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 Ecuador, the trade and distribution of therapeutic products is primarily governed by the Health Law, which establishes the general sanitary control framework and classifies medicines, biological products, and medical devices as products subject to mandatory sanitary surveillance and control. This law is complemented by secondary regulations, technical standards, and resolutions issued by the National Health Authority, which set out the specific requirements for market authorisation, importation, marketing, distribution, and post-marketing surveillance of these products.

The competent authority for sanitary regulation and control is the National Agency for Regulation, Control and Sanitary Surveillance (ARCSA), an entity which reports to the Ministry of Public Health (MSP). The ARCSA is responsible for granting market authorisation, operating permits, exceptional import authorisations, and other sanitary approvals, and for carrying out control, surveillance, inspection, and enforcement actions throughout the therapeutic products supply chain.

The prices of medicine are subject to government control and are overseen by the National Council for Fixing and Reviewing the Prices of Drugs for Human Use and Consumption. In accordance with the Regulation for the Pricing of Drugs for Human Use and Consumption, three pricing regimes apply: regulated, direct, and free pricing.

In the field of foreign trade, the National Customs Service of Ecuador (SENAE) intervenes in import and export processes from a customs perspective, verifying compliance with documentary, tariff, and prior-control requirements, in coordination with the health authority.

The trade and distribution regime for therapeutic products is also influenced by competition and market power regulation. In this context, the Superintendence of Economic Competition is the authority responsible for preventing, investigating, and sanctioning anticompetitive practices, abuses of market power, and economic concentrations that may affect access to, availability of, or conditions for the marketing of therapeutic products, particularly in regulated markets such as pharmaceuticals and medical devices. Although this Superintendence does not exercise sanitary powers, its actions have a significant impact on the industry. These powers are complementary to sanitary control, as they reinforce the protection of end users against defective, misleading, or improperly marketed products.

As Ecuador is a unitary state, there is no distribution of regulatory competencies among federal or municipal levels. Accordingly, sanitary regulation is national and centralised, with ARCSA and the Ministry of Public Health (MSP) being the only authorities vested with regulatory and enforcement powers.

However, for practical purposes and post registration control, the sanitary authority operates through a regional structure made up of zonal coordination offices. At the national level, there are nine zonal offices, located across the different parts of Ecuador.

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 Ecuador, therapeutic products are classified for regulatory purposes primarily according to their nature, level of risk, and conditions of use, which directly determine the requirements applicable to their importation, distribution, marketing, dispensing, and promotion. The law classifies therapeutic products into over-the-counter (OTC), prescription-only, biological, and medical device categories. This classification has significant legal implications for authorised marketing channels, the obligations of economic operators, and the level of control exercised by the health authority.

Prescription only medicines may be dispensed to the final consumer solely on presentation of a valid medical prescription, and their commercialisation is restricted to duly authorised establishments, such as licensed pharmacies and drugstores. In addition, these products are subject to strict limitations on advertising, with direct-to-consumer promotion being prohibited. By contrast, OTC medicines may be marketed without a prescription, although they remain subject to sanitary controls, labelling and consumer information requirements, and restrictions regarding the types of advertising claims that can be made.

As a general principle of the Ecuadorian health regulatory framework, therapeutic products require prior review and approval before being placed on the market by the competent authority. This approval is materialised through the granting of a marketing authorisation, which constitutes a mandatory enabling requirement for the importation, distribution, and commercialisation of therapeutic products subject to sanitary control.

In the absence of marketing authorisation or the corresponding exceptional authorisation, therapeutic products may not be legally imported or marketed in Ecuador, and their distribution may trigger the adoption of sanitary control measures and administrative sanctions.

Obtaining the marketing authorisation does not, however, exhaust the regulatory process required for the effective commercialisation of therapeutic products in the Ecuadorian market. Following the granting of the marketing authorisation, medicines are subject to a price-setting process overseen by the Ministry of Public Health through the National Council for Fixing and Reviewing the Prices of Drugs for Human Use and Consumption.

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?

In Ecuador, wholesale distributors of therapeutic products must obtain an operating permit and a Goods Storage, Distribution and Transportation Practices (BPADT) certificate issued by ARCSA. These authorisations certify compliance with hygienic-sanitary, technical, operational, and pharmacovigilance requirements.

BPADT standards require adequate facilities, a responsible technical officer duly registered with the health authority, trained personnel, appropriate storage and transport conditions, documented Standard Operating Procedures (SOPs), and full product traceability, all of which support post-marketing surveillance. Although Ecuadorian law does not generally mandate specific insurance or financial guarantees for wholesalers, they remain subject to administrative, civil, and criminal liability for regulatory non-compliance.

