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

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REGULATORY FRAMEWORK AND COMPETENT AUTHORITIES

1. What are the principal statutes, regulations and competent authorities that govern the import, wholesale distribution, retail sale and export of therapeutic products (ie, for pharmaceuticals/biologics and medical devices, noting any separate or overlapping regimes)? In the case of a federal state, what is the division of powers between the federal government and the states?

In Panama, the principal statutes and regulations that apply to the import, wholesale distribution, retail sale and export of therapeutic products are Law 419 of 1 February 2024, Law 462 of 18 March 2025, which modifies Law 419, and Executive Decree 27 of 10 May 2024, which implements Law 419.

Law 419, as modified by Law 462 and Executive Decree 27, regulates pharmaceuticals and other products for human health, as well as medical devices and equipment. It regulates not only the registration process of these products in Panama, but also the requirements and procedures for their import, export, procurement and public acquisition.

Depending on the composition of the therapeutic products, they may also be subject to Law 14 of 19 May 2016, its modification, and Executive Deree 183 of 8 June 2018, which implements Law 14. These regulations apply in the event that the specific therapeutic product utilises and/or contains any controlled substance, as classified in Law 14, which will require the parties involved to comply with additional requirements in order to import, distribute, sale and store such products.

In addition to the requirements set forth in Law 419, if the therapeutic products include cannabis or products derived from cannabis, they will also be subject to Law 242 of 13 October 2021, which regulates the medicinal and therapeutic use of cannabis and derived products, and Executive Decree 85 of 1 September 2022, and Executive Decree 6 of 4 April 2025, which implements Law 242.

The competent authorities that govern the import, wholesale distribution, retail sale and export of therapeutic products are the Ministry of Health (*Ministerio de Salud* or MINSA), the Social Security Office (*Caja de Seguro Social* or CSS) and the National Customs Authority (*Autoridad Nacional de Aduanas* or ANA).

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 are attached to each classification with respect to trade and distribution? In particular, is the conclusion of a premarket review and approval process required by a competent authority?

Products classified as pharmaceuticals or medical devices are regulated by Law 419 and its amendments, which require the importer or distributor to obtain the respective sanitary permit from MINSA. The authority classifies such products, depending on their composition and use, into the following categories:

- Hospital use: products that are used for hospital-only presentations and can only be sold to and administered by hospitals, clinics and other MINSA-certified health establishments.
- Special numbered prescriptions: this category is for products that can only be sold upon the presentation of a special numbered prescription, which includes full information on the patient and healthcare professional who prescribed it. These medications may be dispensed exclusively by a licensed pharmacy and are subject to specified quantity limits in regard to their purchase. This classification includes controlled medication that has the potential for dependency, abuse or the management of critical medical conditions.

- Prescription only: these products can only be sold upon the presentation of a prescription signed by an authorised healthcare professional and may only be dispensed by pharmacies. The restrictions applicable to special numbered prescriptions do not apply.
- Over the counter (pharmacies): these products can be sold without a prescription by pharmacies and rural dispensaries.
- Over the counter (common medicines): products that can be sold without a prescription by pharmaceutical and non-pharmaceutical establishments.

Premarket evaluation and authorisation by a competent authority are necessary exclusively for products classified as pharmaceuticals, medical devices, those intended for human consumption or those containing controlled substances or cannabis. MINSA oversees this review as part of the sanitary permit application process and, in certain circumstances, the submission of a product sample may be required for assessment.

LICENSING, AUTHORISATIONS AND DISTRIBUTION CHANNELS

3. Which licences, authorisations, registrations or other official permissions are required for businesses to engage in the wholesale distribution of therapeutic products, and what key conditions (such as good distribution practices, facility standards, personnel-related requirements and insurance or financial guarantees) are attached to them?

For businesses to be able to engage in the wholesale distribution of therapeutic products, they must obtain a pharmaceutical establishment operation licence, after submitting all the requirements set forth in Law 419. The business is also required to have a licensed pharmacist under contract, who must be present on the premises at all times.

These businesses must also comply with good distribution practices, facility standards, personnel-related requirements and transportation standards, as prescribed by Law 419 and its amendments.

When businesses participate in wholesale distribution following a public procurement process, they must pay a single performance bond to the contracting entity in order to guarantee compliance with the respective purchase order or the supply contract, which must be no less than 20 per cent of the total value of the purchase order or the supply contract. Additionally, each public procurement process, depending on its nature and the applicable bidding specifications, may require the business to obtain additional insurance coverage.

4. Are there any distinct licensing or notification requirements for businesses that provide therapeutic products directly to consumers (including community pharmacies, internet pharmacies or other retailers), and what key conditions are attached to them?

According to Law 419, all businesses that provide therapeutic products directly to consumers, products of which are classified as pharmaceutical or non-pharmaceutical products, must have their respective licence or permit authorised by MINSA.

