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?

Bolivia regulates manufacturing, importation and commercialisation of pharmaceutical products under: the Medicines Law No. 1737; Regulation of the Medicine Law (Supreme Decree No. 25235); Creation of the State Agency for Medicines and Health Technology (Supreme Decree No. 2905); Pharmacological Regulations (Ministerial Resolution No. 216); National System for the Surveillance and Control of Medicines (Ministerial Resolution No. 250); Health Registration Manual (Ministerial Resolution No. 0909); and National Medicines Policy (Ministerial Resolution No. 0034).

It is important to note that pharmaceutical regulation in Bolivia encompasses approximately 67 instruments, including laws, supreme decrees, ministerial resolutions, administrative resolutions and circular letters.

The State Agency for Medicines and Health Technology (AGEMED, by its Spanish acronym) is a decentralised body of the Ministry of Health and Sports responsible for granting the Sanitary Registry required for the import, export, and commercialisation of pharmaceutical products (Art 7, clause e, Supreme Decree No. 2905). AGEMED also issues licences for manufacturing, oversees market surveillance and dispensing activities and ensures quality control through the Official Laboratory for Drug Quality Control and Toxicology (CONCAMYT, by its Spanish acronym).

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?

Bolivia classifies medicines by dispensing category and medical devices by risk level.

Medicines are categorised by AGEMED as either prescription-only or over-the-counter (OTC). Prescription-only medicines may be prescribed exclusively by licensed medical and dental professionals (Art 37, Medicines Law No. 1737). Their dispensing is the exclusive responsibility

of authorised pharmaceutical establishments. Public advertising of prescription-only medicines is strictly prohibited, except when directed solely at healthcare professionals (eg, medical conferences) (Art 8, Ethical Standards for the Promotion of Medicines).

Medical devices are classified according to risk: Class I (low risk), Class IIa (moderate-low risk), Class IIb (moderate-high risk), and Class III (high risk) (Art 1.7, Manual for Health Registration of Medical Devices). Bolivia applies the classification framework established by the Global Harmonisation Task Force (GHTF).

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?

Pursuant to Medicines Law No. 1737 and related regulations, any entity intending to engage in the wholesale distribution of pharmaceutical products shall comply with the following obligations: (1) be properly established and duly registered in the Plurinational Commercial Registry Service (SEPREC, by its Spanish acronym); (2) be registered with AGEMED; (3) the entity shall obtain an operating licence issued by the competent municipal government corresponding to its place of business; (4) the entity shall designate and maintain a pharmaceutical regent responsible for technical oversight (Art 30, Medicines Law No. 1737).

For each pharmaceutical product intended for distribution, the entity shall obtain a Sanitary Registry issued by AGEMED (Art 5, Medicines Law No. 1737).

Additionally, any business seeking to commercialise pharmaceutical products within Bolivian territory shall establish a physical presence in the country through incorporation as a local company. This requirement is mandatory, as AGEMED is empowered to verify facilities and domicile not only at the time of granting authorisation to operate, but also at any subsequent moment, in exercise of its supervisory authority (Art 7, clause f, Supreme Decree 2905). It should be noted that, upon establishment, the business may be required to comply with various regulatory provisions, including Good Storage Practices (Art 3, Ministerial Resolution No. 0260), social security system (Art 6, Social Security Code), compliance with Bolivia's labour regulations.

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?

Bolivian national law recognises only the following establishments as authorised points of dispensing for pharmaceutical products: (1) municipal institutional pharmacies; (2) institutional and hospital pharmacies; (3) popular pharmacies; (4) private pharmacies. Online sale of pharmaceutical products from a local, authorised establishment is permitted.

The dispensing of pharmaceutical products outside of these authorised establishments constitutes illegal sale and subject to administrative penalties (Art 4.1. Standard of Good Dispensing Practices, Ministerial Resolution No. 0837). For the business to provide therapeutic products directly to consumers must obtain a Sanitary Permit, issued by AGEMED, for dispensing pharmaceutical products.

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

The sale of therapeutic products to consumers over the internet, including through social media and marketplace platforms is considered forbidden in Bolivia due to the dispensing of pharmaceutical products outside duly authorised establishments constitutes illegal sale and is subject to administrative sanctions (Art 4.1. Standard of Good Dispensing Practices).

There is no provision that forbids online sales when the marketplace platform is directly linked to an authorised establishment, and the products offered do not require a medical prescription.

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)?

Bolivia regulates therapeutic product imports under Medicines Law No. 1737 (Arts 22, 23, 24 and 25) and General Customs Law 1990 (Art 75).

The importing entity must submit certain documents, including, among others: Customs Clearance Authorisation Certificate, invoice, packing list, quality control certificate, valid legal representation from the supplier to the importer and Sanitary Registry.

The tariff rates for pharmaceutical products vary between five per cent, ten per cent and 15 per cent, and in some cases, exceptions are made for certain pharmaceutical products destined for specific treatments in which cases there is no tariff.

