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?

Argentina's regulatory framework governing the import, wholesale distribution, retail sale and export of therapeutic products is primarily centralised at the national level.

The core statute is Law No. 16,463 (Medicines Law), together with its implementing Decree No. 9,763/1964. This framework is supplemented by executive decrees and resolutions, mainly issued by the Ministry of Health, as well as detailed technical regulations adopted by the National Administration of Medicines, Food and Medical Devices (ANMAT).

The principal competent authorities are the Ministry of Health and ANMAT. The Ministry of Health assists the Executive Branch in the formulation and implementation of public health policies and issues health regulations applicable nationwide. ANMAT is a decentralised agency operating under the Ministry of Health's authority, with nationwide jurisdiction and operational autonomy. It is responsible for the authorisation, registration, control and post-marketing surveillance of therapeutic products, as well as licensing and supervising manufacturers, importers, exporters, distributors and other establishments involved in the supply chain.

Argentina is a federal country, and health matters have not been fully delegated to the federal government. Accordingly, provinces retain regulatory powers within their jurisdictions, and additional provincial or local requirements may apply to activities carried out locally, alongside national regulations.

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?

In Argentina, the marketing of any medical or therapeutic product requires prior review and approval from the enforcement authority, ANMAT.

ANMAT determines the conditions of sale (over-the-counter, prescription only, prescription to be retained by the pharmacy, and prescription with decree) considering the nature or potential dangers associated with the misuse of medicines. Within each category of medical product (non-invasive, invasive, surgically invasive, implantable, active therapeutic, diagnostic), a class is assigned depending on its risk.

ANMAT classifies medical devices (MDs) according to the intrinsic risk posed to the user, patient, or operator, into four classes from lowest to highest risk (I, II, III, IV), applying the rules established by the Southern Common Market (MERCOSUR). This includes everything from basic supplies (gloves, syringes) to complex equipment (defibrillators, medical software, prostheses, in vitro diagnostics), under regulations such as Resolution No. 64/2025, which incorporates GMC Resolution No. 25/21 'MERCOSUR Technical Regulation for the Registration of Medical Products' into the federal legal system.

Any breach of the regulations constitutes an offence and may give rise to administrative, civil, and even criminal penalties, both for the pharmacy/company and for the technical director responsible; and in certain cases, for the product holder. ANMAT will impose the relevant sanctions depending on the seriousness of the offence.

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?

Businesses intending to engage in the wholesale distribution of therapeutic products in Argentina must obtain the relevant authorisations and registrations from ANMAT before carrying out any commercial activities involving pharmaceuticals, biologics or medical devices. All activities related to human medicines may only be conducted with prior authorisation, in duly authorised establishments, and under the supervision of ANMAT or any other competent health authority.

Wholesale distributors must obtain prior sanitary authorisation for their establishments, demonstrating compliance with regulatory requirements relating to hygienic and safety conditions, adequate facilities, equipment and operational capacity. In particular, authorised establishments are required to have an analytical quality control laboratory, and to ensure proper documentation of the origin and traceability of the medicines and drugs handled, including their packaging, branding and any applied subdivision or repackaging.

Operations must be carried out under the technical responsibility of a qualified professional duly registered with the competent authority, who is responsible for ensuring the purity, legitimacy and quality of the products.

Distributors engaging in interjurisdictional transactions (ie, outside the province in which they are established) must ensure that their establishments are duly authorised by the relevant provincial or national health authority. Additional permits may be required, depending on the nature and location of the activity, such as municipal authorisations or approvals from provincial health authorities.

Finally, wholesale distributors of medicinal products must comply with the Good Distribution Practices for Medicines adopted in Argentina in 2018, which apply to all storage, distribution and transport activities, excluding retail dispensing to the public.

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. Argentine regulations establish distinct licensing and operational requirements for businesses that provide therapeutic products directly to consumers, with a clear regulatory structure that places pharmacies as the primary channel for the retail distribution of medicines.

The Argentine regulatory framework is designed on the basis that the dispensing of medicines to consumers is predominantly carried out through authorised pharmacies. In particular, the preparation of prescriptions and the dispensing of medicines and pharmaceutical specialties that require a prescription may only be performed in duly authorised pharmacies throughout the country.

Pharmacies must obtain prior authorisation from ANMAT and are subject to ongoing supervision and control. Licensing requirements include compliance with hygiene and safety standards, suitable premises for public service, appropriate installations and equipment, and operation under the technical responsibility of a licensed pharmacist.

