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 Chile, the Public Health Institute (ISP) and its National Medicines Agency (ANAMED) regulate pharmaceuticals, biologics, and medical devices to ensure their quality, safety, and efficacy. Although Chile is a unitary state, while the ISP is the national authority for pharmaceutical control, the Regional Ministerial Secretariats of Health (SEREMI) are the authorities in charge of their respective regions.

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?

Pharmaceutical products (medicines)

Pharmaceuticals are defined as substances intended for the prevention, diagnosis, treatment, or cure of diseases, or for regulating physiological states. They are classified according to condition of sale. The regulatory classification determines how a product can be traded and distributed to the public as follows:

- direct sale – over-the-counter (OTC) products which can be sold without a prescription and may be available in pharmacies and pharmaceutical stores on self-service shelves;
- simple prescription – items requiring a prescription from a qualified professional but the pharmacy does not retain the document;
- retained prescription – products requiring stricter control (eg, certain psychotropics), the pharmacy must retain the prescription;
- official form prescription (*Receta Cheque* – RCH) – mandatory for highly regulated substances such as narcotics and specific psychotropics, in this case the prescription is an official form;
- hospital use only – certain specialised drugs are restricted to administration within healthcare facilities.

Premarket review and approval

Mandatory registration operates in Chile, in that no pharmaceutical product can be distributed or sold in Chile without a Sanitary Registration issued by the ISP. To carry out the registration, the ISP conducts a systematic evaluation of quality, safety, and efficacy. This process requires submission of preclinical and clinical studies.

There are different registration procedures, such as the ordinary, simplified, abbreviated, and accelerated procedures, which allow the registration timeline for products to be shortened in certain specific cases. Similarly, a reliance regulation has been implemented to expedite the registration of products whcih have prior registration with high-surveillance regulatory agencies.

Medical devices

Medical devices include instruments, apparatus, and articles intended for medical purposes that do not act through pharmacological or metabolic means.

Devices are grouped into four classifications of risk, based on the risk associated with their use:

- Class I – very low risk;
- Class II – moderate risk;
- Class III – high potential risk; and
- Class IV – most critical risk (eg, HIV detection tests).

Premarket review and approval:

Unlike pharmaceutical products, not all medical devices require premarket approval. Mandatory certification (Verification of Conformity) only applies to devices specifically designated by the Ministry of Health (eg, gloves, syringes, condoms, HIV tests, etc). The Chilean health authority is currently discussing the incorporation of an extensive list of medical devices into mandatory sanitary control.

Devices subject to mandatory control that are traded without the corresponding certificate are subject to seizure and administrative sanctions.

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?

In Chile, the wholesale distribution of therapeutic products (pharmaceuticals) is strictly regulated by the Sanitary Code and its complementary regulations. Businesses must obtain specific sanitary authorisation and comply with technical standards relating to infrastructure, personnel, and operational practices.

Required licences and authorisations

To engage in wholesale distribution, a business must be authorised as one of the following two types of establishment.

Drugstores/wholesalers are establishments destined for the import, fractionation, distribution, and sale of drugs in bulk, chemical substances, and medical accessories. They may also distribute pharmaceutical products to authorised pharmacies and other health establishments.

Pharmaceutical warehouses are specifically for the storage of finished imported pharmaceutical products and authorised to distribute them directly to other establishments for use or sale.

Key conditions and standards

Establishments must comply with Technical Norm No. 147 on Good Storage and Distribution Practices (GDP). This includes: (1) maintaining a quality control system for all raw materials and pharmaceutical products handled; and (2) maintaining a cold chain for products requiring refrigeration or freezing, compliance with Technical Norm No. 208 is mandatory to ensure the integrity of the thermal chain during storage and transport.

Facility standards

Infrastructure facilities must undergo inspection by the health authority before authorisation is granted. Specific cold substances requirements exist for the storage of narcotics and psychotropic substances, which must be kept in exclusive, locked cabinets.

Personnel (technical direction)

Every wholesale establishment must have a Technical Director who is a pharmacist. This professional is legally responsible for the sanitary operation and ensuring distribution is only made to authorised entities.

Insurance and financial guarantees

The current sanitary regulations do not explicitly require general financial guarantees or insurance as a condition for obtaining the sanitary authorisation for distribution.