In addition, it is important to note that, from time to time, the Bolivian government issues temporary regulations to suspended import tariffs on pharmaceutical products.

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?

Consumers may import therapeutic products for personal use but are obliged to meet the requirements set in both Medicines Law No. 1737 and General Customs Law 1990. In this regard, AGEMED issued Administrative Resolution No. 013 for which consumers, in exceptional cases, will be able to import products for personal use as long as they have authorisation from

AGEMED (letter explaining the reason for the importation), state the duration of the treatment, the number of dosages needed and prescription with detailed quantities (Art 7.3. Administrative Resolution No. 013). The therapeutic product must be recognised by law to enter the country (Art 4 Medicines Law No. 1737).

It is important to note that patients with medicines in their luggage for personal use that enter the country must carry their prescription to avoid confiscation.

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 are not permitted to ship therapeutic products directly to consumers in Bolivia, as national law bans the dispensing and commercialisation of such products outside authorised establishments (Art 4.1, Standard of Good Dispensing Practices, Ministerial Resolution No. 0837). For a foreign supplier to dispense products directly to consumers, it must not only establish a physical presence in Bolivia (by incorporating a local company) but also obtain an operating licence and authorisation from AGEMED to dispense pharmaceutical products.

Alternatively, a foreign distributor may be represented by a local company which already meets all the regulatory and law compliance requirements (as described in the response to Question 3, above). Through such, the foreign supplier may commercialise its products while retaining the brand name of the foreign supplier. In this case, the representative's sole obligations would be to obtain the Sanitary Registry for the products intended for commercialisation and to carry out their importation in accordance with Bolivian regulations.

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 of therapeutic products is permitted under Bolivian law. In circumstances where more than one party seeks to import and commercialise a cosmetic product registered with an NSO code; each interested party is required to notify the Competent National Authority of the product under the same NSO code. The latter is only valid when the product maintains identity with the version already registered in relation to same brand name, basic qualitative and quantitative composition, generic name, secondary composition, manufacturer, and labelling or marking as already notified (Art 11, Decision 833 Andean Community).

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?

The Bolivian government could impose restrictions on export of therapeutic products in order to mitigate shortages or address public health emergencies.

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 form of export-only authorisation within the Bolivian national law that permits the manufacture and export of therapeutic products not approved for domestic commercialisation (Art 5, Medicines Law No. 1737). Any therapeutic product or device must first be authorised for domestic marketing to qualify for export due to Sanitary Registry being a requirement for export (Art 6.1.3., Administrative Resolution No. 015). This is because the Sanitary Registry constitutes the rigorous procedure through which a product undergoes prior evaluation before being placed on the national market (Art 6, Medicines Law No. 1737).

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?

Packaging, labelling, and cases for therapeutic products and medical devices could be presented in multiple languages, provided that Spanish is included as one of them (Art 2.1.7., clause c, Manual for Health Registration). The mandatory information to be displayed comprises product name, strength, pharmaceutical form, expiry date, warnings, number of Sanitary Registry, and storage instructions (Annex No. 5, Manual for Health Registration).

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?

AGEMED has the authority to control and regulate prices of medicines and health technologies, to prevent excessive pricing and accessibility for the Bolivian population (Art 7, clause c, Supreme Decree No. 2905). Pursuant to the latter, AGEMED elaborated the National List of Essential Medicines 2022-2024 (LINAME, by its Spanish acronym), which establishes the pharmaceutical products considered indispensable and has referential prices for almost 777 therapeutic products, prices cannot be higher than the ones expressed in the list. Its application is mandatory across all health establishments within the National Health System.

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 State Agency for Medicines and Health Technology (AGEMED) is vested with the authority to evaluate, authorise, regulate, monitor, control, and supervise the production, manufacture, import, export, storage, distribution, transport, marketing, promotion, advertising, prescription, dispensing, and pricing of medicines and health technologies (Art 7, Supreme Decree No. 2905).

Pursuant to Medicines Law No. 1737, Article 59 describes offenses punishable by administrative means. AGEMED shall issue a report addressed to the offender. Administrative sanctions are applied directly by AGEMED, whereas criminal penalties fall under the jurisdiction of the Public Ministry (Art 61, Medicines Law No. 1737; Art. 216, numeral 3, 4, 5, 6, 8, 9, Criminal Code of Bolivia).

In accordance with the Medicines Law No. 1737 and Regulation to the Medication Law (Supreme Decree No. 25235), violations of these provisions shall be penalised depending on the severity of the case. Administrative sanctions may consist of monetary fines, confiscation of infringing products or their components, temporary closure for 30 days, or permanent closure, depending on the seriousness of the violation or repeated infringements.

AGEMED maintains an official website where it publishes 'Alerts' directed to the population, notifying when an entity is commercialising a product without a Sanitary Registry or falsified.

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?

In December 2025, the newly appointed Minister of Health held a meeting with the President of the Bolivian College of Biochemistry and Pharmacy to coordinate updates of the Medicines Law No. 1737, and other applicable regulation. No official draft laws were submitted as of the date of this report.