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 Paraguay, the competent authority for the regulation of pharmaceutical products, biological products, herbal and homeopathic products and medical devices is the National Directorate of Health Surveillance (*Dirección Nacional de Vigilancia Sanitaria* or DINAVISA). The applicable regulatory framework comprises general legislation, complemented by specific provisions depending on the type of product involved.

The general regulatory framework is made up of the following:

- Law No. 836/1980 – the Health Code;
- Law No. 1119/1997 – on Health Products and Others;
- Law No. 6788/2021 – which establishes the powers, functions and organisational structure of DINAVISA; and
- Law No. 7361/2024 – which amends and expands the provisions set out in Law No. 6788/2021.

The product-specific regulations are listed below.

The following regulations relate to pharmaceutical products:

- Decree No. 2479/2024 – regulates Articles 6 to 19 of Law No. 1119/1997 and establishes the requirements for the issuance and renewal of marketing authorisations for medicinal products, repealing Decrees No. 10,262/2012, No. 3,586/2015 and No. 6,611/2016;
- DINAVISA Resolution No. 147/2025 – concerns the ordinary procedure for obtaining a marketing authorisation;
- DINAVISA Resolution No. 148/2025 – concerns the abbreviated procedure for obtaining a marketing authorisation;
- DINAVISA Resolution No. 151/2025 – concerns the procedure for post-marketing authorisation variations; and
- DINAVISA Resolution No. 168/2025 – concerns the procedure for the renewal of marketing authorisations.

The following regulations relate to biological products:

- DINAVISA Resolution No. 233/2024 – sets out the requirements for the issuance of marketing authorisations for biological medicinal products;
- DINAVISA Resolution No. 224/2025 – sets out the procedures for post-marketing authorisation variations, in accordance with World Health Organization (WHO) Guideline No. 1011/2018 on changes to registered biological products; and
- DINAVISA Resolution No. 215/2025 – sets out the requirements for the renewal of marketing authorisations for biological medicinal products and vaccines, repealing Articles 18 and 19 of Resolution No. 233/2024.

The following regulations relate to herbal and homeopathic products:

- DINAVISA Resolution No. 89/2025 – sets out the requirements for the registration and authorisation renewal for herbal medicinal products; and
- DINAVISA Resolution No. 480/2025 – sets out the procedure for post-marketing authorisation variations for herbal medicinal products.

The following regulations relate to medical devices:

- DINAVISA Resolution No. 226/2024 – establishes the requirements for marketing authorisations, post-authorisation modifications, and authorisation renewals for medical devices.

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?

Within the category of therapeutic products, the regulatory framework establishes specific rules for pharmaceutical products, which are classified according to their dispensing status into the following categories:

- over the counter (OTC) – available in pharmacies without a prescription;
- prescription only (simple prescription);
- prescription only (simple prescription retained/archived by the pharmacy); and
- prescription-only (quadruplicate prescription).

Biological products, in turn, may be marketed exclusively under the prescription-only category. Herbal and homeopathic products are generally classified as OTC, except in specific cases where, for safety reasons, DINAVISA determines that prescription-only dispensing is required.

Medical devices are classified, according to the risk posed, into four classes:

- Class I: authorised through a mandatory sanitary notification (*Notificación Sanitaria Obligatoria* or NSO) under a simplified procedure; and
- Classes II, III and IV: require a formal marketing authorisation (sanitary registration), subject to an evaluation of the technical documentation.

This classification is based on the intended purpose and mode of use declared by the manufacturer, as well as specific rules established by DINAVISA.

All therapeutic products (according to their respective class or type) are subject to prior evaluation and approval by DINAVISA in order to be lawfully marketed. This process is carried out through the granting of sanitary registration, such as the mandatory sanitary notification in the case of low-risk medical devices.

Without such authorisation, the importation, distribution, sale or advertising of a medicinal product in Paraguay is not permitted.

Additionally, exceptional procedures exist, such as temporary authorisation for the use of therapeutic products in public health emergencies, which allow for expedited access in specific conditions and for specific purposes, while remaining subject to DINAVISA's oversight.

