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

Author(s): Juan Ignacio Torres Negreira and Jonás Bergstein

Firm: Bergstein Abogados

itorresnegreira@bergsteinlaw.com; jbergstein@bergsteinlaw.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?

Uruguay has a unitary (non-federal) legal system, so the regulation of therapeutic products is exercised exclusively at the national level. There is no division of powers between federal and state authorities.

Competent authority

- The Ministry of Public Health (Ministerio de Salud Pública or MSP) is the central authority responsible for regulating pharmaceutical and biologic products, and medical devices throughout their lifecycle. Within MSP, specialised technical units handle evaluation, registration, authorisation, inspections, pharmacovigilance and market surveillance. MSP also licenses and supervises manufacturers, importers, exporters, wholesalers, pharmacies and other regulated establishments.
- The National Customs Authority (Dirección Nacional de Aduanas or DNA) plays a complementary role in controlling imports and exports, but customs clearance is conditional upon prior or concurrent sanitary authorisation issued by MSP.

Principal legal framework

For pharmaceutical and biologic products, the core legal basis is provided by Law No 9,202 (1934), which created MSP, defined its institutional structure and powers, and established the foundational framework for pharmaceutical regulation in Uruguay. This regime was later strengthened and systematised by Law No 15,443, which sets out more specific rules governing pharmaceutical and biological products.

This statutory framework is further developed through executive regulations, notably Decree No 521/984, Decree No 18/989, Decree No 324/999, Decree No 80/025 and related provisions. Together, these instruments regulate marketing authorisation procedures, registration dossier requirements, manufacturing standards, import and export conditions, wholesale distribution, advertising and post-marketing controls. Compliance with Good Manufacturing Practice (GMP) is mandatory pursuant to Decree No 165/999 and complementary regulations. Biological products are regulated within the general medicines framework, but are subject to heightened technical and regulatory scrutiny due to their complexity and specific risk profile.

For medical devices, the applicable regime is primarily established by Decree No 3/008, which governs the classification, registration, importation, commercialisation, control and post-market surveillance of these products. The decree adopts a risk-based classification approach and sets out the obligations applicable to manufacturers, importers and distributors, as well as requirements

for prior authorisation. Although the regulatory framework for devices is formally distinct from that applicable to medicines, both regimes are administered by the same competent authority (MSP), and are based on common principles of prior authorisation, traceability, market control and patient safety.

Import, distribution, sale and export
Imports and exports require MSP authorisation and compliance with product registration. Wholesale distributors must be licensed and comply with GMP. The retail sale of medicines is restricted to authorised pharmacies under the technical direction of a licensed pharmacist, while medical devices may be sold through authorised establishments, with stricter controls for higher-risk products.

2. How are therapeutic products classified for regulatory purposes (eg, prescription-only, over-the-counter, hospital-use and risk classes for devices) 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?

The classification of therapeutic products determines the applicable authorisation pathway, distribution conditions and advertising restrictions. As a rule, premarket review and authorisation by MSP are mandatory for pharmaceuticals, biologics and medical devices before they may be imported, manufactured, distributed or marketed.

Pharmaceuticals and biologics
Pharmaceutical and biologic products are subject to prior marketing authorisation granted by MSP, based on an assessment of quality, safety and efficacy. Classification for regulatory purposes is reflected in several legal instruments, including Decree No18/989, which remains relevant for distinguishing categories of medicines, particularly in relation to prescription status and advertising controls.

In practice, medicines are classified as:

- prescription-only medicines (POM), which require a valid medical prescription and may only be dispensed through authorised pharmacies; advertising to the general public is restricted; and
- over-the-counter (OTC) medicines, which do not require a prescription, but must still be sold through authorised pharmacies and remain subject to registration, labelling and pharmacovigilance obligations.

Medicines subject to special control (eg, narcotics and psychotropics) are subject to stricter prescription, storage and monitoring requirements.

Biological products (such as vaccines and blood-derived products) are regulated within the general medicines framework, but are subject to heightened technical analysis, including stricter dossier requirements and post-marketing controls due to their higher risk profile.

Medical devices
Medical devices are regulated under Decree No 3/008, which establishes a specific regime for diagnostic reagents, medical devices and medical equipment. The system follows a risk-based approach, and all devices must be registered with MSP by an authorised company before commercialisation. Higher-risk products are subject to more demanding documentation and stronger post-market surveillance obligations.

Legal consequences
Product classification affects prescription requirements, permitted distribution channels, advertising limitations and the intensity of regulatory oversight. MSP authorisation is required for lawful commercialisation in the country.

