

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?

Colombia regulates therapeutic products under a centralised regulatory framework established by Law 9 of 1979 (General Health Code) and complemented by the following sector-specific provisions: for medicinal products and biologics, Decree 677 of 1995 and technical regulations on Good Manufacturing Practices; for medical devices and in vitro diagnostics, Decree 4725 of 2005 and subsequent amendments; together with resolutions detailing requirements for authorisation, commercialisation, post-market surveillance, and vigilance. These rules align with international standards of quality and safety.

The National Institute for Food and Drug Surveillance (INVIMA), attached to the Ministry of Health and Social Protection (Ministry), is the competent authority responsible for granting marketing authorisations for medicines, biologics, and medical devices, issuing licences and certifications for manufacturing and importation, inspecting establishments, and conducting post-market surveillance. The Ministry, in turn, defines public health policy and issues enabling regulations, while territorial health authorities, and the National Health Superintendence carry out inspection and operational oversight without authority to enact substantive product regulations. For foreign trade operations, the Single Window for Foreign Trade (VUCE) is the competent authority for import and export procedures.

The importation, distribution, and export of medicines, biologics, and medical devices require a valid marketing authorisation issued by INVIMA, as well as the corresponding sanitary licence for the establishment and compliance with applicable Good Practices (GMP for medicines and technical storage conditions for devices). INVIMA supervises the supply chain, including traceability, storage, and sanitary documentation, while retail supply is subject to local sanitary licences and territorial oversight.

Colombia is a social state under the rule of law with a centralised administrative structure, as defined by its Political Constitution. This means that regulatory and authorisation powers for therapeutic products reside at the national level (Ministry and INVIMA), while territorial authorities perform inspection and surveillance functions.

Additionally, Law 780 of 2016 classifies wholesale pharmaceutical establishments such as pharmaceutical laboratories, specialty pharmaceutical agencies, and drug warehouses; and retail pharmaceutical establishments such as pharmacies-drugstores and drugstores.

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?

Colombia classifies therapeutic products according to their nature and risk, assigning specific legal consequences to each category for prior authorisation, commercialisation, and control. In the case of medicinal products – whether of chemical synthesis or biological origin – classification distinguishes between prescription-only (Rx) and over-the-counter (OTC) products. OTC status is determined by technical criteria (broad safety margin, proven track record of safe use, labelling conditions), established by the Ministry of Health following recommendations from the Review Commission (technical advisory body to INVIMA) and INVIMA’s evaluation, and published on official platforms. In all cases (Rx or OTC), commercialisation requires a valid marketing authorisation issued by INVIMA, following a technical and legal review of the dossier (including quality, safety, efficacy, and labelling). Sale and distribution must take place in authorised establishments, in compliance with applicable rules on dispensing, storage, and traceability.

For medical devices and in vitro diagnostics, the regulatory framework adopts a risk-based classification (Classes I, IIa, IIb, and III), based on factors such as invasiveness, duration of use, and product function. This classification determines the regulatory burden prior to commercialisation and the conditions for establishment certification (eg, storage and conditioning capacity for importers), as well as post-market surveillance requirements. In particular, Class IIa, IIb, and III devices are subject to marketing authorisation with technical documentation review by INVIMA before being placed on the market. For Class I devices, proportional requirements apply as defined in regulations and technical guidelines. Authorisation enables activities such as manufacturing, importing, marketing, storage, and sale of the device, provided that sanitary and traceability conditions are met.

INVIMA exercises market surveillance for both medicinal products and medical devices, and may impose corrective or sanctioning measures in cases of non-compliance.

Consequently, with respect to trade and distribution, classification affects: (1) the requirement and depth of premarket review by INVIMA, which is mandatory for all medicinal products, whether chemically synthesised or biologically derived, and for devices according to their risk class; (2) the conditions of supply (prescription versus OTC medicines); and (3) the establishment requirements and traceability/storage obligations which must be met by those involved in the supply chain. Premarket review and approval by the competent authority are therefore prerequisites in Colombia for the commercialisation of chemically synthesised and biological medicines, and for most medical devices applying A proportional regulatory approach is applied, based on product category and level of risk.

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?