Pharmaceutical establishments are community pharmacies, hospital pharmacies, radio pharmacies, medical stations, rural dispensaries, distribution agencies, laboratories and drugstores. An operating licence approved by MINSA is required for these businesses to operate, as set forth in Executive Decree 27.

Non-pharmaceutical establishments are businesses that sell common medicines that do not require a prescription. These establishments need a permit approved by MINSA in order to carry on their operations. In this case, the requirements and length of the process is shorter than that required for pharmaceutical establishments.

Non-pharmaceutical establishments, known as automatic medicine dispensing machines, must be granted a special permit and have their registration approved by MINSA in order to conduct their operations.

Non-pharmaceutical establishments dedicated to the production of artisanal cosmetic products must obtain a special permit and have their registration approved by MINSA in order to operate. The personnel that

manufacture the products must wear protection equipment, such as masks, hair covers, protective eyewear, gloves and aprons, which shall at all times be clean and in good condition.

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

Businesses selling therapeutic products over the internet must have their respective pharmaceutical establishments operation licence or permit for non-pharmaceutical establishments approved by MINSA.

The sale of these products is also governed by the publicity regulations set forth in Law 419, which prescribes that businesses have an obligation to inform consumers on relevant information about the products being sold, their instructions for use and any pertinent warnings, presented in an easy-to-understand manner, in order to ensure that their use is safe and free from unjustified risks to the health and life of consumers. Any information or publicity transmitted by any media or through any form of communication, in relation to the offered products, shall be binding upon the supplier who requests, authorises or pays for the corresponding dissemination.

The publicity of any over-the-counter product related to health must be approved by MINSA before being divulged through any media. These products must have a valid sanitary permit specific to Panama.

Law 419 prohibits any advertising on the containers, labels, markings, packaging, inserts or package leaflets accompanying prescription-only pharmaceutical products. For this purpose, the use of colours, drawings, logos or similar elements that are not related to the characteristics or properties of the product are not considered to be advertising. Advertising of prescription-only products is only permitted when directed to professionals who prescribe and dispense them, as well as to professional representatives of pharmaceutical companies. In regard to graphic advertising, it may only be carried out through specialised journals, brochures, leaflets or any other printed format containing technical and scientific information. All types of advertising of these products must be approved by MINSA.

IMPORT

6. What requirements are set as part of the import control framework for therapeutic products (eg, import licences, product registration or listing prerequisites, customs classification, tariff rates, national or regional exemptions and routine or risk-based border inspections)?

Importation requires authorisation from MINSA, a pharmaceutical establishments operation licence, a valid sanitary permit or an exemption, a customs pre-declaration, invoices that comply with the current health regulations, packing lists and cargo manifests. Products must generally have a shelf life of at least six to 18 months, with exceptions for radiopharmaceuticals and controlled substances. Sanitary permit exemptions may be granted in regard to emergencies, humanitarian efforts, supply shortages, research, unavailable treatments or attempts to carry out more cost-effective procurement, provided the adherence to good manufacturing practices is certified. Frequent exemptions trigger mandatory registration.

MINSA oversees pharmacovigilance and quality control to ensure product safety and efficacy. During the renewal period for cosmetics, pesticides and disinfectants, they may be imported and sold freely, provided that the relevant applications are filed in a timely manner. No such exemption or leeway is permitted for other products.

Law 419 and its amendments mandate compliance with good practices in regard to the storage, distribution, transportation and dispensing of medicinal products, which is supervised by MINSA and ANA.

7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by post), and what quantitative limits, prescription requirements, customs declarations, duties or other restrictions apply?

Consumers may import therapeutic products for personal use, subject to MINSA and ANA requirements. Imports without a sanitary permit are only permitted pursuant to MINSA-authorised exceptions (including

emergencies, humanitarian efforts, etc), and such imports must meet good manufacturing practices and pharmacovigilance conditions.

Cosmetics received by courier or transported by travellers are limited to six units per person (or kits of up to six products) and 500 ml per month. However, samples for registration and analysis are limited (generally up to three units). Medicines for personal use require a prescription where applicable, supporting documents (including a detailed invoice, airway bill, a copy of the individual's ID or passport and a MINSA release-of-liability letter) and, for travellers, a retention certificate.

Parenteral, biological, biotechnological and blood-derived products require the importer to maintain cold-chain conditions. The quantity of medicines imported in this context is generally capped at six months' treatment. Raw materials and unfinished products may not be imported via couriers or travellers.