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 Ecuador, businesses that supply therapeutic products directly to consumers are subject to a differentiated sanitary licensing regime, depending on the type of establishment. Pharmacies and drugstores must hold a valid operating permit issued by ARCSA, which authorises the dispensing and retail sale of medicines and other therapeutic products.

Private pharmacies must comply with Good Pharmacy and Dispensing Practices, operate under the technical responsibility of a licensed pharmacist, and meet requirements relating to infrastructure, opening hours, generic medicine availability, and pharmacovigilance, with stricter controls for biological products, including enhanced storage, traceability, and reporting obligations to ARCSA. Private drugstores are subject to a more restrictive regime, generally limited to rural areas, may only dispense authorised products, and are banned from dispensing controlled medicines and biological products.

Regulations regarding the sale of therapeutic products via electronic channels or digital platforms do not recognise an autonomous licensing regime for ‘online pharmacies’. Consequently, any supply of therapeutic products to consumers, even when digital channels are used, must be carried out by a physically authorised pharmaceutical establishment, holding a valid operating permit, with a designated technical officer and full compliance with applicable sanitary obligations. Digital sales do not exempt operators from compliance with rules on dispensing, the presentation of medical prescriptions where required, price controls, or bans on the advertising and promotion of prescription-only medicines.

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

The sale of therapeutic products through the internet, including social media and e-commerce platforms, does not constitute an autonomous channel of commercialisation and is therefore subject to the same sanitary regulatory regime applicable to in-person sales.

Sanitary regulations impose strict restrictions on online advertising and promotion, particularly with respect to prescription-only medicines, for which direct-to-consumer promotion is prohibited. Digital commercialisation does not exempt operators from compliance with dispensing rules, prescription requirements where applicable, price-control regulations, or pharmacovigilance and techno-vigilance obligations. ARCSA retains oversight authority over digital offerings and may order the suspension or removal of content or products in cases of regulatory non-compliance.

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 Ecuador, the importation of therapeutic products is subject to prior sanitary control, the cornerstone of which is the existence of a valid marketing authorisation. Medicines, biological products, and medical devices may only be imported if they have been previously evaluated and authorised by the competent health authority.

Limited exceptions apply. ARCSA may grant exceptional import authorisations in specific cases provided by law, such as donations, public health programmes, research activities, or sanitary emergencies, subject to conditions on quantity and destination.

From a customs standpoint, import operations are processed before the National Customs Service (SENAE), which verifies tariff classification, compliance with prior-control requirements, and supporting documentation. Imports are subject to documentary review and, where applicable, risk-based physical inspections. In cases of non-compliance, the authorities may order the detention, rejection, immobilisation, or seizure of goods.

Imports of therapeutic products are subject to several taxes and charges. Customs duties generally range from nought to ten per cent, depending on the applicable tariff classification, and are calculated on the customs value, which includes the transaction value, transport and handling costs to the point of importation, and insurance. In addition, imports are subject to a 0.5 per cent FODINFA (Children's Development Fund) contribution, calculated on the customs value. The standard Value Added Tax (VAT) rate is 15 per cent; however, medicines for human use, as well as the raw materials and manufacturing inputs used in their production, and certain medical devices and health products, are not subject to VAT. Finally, while the general Outflow Tax (ISD) rate is five per cent, imports in the pharmaceutical sector are subject to nought per cent ISD, provided the products fall within the tariff subheadings designated by the Ministry of Production.

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?

The importation of therapeutic products by consumers for personal use is only permitted on a limited and exceptional basis and does not constitute an ordinary channel of market access. Such importation is subject to prior authorisation by ARCSA, granted on a case-by-case basis, and is conditional on the product being intended exclusively for the applicant's personal use. The consumer must submit a medical prescription or medical certificate justifying the need for the product and indicating the dosage and duration of treatment. Authorisation is only granted for limited quantities strictly related to the prescribed treatment and excludes controlled medicines or products subject to public health restrictions.

Ecuadorian customs regulations also provide for a simplified import regime known as the courier or '4×4' regime, which allows individuals to import goods for personal use through postal or express courier services, subject to value, weight, and annual shipment limits. This regime is intended exclusively for non-commercial imports and benefits from simplified customs clearance. However, goods subject to prior control, such as therapeutic products, remain fully subject to applicable sanitary regulations and may require authorisation from the health authority, regardless of their eligibility under the courier regime.

