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?

The National Health Surveillance Agency (ANVISA) is the principal federal regulatory authority for therapeutic products in Brazil, including medicines, biological products, and medical devices. ANVISA serves as the central body of the National Health Surveillance System (SNVS) and is responsible for health regulation at the national level, including:

- granting products' marketing authorisations;
- certifying Good Manufacturing Practices (GMPs);
- authorising and controlling import and export activities; and
- issuing technical standards and regulations, particularly through Collegiate Board Resolutions (RDCs), which establish detailed requirements for the manufacture, distribution, marketing, and post-marketing monitoring of therapeutic products.

While the same general regulatory framework applies to both pharmaceuticals/biologics and medical devices, ANVISA maintains separate technical regulations for each category, with distinct registration pathways, documentation requirements, and risk-based classifications.

ANVISA coordinates with other agencies in controlling foreign trade operations. The Brazilian Federal Revenue Service (RFB) is responsible for customs procedures, tax inspection, and the clearance of goods at ports, airports, and border points. State and municipal health surveillance authorities are responsible for health licensing of establishments, local inspection, and the application of administrative sanctions, in accordance with federal regulations.

With respect to the division of powers, in Brazil, health is a matter of concurrent jurisdiction among the federal government, the states, and the municipalities. The federal government, through ANVISA, is responsible for issuing general rules, granting national registrations and authorisations, and controlling imports and exports. The states and municipalities are responsible for supplementing federal legislation, licensing establishments, inspecting activities, and applying administrative sanctions in their respective territories.

As of February 2026, the following are the principal statutes and regulations governing therapeutic products in Brazil:

- Law No. 6,360/1976 and Decree No. 79,094/1977 – subjects medicines, pharmaceutical supplies, drugs, related products, and cosmetics to the health surveillance system.;
- Law No. 8,080/1990 – establishes the basis for the Brazilian Public Health System (SUS) and defines health surveillance actions;
- Law No. 9,782/1999 – creates ANVISA and defines its scope of action and regulatory authority;
- Law No. 13,021/2014 – governs the exercise and supervision of pharmaceutical activities, including pharmacy operations and retail sale requirements;
- RDC No. 430/2020 – establishes good practices for the distribution, storage, and transportation of medicines; and
- RDC No. 939/2024 – sets criteria for applying for Operating Authorisation (AFE) and Special Authorisation (AE) for companies operating at ports, airports, and borders, directly relevant to import and export activities.

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 Brazil, therapeutic products are classified by their nature, intended use, risk level, and need for professional oversight. ANVISA applies different regulatory regimes to medicines, biological products, and medical devices. This classification determines requirements such as medical prescriptions, sales conditions, authorised distribution channels, and the extent of pre- and post-marketing health controls.

For medicines, the primary classification concerns the prescription regime. Medicines are categorised as follows:

- Over-the-counter medicines (OTC) – freely sold in pharmacies, drugstores, and some authorised establishments. Advertising to consumers is allowed, subject to observance of several rules and conditions.
- Prescription medicines – dispensed only in pharmacies and drugstores on presentation of a prescription, which is not retained. Advertising is restricted to healthcare professionals.
- Prescription medicines with prescription retention – pharmacies must retain the original prescription for inspection.
- Specially controlled medicines – subject to strict regulations, including special prescriptions and registration in the National Controlled Products Management System (SNGPC). Distribution is limited to authorised distributors, and strict inventory controls apply.
- Hospital or professional use – Medicines administered only in healthcare settings under supervision by qualified professionals, due to their complexity, risk, or specific form of presentation. These products may not be sold through retail pharmacies.

Biological products (eg, vaccines, blood-derived products, biotechnology medicines) follow the same general prescription classifications as conventional medicines but are subject to additional

requirements, including stricter storage and cold-chain distribution controls, batch-by-batch release protocols, and enhanced traceability requirements throughout the supply chain.

Medical devices (eg, equipment, materials, implants) are classified based on potential risk to the health of the patient and user, ranging from Class I to Class IV.

Premarket analysis and approval by ANVISA are mandatory for the marketing and distribution of all therapeutic products, with the level of documentation and procedural requirements varying according to the classification.

The sale of non-compliant products subjects those responsible to a range of a penalties, including fines, product seizure and destruction, suspension or cancellation of operating licences, prohibition from participating in public biddings, and criminal liability for serious violations involving public health risks, including potential imprisonment.

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?

The main authorisations required for companies to distribute therapeutic products are outlined below.