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

Foreign suppliers may ship therapeutic products to Panama only if the importation complies with MINSA's and ANA's requirements. For commercial imports, the importer must be a licensed pharmaceutical establishment that holds import authorisation; the products must have valid MINSA-issued sanitary permits or an authorised exemption. For instance, prescription-only medicines are only allowed to be dispensed through pharmacies; over-the-counter products are only allowed to be sold by registered non-pharmaceutical establishments. The establishment that will sell the end product must register with MINSA as well. As a result, foreign suppliers typically partner with a local importer or an authorised representative with the required operating licence and registration in order to import and distribute medicinal products.

All labelling must be in Spanish and must comply with MINSA's regulations. Re-labelling and over-labelling are not permitted. Advanced or controlled products are subject to additional handling, cold-chain and regulatory obligations.

The law does not expressly create an online platform registration regime, but e-commerce operators and foreign sellers must ensure that they are compliant with the relevant MINSA, ANA, good manufacturing practices, pharmacovigilance and consumer protection requirements, as well as internationally accepted standards.

Furthermore, Law 14 prohibits the importation and exportation of controlled substances via postal services, courier companies or any other means not authorised by MINSA.

9. How is the parallel importation (ie, of products licensed and sold in other jurisdictions) of therapeutic products by businesses regulated, particularly with respect to intellectual property rights, product re-labelling or re-packaging and requirements to maintain the product's original quality, safety and traceability?

The regulation of parallel importation of essential medication (as per the World Health Organization's (WHO) list of essential medicines) in Panama was established under Law 462. The law expressly refers to 'medication' without extending the definition to the broader category of 'therapeutic' products. Under its provisions, public health institutions, such as MINSA and the CSS, are authorised to import patented essential medicines at reduced prices provided that international intellectual property rules are observed.

Imports may be conducted directly from countries where medicines are available at more affordable prices, exclusively for public distribution and without reliance on exclusive distributors. A special permit is required for such imports, which is valid for up to two years, with the possibility of an extension. To qualify, medicines must be deemed essential, demonstrate cost effectiveness and be of the same quality as those patented and marketed in Panama.

Importation under this framework is restricted to public health institutions, ensuring that access to lower-cost essential medicines is managed within Panama's public health system.

EXPORT

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

While Panamanian legislation primarily concentrates its regulatory framework on the importation of therapeutic products, the export of such products is also subject to regulation. The export of therapeutic products, particularly controlled substances, is governed by strict requirements, including the need for permits and quantitative quotas administered by MINSA. Compliance is enforced through licensing procedures, customs controls and oversight from MINSA and the customs authority.

Law 419 establishes that individuals or entities engaged in the export, distribution or other activities involving medical devices must obtain an operating licence issued by MINSA. Furthermore, as noted in response to Question 8, Law 14 expressly prohibits the exportation and importation of controlled substances via unauthorised postal services, courier companies or any other unapproved means of transportation.

While there is not a specific quantitative quota to limit the export of therapeutic products, MINSA may declare critical shortages of medicines or other products related to human health and a sub-committee (the Committee for the Evaluation of Critical Shortages) can provide recommendations related to the suspension of exports of medicines in short supply.

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?

Panama does not provide for a standalone 'export-only' or 'dual-labelling' marketing authorisation as a separate category of sanitary registration. Generally, therapeutic products require a sanitary permit granted by MINSA to be commercialised in Panama, subject to the exceptions provided in Article 45 of Law 419.

For export-only operations, the regulatory framework is based solely on establishment licensing and oversight, together with the principle that the product must not be placed on the Panamanian market. Companies located in special customs or fiscal territories may import, condition, manufacture or otherwise handle therapeutic products destined exclusively for export. In such cases, MINSA may verify the company's compliance with the applicable rules, but a sanitary permit is not required, provided the products are not commercialised domestically.

Even for export-only products, commercial activities must be carried out through duly licensed pharmaceutical establishments and involve a licensed pharmacist. Operators remain subject to the applicable good practices and to inspections by the National Directorate of Pharmacy and Drugs, which is part of MINSA.

There is no specific 'export-only' labelling regime in Panama. Products handled exclusively for export are typically labelled in accordance with the destination country's requirements, with appropriate controls in place to prevent diversion to the local market.

Export-only operators must maintain the standard records required to be kept by licensed establishments, including batch or packaging records and distribution or dispatch documentation identifying the product, lot or batch, quantities, dates and the consignee, together with supporting shipping or commercial documents.

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?

For domestic circulation, the labelling of therapeutic products is regulated by MINSA. The information provided on product labels may be in two or multiple languages, as long as Spanish is included. As a general rule, re-labelling or over-labelling is not permitted, subject to limited exceptions that are authorised by MINSA. Before commercialisation, the commercial pack must also include an additional label identifying the local distributor.

Patient-facing information (such as inserts) must be consistent with the approved product documentation and comply with the labelling and packaging standards adopted by the National Directorate of Pharmacy and Drugs. In limited cases (such as orphan medicines), the authority may authorise Spanish over-labelling provided that the product includes an insert that features the essential safety and use information.