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 Practice, facility standards, personnel, insurance or financial guarantees) attach to them?

Companies that intend to engage in the wholesale distribution of therapeutic products (medicines, biologics and medical devices) must obtain prior authorisation from MSP. Wholesale activity without such authorisation is unlawful and may result in administrative sanctions, suspension of operations and seizure of products.

Licenses and authorisations
Wholesalers must obtain a sanitary establishment licence ('habilitación sanitaria') issued by MSP, which authorises the company to store and distribute therapeutic products. This authorisation applies to the establishment itself and is separate from the product registration that must exist for each medicine or device handled.
To obtain the licence, the company must:

- register with MSP as an authorised distributor;
- obtain approval for its facilities after they have been inspected; and
- designate a technically responsible professional, who, for medicinal products, must be a licensed pharmacist legally accountable for regulatory compliance.

Key regulatory conditions
Authorised wholesalers are subject to continuous compliance obligations, including:

- Good Distribution Practice (GDP): distributors must implement systems to ensure adequate storage, transport, traceability, stock rotation and documentation, safeguarding product quality throughout the supply chain;
- facility standards: warehouses must comply with MSP requirements regarding infrastructure, hygiene, security, pest control and, where applicable, temperature-controlled storage (eg, cold chain management);
- qualified personnel: operations involving medicines must be supervised by a responsible pharmacist, who bears professional and regulatory responsibility;
- record-keeping and traceability: companies must maintain detailed records of product movements to enable effective recalls and regulatory oversight; and
- inspections: MSP has the authority to conduct periodic or unannounced inspections and to suspend or revoke authorisation in the case of non-compliance.

Regulation does not impose specific mandatory insurance or financial guarantees for wholesalers, but companies remain subject to ordinary civil, commercial and consumer protection liability regimes. The wholesale distribution system is based on prior licensing, ongoing supervision and compliance with GDP principles, aligned with international regulatory standards.

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. Regulation sets specific licensing and operational standards for businesses supplying pharmaceuticals directly to consumers, with stricter rules for retail medicine sales.

The retail sale of medicinal products to the public is legally restricted to authorised pharmacies. Pharmacies must obtain a prior sanitary establishment licence (*habilitación sanitaria*) from MSP and are subject to ongoing supervision and inspection.

Key conditions include: (1) operation under the technical direction of a licensed pharmacist, who is legally responsible for regulatory compliance; (2) the facility must comply with hygiene standards, including appropriate storage conditions and, where applicable, cold chain management; (3) meet prescription requirements: POM may only be dispensed upon the presentation of a valid prescription; (4) compliance with advertising restrictions, particularly for POM; and (5) record-keeping obligations and cooperation with pharmacovigilance and recall activities.

Pharmacies must obtain products from authorised wholesalers and dispense only MSP-registered items. Regulation is restrictive with respect to online sales of medicines. In practice, the supply of medicines through purely online pharmacies or uncontrolled e-commerce platforms is not permitted. Any digital channel that sells medicines must operate as an extension of a licensed establishment and must ensure compliance with all applicable rules on professional supervision, prescription control and patient safety.

The retail sale of medical devices may be carried out by authorised commercial establishments, depending on the type and risk level of the product. Higher-risk devices are typically limited to supply through healthcare institutions or specialised providers.

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

Local regulation applies a restrictive, safety-orientated approach to the online sale of therapeutic products, under the supervision of MSP.

The retail sale of medicines is legally reserved to authorised pharmacies. Accordingly, online sales are only lawful when conducted by a duly licensed physical pharmacy and operates as an extension of that establishment. The same regulatory requirements apply as for face-to-face dispensing.

POM may not be freely sold over the internet. Their supply requires professional intervention and verification of a valid prescription, which, in practice, limits online sales. OTC medicines may be offered through digital channels only by authorised pharmacies and remain subject to advertising, labelling and traceability rules.

Sales of medicines through unlicensed websites, social media accounts or marketplace platforms are considered unlawful. MSP has the authority to investigate, order the withdrawal of products and impose administrative sanctions where illegal online sales are detected.

For medical devices, online sales may be permitted for low-risk devices, provided the products are duly registered and the seller is an authorised establishment. Devices with higher risk profiles are generally restricted to supply through healthcare institutions or licensed professionals.

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)?

Uruguay applies a centralised import-control framework for therapeutic products under the authority of MSP, coordinated with the DNA. Generally, therapeutic products may not be imported unless they are duly authorised and registered with MSP.