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?

In Chile, retail distribution of therapeutic products to consumers is categorised into different types of establishment, each with distinct licensing requirements and operational conditions.

Types of retail establishments and licensing:

- Community pharmacies (*farmacias*) – considered as health centres and require a Sanitary Authorisation for installation and operation.
- Pharmaceutical stores (almacenes farmacéuticos) – subsidiary establishments which can only be authorised in communes where no pharmacy exists, or where geographical/transport barriers justify them. They have a restricted list of authorised products for sale.

- Medicine cabinets (*botiquines*): authorised in healthcare facilities (hospitals, clinics) to maintain and dispense medications necessary for the health actions performed within those facilities.

Key conditions for operation

Technical direction (personnel)

Pharmacies must be technically directed by a pharmacist or pharmaceutical chemist. This professional must be present during the entire operating hours of the establishment. Pharmaceutical stores may be directed by a pharmacy technician (*práctico de farmacia*) authorised by the health authority.

Infrastructure and inventory

Pharmacies and warehouses must maintain a minimum stock of medications (*petitorio*) defined by the Ministry of Health. Pharmacies are required to offer a fractioning service (dispensing the exact number of units prescribed). This requires a circumscribed and exclusive area within the pharmacy, with strict hygiene and traceability standards.

Internet and electronic sales (e-pharmacies)

Pharmaceutical stores can sell medications through electronic means, subject to a specific Authorisation for Electronic Commercialisation from ISP. Key conditions include:

- there must have a dedicated online platform which complies with data privacy laws;
- for prescription-only drugs, the site must allow for the upload of digital or electronic prescriptions;
- for 'retained prescriptions' (*receta retenida*), the physical document must be collected on delivery; and
- the delivery service (own or third-party) must ensure the stability and quality of the products.

Medications requiring 'check-prescriptions' cannot be sold electronically.

Ownership and location

Any natural or legal person can own a pharmacy, provided they comply with sanitary regulations. Municipalities can operate public/municipal pharmacies (*farmacias populares*) as part of their primary healthcare services.

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

Chile regulates the sales of medicines over the internet.

Only ISP-authorised pharmacies may sell medicines online

The Institute of Public Health (ISP) must clearly state that it is the authority responsible for authorising electronic commerce of medicines nationwide. There is an official list of pharmacies authorised to conduct electronic commerce medicines. This confirms that online sale of therapeutic products is not open to general retailers, platforms, or informal vendors.

Only pre-authorised pharmacies/pharmaceutical stores may apply for online sale authorisation

According to ISP instructions, online dispensing authorisation may be requested exclusively by a pharmacy or pharmaceutical store that is already authorised. Products sold online must be stored in the pharmacy or pharmaceutical store and may be dispensed and delivered from that location. This means that no separate warehouse or drop-shipment model is permitted: all products must originate from the licensed pharmaceutical establishment.

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)?

Sanitary registration is a prerequisite for pharmaceutical products and for certain medical devices, as a condition for their importation and subsequent distribution.

The foreign trade of sanitary controlled products is regulated by ISP (through ANAMED), in coordination with National Customs, via electronic information exchange systems.

CDA (*Certificado de Destinación Aduanera*) must be obtained for the importation of medical devices and other sanitary controlled products, indicating the destination establishment.

Importers/distributors must obtain a UyD (Use and Disposition authorisation) for medical devices under sanitary control. This enables the legal use, distribution and commercialisation of imported devices. For certain devices a UyD is provided on the condition of having a valid sanitary registration.

For commercial imports of medicines, each import requires quality control by ISP. Narcotics and psychotropics also require annual import/export forecasts for authorised establishments.

Personal-use imports are processed via the SIPRO electronic system, which manages individual applications and issues resolutions electronically.

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 pharmaceutical products for personal use, but only following ISP approval through the SIPRO electronic system.

SIPRO manages the entire process: application, clarifications, tracking, and resolutions issued with advanced electronic signature.

The quantity which can be imported is limited to a maximum of six months' treatment. The product must be for the 'exclusive consumption of the importer' and cannot be resold.

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?