Pharmacies must also meet specific requirements regarding laboratories, instruments, medicinal substances, chemical products, official preparations, and vaccines. Pharmacies that perform compounding or preparation of medicines are subject to additional laboratory requirements, which may include dedicated areas for specialised preparations, such as homeopathic products, when applicable.

Argentine regulations also allow for a limited retail sale of over-the-counter (OTC) medicines outside pharmacies. Within pharmacies, OTC medicines may be displayed on shelves accessible to the public. In non-pharmacy establishments, however, the sale of OTC medicines is restricted to specific categories, limited to antacids and analgesics, subject to compliance with applicable storage and display conditions.

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 through internet-based channels in Argentina has been the subject of regulatory changes and subsequent legal controversy. Within the framework of a broader deregulatory agenda, Decree No. 70/2023 and its complementary regulations sought to liberalise the existing regime by enabling the electronic sale and home delivery of medicines. This reform was aimed at relaxing traditional restrictions on pharmaceutical distribution, permitting transactions to be arranged through digital channels, subject to compliance with applicable sanitary and safety requirements.

Following these changes, the regulatory framework was challenged, and, in April 2025, the Argentine courts ordered the precautionary suspension of several provisions of Decree No. 70/2023 and related implementing regulations concerning the electronic sale and delivery of medicines. As a result, the legal regime previously in force was provisionally reinstated, reaffirming the requirement that the dispensing of medicines be carried out through authorised pharmacies and under direct professional supervision.

In this context, the Ministry of Health intensified its supervisory and enforcement activities. Based on administrative complaints, inspections were conducted at pharmacies identified as offering medicines through digital platforms. Consequently, official records were issued requiring the establishments involved to cease the commercialisation and online publication of medicines and to discontinue sales through electronic channels and home delivery modalities that were inconsistent with the precautionary measure in force. At the time of writing, the suspension remains effective, and the legality of online sales of medicines continues to be unsettled under Argentine law.

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)?

In Argentina, the import of medical devices is subject to sanitary oversight by ANMAT and compliance with applicable health regulations. Generally, the importation of medical devices intended for human use is subject to prior authorisation by ANMAT.

However, under the current regulatory framework, a simplified regime applies to medical devices classified as risk classes I and II. For these products, ANMAT does not intervene in the prior import authorisation process, provided that the products are duly registered, correctly classified, and imported by establishments authorised by ANMAT for purposes of commercialisation or free distribution. In such cases, products may be released to customs without prior authorisation, subject to the submission of a post-import notice within 48 hours of customs clearance and subsequent *ex post* controls. The importation of parts and spare parts for medical devices classified as risk classes I and II is also exempt from the import notice requirement.

Medical devices classified as risk classes III and IV, in vitro diagnostic products, temporary imports of medical devices, and imports of non-registered medical device samples, regardless of their risk class, remain subject to previous import authorisation by ANMAT. Likewise, imports carried out by ‘direct users’ (including healthcare institutions and non-profit entities) importing

medical devices for their own use, remain subject to the previous authorisation regime for all risk classes.

Regardless of the applicable import regime, companies must comply with the quality testing and control requirements applicable to each type of medical device, including those established under the relevant MERCOSUR Technical Regulations. Such tests and controls are not required for the customs release of the goods but must form part of the product release records and remain subject to inspections and enforcement actions by ANMAT.

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?

In Argentina, individuals are allowed to import therapeutic products for personal use under specific regulatory frameworks established by ANMAT. These regimes permit personal imports subject to certain conditions and requirements, depending on the type of product and its risk profile.

For medical devices and health products intended for personal use that do not require a medical prescription, ANMAT does not intervene in the import process when such products are imported by individuals for their own use, provided they are not commercialised, distributed or used for profit. This exemption applies to low-risk products, including mobility and assistance devices, respiratory care products, home self-care items, disposable medical supplies and similar goods. Standard customs clearance and declaration requirements remain applicable, meaning that the import must be duly declared before the customs authorities, although no prior authorisation or intervention by ANMAT is required in these cases.

Argentina operates an Exceptional Access Regime for Non-Registered Medicines (RAEM-NR) with respect to medicines, which allows the importation of medicines that are not registered or temporarily unavailable in the country, exclusively for the treatment of an individual patient. This regime requires prior authorisation from ANMAT, a valid medical prescription issued by a licensed physician, and clinical justification demonstrating the absence of an adequate therapeutic alternative in Argentina. Quantities are strictly limited according to the prescribed treatment duration, generally up to 90 days for short-term or oncological treatments and up to 180 days for prolonged treatments.