For pharmaceuticals and biologics, a valid marketing authorisation (*registro sanitario*) issued by MSP is a legal prerequisite for importation. In addition, importers must be licensed establishments authorised by MSP. Each shipment is subject to sanitary oversight, and MSP may require supporting documentation such as batch information, certificates of analysis and evidence of compliance with the approved registration.

For medical devices, products must likewise be registered with MSP under the regime established by Decree No 3/008 and only authorised companies may import them. Products that are not registered cannot be lawfully released into commerce.

Customs clearance is conditional upon compliance with all sanitary requirements. The Customs Authority verifies the existence of MSP authorisations and may detain or block shipments that lack proper documentation.

Therapeutic products are classified for customs purposes under the Mercosur Common Nomenclature (Nomenclatura Común del Mercosur or NCM), which determines the applicable tariff treatment. Tariff rates generally follow the Mercosur common external tariff, although certain products may benefit from exemptions or preferential regimes, particularly vaccines, public health supplies or products imported by public entities.

Border controls operate under a risk-based approach. While not every shipment is physically inspected, MSP and customs authorities retain broad powers to inspect consignments, request additional documentation, take samples for quality testing and order the retention or rejection of non-compliant 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?

Personal importation of therapeutic products by consumers in Uruguay is permitted only on a limited and exceptional basis, and remains subject to oversight by MSP and DNA.

Generally, therapeutic products must be registered with MSP and imported through authorised companies. Accordingly, individual consumers are not entitled to freely import medicines or medical devices outside the formal regulatory and distribution system.

Exceptionally, MSP may authorise the importation of unregistered health products for an individual patient when certain conditions are met. This mechanism applies only where no equivalent registered product is available in Uruguay and requires a specific medical prescription. The request must be supported by the treating physician, with the involvement of the patient's healthcare provider, and must be accompanied by the patient's informed consent. Authorisation is granted on a case-by-case basis, and under the professional responsibility of the treating physician and healthcare institution.

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 not lawfully ship therapeutic products directly to consumers in Uruguay through e-commerce websites, social media platforms or mail order channels as regular commercial practice. The regulatory framework is designed to ensure that all therapeutic products entering the market are subject to prior authorisation, traceability and effective local accountability.

To lawfully commercialise therapeutic products in Uruguay, a foreign manufacturer or supplier must operate through a locally established importer or distributor licensed by MSP. This local authorised entity assumes legal responsibility for regulatory compliance, including: (1) product registration and maintenance of marketing authorisation before MSP; (2) compliance with mandatory labelling requirements in Spanish; (3) fulfilment of pharmacovigilance or post-market surveillance obligations; and (4) acting as the official regulatory liaison with the health authority.

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 relabelling or repackaging, and requirements to maintain original quality, safety and traceability?

Parallel importation of therapeutic products by businesses is not permitted outside the ordinary regulatory framework and remains subject to strict controls designed to protect public health and regulatory traceability.

As a starting point, all pharmaceuticals, biologics and medical devices commercialised in Uruguay must be duly registered with MSP and may only be imported by authorised companies. A business cannot lawfully import and place on the market a product merely because it is licensed and marketed in another jurisdiction. The product must correspond to an existing local registration, and the importer must be the holder of that registration or an authorised representative. This requirement significantly limits the practical feasibility of parallel importation.

From an intellectual property (IP) perspective, Uruguay recognises trademark and patent protection under its general IP legislation. Parallel importation that infringes trademark rights, patent rights or exclusive commercialisation rights may be challenged by the rights holder through judicial or administrative mechanisms. In practice, IP considerations often operate as an additional barrier to unauthorised parallel trade.

With respect to relabelling and repackaging, any modification to packaging, labelling or product presentation must be previously approved by MSP and must strictly comply with the conditions of the registered product (including Spanish labelling, approved leaflet and presentation). Unauthorised alterations are prohibited.

Importers and distributors remain fully responsible for ensuring that products maintain their original quality, safety and efficacy, including compliance with storage conditions, cold chain where applicable and full traceability throughout the supply chain. Products that cannot guarantee these conditions may be detained, withdrawn or prohibited from commercialisation.

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?

Uruguay does not apply a system of routine quantitative export quotas for therapeutic products. In ordinary circumstances, the export of pharmaceuticals, biologics and medical devices is permitted, provided that exporters comply with the general regulatory framework administered by MSP and DNA.