Direct shipment of therapeutic products from foreign suppliers to consumers in Chile via e-commerce is strictly regulated and generally prohibited for commercial purposes. Chilean law distinguishes between commercial distribution, which requires local presence and registration; and importation for personal use, which is an exceptional, non-commercial procedure.

Commercial sales and e-commerce

Foreign suppliers cannot sell therapeutic products directly to Chilean consumers through e-commerce platforms without a local authorised establishment. Any entity seeking to register or commercialise pharmaceutical products must be domiciled in Chile and have a legal representative in the country.

Importation for personal use

Individual consumers may import medications directly from abroad for their exclusive personal consumption. However, this is not a 'commercial sale' by the foreign supplier, it is a regulated import by the patient. Typically, this mechanism is used by foreign suppliers to sell medicines to patients in Chile.

Verification and labelling obligations

If a foreign supplier were to establish a local subsidiary to sell products:

- all products must comply with Chilean labelling standards, which include being in Spanish, stating the sanitary registration number, expiry date, and storage conditions;
- the seller is responsible for ensuring the quality of the product during transport, including maintaining temperature and humidity controls as specified in the product's monograph; and
- direct advertising of prescription-only medications to the public is strictly prohibited, only OTC (over-the-counter) direct sale products may be advertised, subject to prior ISP approval.

Medical devices

The rules for medical devices are similar regarding importation. While not all devices require sanitary registration, those under mandatory control (eg, condoms, gloves, needles) must have a Certificate of Verification of Conformity to be imported and traded.

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 legally permitted and protected in Chile under the principle of international exhaustion of intellectual property rights. This allows businesses to import original products legitimately sold in other countries without the consent of the local trademark or patent holder.

Intellectual property rights (exhaustion)

Chile follows a broad international exhaustion regime for both trademarks and patents:

- the owner of a registered trademark cannot ban third parties from using it for products legitimately marketed in any country by the owner or with their specific consent;
- a patent does not confer the right to prevent third parties from commercialising a product they have legitimately acquired after it was legally introduced into commerce in any country by the patent holder or an authorised third party;
- the National Economic Prosecutor's Office (FNE) and the Antitrust Court (TDLC) have consistently ruled that using trademark registrations to block parallel imports of original products is an anti-competitive practice.

Re-labelling and re-packaging

Parallel imported products must meet Chilean standards for information and safety and comply with Chilean labelling regulation. If the product is subject to bioequivalence requirements, the packaging must include the mandatory distinctive symbol (*isologo*).

Quality, safety, and traceability

The parallel importer assumes significant legal responsibilities:

- every imported batch must undergo local quality control analysis (unless specifically exempted) to verify it matches the registered specifications;
- importers are considered 'authorisation holders', and must implement a pharmacovigilance system to monitor and report adverse reactions to the ISP; and
- the importer is responsible for traceability, the entire distribution chain and must be able to recall products if the authority detects quality failures.

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?

In Chile, the export of therapeutic products is generally permitted but subject to notification and authorisation by the ISP, which is requested through the ISP's GICONA platform. While there

are no permanent quantitative quotas for most products, the government holds extraordinary powers to restrict or condition exports during public health emergencies or to mitigate shortages.

General export requirements

Under normal circumstances, the export of pharmaceutical products is regulated by the Sanitary Code and D.S. No. 3/2010:

- only products with a valid sanitary registration in Chile can be exported, the exporter must notify the ISP before the operation;
- products manufactured exclusively for export must still undergo a registration process, although they are exempt from local labelling and patient leaflet requirements; and
- all exports require a 'Visto Bueno' (clearance permit) from the ISP, which is processed through the Integrated Foreign Trade System (SICEX) or the ISP's digital platform.

Extraordinary measures and restrictions

During public health emergencies, such as the Covid-19 pandemic, the Ministry of Health (MINSAL) can exercise extraordinary powers:

- Under a 'Sanitary Alert' (*alerta sanitaria*), the Ministry can limit the sale and delivery of health-related goods to ensure domestic supply.
- During the Covid-19 emergency, Chile implemented temporary export bans or restrictions on critical supplies (eg, masks, gloves, and specific medications) to prevent domestic shortages. These measures are typically enacted via Exempt Resolutions and enforced at the border by Customs in coordination with the ISP.
- Pharmaceutical companies are legally required to inform the ISP and the Ministry of Health of any intention to suspend the distribution of a product three to six months in advance, allowing the authority to take preventive measures.