Operating Authorisation (AFE)

The AFE (*Autorização de Funcionamento de Empresa*) is the document which authorises the operation of companies or establishments that carry out activities involving the storage, distribution, packaging, shipping, export, extraction, manufacture, fractionation, import, production, purification, repackaging, synthesis, transformation, and transportation of medicines and pharmaceutical inputs intended for human use, health products, and other products.

Special Authorisation (AE)

The AE (*Autorização Especial*) is specifically required for companies that work with substances subject to special control, such as those listed in Ordinance No. 344/98 (eg, controlled medicines, narcotics, psychotropic medicines). Companies handling these substances must obtain AE in addition to AFE.

Certificate of Good Distribution and Storage Practices (CBPDA)

The CBPDA is the document that certifies that a given establishment complies with Good Distribution and Storage Practices (GDP) as set out in current legislation. This certificate applies to companies engaged in the storage, distribution, and importation of medicines, pharmaceutical inputs, and health products.

Sanitary Permit (*Alvará Sanitário*)

In addition to federal authorisations, establishments must obtain a Sanitary Permit (*Alvará Sanitário*) from the competent state or municipal health surveillance authority.

For wholesale distribution of medical devices, the same general licensing framework applies (AFE, Sanitary Permit). However, distributors of higher-risk devices (Classes III and IV) may be subject to additional ANVISA oversight, including more frequent inspections and specific traceability requirements. The CBPDA or equivalent certification for Good Storage Practices is also required for medical device distributors.

Companies and establishments which dispense, market, supply, and distribute pharmaceutical products and health products must operate under the supervision of a technical manager (*Responsável Técnico*) who is duly registered with a competent professional council. The establishment must obtain a Technical Responsibility Certificate (CRT), which formalises the relationship between the professional and the establishment.

In terms of facilities and infrastructure, the establishment must have segregated areas for different product categories and for quarantined, rejected, or recalled products; access control to prevent unauthorised entry; adequate environmental conditions, including temperature and humidity monitoring and control; control and traceability systems for inventory management; standard operating procedures for all critical activities; deviation and complaint management systems; and recall plans and procedures.

Brazil's regulations do not impose specific mandatory insurance requirements or financial guarantees (such as bonds or minimum capital) for wholesale distributors of therapeutic products as a condition of obtaining AFE or AE. However, distributors commonly obtain general civil liability insurance and product liability coverage as a matter of commercial practice and contractual requirements from manufacturers or principals. Companies should also be aware that liability for defective products under the Brazilian Consumer Protection Code (Law No. 8,078/1990) may create significant exposure, making adequate insurance coverage advisable even if not legally mandated.

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 Brazil, there are distinct licensing requirements and specific conditions for companies that supply therapeutic products directly to consumers, depending on the type of establishment and the products sold.

Physical pharmacies and drugstores are the primary retail channel for medicines in Brazil. These establishments must obtain Operating Authorisation (AFE) from ANVISA; Sanitary Permit (*Alvará Sanitário*) from the state or municipal health surveillance authority; Technical Responsibility Certificate linking a licensed pharmacist to the establishment; and Certificate of Good Distribution and Storage Practices or equivalent certification.

The key conditions include: (1) a licensed pharmacist (*Responsável Técnico*) who must be present during all operating hours; (2) prescription medicines may only be dispensed on presentation of a valid prescription; (3) for prescription medicines with retention requirements, the original prescription must be retained and filed; (4) controlled substances (narcotics,

psychotropic medicines) require registration in the National Controlled Products Management System (SNGPC), special prescription forms, and strict inventory controls; (5) facilities must maintain appropriate storage conditions, including temperature and humidity controls; and (6) advertising of prescription medicines to consumers is prohibited.

Compounding pharmacies (*Farmácias de Manipulação*) prepare customised medicines based on individual prescriptions. In addition to the general requirements above, these establishments are subject to additional regulations under ANVISA RDC No. 67/2007.

Online pharmacies must comply with all requirements applicable to physical pharmacies, plus additional rules for non-face-to-face sales under ANVISA RDC No. 44/2009 and related regulations, including: (1) the online pharmacy must have a licensed physical establishment-purely virtual operations are not permitted; (2) the website must be registered with or communicated to ANVISA; (3) a licensed pharmacist must be available to provide guidance to consumers (eg, via chat, telephone, or video); (4) controlled substances and medicines subject to special control generally cannot be sold online; (5) delivery must ensure product integrity, including cold-chain requirements where applicable; (6) the consumer must have access to clear information about the product, including package insert and contraindications; and (7) returns and complaints must be managed in accordance with consumer protection regulations.