Medicines imported under the RAEM-NR must be declared to customs and are typically cleared through designated customs offices. These imports are exempt from customs duties and may only be released to the patient or a duly authorised representative.

Finally, the compassionate use of medical devices is permitted for patients with serious or life-threatening conditions on a case-by-case basis, subject to ANMAT approval, informed consent and robust clinical justification.

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?

Argentine health regulations require prior control, traceability, and local responsibility, which preclude the direct cross-border marketing of these types of products. Only products authorised by ANMAT and introduced into the market through a duly licensed local holder may be marketed in Argentina. Consequently, as a rule, foreign suppliers are not permitted to send therapeutic products directly to end consumers via e-commerce or mail order, except in very limited circumstances.

Exceptions include individual importation for personal use, under a special regime and with prior authorisation, as well as compassionate use cases or treatments unavailable in Argentina. However, these exceptions do not permit commercial activity, nor do they allow advertising or mass sales, and are subject to case-by-case review.

The following are required to market therapeutic products in Argentina: (1) a sanitary registration holder domiciled in Argentina; (2) an establishment authorised by ANMAT (laboratory, importer or distributor); and (3) a responsible technical director (pharmacist or other qualified professional, depending on the product). Foreign suppliers may not operate without a local representative or holder, even when sales are conducted via digital means.

Prior to marketing, the product must be registered or authorised by ANMAT, and all requirements regarding quality, safety, and efficacy must be fulfilled. In the case of medical devices, the risk classification must also be observed. Prior review and approval by ANMAT before commercialisation is mandatory.

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?

In Argentina, any importation of therapeutic products (medicines and medical devices) for commercial purposes – including parallel importation of products authorised in other jurisdictions – requires the prior involvement of ANMAT. Please see the response to Question 6, above.

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?

ANMAT does not intervene in the export of medical devices. Its involvement is limited to issuing the Certificate of Free Sale (CLV) for domestic manufacturers, but only when requested by the health authority of the destination country.

There are various procedures and specific certificates for medicines, depending on the type of export or the product involved, such as: (1) the certificate of batch release for pharmaceutical products manufactured for export; (2) the certificate for bulk medicines manufactured for export, the plant certificate for export; (3) the plant and product certificate for export; (4) the certificates for the export of biological or radiopharmaceutical products; and (5) written confirmation for the export of APIs to the European Union. These certificates are mainly issued by INAME (National

Institute of Medicines), an agency under ANMAT. Exporters must also be registered with ARCA under an exporter profile, and manufacturing and export activities must comply with Good Manufacturing Practices (GMP) in accordance with Argentine regulations, which adopt recommendations from the World Health Assembly (WHA), the Pharmaceutical Inspection Cooperation Scheme (PIC/S), and the International Conference on Harmonisation (ICH).

Although Argentina's foreign trade regime has undergone a process of deregulation, the legal framework preserves the possibility of restricting exports on public health grounds. However, such restrictions cannot be applied automatically or at their sole discretion. Any measure limiting or conditioning exports on health grounds must be explicitly established through a formally sanctioned normative act that provides a clear legal basis, scope, and justification for the restriction.

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?

Argentine regulations allow the export and import of medical devices provided they are not included on ANMAT's official list of prohibited products. As a general requirement, companies must have an authorised laboratory, a qualified technical director, and a licensed manufacturing plant to ensure compliance with regulatory standards.

In the specific case of medicines, there is a certificate issued by INAME called 'Certificate for products exclusively for export', which certifies that the product is manufactured solely for export and that the manufacturing plant complies with Good Manufacturing Practices under Argentine regulations. This certificate requires the name of the company, the manufacturing plant, the technical oversight of the pharmacist responsible, the pharmaceutical form, the presentation, and the qualitative and quantitative formula of the product. It is valid for 12 months and is issued on the company's request for submission to the health authorities of the destination country.

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?

According to the MERCOSUR Technical Regulation on Medical Devices, as adopted by Argentina as a Member State, manufacturers and importers of medical devices must comply with its established requirements.

All medical devices must be registered with ANMAT before they can be marketed in Argentina. Labelling and instructions for use must be provided in Spanish, either on the product, the unit package, or, where appropriate, in the commercial packaging or accompanying instructions. Low-risk devices (classes I and II) may omit printed instructions if safe use can be guaranteed. Labels must include the manufacturer and importer details, country of origin, product identification, lot or serial number, manufacturing and expiry dates, single-use indication if applicable, storage and

handling conditions, sterilisation method, warnings and precautions, the legally responsible technical person, and the ANMAT registration number.