From a customs perspective, the consumer must comply with declaration obligations of the National Customs Service of Ecuador (SENAE) and, where applicable, with the payment of duties. Shipments sent by mail or courier services may be detained if they lack prior sanitary authorisation or exceed the permitted limits. In the absence of such authorisation, the products may not be cleared through customs and may be seized or returned to their country of origin.

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?

The Ecuadorian regime does not allow the direct cross-border sale of therapeutic products to the final consumer through e-commerce, mail-order sales, or postal shipments as an ordinary channel of commercialisation. Ecuador's sanitary framework requires that therapeutic products intended for the national market first comply with sanitary control requirements, including obtaining marketing authorisation and distribution through authorised channels.

Regulations require that products subject to sanitary control have a marketing authorisation holder (MAH) domiciled in Ecuador, who assumes sanitary responsibility before the competent authority. In this regard, direct commercialisation from abroad, without the involvement of a duly authorised local operator, does not meet the requirements of local presence and sanitary responsibility established under the Health Law and its implementing regulations. The competent authority in this matter is the National Agency for Regulation, Control and Sanitary Surveillance (ARCSA).

Imported therapeutic products must also comply with labelling and information requirements in Spanish, in accordance with what has been approved in the market authorisation, as well as with dispensing rules and the restrictions applicable to advertising and promotion, particularly with respect to prescription-only medicines. These obligations may not be circumvented using digital platforms or international marketplaces.

The only exceptions apply in the context of exceptional importation for personal use, which is granted on a limited basis, subject to prior authorisation by ARCSA and under strict conditions, without enabling foreign suppliers to freely operate direct shipments to Ecuadorian consumers as a regular commercial activity.

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 Ecuador, parallel importation of therapeutic products is not regulated as a separate regime and is therefore subject to the same sanitary and regulatory requirements applicable to ordinary imports of products under sanitary control. The mere fact that a product is lawfully marketed in another jurisdiction does not authorise its importation or commercialisation in Ecuador. As a general rule, only the marketing authorisation holder or a third party explicitly authorised by it and fully compliant with local requirements may import therapeutic products into the country.

Parallel importation is further limited by intellectual property protections. Importation is not permitted where a product is protected by a patent, data exclusivity, or a registered trademark in force, unless the importer holds the corresponding authorisation or licence from the rights holder. Patent and data protection may prevent third parties from obtaining a marketing authorisation or placing pharmaceutical products on the market during the protection period. Trademark rights may also restrict parallel imports where the importer is not authorised or where differences in packaging or labelling could mislead consumers.

Re-labelling or re-packaging of therapeutic products is only permitted if specifically authorised by the health authority and strictly consistent with the approved marketing authorisation, including mandatory Spanish-language information. Unauthorised modifications may constitute sanitary infringements and trigger enforcement actions.

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 Ecuador, the export of therapeutic products is not subject to permanent quantitative quotas. However, this is provided that it complies with specific sanitary requirements established in the Technical Sanitary Regulation for Products for Human Use and Consumption Exclusively for Export. Therapeutic products manufactured or conditioned in Ecuador for export must obtain a Sanitary Export Certificate or, in the case of medicines, a Certificate of a Pharmaceutical Product (CPP), issued by ARCSA, on a product and, where applicable, batch specific basis.

Although no general quantitative export limits apply, the health authority may verify that export-only products are not marketed domestically and that they meet the destination country's sanitary and quality requirements. In exceptional circumstances, such as public health emergencies or risks of domestic supply shortages, the government may adopt temporary administrative

measures to restrict or condition exports. These measures are administered by the Ministry of Public Health and enforced in coordination with customs authorities, and non-compliance may result in refusal of certification, product retention, and administrative sanctions.

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?

In Ecuador, there is a specific authorisation regime for therapeutic products intended exclusively for export, which allows for the manufacture, conditioning, and export of products that do not hold a marketing authorisation for commercialisation in the domestic market. This regime is regulated by the Technical Sanitary Regulation for Products for Human Use and Consumption Exclusively for Export and is administered by the National Agency for Regulation, Control and Sanitary Surveillance (ARCSA).

Under this framework, therapeutic products manufactured or conditioned in Ecuador exclusively for export purposes do not require an Ecuadorian marketing authorisation, provided that they are not commercialised, distributed, or promoted within the national territory. Instead, the operator must obtain a Sanitary Export Certificate or, in the case of medicines, a Certificate of a Pharmaceutical Product (CPP), which certifies that the product has been manufactured under controlled sanitary conditions and in accordance with the standards required by the country of destination.