Companies that export therapeutic products must be duly authorised by MSP (eg, licensed manufacturers, laboratories or distributors). Products intended for export must comply with applicable quality and safety standards, and exporters must ensure proper documentation, traceability and compliance with destination-country requirements. Customs formalities apply, including export declarations and classification under the NCM.

Although there is no permanent export quota regime, local regulation allows the Executive Branch, in coordination with MSP, to adopt exceptional measures in situations that threaten public health, such as: (1) drug shortages; (2) public health emergencies; or (3) extraordinary sanitary situations (eg, pandemics).

In such circumstances, the authorities may adopt temporary restrictions or conditions on exports.

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?

Regulation does permit a form of 'export-orientated' authorisation for therapeutic products through a specific regime applicable to pharmaceutical operators located in free-trade zones (*zonas francas*). Under Decree No 80/025, such operators can import, store and export medicines, raw materials and semi-finished products without requiring registration in Uruguay, provided certain conditions are met.

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 Uruguay, imported therapeutic products may only circulate domestically once they comply with local labelling, information and traceability requirements established by MSP. These requirements aim to ensure patient safety, proper use and regulatory oversight.

All medicines marketed in Uruguay must bear labelling and patient information in Spanish, consistent with the terms of their MSP registration. This includes, at minimum: (1) product name and pharmaceutical form; (2) active ingredient(s) and strength; (3) route of administration; (4) batch number and expiry date; (5) marketing authorisation holder; (6) storage conditions, and (7) approved indications and warnings.

Each product must include an approved patient information leaflet (*prospecto*) in Spanish. Any changes to labelling or leaflet content require prior MSP approval. Products imported with foreign-language packaging must generally be relabelled or over-labelled to comply with local requirements before commercialisation.

Medical devices must also comply with Spanish labelling requirements, including the identification of the manufacturer, importer, intended use and relevant warnings.

For products manufactured for export, labelling must generally comply with the requirements of the destination country, although manufacturers must still maintain internal records, batch documentation and traceability available for MSP inspection.

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?

No. Local regulation does not impose statutory price controls on therapeutic products. That said, several reimbursements, public procurement and supply-related regimes materially influence distribution channels and product availability.

Under the National Integrated Health System (Sistema Nacional Integrado de Salud), medicines included in the Positive Medicines List (Formulario Terapéutico de Medicamentos or FMT) are reimbursed or directly financed by healthcare providers. Inclusion in the FTM is therefore a key determinant of market access, prescribing patterns and effective demand, and it notably encourages distribution through institutional channels (hospitals and clinics) rather than exclusively through retail pharmacies.

In addition, high-cost medicines and certain specialised therapies may be financed through the National Resources Fund (Fondo Nacional de Recursos), which reimburses specific treatments based on clinical protocols. This mechanism significantly influences which products are purchased and used within the healthcare system.

Public procurement also plays an important role. Public healthcare entities acquire large volumes of medicines and medical devices through tenders and framework agreements, which also can affect pricing, supplier selection and continuity of supply.

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?

Compliance with trade and distribution rules for therapeutic products is primarily supervised by MSP, through its technical units.

MSP has broad investigative powers, including on-site inspections (scheduled or unannounced), requests for documentation, traceability audits, sampling and laboratory testing of products, and the power to order precautionary measures where public health risks are identified.

Administrative sanctions are the most applied and range from formal warnings and fines to the suspension or revocation of authorisations, registrations, manufacturing or distribution licences, and product recalls or market withdrawals. MSP may also order corrective actions, compliance plans and temporary closures of facilities. In practice, precautionary measures are frequently adopted to immediately mitigate health risks, even before the conclusion of administrative proceedings.

Civil liability may arise under general tort law where non-compliance causes damage, including to patients or consumers. Criminal liability may apply in cases involving public health offences, adulteration, falsification, illegal commercialisation or serious breaches endangering public health, pursuant to the Uruguayan Criminal Code. Overall, enforcement is predominantly

administrative, with criminal action reserved for severe or intentional violations.

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 the trade, distribution and cross-border movement of therapeutic products is a field in constant evolution, driven by technological developments, regional integration and public health challenges. Regulatory authorities have progressively updated technical criteria, reinforced traceability requirements and strengthened enforcement practices, mainly through secondary regulation and administrative guidance rather than structural legal reforms.

Despite these ongoing adjustments, no drastic or disruptive changes to the core regulatory framework are currently anticipated. The existing legal regime, based on long-standing public health statutes and Mercosur technical regulations, continues to provide the backbone for market authorisation, distribution controls and import/export oversight.