Medical devices intended for home use (eg, blood pressure monitors, glucose meters, mobility aids) may be sold through pharmacies, specialised medical supply retailers, or general retailers depending on the device classification, as follows: (1) Class I and II devices may generally be sold through a broader range of retail channels; (2) Class III and IV devices typically require sale through specialised establishments with appropriate technical support. Certain devices (eg, prescription-only devices) may only be sold on presentation of a medical prescription.

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

In Brazil, the sale of therapeutic products over the internet is strictly regulated and is only permitted by duly licensed establishments. The rules apply to all online channels, including proprietary websites, social media platforms, and third-party marketplaces.

Only pharmacies and drugstores holding the following authorisations may sell therapeutic products online: (1) Operating Authorisation (AFE) from ANVISA; (2) Sanitary Permit (*Alvará Sanitário*) from state or municipal health authorities; (3) Technical Responsibility Certificate linking a licensed pharmacist (*Responsável Técnico*) to the establishment; and (4) a registered physical establishment; purely virtual operations without a licensed physical location are prohibited. The website or online sales channel must be registered with or communicated to ANVISA.

Sales by individuals or unlicensed companies are strictly prohibited and not all therapeutic products may be sold online.

Sales of therapeutic products through social media (eg, Instagram, Facebook, WhatsApp) are subject to the same requirements as other online sales, as the seller must be a licensed pharmacy or drugstore with AFE and Sanitary Permit. Direct sales by individuals, influencers, or unlicensed accounts are banned.

Third-party marketplaces (eg, Mercado Livre, Amazon Brazil, Magazine Luiza) may host sales of therapeutic products only if the seller is a licensed pharmacy or drugstore with valid AFE and Sanitary Permit; the marketplace verifies seller credentials before allowing listings (though enforcement varies); banned products (controlled substances, unregistered medicines) are not listed; and the marketplace platform itself is not the seller of record for medicines (liability remains with the licensed pharmacy).

Online sales must comply with delivery and consumer protection requirements and complaints must be managed in accordance with consumer protection regulations.

All online advertising of therapeutic products must comply with RDC No. 96/2008, the Consumer Defence Code, the Brazilian Advertising Self-Regulation Council (CONAR) Code and guidelines and other applicable rules to the promotion of therapeutic products.

Unlicensed online sales of therapeutic products subject violators to administrative fines from ANVISA and state/municipal health authorities, product seizure and destruction, suspension or cancellation of operating licences (for licensed establishments that violate rules), platform account suspension or removal; and criminal prosecution for serious violations, including sale of controlled substances without authorisation, which may result in imprisonment.

The key regulations on this topic are RDC No. 44/2009, RDC No. 96/2008, Ordinance No. 344/98 and Law No. 8,078/1990 (Consumer Defence Code).

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 Brazil, the import control of therapeutic products is governed by a set of health, customs, and tax laws and regulations, aimed at ensuring legal certainty for the Brazilian market.

Article 10 of Law No. 6,360/1976 establishes that medicines and medical devices must be previously regularised (ie, through registration or notification) with ANVISA before importation, according to the nature and specific characteristics of the product, as well as its respective risk class.

Importing companies must hold the following authorisations: Corporate Taxpayer ID Number (CNPJ); authorisation in the Customs Intervening Parties Registration and Tracking System (RADAR/Siscomex) issued by the Brazilian Federal Revenue Service (RFB); Operating Authorisation (AFE) issued by ANVISA; and for controlled substances listed in Ministry of Health Ordinance No. 344/1998, Special Authorisation (AE) is also required.

Importation is formalised through the Import Declaration (DI) in Siscomex, linked to the Import Licence (LI). LI approval is granted by ANVISA and depends on the submission of complementary documents, which vary according to the classification of each product (RDC No. 81/2008 and RDC No. 977/2025). LI of therapeutic products must generally be requested prior to the shipment of the goods to Brazil (non-automatic licensing).

The fiscal classification of therapeutic products follows the Mercosur Common Nomenclature (NCM), which determines the incidence of the following taxes: Import Tax (II): Rates vary by NCM code, typically ranging from nought to 18 per cent for therapeutic products; Tax on Industrialised Products (IPI): Rates vary by product type; COFINS-Importation: Standard rate of 9.65 per cent for most products, subject to exemptions; and PIS-Importation: Standard rate of 2.1 per cent; and, finally, the State VAT (ICMS), which rates also vary according to the NCM.