Controlled substances (narcotics and psychotropics)

Export of controlled substances are subject to much stricter, permanent quotas. The ISP must approve annual import and export forecasts for narcotics and psychotropics. Each individual export operation requires a specific 'Official Export Authorisation' issued by the ISP's Controlled Substances Department.

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?

Chilean law provides a specific framework for 'export-only' therapeutic products, allowing for the manufacture and export of products that may not be intended for the domestic market. However, these products are still subject to mandatory registration and strict quality standards.

'Export-only' authorisation and registration

Under the Sanitary Code, products intended exclusively for export must undergo a registration process.

Labelling standards ('dual-labelling')

Products designated as for export (*productos para la exportación*) benefit from significant exemptions regarding their presentation:

- they are not required to comply with Chilean regulations for standard packaging, graphic labelling, or patient information leaflets;
- the finished product must still include the following mandatory minimum information in its identification –
  - product name (including International Nonproprietary Name – INN);
  - pharmaceutical form;
  - ISP registration number;
  - Manufacturer's name;
  - batch/serial number and expiry date;
- while the regulation for domestic products requires Spanish, export-only products can be labelled according to the language requirements of the destination country, provided the mandatory identification elements are present.

Manufacturing and quality standards

Manufacturers of export-only products must adhere to the same technical standards as those producing for the domestic market. GMP/GLP Compliance, and the manufacture or conditioning of these products must be carried out by authorised laboratories or drugstores.

Notification and record-keeping

- Before exporting, the holder of the registration must notify the ISP, providing details of the exporter, manufacturer, and the specific product registration.
- Manufacturers must maintain records that allow for full traceability. Failure to include batch numbers or expiry dates on export-only products is a sanctionable offence, as it prevents the authority from verifying the product's validity.
- Exporters may request a Certificate of Pharmaceutical Product (CPP) from the ISP, which is typically required by the importing country to prove the product is manufactured under GMP.

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?

The circulation of therapeutic products in Chile is subject to strict requirements relating to language, serialisation, and traceability. These differ significantly depending on whether the product is for domestic use or export.

Local language and patient information (domestic)

For products circulating within Chile, the primary requirement is the use of the local language. Labels must include the product name, pharmaceutical form, quantity, storage conditions, and the ISP Registration Number. A patient leaflet must be included in the packaging and provide clear instructions on dosage, contraindications, and adverse effects, all in Spanish. This information is part of the registry of the product.

Serialisation and traceability (pharmaceuticals)

Chile has implemented a robust traceability system to ensure the safety of the supply chain and prevent counterfeiting. Products must have: (1) a unique identification batch/serial number and an expiry date printed on both primary and secondary packaging; (2) proven therapeutic equivalence must display a specific isologue (a distinctive yellow and red symbol) on at least four of the six faces of the secondary packaging, covering 20 per cent of the area.

Medical device identification

For medical devices, the requirements focus on identification and conformity:

- devices must clearly state the product name, manufacturer, distributor, and the batch or serial number;
- devices subject to mandatory control, must display the registration number assigned by the ISP on the device or its packaging;
- there are specific rules for traceability of medical devices from institutional healthcare providers.

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?

Several non-trade regimes in Chile materially influence the distribution and availability of therapeutic products through price controls, public procurement, and supply obligations.

Price control and intermediation (CENABAST Law)

While Chile generally operates under a free-market pricing system for pharmaceuticals, the CENABAST Law (Ley 21.198) introduced a significant price-control mechanism:

- the National Supply Centre (CENABAST) is authorised to intervene in the purchase of medications for private pharmacies and non-profit health centres;
- for medications acquired through this system, CENABAST establishes the maximum retail price which pharmacies are allowed to charge the public
- the Public Health Institute (ISP) monitors compliance with these maximum prices.

Extraordinary price controls (sanitary alerts)

During public health emergencies, the Ministry of Health (MINSAL) can exercise extraordinary powers which allow price caps to be imposed on critical pharmaceutical products, as well as

medical devices and health services. The authority can also limit the number of units that can be sold to each person to prevent hoarding and ensure equitable distribution.

