therapeutic products in El Salvador is primarily centralised and administered by specialised authorities, with a strong emphasis on public health protection, product quality, and market control.

The principal statutes and regulations include:

- Medicines Law;
- General Regulation of Medicines Law;
- Special Law on Fees for Services of the National Directorate of Medicines;
- Law of the Superintendence of Sanitary Regulation;
- Law for the Creation of the Import and Export Processing Centre (CIEX);
- Customs Regime for Duty-Free Shops Law;
- Law for the Facilitation of Non-Commercial Online Purchases;
- RTCA 11.03.59:18. Pharmaceutical Products: Medicines for Human Use – Sanitary Registration Requirements; and
- RTS 11.03.02:21. Medical Devices: Regulatory Requirements. 10–14. Technical guidelines governing specific product categories, including biologics, homeopathic products, medicinal gases, and medical devices.

From an institutional perspective, the system is led by the Superintendence of Sanitary Regulation (SRS), which acts as the primary regulatory authority overseeing therapeutic products throughout their lifecycle. The SRS is responsible for granting marketing approvals, supervising compliance, and conducting post-market surveillance.

In addition, the Import and Export Processing Centre (CIEX) plays a key role in the administrative processing of import documentation, particularly through the invoice endorsement (visa) mechanism, while the General Directorate of Customs (DGA) oversees customs clearance and border control.

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?

Pre-market review and approval is required and is carried out by the SRS.

Pharmaceuticals are classified by:

- origin – chemical synthesis (innovator, generic, multi-source, radiopharmaceuticals, medicinal gases), biologics (biosimilars, vaccines), homeopathic, nutritional supplements (including probiotics), biotechnological products; natural products;
- development – innovator medicines and generic medicines (branded or unbranded);
- dispensing conditions – over the counter (OTC), prescription-only, controlled substances (special prescription), long-term use medicines.

Medical devices are classified by: risk – Class I (A), IIa (B), IIb (C), III (D); nature – antiseptics/disinfectants, in vitro diagnostics (IVDs), medical software, and other devices.

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?

The following authorisations are required for pharmaceuticals:

- establishment licence (wholesale distributor) before the SRS;
- appointment and authorisation of a responsible pharmacist;
- marketing authorisation (sanitary registration);
- Good Storage and Distribution Practices authorisation; and
- registration of a distribution power of attorney for each marketing authorisation holder.

Key conditions include: adequate facilities, defined storage areas, quarantine and rejection zones, covered loading/unloading areas, temperature-controlled storage (including cold chain where required), pest control, appropriate shelving and pallet systems, backup power supply, and occupational safety measures.

For medical devices, similar requirements apply, including:

- importer establishment authorisation;
- responsible professional authorisation;
- sanitary registration;
- good storage and distribution practices; and
- distribution authorisation.

Key conditions include: proper storage infrastructure, environmental controls, compliance with manufacturer specifications, safety equipment, technical documentation availability, and occupational health compliance.

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?

Yes, distinct requirements apply, particularly for pharmacies, and for OTC dispensers in supermarkets.

General requirements include: adequate infrastructure (walls, floors, ceilings), sanitation facilities, controlled temperature and humidity, restricted access, appropriate shelving, fire safety equipment, and segregation of controlled products.

Pharmacies must also comply with: minimum size requirements, separation of sales and storage areas, presence of a responsible pharmacist, proper handling of expired products, backup electricity (if applicable), access to pharmaceutical references, and appropriate patient-care areas.

Supermarket dispensers, which are limited to OTC medicines, must comply with storage and inspection requirements, and maintain updated authorised OTC lists.

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

There is currently no specific regulation governing the online sale of pharmaceutical products.

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)?

Key regulatory requirements include:

- marketing authorisation (sanitary registration);
- authorised importer/wholesaler establishment;
- first-batch analysis (if applicable); and
- invoice endorsement (visa) process.

The invoice endorsement process is particularly in practice, as it serves as a checkpoint to verify that the import complies with the conditions of the marketing authorisation. This includes the identity of the authorised distributor and the involvement of the responsible professional.

From a Salvadoran customs law perspective (ie, CAUCA/RECAUCA), imports of therapeutic products must be declared under the applicable tariff classification in the Central American Tariff depending on the type of product, with the corresponding import duties (*derechos arancelarios de importación*) and supporting documents (invoice, transport document, value declaration where applicable, certificate of origin where applicable, and any required permits or licences). Any import duty exemption must arise from an applicable treaty or statutory exemption regime for a specific product; otherwise, the ordinary tariff treatment applies. Once the declaration is accepted, it is subject to the customs risk analysis system, which may result in immediate release or documentary/physical inspection, which generally relies on random and risk-based selection.

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?

For OTC medicines purchased online, under the Law for the Facilitation of Non-Commercial Online Purchases, imports up to US$300 are exempt from import duties and non-tariff requirements. This only applies to natural persons for non-commercial purposes. Prescription medicines and controlled substances are exempt.

For medical devices, special import permits may be required (eg, for personal use, samples, research, or donations), typically subject to a fixed administrative fee.

For cross-border personal imports, if the value does not exceed one monthly minimum wage (US$365), imports may be exempt from regulatory procedures and fees, provided conditions are met.

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?

Foreign suppliers may ship directly to consumers under the above personal import rules. No local presence, platform registration, or specific labelling requirements are imposed in such cases.

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?

Parallel importation is generally permitted under the principle of exhaustion of intellectual property rights.

However, for regulated products, this principle is effectively limited by the regulatory framework. Even if IP rights are exhausted, products must still comply with sanitary registration requirements and may only be imported by authorised distributors.

In practice, this means that unauthorised parallel imports are likely to be considered regulatory violations, potentially leading to administrative sanctions, product seizure, or market withdrawal.

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 currently no quantitative restrictions, quotas, or specific permits limiting the export of therapeutic products.

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?

There is no 'export-only' regulatory pathway. A marketing authorisations enables full commercialisation of the product, including export, leaving it to the discretion of the holder to determine whether the product is marketed domestically, internationally, or both.

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?

Requirements are established under: RTCA 11.01.02:04 (pharmaceutical labelling); and RTS 11.03.02:21 (medical devices regulation).

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?

El Salvador operates a price control system for medicines, under which the SRS establishes a Maximum Retail Price.

This system is based on international and regional reference pricing and is intended to ensure affordability and prevent excessive pricing.

Compliance is actively monitored by both the SRS and the Consumer Protection Agency, and non-compliance may result in administrative sanctions.

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?

Since 2024, the SRS has implemented market surveillance for all regulated products.

Sanctions include: fines; suspension of marketing authorisation; and revocation or cancellation.

Inspections may lead to administrative proceedings handled by the SRS litigation unit.

Additionally, depending on the circumstances, the SRS may seek support from other institutions, such as the Consumer Protection Agency for the verification, inspection, and seizure of products, as well as from the Office of the Attorney General of the Republic in connection with non-compliance related to the commercialisation and distribution of therapeutic products.

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?
No major legislative or policy developments have been identified that significantly alter the current framework. However, increased market surveillance and the absence of specific regulations for e-commerce suggest potential areas for future reform.