To engage in wholesale distribution of medicinal products, companies must operate within a pharmaceutical establishment duly authorised by the territorial health authority (departmental/district secretariats), in accordance with the Pharmaceutical Service Management Model and the Manual of Essential Conditions and Procedures. This entails, inter alia, a quality system compliant with Good Distribution Practices (GDP), documented procedures for receipt, storage, and dispatch, temperature and humidity control (including cold chain where applicable), segregation of quarantined or expired products, traceability of batches and transactions, a contingency plan, and an appropriate technical director responsible for regulatory compliance. These conditions are set out in Resolution 1403 of 2007, compiled under the Unified Decree 780 of 2016, and are subject to territorial inspection. In addition, commercialisation is only permitted for products holding valid marketing authorisation issued by INVIMA (premarket review of the dossier, including quality, safety, efficacy, and labelling). The INVIMA may audit/certify Good Practices, including distribution, where applicable to the operator's role.

Distributors of medical devices must comply with technical standards proportionate to the device's risk class and, when acting as importers, must obtain the Certificate of Storage and Conditioning Capacity (CCAA) from INVIMA for the establishment. The CCAA covers facilities, personnel, procedures, environmental conditions, cleaning and sanitation, equipment, traceability and post-market vigilance, recalls, and internal audits. Devices in Classes IIa, IIb, and III require prior marketing authorisation, while Class I is subject to proportionate requirements. Post-market surveillance and technovigilance are carried out by INVIMA.

In all cases, distribution may not commence without prior compliance with: (1) the product's marketing authorisation (INVIMA); and (2) the establishment's authorisation/CCAA, as applicable to the product type and operator role. Non-compliance with GDP standards, infrastructure or personnel requirements, or traceability obligations may result in sanitary measures and administrative sanctions being imposed by INVIMA.

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 Colombia, businesses that provide therapeutic products directly to consumers, including community pharmacies, drugstores, online pharmacies, and other retailers, must obtain sanitary authorisation granted by the territorial health authority (departmental or district secretariats), in accordance with the Pharmaceutical Service Management Model and the Manual of Essential Conditions and Procedures, as compiled in Unified Decree 780 of 2016. This authorisation requires adequate infrastructure (minimum area, washable materials, proper signage, sanitary facilities), documented procedures for receipt, storage, dispensing, temperature control, and traceability, as well as a qualified technical director (pharmacist or pharmacy technician, depending on the complexity level of the service) responsible for regulatory compliance. Personnel must be properly trained and formally employed, and the establishment must implement a quality system ensuring Good Dispensing Practices and safe handling of medicines,

including segregation of expired products, contingency planning, and waste management. Commercialisation may only occur for products holding a valid marketing authorisation issued by INVIMA. Online pharmacies are subject to the same requirements as physical establishments, with additional obligations regarding digital traceability, secure delivery, and preservation of sanitary conditions during transport. Non-compliance with these conditions may result in sanitary measures and administrative sanctions imposed by the territorial health authority and, with respect to products and controlled substances, by INVIMA.

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

In Colombia, the online sale of therapeutic products via websites, social-media channels, and marketplace platforms, is subject to two concurrent regulatory types: (1) authorisation of the retail establishment; and (2) sanitary rules governing product information disclosures and commercialisation.

First, the pharmacy or drugstore must be authorised by the relevant territorial health authority (departmental or district secretariats) under Decree 780 of 2016. This entails suitable infrastructure, an appropriately qualified technical director, written standard operating procedures, temperature control (including cold-chain, as applicable), and full traceability. Distance sales must be executed from the authorised establishment, ensuring that transport preserves the product's approved storage conditions. Without this authorisation, offering consumers such services is unlawful.

Second, regarding the information displayed on digital platforms and accompanying each product, Decree 334 of 2022 and Resolution 1896 of 2023 require that every product hold a valid marketing authorisation and that all published information strictly conform to what has been approved in the marketing authorisation, including indications, warnings, and contraindications. Prior approval of advertising is not required. However, content is subject to post-market oversight by INVIMA, which may impose sanitary measures in case of non-compliance. Operators must also ensure digital traceability, transparency (publication of establishment contact details and a verification link), establishment responsibility for delivery and preservation of the product, and the involvement of authorised personnel in dispensing.