Due to the relevance of therapeutic products for public health, certain tax reductions or exemptions are provided by law.

Sanitary control at borders is carried out by the RFB and by ANVISA's General Management of Ports, Airports, Borders, and Customs Facilities (GCPAF). ANVISA employs a risk-based inspection approach. All therapeutic product imports undergo documentary review to verify compliance with registration, licensing, and labelling requirements. Physical inspection of shipments is determined based on risk factors including: product type, importer compliance history, and country of origin, among others. For temperature-sensitive products, ANVISA may verify temperature records and inspect packaging integrity.

GCPAF has authority to seize or prohibit irregular products and/or those with insufficient documentation (Laws No. 9,782/1999 and No. 6,437/1977, as well as RDC No. 585/2021), to ensure compliance with local laws and regulations.

Import licence processing times vary depending on product complexity and documentation completeness. ANVISA may grant expedited processing for urgent public health needs.

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 medicines and medical devices for personal use, either by bringing them in their luggage or receiving them via express or postal shipment, provided they comply with health and customs regulations.

Under the general rules for personal import set out in RDC No. 81/2008, it is not necessary to obtain ANVISA authorisation or submit prior documentation for the importation of medicines, provided that: (1) the products are intended for personal use (ie, quantity and frequency compatible with the duration and purpose of treatment); (2) the products are not intended for commercial purposes; and (3) the products do not contain substances listed as banned under Ordinance No. 344/1998.

The importation of medicines subject to special control is only allowed when there are no therapeutic alternatives available in Brazil and on exceptional authorisation from ANVISA. In such cases, a specific ANVISA form must be completed and submitted; a copy of the prescription and medical report must be provided; a liability statement signed by both the physician and the patient is required. Processing may take several weeks, so advance planning is essential.

Individuals may import medical devices for personal use. However, importation is not permitted for devices that are classified as for exclusive professional use, intended for providing services to third parties, or intended for commercial purposes.

Travellers entering Brazil with medicines in their luggage should declare them on the customs declaration form if quantities exceed personal use thresholds or if carrying controlled substances with ANVISA authorisation.

Postal and express courier shipments are processed through *Siscomex* and subject to documentary review by RFB and ANVISA. No advance declaration by the consumer is required, but shipments may be held for verification.

Travellers may carry medicines for personal use. Quantities consistent with personal treatment are generally accepted without issue. Express courier is admitted, subject to customs clearance procedures. The courier handles documentation, but shipments may be inspected and require proof of personal use. Postal service is also subject to inspection by RFB at international mail processing centres.

According to Law No. 15,071/2024, imports of medicines by individuals via postal shipment are exempt from Import Tax (II), limited to purchases of up to USD10,000, provided they are for personal or individual human use. However other federal taxes (IPI, PIS-Importation, COFINS-Importation) may still apply depending on the product and its NCM; the State VAT (ICMS) may apply to certain shipments, also depending on the NCM; and applicable rates are determined under Decree No. 6,759/2009 and local tax legislation.

Consumers who break personal import rules may face seizure of the products by customs authorities, administrative fines; and for banned substances, criminal prosecution under drug trafficking laws.

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

Foreign suppliers are generally not authorised to sell therapeutic products directly to Brazilian consumers via e-commerce or mail order without establishing a local presence and complying with all applicable sanitary regulations.

Under Law No. 5,991/1973 dispensing of medicines, including through e-commerce, is restricted to pharmacies and drugstores legally established in Brazil, with valid sanitary licences and the presence of a responsible pharmacist, as provided by ANVISA's RDC No. 44/2009. Offering medicines on websites that do not belong to authorised and licenced pharmacies or drugstores is forbidden.

Foreign suppliers wishing to sell therapeutic products in Brazil must either: (1) establish a legal entity and obtain all the applicable licences for the legal entity, and register or notify each product with ANVISA before commercialisation; or (2) partner with a licensed Brazilian importer or distributor who assumes responsibility for regulatory compliance. In this model, the Brazilian partner handles importation, registration, and distribution, while the foreign supplier remains the manufacturer.

All therapeutic products sold in Brazil must comply with Portuguese language labelling requirements.