Reimbursement and coverage regimes

Two major systems influence product availability by guaranteeing financing. The GES/AUGE System (Ley 19.966) provides explicit health guarantees for a prioritised set of diseases. It ensures access, quality, and financial protection (capping co-payments at 20 per cent) for specific medications and treatments. The Ricarte Soto Law (Ley 20.850) is a financial protection system for high-cost diagnoses and treatments. It provides total coverage for specific expensive drugs and devices defined by supreme decree.

Supply and stock obligations

All pharmacies and pharmaceutical stores are legally required to maintain a permanent stock of a minimum list of essential medicines (*petitorio mínimo*), as defined by the Ministry of Health. Registration holders must inform the Ministry, the ISP, and CENABAST of any intention to temporarily or permanently suspend the distribution of a product with three to six months' notice.

Public procurement impact

CENABAST centralises the demand for the entire public health network, achieving significantly lower prices than the private retail channel through centralised purchasing.

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?

Regulators in Chile, primarily the ISP and the SEREMI, possess broad investigative and sanctioning powers to ensure compliance with the trade and distribution rules for therapeutic products. These powers range from administrative measures to criminal prosecution.

Investigative powers

Authority to investigate is grounded in the Sanitary Code:

- health authorities can inspect and search any site, building, or workplace, whether public or private, to ensure compliance with sanitary regulations;
- regulators have the power to access and review all technical documentation, batch records, and distribution logs;
- officials can take samples of products for quality control analysis at the ISP's national reference laboratory;
- the Inspection Act (*Acta de Inspección*) raised by a health official serves as a legal presumption of the facts stated therein.

Administrative sanctions

Non-compliance detected through a Sanitary Summary (*sumario sanitario*) can result in several penalties, including:

- fines – ranging from UTM0.1–1,000 (approx. US$8–79,000), which can be doubled for repeat offenders;
- temporary or permanent closure of establishments (pharmacies, laboratories, or drugstores);
- revocation of sanitary registrations or operating permits; and
- immediate confiscation and destruction of adulterated, counterfeit, or unauthorised products.

Urgent remedial measures

In cases of imminent risk to public health, the authority can impose immediate measures without a prior summary. These include ordering the immediate withdrawal of specific batches or entire product lines from the market; and suspending the distribution and administration of a product until safety is verified.

Criminal sanctions

Serious violations involving counterfeit or dangerous substances are referred to the Public Ministry for criminal prosecution under the Penal Code. These include manufacturing or knowingly selling medicinal substances that are deteriorated or adulterated and dangerous to health is punishable by imprisonment and fines; and practicing as a pharmacist or doctor without the required authorisation is also a criminal offence.

Civil liability

The Sanitary Code establishes a strict liability regime for damages caused by defective therapeutic products. The registration holder, manufacturer, and importer are jointly liable for any harm caused by a defective product. Defendants cannot exempt themselves from liability by claiming the defect was not foreseeable according to a 'state of the art defence', that scientific knowledge available at the time of circulation.

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?

The regulation of therapeutic products in Chile is undergoing a period of significant transformation, driven by legislative reforms aimed at reducing prices, increasing competition, and modernising the oversight of medical devices and digital health.

Anticipated legislative reforms: 'Ley de Fármacos II'

The most significant reform currently in the legislative pipeline is the 'Ley de Fármacos II' (Bulletin 9914-11). As of early 2026, it remains under discussion in Congress. Its core objectives are:

- mandatory prescription by their International Nonproprietary Name (INN) to facilitate substitution with cheaper bioequivalents;
- introducing more robust mechanisms for price transparency and potentially capping margins or prices for certain essential drugs; and
- the return of certain enforcement powers from the ISP to the Regional Ministerial Secretariats of Health (SEREMI), addressing the ISP's lack of regional presence.

Modernisation of medical device regulation

There is a strong policy trend towards treating medical devices with the same regulatory rigor as pharmaceuticals. Technical Norm 226 (2022) now mandates a data registration system for the traceability of medical devices upon receipt by health providers. New bills are being drafted to expand the list of devices under mandatory ISP control, moving away from the current limited list (condoms, gloves, etc.) to a broader risk-based classification system.