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?

Any company engaged in the distribution of therapeutic products must hold a certificate of authorisation to operate, issued by DINAVISA, specifically covering the relevant authorised activities. This certificate is valid for a period of five years.

With respect to the key requirements for obtaining sanitary authorisation, the company must have a registered legal address in Paraguay, as well as a technical director duly registered with the Ministry of Public Health and Social Welfare. The company must also have owned or leased warehouse facilities, submit facility layout plans and be equipped with mandatory safety equipment (such as fire extinguishers, helmets, among others). In addition, the company must hold a valid registration with the Single Business Registry (*Registro Único de Empresa* or RUE), which details the authorised activities, scope of authorisation and expiration date, and which must be renewed on an annual basis. As part of the authorisation process, DINAVISA conducts an on-site inspection to verify compliance with all of the applicable requirements prior to issuing the corresponding certificate.

Distributors must comply with infrastructure standards that include designated reception and storage areas, sanitary facilities and changing rooms, fire safety systems, cold storage or air-conditioning systems where applicable, emergency showers and eyewash stations, as well as appropriate finishes for the walls, floors, ceilings and lighting. Compliance with these conditions allows for the issuance of a good storage and distribution practices certificate (*Buenas Prácticas de Almacenamiento y Distribución* or BPAyD), which is valid for two years for medicinal products and three years for medical devices.

With respect to medicinal products, Paraguay adopts as its official technical standard the international guideline 'PIC/S Guide to Good Distribution Practice for Medicinal Products' (PE 011-1). For medical devices, the applicable standard is the MERCOSUR Technical Regulation on Good Manufacturing Practices for Medical Devices and In Vitro Diagnostic Products.

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 are attached to them?

In Paraguay, the retail sale of therapeutic products directly to consumers, whether through community pharmacies, brick-and-mortar establishments or online platforms, is subject to strict sanitary authorisation and regulatory oversight.

Establishments engaged in the dispensing of medicinal products and related items must obtain prior authorisation from DINAVISA and comply with requirements concerning infrastructure, storage conditions, temperature control, product record-keeping and the presence of a licensed pharmacist acting as the technical director responsible for the establishment.

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

Recently, a resolution has been issued regulating the remote dispensing and delivery of human medicinal products authorised by DINAVISA through websites, digital platforms and telephone-based services operated by duly authorised pharmacies. This regulation will enter into force in May 2026.

The regulation provides that authorised pharmacies intending to engage in remote delivery activities must notify the health authority prior to the commencement of such activities and demonstrate compliance with the technical guidelines established by DINAVISA.

Likewise, the resolution establishes that the rules applicable to conventional dispensing of medicinal products are equally binding on remote sales, particularly with regard to the responsibilities of the pharmacy, storage and transportation conditions and the prevention of counterfeit medicines from entering the lawful supply chain.

The regulation recognises as lawful only those digital platforms and telephone-based services operated directly by authorised pharmacies, whether operating individually or as part of a chain, under the supervision of a licensed pharmacist holding a valid professional registration with the Ministry of Public Health and Social Welfare. The remote sale of medicinal products through any other means that fails to meet these conditions is expressly prohibited.

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)?

In Paraguay, the control of imports of therapeutic products is structured around an integrated sanitary–customs system, the cornerstone of which is the prior sanitary authorisation granted by DINAVISA, complemented by controls exercised by the customs authority.

As a general rule, all imported therapeutic products must have prior sanitary authorisation before entering the country and being placed on the market. The importation of products that lack sanitary registration is prohibited, except in cases expressly provided for by the applicable regulations, which, although exceptional in nature, are nevertheless subject to prior authorisation.

Specific regulatory regimes apply, inter alia, to medicinal products for personal use (within established limits), donations, public health programmes, public health emergencies and compassionate or temporary use. In such cases, the regulations may waive the requirement for sanitary registration, without eliminating the corresponding sanitary controls.

Each import operation requires the submission of an import authorisation request to DINAVISA, accompanied by a product declaration including the batch number, quantity, origin and destination, as well as its linkage to a valid sanitary registration, where applicable.