Foreign suppliers who attempt to sell directly to Brazilian consumers without proper authorisation face the following consequences: (1) shipments may be intercepted and seized by customs authorities (RFB and ANVISA); (2) ANVISA may issue public warnings about unauthorised foreign websites; (3) marketplace platforms may be required to remove listings from unauthorised sellers; (4) Brazilian consumers who receive unauthorised products may face seizure at customs; and (5) repeat violations may result in blocking of the foreign supplier's shipments.

The exception is imports for personal use, as detailed in the response to Question 7, above. Nevertheless, this exception does not authorise foreign suppliers to market to Brazilian consumers, it only permits consumers to purchase products independently for their own use.

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 Brazil, parallel importation of therapeutic products faces significant legal and regulatory barriers.

Brazil follows a national (territorial) exhaustion regime applicable to both trademarks and patents, under which rights are exhausted only with respect to products that have been lawfully placed on the Brazilian market by the rights holder or with its consent (Arts 43, IV and 132, III of the Brazilian Industrial Property Law-Law No. 9,279/1996). Prior commercialisation of original products abroad does not exhaust IP rights in Brazil or authorise parallel importation. Consequently, parallel importation of therapeutic products without the rights holder's consent is generally not permitted in Brazil and may constitute trademark and/or patent infringement, exposing the importer to civil liability and seizure of goods.

Notwithstanding the statutory national-exhaustion regime, Brazilian courts have, in certain cases, required evidence of an exclusive trademark/patent licence agreement duly recorded with the Brazilian Patent and Trademark Office (INPI – *Instituto Nacional da Propriedade Industrial*) to uphold the rights holder's position fully against third parties, including parallel importers.

From a sanitary standpoint, parallel importers face an additional barrier, in that therapeutic products require ANVISA registration or notification before commercialisation in Brazil. A parallel importer generally cannot rely on the existing ANVISA registration held by the rights holder's authorised distributor. Obtaining a separate registration would require: (1) authorisation from the original manufacturer, which is unlikely if the manufacturer opposes parallel importation; (2) submission of complete technical dossiers; and (3) compliance with all Brazilian regulatory requirements.

This effectively makes lawful parallel importation of registered therapeutic products extremely difficult without the rights holder's cooperation.

As a practical matter, parallel importation of therapeutic products by businesses is generally not viable in Brazil due to the combination of: (1) the national IP exhaustion regime, which does not permit unauthorised parallel imports; (2) ANVISA registration requirements, which cannot typically be satisfied without manufacturer cooperation; and (3) re-labelling and re-packaging requirements that require regulatory approval. Businesses seeking to import therapeutic products should work with authorised distributors or obtain proper licensing from the rights holder.

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?

Brazil does not maintain permanent quantitative export quotas for therapeutic products. However, export-restrictive measures may be adopted in response to public health needs. For example, during the Covid-19 pandemic, Law No. 13,993/2020 and Decree No. 10,407/2020 established an exceptional control regime authorising the federal government to condition, limit, or ban exports of medicines, vaccines, pharmaceutical inputs, and medical devices to safeguard national supply.

The Ministry of Health and ANVISA administer export restrictions and designate affected products. The Brazilian Federal Revenue Service (RFB) enforces restrictions at customs. Violations may result in shipment seizure and administrative penalties. Exporters should monitor official announcements from ANVISA and the Ministry of Health to verify whether specific products are subject to restrictions.

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?

Yes. Brazilian regulation allows the manufacture and export of therapeutic products which are not approved for domestic marketing, under a specific 'export-only' authorisation regime administered by ANVISA. The key requirements include obtaining an Operating Authorisation (AFE) from ANVISA for the manufacturing facility and certificate of Good Manufacturing Practices (CBPF) from ANVISA, when applicable. The product must comply with the destination country's regulatory requirements and labelling may be in the destination country's language but must clearly identify the manufacturer and batch number. Such products must comply with Brazilian labelling requirements (Portuguese language, ANVISA registration number) in addition to destination country requirements. Manufacturers must maintain production batch records, quality control documentation, and export records for the period required by ANVISA.

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?

Imported medicines and medical devices must bear labels and package inserts in Portuguese, containing product name, composition, concentration, pharmaceutical form, batch number, expiry date, manufacturer and importer identification, storage conditions, and ANVISA registration number. Medicines must include patient information leaflets (*bulas*) approved by ANVISA (RDC No. 71/2009 for medicines; RDC No. 751/2022 for devices).