With respect to applicable standards, manufacturing establishments must comply with Good Manufacturing Practices and other technical requirements mandated by Ecuadorian sanitary regulations, even when the product is not intended for the domestic market. The health authority retains inspection and control powers to verify compliance with such practices and to ensure that products intended exclusively for export do not pose a risk to public health.

Regarding labelling, the regulations allow products intended exclusively for export to comply with the requirements of the importing country, without the obligation to fully meet the labelling requirements applicable to the Ecuadorian market. Nevertheless, labelling must ensure proper identification of the product and its exclusive export destination and must not be misleading or facilitate diversion into the domestic market.

Finally, operators must maintain documentary records and traceability systems that enable identification of products manufactured or conditioned for export, the batches produced, the international destinations, and the quantities exported. These records must be available to the health authority and constitute an essential element for supervision, control, and the potential adoption of administrative measures in the event of non-compliance.

The Ecuadorian regime explicitly recognises an 'export-only' authorisation, distinct from the national marketing authorisation, which enables the manufacture and export of therapeutic products not approved for the domestic market, subject to controlled sanitary standards and specific obligations relating to certification, labelling, and traceability.

LABELLING, TRACEBILITY, AND PRODUCT INFORMATION

12. What local language labelling, patient information, unique device identification, serialisation, anti-counterfeiting, or traceability requirements must be met before imported therapeutic products may circulate domestically or before therapeutic products may be exported?

In Ecuador, before imported therapeutic products may circulate in the domestic market, they must comply with the labelling, information, and traceability requirements approved in the applicable marketing authorisation. Labelling must be in Spanish and include essential information such as product identification, composition or technical characteristics, storage conditions, expiry date, batch or serial number, and the manufacturer's identification, including its name, city, and country of origin, as well as the marketing authorisation holder's identification.

For medicines, the inclusion of patient information through packaging or package leaflets is mandatory, in accordance with what has been approved by the health authority, as part of the prior sanitary control. For medical devices, labelling must ensure proper identification and safe use, in line with the applicable risk classification, and include instructions, warnings, and relevant technical information.

Ecuadorian regulations require basic traceability for both medicines and medical devices, allowing identification of origin, batches or serial numbers, and movement along the distribution chain. While there is no generalised system of advanced serialisation or unique device identification, documentary traceability is mandatory and supports post-marketing surveillance and product recalls.

Anti-counterfeiting measures rely primarily on prior sanitary control, approved labelling, and the inspection and enforcement of ARCSA, together with customs controls. For products intended exclusively for export, labelling may comply with the requirements of the destination country, provided that the product is covered by a Sanitary Export Certificate or a Certificate of a Pharmaceutical Product and that traceability records are maintained to prevent diversion into the domestic market.

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?

In Ecuador, there is no generalised system for the reimbursement of medicines or therapeutic products comparable to universal insurance schemes that provide direct reimbursement to patients. Instead, access to medicines within the public health system is primarily ensured through direct provision by the public healthcare network, without an individual reimbursement mechanism.

Ecuador also operates a medicine price control and price fixing regime, under which medicines must undergo price fixing or price notification before the competent authority as a prerequisite for commercialisation, in addition to obtaining marketing authorisation. This regime is administered by the Ministry of Public Health and overseen by the National Council for Fixing and Reviewing the Prices of Drugs for Human Use and Consumption. In accordance with the

applicable regulation, three pricing regimes apply: regulated, direct, and free pricing. Under the regulated regime, price caps are established for essential or new medicines by market segment; the direct regime applies in exceptional cases where the government unilaterally sets prices such as when regulated medicines are marketed without approved prices or when fixed prices are not complied with; and the free pricing regime applies to medicines not covered by the other regimes, allowing manufacturers to set prices subject to price notification. Price controls do not apply to medical devices.

Public procurement in the health sector further shapes market availability, as government acquisitions of medicines and medical devices are subject to specific rules on prices, volumes, technical specifications, delivery timelines, and quality standards. The regulatory framework also establishes a mandatory medicine exchange mechanism applicable to public procurement contracts. This mechanism may be implemented through: (1) replacement with the same product with at least 12 months of remaining shelf life; (2) substitution with another product included in the National Basic Medicines List, also with a minimum of 12 months of shelf life; or (3) reimbursement of the value of the expired medicines. Options (2) and (3) require agreement with the relevant public entity. Exchanges are generally limited to one exchange per procurement process and a maximum of ten to 15 per cent of the purchased quantity, depending on the procurement procedure. These quantitative limits do not apply to essential medicines.