For medical devices, Decree 4725 of 2005 applies in addition to territorial authorisation. This requires marketing authorisation for Classes IIa, IIb, and III (with proportionate requirements for Class I). Where the business also acts as an importer, it must obtain from INVIMA the Certificate of Storage and Conditioning Capacity (CCAA) for the establishment.

To summarise, digital sales require territorial authorisation, a valid marketing authorisation, compliance with INVIMA's information and advertising rules, traceability, and responsible delivery under sanitary conditions. Non-compliance may result in sanctions by the territorial health authority and INVIMA.

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)?

Colombia applies a product-category-based import-control framework. Medicines are governed by Decree 677 of 1995, and medical devices and in vitro diagnostic devices by Decree 4725 of 2005. Customs procedures, tariff classification and customs clearance are regulated by Decree 1165 of 2019. These controls are operationally integrated through the VUCE, Colombia's Single Window for Foreign Trade, an electronic platform that centralises, standardises and coordinates import and export procedures and the issuing of permits, authorisations and clearances by competent authorities.

For products within its competence, the INVIMA exercises import control through the sanitary clearance (*visto bueno*) issued within VUCE, and no standalone sanitary import licence is required. As a general rule, importation requires that the product is covered by a valid sanitary authorisation (marketing authorisation, permit or notification, as applicable), and that the import application strictly matches the authorised administrative act. In the case of medicines, importation is only permitted for products holding a valid marketing authorisation, subject to specifically regulated exceptions, such as Vital Unavailable Medicines, which are processed on a case-by-case basis before INVIMA, pursuant to Decree 481 of 2004.

Tariff classification, customs duties and VAT are determined independently by the customs authority (DIAN) in accordance with the Customs Tariff and the MUISCA system, and the applicable tariff subheading is not contingent on the existence of a sanitary authorisation. Border controls are risk-based, and INVIMA determines the scope and type of inspection at ports, airports and border crossings, and may order sanitary measures where non-compliance is identified.

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 Colombia, the importation of medicines and medical devices by individuals is not recognised as a general right, rather as a limited and controlled possibility within the applicable sanitary and customs framework. Generally, medicines require a marketing authorisation (Decree 677 of 1995), and medical devices must comply with the requirements set forth in Decree 4725 of 2005.

Nevertheless, in accordance with the administrative practice and operational guidelines of the INVIMA, the entry of therapeutic products for personal use may be admitted under a proportionality and risk-based approach, provided that non-commercial use, a medical prescription, and reasonable quantities are verified. For medicines, this typically occurs in three scenarios: entry by travellers carrying the product with medical support; shipments by mail or courier subject to INVIMA's postal-traffic guidelines; and the exceptional regime for Vital Unavailable Medicines, which requires prior authorisation pursuant to Decree 481 of 2004.

With respect to medical devices, personal importation is primarily admitted for low-risk devices, subject to verification of personal use and, where applicable, a medical prescription. In all cases,

such imports are subject to customs declaration and control by the DIAN, including the potential application of customs duties and VAT, as well as risk-based border controls, and the authorities may order inspections, retention, or deny entry if the applicable requirements are not met.

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?

In Colombia, foreign suppliers are not generally authorised to ship therapeutic products directly to end consumers through e-commerce or mail-order sales. The commercialisation of medicines and medical devices typically requires the involvement of a locally authorised operator, holding the relevant sanitary authorisation issued by the INVIMA, and compliance with the sanitary clearance (*visto bueno*) procedure through the VUCE, in accordance with Decree 677 of 1995, Decree 4725 of 2005, and Decree 1165 of 2019, as well as the INVIMA Guide for Completing Import Applications in the VUCE – Version 6 (2024).

Nevertheless, in line with INVIMA’s administrative practice and its applicable operational guidelines, direct-to-consumer shipments may be admitted on an exceptional basis in non-commercial scenarios, primarily for personal use, subject to medical prescription, limited quantities, and sanitary verification. In the case of medicines, such shipments may require prior sanitary authorisation where the product does not hold Colombian marketing authorisation, particularly under the Vital Unavailable Medicines regime, regulated by Decree 481 of 2004 and further developed through the INVIMA–MSPS Guidelines for the Importation of Vital Unavailable Medicines, as well as the INVIMA Guide on Postal Traffic and Urgent Shipments of Medicines and Medical Devices. For medical devices, direct shipment is generally limited to low-risk devices intended for personal use, in accordance with Decree 4725 of 2005 and INVIMA’s operational criteria.