Medicines are subject to the National Drug Control System (SNCM), which requires unique serial identifiers on secondary packaging, enabling end-to-end supply chain traceability and serving as the primary anti-counterfeiting measure (Law No. 13,410/2016; RDC No. 319/2019).

Medical devices must comply with Unique Device Identification requirements, ensuring traceability throughout the supply chain and supporting post-market surveillance.

Products manufactured exclusively for export need not comply with Brazilian labelling requirements but must meet destination country standards. Manufacturers must maintain traceability documentation (batch records, serialisation data, distribution records) available for ANVISA 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?

Yes. Several regimes materially influence distribution channels and availability of therapeutic products in Brazil.

Medicines are subject to federal price regulation administered by the *Câmara de Regulação do Mercado de Medicamentos* (CMED), which establishes maximum factory and retail prices (PF and PMC), authorises price adjustments, and may impose price freezes for essential products (Law No. 10,742/2003). This directly affects commercial strategies and distribution margins.

The Brazilian Public Health System (SUS) operates a nationwide reimbursement and centralised procurement system. High-cost and strategic medicines are acquired through federal, state, and municipal tenders, with binding supply obligations for winning suppliers. CONITEC (*Comissão Nacional de Incorporação de Tecnologias no SUS*) evaluates products for SUS incorporation, affecting reimbursement eligibility.

The Ministry of Health may classify products as strategic for public health, triggering priority procurement, mandatory supply commitments, stock-maintenance requirements, and emergency requisition powers during shortages.

Medical devices are not subject to CMED price controls but are included in SUS procurement for products incorporated into public health programmes.

Together, these regimes significantly affect how therapeutic products are priced, distributed, and made available in Brazil.

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?

ANVISA has broad authority under Law No. 9,782/1999 to investigate non-compliance, including: (1) conducting announced or unannounced facility inspections; (2) requesting documents, records, and information from companies; (3) sampling and testing products; and (4) coordinating with customs (RFB) on import inspections.

State and municipal health authorities have concurrent jurisdiction to conduct inspections and apply sanctions within their territories.

Violations of federal health legislation under Law No. 6,437/1977 may result in: fines, product seizure and destruction; cancellation of product or company registration; and facility interdiction.

When there is evidence of fraud, falsification, or adulteration, cases may be referred to civil and criminal authorities, leading to liability for damages and penalties under the Brazilian Penal Code.

Companies must also observe anti-corruption regulations under Law No. 12,846/2013. Violations (eg, bribing regulators, bid-rigging in pharmaceutical procurement) may result in fines of 0.1 per cent to 20 per cent of gross revenue, exclusion from public contracts, and reputational penalties.

Effective integrity and compliance programmes may be considered as mitigating factors in penalty determinations.

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?

Several recent developments may significantly affect the regulation of trade and distribution of therapeutic products in Brazil. These are outlined below.

Judicialisation of medicine access

The Brazilian Supreme Court (STF), through General Repercussion Theme No. 1234, established the need for objective and transparent parameters governing medicine sales to public authorities pursuant to Court decisions. In response, CMED issued Resolution No. 3/2025 with detailed pricing criteria, and Public Consultation No. 1/2026 is gathering input on further refinements. These developments affect pricing and distribution strategies for companies supplying the public sector.

Regulatory modernisation: facilitation of imports

ANVISA has modernised regulatory reliance mechanisms under Normative Instruction No. 289/2024, allowing assessments by equivalent foreign authorities (including FDA and EMA) to

be considered for drug registration and post-authorisation changes. This significantly facilitates cross-border movement by streamlining import approvals for products already approved in trusted jurisdictions.

SNCM serialisation rollout

The National Drug Control System (SNCM) continues phased implementation, with expanding traceability requirements affecting distribution operations and supply chain systems.

Pharmacies in supermarkets

Law No. 15,357/2026 was published in the *Official Gazette* on 23 March 2026. It authorises the installation of pharmacy sections within supermarkets, provided they operate in a physically delimited, segregated, and exclusive area for pharmaceutical activities. Law No. 15,357/2026 expanded retail distribution channels for therapeutic products by allowing pharmacies to operate within larger retail establishments, subject to compliance with existing licensing and operational requirements.

Enforcement trends: anti-corruption

Recent enforcement has concentrated on public procurement, with leniency agreements and sanctions involving pharmaceutical and medical device companies. Accordingly, public-sector sales warrant enhanced compliance controls.

Expected developments include further regulatory reliance expansion, potential updates to online pharmacy rules, and continued SNCM implementation deadlines.