Finally, sanitary regulations impose mandatory stock and supply obligations on pharmaceutical establishments, requiring the continuous availability of essential and generic medicines, as well as medicines designated for the treatment of catastrophic, rare, and orphan diseases, in line with public health priorities. These regulatory obligations operate alongside the constitutional recognition of health and access to medicines as a fundamental right, which obliges the State to adopt measures to ensure availability, continuity, and non-discriminatory access throughout the healthcare system.

ENFORCEMENT, COMPLIANCE, AND RECENT DEVELOPMENTS

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

The ARCSA has broad powers to conduct sanitary inspections, request information and documentation, verify pharmaceutical establishments, take samples, and carry out post-market control actions over medicines, biological products, and medical devices. When non-compliance with sanitary regulations is detected, ARCSA has its own sanctioning authority and may initiate a Special Sanitary Procedure, through which the facts are investigated, violations are determined, and administrative decisions are adopted in accordance with due process guarantees. Where there is a risk to public health, ARCSA may order immediate preventive or corrective measures, including product immobilisation, market recalls, suspension of activities, closure of establishments, or the suspension or cancellation of marketing authorisations and operating permits.

In parallel, compliance with regulated medicine prices is monitored by the Technical Secretariat for the Fixing of Medicine Prices, which is empowered to verify adherence to fixed or notified prices and to impose administrative sanctions for non-compliance. These sanctions may include the direct fixing of the price of medicines.

Moreover, competition related aspects of the sale and distribution of medicines fall under the authority of the Superintendence of Economic Competition, the body responsible for enforcing competition law in Ecuador. This authority has investigatory and sanctioning powers over anticompetitive conduct, including abuse of market power, restrictive practices, or unlawful pricing or distribution arrangements in the pharmaceutical sector.

Certain violations may also give rise to civil liability for damages caused to consumers or patients and, in the most serious cases, to criminal liability, particularly where the manufacture, importation, or commercialisation of adulterated, falsified, or dangerous therapeutic products is involved. In such circumstances, the health authority may refer the matter to the Office of the Attorney General to initiate the corresponding criminal investigations.

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?

No recent comprehensive legislative reforms have been adopted in Ecuador that fundamentally alter the regime governing the trade, distribution, or cross-border movement of therapeutic products. Nevertheless, ARCSA has continued to update technical regulations and administrative guidelines to strengthen sanitary control, traceability, and post-marketing surveillance. These efforts include the modernisation and digitalisation of sanitary registration procedures, such as registrations, amendments, and cancellations, and their integration with the Ecuadorian Single Window for Foreign Trade (*Ventanilla Unica Ecuatoriana*) for import operations, with practical effects on regulatory requirements, timelines, and cross-border transactions.

From an enforcement perspective, ARCSA has intensified sanitary inspections and post-marketing controls, particularly to prevent the commercialisation of unregistered, adulterated, or unlawfully imported products, while adopting a predominantly preventive approach through technical guidance and corrective measures prior to sanctions.

As part of its ongoing regulatory reforms, ARCSA has signalled further regulatory modernisation, including the implementation of a digital package leaflet for medicines, incorporated into the 2024 regulatory framework and pending the designation of an official web platform. In parallel, to strengthen traceability, ARCSA has requested that the Customs Authority (SENAE) eliminates the endorsement mechanism (*endoso*), which allowed marketing authorisation holders to authorise third parties to import their products through the customs platform. As a result, importers must now be explicitly included in the relevant marketing authorisation, enabling enhanced regulatory oversight and traceability throughout the supply chain.

In late 2025, ARCSA issued Resolution ARCSA-DE-2025-052-DASP, adopting a new technical regulation to replace the existing framework governing the National Pharmacovigilance System. The new regulation introduces a more comprehensive and risk-based approach to post-authorisation oversight, expands pharmacovigilance obligations for marketing authorisation holders, aligns the national system with international standards, and reinforces ARCSA's role as the central coordinating authority. Although the resolution has been formally issued, it has not yet entered into force, as its applicability is subject to a nine-month transitional period starting from

its publication in the *Official Gazette*, which has yet to occur. As a result, the prior regulatory framework remains applicable pending the regulations effective date.

In the area of public procurement, the CONSAP (National Public Health Council) was created in August 2025. It consists of key public health and government authorities, including the Ministry of Public Health, ARCSA, and the Vice Presidency of Ecuador. CONSAP acts as a coordinating body, centralising and planning public sector purchases of medicines and medical devices to enhance transparency, efficiency, and the continuity of supply within the public healthcare system.

Looking ahead, current developments suggest intensified institutional activity in Ecuador, with emphasis on health policy, particularly public health, which has faced significant challenges in recent years. In this context, further regulatory changes and updates may be expected in the coming months.