During border control or customs clearance, authorities routinely verify the import authorisation issued by DINAVISA, the validity of the sanitary registration, the consistency between the declared product, batch and quantity, as well as the commercial and transport documentation.

Based on the product's risk profile, taking into account factors such as the importer's compliance history, the existence of sanitary alerts or the country of origin, the competent authority may order a physical inspection of the product, sampling or its preventive detention.

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 solely for personal use, in limited quantities, for non-commercial purposes and subject to sanitary controls.

Pursuant to the Law on Health Products and Others, medicinal products for personal use entering the country, whether carried by the users themselves or by duly authorised third parties, in strictly necessary and reasonable quantities, are exempt from the requirement to obtain prior authorisation.

The regulations do not specify an exact permitted quantity, leaving this determination to the discretion of the competent authority. However, the quantity may need to be substantiated by the patient through a medical prescription duly signed by the treating physician, where applicable, depending on the type and quantity of the medicinal product involved. Likewise, the regulations do not expressly address customs declaration requirements or applicable duties, without prejudice to the possibility that such formalities may be required on a case-by-case basis.

Additionally, DINAVISA Resolution No. 203/2025 establishes the procedure for authorising the importation of unregistered medicinal products and medical devices for compassionate use, intended for specific patients diagnosed with a defined pathology by a specialist treating physician, who holds a valid professional licence issued by the Ministry of Public Health and Social Welfare.

Although this regulation does not exclusively address non-commercial personal-use imports, it confirms the exceptional regulatory framework under which DINAVISA may authorise imports that fall outside the standard sanitary registration process.

8. Are foreign suppliers allowed to ship therapeutic products directly to consumers via ecommerce or mail order, and what local presence, platform registration, verification or labelling obligations – if any – must they satisfy?

In Paraguay, foreign suppliers are not permitted to send therapeutic products directly to end consumers through e-commerce, mail order, courier services or online marketplaces without complying with the local sanitary regulatory framework.

Accordingly, the product must benefit from sanitary registration in Paraguay, and there must be a local responsible party authorised by DINAVISA (the registration holder). Direct sales from abroad to the consumer bypass these regulatory controls and are, therefore, prohibited.

Such sales may only occur as a result of exceptional authorisation within the regulatory framework, for example, in the case of medicinal products intended for compassionate use. Provided that the activity is authorised by DINAVISA, the manufacturer may ship the products from abroad directly to the patient in Paraguay.

The applicable regulations governing the importation of unregistered products for compassionate use do not impose specific labelling requirements. However, they do establish that the natural or legal person responsible for the importation must provide the package leaflet or instructions for use duly translated into Spanish.

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?

In general, for therapeutic products to be imported, sanitary registration must be granted by DINAVISA, except for exceptions explicitly provided in the regulations.

Among the essential requirements for the submission of a sanitary registration application, for both medicinal products and medical devices, is the presentation of a power of attorney, letter or representation agreement granted by the manufacturer or the foreign product holder.

Such an instrument may confer on the local representative limited sole authority to apply for and maintain the sanitary registration before DINAVISA, as well as to import, distribute and market the product within the national territory, as applicable. Through this designation, the health authority identifies a local responsible party before the Paraguayan state, who assumes the regulatory obligations associated with the product's lifecycle in the country. In the absence of a valid power of attorney or representation letter, DINAVISA will not process the sanitary registration nor authorise regular imports, which, in practice, prevents the legal entry of the product into the market. This document may also serve to directly place the relevant intellectual property rights with the local representative in Paraguay.

From a sanitary perspective, the representation document also serves a key function as a guarantee of the authenticity, quality and traceability of the product, together with mandatory registration documents, such as the certificate of free sale or pharmaceutical product certificate and the good manufacturing practices (GMP) certificate, all of which must be issued by the health authority in the product's country of origin. These documents certify that the product originates from an authorised manufacturer and that the original supply chain is maintained. DINAVISA may additionally require technical information, stability data, batch tracking and compliance with pharmacovigilance or technovigilance obligations as part of the control and surveillance measures to ensure product quality, safety and traceability.