Instructions for use must provide the intended purpose, potential side effects, installation and connection guidance if combined with other devices, maintenance and calibration requirements, risks associated with implantation, reuse procedures, sterilisation instructions, and any applicable radiation or drug administration information. They must also cover precautions for environmental exposure, unusual disposal risks, and patient counselling requirements.

Traceability is ensured through the National Medical Device Traceability System (SNT-PM), initially applied to high-risk implantable devices. Each unit must carry a GS1-compliant device or label containing a unique identifier, including the Global Trade Item Number (GTIN), serial number, batch, and expiry date, and distribution requires registration in the SNT-PM database using the Global Location Number (GLN).

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?

Argentina does not operate a strict price-control regime for therapeutic products. Manufacturers and laboratories are generally free to set their own prices. However, the Ministry of Health publishes reference price lists that, while not binding on laboratories, establish the maximum price base used by social security health insurance schemes (*obras sociales*) and private health insurers (*prepagas*) to calculate reimbursements and discounts. As a result, these reference prices materially influence reimbursement levels and market dynamics, even though they do not formally cap prices.

In addition, the State may enter into specific agreements with domestic laboratories aimed at ensuring more affordable prices for certain medicines supplied within the public health system. These agreements are negotiated on a case-by-case basis and are intended to support access rather than impose mandatory pricing.

Public procurement also plays a significant role in market access and distribution. The State conducts national and international public tenders for the acquisition of medicines through official procurement platforms, particularly for large-scale public health programmes and for social security entities such as PAMI. One of the most relevant programmes is the REMEDIAR Programme, which ensures access to essential medicines through direct distribution to public health centres nationwide, supplying a broad range of commonly used therapeutic products to patients who rely exclusively on the public 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?

Regulatory authorities have broad powers to investigate and enforce compliance with rules governing the trade and distribution of therapeutic products.

Sanctions for violations include a range of administrative measures, proportionate to the severity or recurrence of the infraction. These measures include: warnings; fines; temporary or permanent closure of facilities; suspension or disqualification from practicing the profession for up to three years (or permanently in cases of repeated or extremely serious violations); and confiscation of products or substances involved in the infringement. Authorities may also revoke the authorisation to manufacture or sell the products in question.

If fines are not paid voluntarily, authorities may initiate judicial enforcement proceedings before the competent criminal-economic or federal courts. In practice, these powers are applied through inspections, administrative proceedings, and, when necessary, legal action to ensure compliance, prevent public health risks, and maintain the integrity of the pharmaceutical supply chain.

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?

Recent regulatory developments relating to the distribution of therapeutic products to customers in Argentina aim at enhancing transparency in pharmaceutical pricing, improving patients' access to pricing information, and promoting informed decision-making. These regulations provide electronic price transparency for prescription medicines through QR codes. Under the rules issued by the Undersecretariat for Consumer Protection and Commercial Loyalty, each QR code must link to a price list that meets specific technical specifications.

The list must include the active pharmaceutical ingredient (IFA), commercial name, presentation, manufacturer, retail price, and, where applicable, the PAMI-affiliated price. Only presentations accessible to retail customers are included, excluding hospital-only forms. Products must have updated prices and be available for dispensing at the pharmacy. The list must be ordered by IFA, presentation, and ascending price to facilitate comparison between products with similar characteristics.

With respect to anticipated reforms, Argentina, which is a member of the TRIPS Agreement, is expected to approve the Patent Cooperation Treaty (PCT) in the near future, at the initiative of the current government. This development would significantly facilitate and increase the filing of foreign pharmaceutical patent applications through the PCT system and, consequently, substantially affect the import and distribution of these products in Argentina.

In addition, from a substantive law perspective, there is a possibility that the current patentability criteria that restrict the phenomenon commonly referred to as 'evergreening' may be repealed or relaxed. Should this occur, a rise in pharmaceutical patent filings in Argentina is likely, as the existing limitations on patent protection (particularly those affecting second medical uses, new dosage regimens, pharmaceutical combinations, crystalline forms, salts, and alternative manufacturing or preparation methods) would be reduced.

Finally, there have been discussions regarding a potential reform of the current data exclusivity (test data protection) regime in favour of a more innovation-friendly framework. However, at this stage, no concrete measures or official proposals have been announced by the Argentine

government in this respect. These reforms would significantly affect the import and distribution of therapeutic products.