In these exceptional scenarios, foreign suppliers are not required to establish a local presence or register an e-commerce platform. However, shipments remain subject to customs declaration and control by the DIAN, including tariff classification, the application of customs duties and VAT where applicable, and risk-based sanitary controls pursuant to the INVIMA Guide to the Inspection, Surveillance and Control (IVC) Model at Ports, Airports and Border Crossings. Non-compliance with the applicable requirements may result in inspection, retention, or denial of entry.

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 Colombia, commercial parallel importation of medicines and medical devices by companies not authorised in the sanitary registration is not permitted. Pursuant to Decree 677 of 1995 and Decree 4725 of 2005, only the holder of the sanitary registration or explicitly authorised importers may import and commercialise these products. An unauthorised third party cannot obtain the sanitary clearance (*visto bueno*) from the INVIMA through the VUCE.

Similarly, products must be imported exactly in the packaging and presentations approved by INVIMA, including all essential information (batch number, expiry date, warnings). Accordingly, parallel importation – understood as commercial importation by a third party not authorised in the sanitary registration – is neither recognised nor permitted in Colombia for medicines and medical devices. Only exceptional, non-commercial regimes (eg, personal use, Vital Unavailable Medicines) may apply, which do not constitute commercial parallel importation.

EXPORT

10. Are there quantitative quotas, permits, or other measures that restrict or condition the export of therapeutic products (eg, to mitigate shortages or address public-health emergencies), and how are such measures administered and enforced?

In Colombia, the export of medicines and medical devices is not subject to quantitative quotas or special permits which restrict the volume of products exported. The only legal requirement is to obtain the sanitary export certificates issued by INVIMA, which confirm compliance with Good Manufacturing Practices and the product's technical specifications. There are no legal measures which ban or limit exports to address domestic shortages or public health emergencies; while INVIMA and the Ministry of Health monitor national availability, such monitoring does not translate into export restrictions. Oversight is exercised through documentary and technical review for the issuing of certificates, and the DIAN verifies documentation during clearance. Exports are conditioned solely on compliance with sanitary requirements, without restrictive mechanisms based on public health considerations.

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?

Colombia does provide an 'export-only' scheme for medicines, where medicines are manufactured in Colombia exclusively for export by laboratories that comply with Good Manufacturing Practices (GMP/BPM). They do not require a Colombian sanitary registration (marketing authorisation), unless the applicant elects to obtain a 'manufacture and export' authorisation or the importing country requires it. Instead, INVIMA issues an Export Certificate supported by technical documentation (eg, composition, manufacturing process, specifications, quality certificates, etc.). Such products may not be marketed in Colombia. The current validity of INVIMA-issued export certificates is five years. (Decree 2510 of 2003, Arts. 2 and 3, para. 2; Decree 334 of 2022, Art. 24).

There is no separate authorisation referred to as 'dual labelling' for medicines intended for the Colombian market. Packaging is approved as part of the marketing authorisation, and the sale or supply of medicines outside of the approved packaging is forbidden. Moreover, the content/wording of labels, cartons and packaging materials requires INVIMA approval, including the mandatory minimum information. (Decree 677 of 1995, Arts. 70 and 72).

The current regime does not establish an 'export-only' pathway for medical devices which is equivalent to that for medicines. Depending on their class, devices also require sanitary registration also export, and the regulatory dossier includes, among other items, final artwork for labels and inserts and evidence of an applicable quality system (eg, a Certificate of Conditioning

and Storage Capacity or GMP/BPM or equivalent). The label of origin may be accepted for imported devices. However, an additional Spanish label is required with the importer's details and the registration number, and any sticker must not cover existing information. (Decree 4725 of 2005, Arts. 16, 17, 18(b) and (g), and 57).