Furthermore, any re-labelling or re-packaging activities required to adapt the product to the local market must be expressly declared in the sanitary registration application and receive prior authorisation from DINAVISA before implementation.

The preservation of product quality, safety and traceability constitutes a direct responsibility of the authorised importer, without prejudice to the oversight powers of the health authority. DINAVISA conducts controls and inspections, including random verifications, to corroborate compliance with the conditions approved at the time of registration. Should any modifications occur that impact the originally declared aspects, including changes to the product, its packaging, supply chain or authorised processes, such variations must be timely notified to and approved by DINAVISA prior to implementation, in accordance with the applicable regulations.

EXPORT

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?

In general, Paraguayan regulations do not establish quantitative quotas for the export of therapeutic products. However, such activity is subject to compliance with the applicable regulatory requirements and is subject to control measures related to the protection of public health.

Furthermore, the Organic Health Law assigns the state with the responsibility to adopt the necessary measures to ensure access to and availability of essential medicines and supplies during public health emergencies, using the mechanisms provided by domestic legislation and applicable international treaties.

Accordingly, the Ministry of Public Health and Social Welfare (MSPyBS) and DINAVISA may exercise the relevant powers in this regard, which implies that quantitative limitations could be imposed in the event of a public health emergency in the country.

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?

In Paraguay, this measure is expressly contemplated under the regulatory framework, although its application is subject to compliance with certain requirements. Where a product is intended exclusively for export, it is not necessary to obtain a sanitary registration.

However, the manufacturing, packaging or exporting company must be duly authorised by DINAVISA, hold valid GMP certificates and submit an application for the corresponding export certificate, attaching the documentation required by the health authority.

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?

In Paraguay, the labelling requirements for therapeutic products constitute a mandatory precondition for commercialisation. No medicinal product or medical device may be marketed unless its labelling, patient information and identification systems have been previously approved by DINAVISA within the framework of sanitary registration.

For both medicinal products and medical devices, the mandatory language to be displayed on primary and secondary packaging, package inserts and instructions for use is Spanish. Additional information in other languages may be included, provided it does not contradict or replace the information required in Spanish.

In general terms, the regulations require that the labelling, packaging and package inserts for medicinal products to provide clear, sufficient and truthful information to patients and healthcare professionals, enabling the correct identification, use and storage of such products. Both the primary and secondary packaging must include essential product information, such as name of the product, composition, pharmaceutical form, route of administration, identification of the manufacturer or sanitary registration holder, batch number, expiration date, dispensing status, sanitary registration number, storage conditions and mandatory statements required by the health authority

The regulations also contemplate certain particularities depending on the product type and regulatory status. Specific requirements are established for small-volume parenteral solutions, pharmaceutical specialties used in anaesthesia, controlled substances, medical samples and imported products, where certain information may be added via stickers or inkjet systems, provided that the original labelling is not obscured. Additional requirements may apply regarding the use of quick response (QR) codes, special markings and supplementary warnings, as appropriate.

The package insert must contain essential technical and clinical information about the medicinal product, including, but not limited to, therapeutic indications, the method of administration, dosage, warnings, contraindications, possible interactions and adverse reactions, as well as relevant information regarding the mechanism of action and safety, ensuring that users have adequate instructions in order to use the product responsibly.

For medical devices, the regulations provide that the labelling, packaging and instructions for use must contain clear, sufficient and understandable information, enabling proper product identification, ensuring product traceability and guaranteeing safe use of the product and its adequate preservation. This information may be placed on the device itself, on the primary or secondary packaging or on the accompanying materials, as appropriate, and must be presented in Spanish.

Labelling must also include the information necessary to identify the medical device and the parties involved in its manufacture and commercialisation, along with the authorised dispensing status, the record of sanitary authorisation granted by DINAVISA and the elements required for its traceability, such as the batch or serial number, relevant dates and the product's shelf life. The storage, conservation and handling conditions must be indicated, as well as warnings, precautions and instructions required for its proper operation and use.