From a traceability perspective, the system relies mainly on batch or lot identification and expiry-date control, together with the import documentation and distribution records maintained by licensed operators. Importers and distributors are expected to keep distribution registers with key product and shipment information, and the responsible pharmacist must verify that incoming products match the sanitary registration details and report any discrepancies.

For exports, the regulatory framework does not establish a specific 'export labelling' regime. Where products are manufactured or handled in Panama exclusively for export and are not placed on the Panamanian market, labelling is generally determined by the destination country's requirements, with an emphasis on preventing diversion to the local market and maintaining adequate batch and shipment traceability.

PRICING, REIMBURSEMENT AND MARKET ACCESS

13. Are there any price control, reimbursement, public procurement or stock/supply-related obligations that (while not trade measures per se) materially influence the distribution channels or availability of therapeutic products?

Yes, Panama's distribution channels and product availability are materially influenced by a set of public sector procurement and supply frameworks and, in certain cases, by price-monitoring and exceptional price-cap mechanisms.

First, the public sector is a major access channel, as MINSA and the CSS, together with other public health entities, procure and supply medicines and other health products through institutional lists/forms and centrally organised procurement processes. In this context, Panama has also established a national reference-pricing framework for public acquisitions, designed to consolidate demand and support procurement decisions and supply planning.

Second, while private sector pricing is generally market driven, the system includes ongoing price transparency/monitoring obligations (including reporting of purchase/sale prices for medicines to the competition authority (*Autoridad de Protección al Consumidor y Defensa de la Competencia* or ACODECO) and monitoring of the prices for a basic basket of medicines). The framework also contemplates exceptional, time-limited 'reference price cap' measures. For instance, such mechanisms were applied during the Covid-19 pandemic (for example, through temporary maximum price or margin controls on essential health products) and, more recently, through Executive Decree 36 of 30 September 2025, which set maximum reference prices for a defined list of essential medicines used to treat chronic conditions.

Finally, recent reforms place stronger emphasis on the continuity of supply within the public health system through structured monitoring (eg, by the National Observatory of Medications) and specific mechanisms to address or prevent critical supply shortages.

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?

Health regulators (primarily MINSA, through the National Directorate of Pharmacy and Drugs) have broad oversight powers over licensed establishments (manufacturers, importers, warehouses, distributors and pharmacies). These powers include the ability to conduct routine and targeted inspections and audits and review records. National authorities rely on inspection reports and laboratory analyses to support enforcement actions. Regulators may also require corrective actions and may activate product quality incident management tools, including investigations and, where appropriate, product withdrawals, supported by distribution traceability records.

Available sanctions include written warnings, fines (according to the severity of the breach), the suspension or cancellation of sanitary registrations, the suspension or cancellation of establishment operating licences and the temporary closure of establishments. In addition to sanctions, the authorities can adopt preventive measures to protect public health and consumers, including issuing public health alerts or official communications (such as notices relating to product withdrawals, recalls or non-compliant products), temporarily closing premises, as well as ordering the retention, immobilisation or seizure of non-compliant products.

Enforcement may involve different authorities depending on the issues involved. For instance, MINSA focuses on sanitary compliance (authorisations, quality, storage, traceability), while ACODECO may intervene in consumer-facing matters (including price-related measures and certain preventive actions). Where the conduct may constitute a crime (eg, counterfeit/adulterated products, smuggling or other conduct that endangers public health), the matter may be referred to the competent criminal authorities, and enforcement will proceed under the general criminal and customs framework in parallel with the applicable administrative action.

15. Is there any recent case law, legislative or policy developments, noteworthy enforcement trends or anticipated reforms that may significantly alter the regulation of trade, distribution or cross-border movement of therapeutic products in the future?

Recent developments have been driven primarily by legislative and administrative reforms. Key developments include: (1) Law 419 and its implementing regulation (Executive Decree 27) and its amendments, which replaced in its entirety the outdated regulatory framework for medicines and other health products and reinforced public sector planning and procurement tools that can materially affect market access and supply; (2) an expedited pathway based on the recognition/automatic recognition of certain foreign distribution authorisations for medicines registered in jurisdictions with WHO-listed authorities, implemented by Executive Decree 2 of 7 January 2025; and (3) the continued use of price-reference/price-cap measures for a defined list of essential medicines for chronic conditions (including Executive Decree 36).

For medical devices, MINSA launched a public consultation in October 2025 on a draft executive decree to update the relevant regulatory framework. The consultation period has been extended to early 2026, with additional stakeholder meetings announced.

In practice, these developments have been accompanied by an increased focus on price transparency and monitoring (for covered products), the continuity of supply (particularly in the public sector) and tighter oversight of operators and distribution channels through inspections and the application of administrative measures.