LABELLING, TRACEABILITY, 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 Colombia, before imported therapeutic products may circulate in the domestic market, medicines must be marketed exclusively in the packaging approved by INVIMA, with labelling and product information in Spanish in accordance with the sanitary registration. The sale or supply of medicines outside the approved packaging is forbidden, and the content of labels, cartons and packaging materials must include the essential authorised information (eg, batch/lot number and expiry date). (Decree 677 of 1995, Arts. 70 and 72).

The label from the country of origin may be accepted for imported medical devices. However, an additional label in Spanish is required with minimum information, including identification of the importer or responsible party in Colombia and the registration or permit number, and such additional label may not cover pre-existing information on the original label. (Decree 4725 of 2005, Art. 57). With respect to serialisation, anti-counterfeiting and traceability, these are ensured primarily through batch/lot or serial identification, the approved labelling, and the applicable post-market surveillance obligations. Any identifier incorporated by the manufacturer or required by the destination market must remain visible and must not be altered. (Decree 677 of 1995, Arts 70 and 72; Decree 4725 of 2005, Art 57).

For the export of medicines manufactured exclusively for export under an export certificate, labelling and product information may be aligned with the requirements of the importing country, while maintaining documentary batch traceability and clear identification that the products are not intended for the Colombian market. Such certificates are valid for five years. (Decree 2510 of 2003, Art 2 and para 2; Decree 334 of 2022, Art 24).

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. In Colombia, four regimes materially influence distribution channels and the availability of medicines and medical devices: (1) price control by the CNPMDM (National Commission for the Pricing of Medicines and Medical Devices), which sets/updates PMVs (Maximum Sale Prices) and thereby affects margins and supply decisions; (2) health-system financing and access, whereby technologies included in the PBS (Health Benefits Plan) are funded through the UPC (Capitation Payment Unit), while non-UPC technologies are managed via MIPRES ('My Prescription') and financed under 'Maximum Budgets' administered by ADRES (the Administrator of the Health System's Resources), which channels demand primarily through the

institutional market; (3) public procurement through Framework Price Agreements administered by Colombia *Compra Eficiente*, which aggregate public demand and standardise supplier and logistics conditions; and (4) continuity-of-supply management, including mandatory reporting and preventive management of temporary non-marketing and shortage risk operated by INVIMA, which can drive substitution, prioritisation and supply-assurance measures.

ENFORCEMENT, COMPLIANCE, AND RECENT DEVELOPMENTS

14. What investigative powers, sanctions, and remedial measures (administrative, civil, or criminal) are available to regulators when they detect non-compliance with trade and distribution rules for therapeutic products, and how are these powers used in practice?

In Colombia, where non-compliance is detected in the distribution or marketing of therapeutic products, INVIMA and the territorial health authorities exercise inspection, surveillance and powers of control, including inspections, information requests, and sampling/testing. Immediate sanitary safety measures may be adopted to protect public health, such as temporary closure, suspension of activities, seizure (*decomiso*), and destruction/denaturation. This is without prejudice to the sanctions applicable within formal administrative sanctioning proceedings (eg, fines of up to approximately US\$4.75m, seizure, and suspension or cancellation of the sanitary registration). (Law 9 of 1979, Arts 576 and 577; Decree 780 of 2016, Art 2.5.1.7.5).

The authorities may also order market withdrawals/recalls and issue sanitary alerts. These measures do not exclude potential civil or criminal liability. (Law 9 of 1979, Arts. 576 and 580).

At the border, DIAN applies customs measures such as apprehension (*aprehensión*) and forfeiture/seizure (*decomiso*) where required formalities are not met (including sanitary clearances), thereby preventing entry or domestic circulation. (Decree 1165 of 2019).

Where serious conduct endangering public health is involved (eg, adulteration of medical products), criminal investigations may be initiated for offences such as corruption/adulteration of foods, medical products, or prophylactic materials. (Criminal Code – Law 599 of 2000, Art. 372).

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 following draft regulations have recently been published on the official website of the Colombian Ministry of Health and Social Protection: (1) the draft decree on a new medicines regime that would replace/repeal Decree 677 of 1995 (including supporting documents such as the Explanatory Memorandum); and (2) the draft decree on the sanitary framework for medical devices and in vitro diagnostic (IVD) products.