The regulations also establish specific requirements depending on the type and characteristics of the medical device. In this context, requirements are provided for sterile devices, single-use devices and devices that require sterilisation method indication. For devices intended exclusively for professional use, instructions may be provided in digital format via QR codes, DataMatrix or equivalent systems. Finally, labelling must include statements and mechanisms related to technovigilance, aimed at facilitating the reporting of incidents or adverse events to the health authority.

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?

In Paraguay, there is a regulatory framework for the pricing of chemically synthesised medicines and biological medicinal products, which significantly influences their availability and distribution channels. This framework is based on the express powers of DINAVISA to set and supervise public sale prices, as well as a national system for price transparency and monitoring.

Since November 2024, an updated methodological regulation has been in force, modernising the pricing system for medicinal products and establishing a Medicines Price Observatory to enhance transparency and the monitoring of compliance with public sale price regulations.

DINAVISA Resolution No. 174/2024 establishes a new methodology for regulating public sale prices of medicinal products, based on international price referencing rather than intermediary margins, with the objective of ensuring that prices are set transparently and equitably.

It should be noted that herbal medicinal products currently do not require a fixed public sale price.

Regarding the supply of medicines, Paraguay does not have general specifications or a comprehensive regulatory framework establishing uniform supply obligations for the market as a whole. Nevertheless, in the context of public procurement, suppliers awarded contracts through tendering processes are required to comply with the supply conditions established in the respective contracts, including volumes, deadlines and delivery conditions.

Although there is no general obligation to maintain stock or continuous supply for the private market, the health authority retains the power to require the maintenance of a certain level of supply in specific, duly justified cases. This power may be exercised in exceptional situations, taking into account the type of product involved and the context of a potential public health emergency, in order to protect public health and ensure access to essential medicines.

Complementarily, regarding the public sector, Paraguay has made progress in regard to strengthening its information and control systems related to the availability and distribution of medicines within the public health system. Through the implementation and expansion of the Health Information System (HIS), medicine traceability has been improved and electronic prescriptions strengthened, optimising patient care, stock control and management within facilities governed by the Ministry of Public Health and Social Welfare.

In the same vein, the Automated Inventory Control and Information System of Paraguay (SICIAP) enables an online record of medicines to be distributed at central and departmental levels, with direct connection to regional health authorities. This facilitates better needs estimation, public procurement planning and prevents supply shortages within the public sector network.

However, these mechanisms do not constitute a comprehensive national supply control system, as the private sector is not currently subject to a mandatory stock or availability reporting scheme. Consequently, supply

shortages within the private sector continue to respond primarily to commercial, logistical or regulatory dynamics, without centralised real-time monitoring.

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?

In Paraguay, DINAVISA has the authority to investigate non-compliance related to the manufacture, distribution, marketing and importation of therapeutic products. The agency may conduct inspections, request documentation and adopt preventive measures, such as quarantining batches, withdrawing products from the market or temporarily suspending business activities.

Following the corresponding administrative procedure, the authority may impose sanctions, including fines, the closure of establishments or the cancellation of sanitary registrations, depending on the severity of the infraction. Law No. 6788/2021 and DINAVISA Resolution No. 265/2022 establish the regulatory framework in this regard. Actions arising from this process may also lead to civil or criminal proceedings, as applicable.

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?

In recent years, there has been a sustained trend by DINAVISA towards strengthening the post-marketing control of therapeutic products, with an increasingly pronounced focus on the detection and combatting of counterfeit, illegal or unregistered products. In this context, the health authority has been reinforcing its surveillance, inspection and technovigilance/pharmacovigilance capabilities, promoting more active mechanisms for market control and product monitoring once products have become commercially available.

At the same time, DINAVISA has expressed its objective to establish itself as a regional reference authority, which is reflected in an institutional policy aimed at strengthening control systems, continuously improving inspection and monitoring processes and enhancing regulatory requirements regarding the traceability, compliance and control of trade and cross-border movement of therapeutic products.

These lines of action could, in the medium term, result in regulatory and operational adjustments, which may have a direct impact on the marketing, distribution and importation of medicinal products.