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

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REGULATORY FRAMEWORK AND COMPETENT AUTHORITIES

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

The Republic of Ecuador is a unitary state. Accordingly, there is no system of divided legislative powers at the sub-national level. Legislative authority rests exclusively with the National Assembly, while regulatory instruments are issued by the Executive Branch.

The Ministry of Public Health (MSP) is the National Health Authority, responsible for the stewardship of the health system and for formulating national health policy. Regulatory oversight and enforcement functions are exercised by specialised agencies attached to the MSP, which implement policy and conduct regulatory surveillance.

With respect to products for human use and consumption – including pharmaceuticals, biologics, and medical devices – regulatory control and surveillance are the responsibility of the National Agency for Regulation, Control and Health Surveillance (ARCSA). ARCSA issues binding technical regulations, grants marketing authorisations, conducts post-marketing surveillance, certifies establishments engaged in manufacturing, importing, distributing, and dispensing regulated products, and exercises sanctioning powers.

Health regulation in Ecuador has a constitutional foundation. In addition to the directly applicable constitutional right to health, the Constitutional Court issued Judgment No. 679-18-JP/20, which has *Erga omnes* effect and is therefore binding on all authorities and private actors. This judgment is considered to have constitutional normative rank, as it sets out detailed rules governing the right of access to medicines.

The main legal regulations applicable to the import, distribution, sale, and export of therapeutic products in Ecuador are the Organic Health Law and the Generic Medicines Law.

At the regulatory level, rules govern the entire chain of production, import, and marketing of products for human use or consumption.

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?

The Health Law establishes that medicines in general, biological products, and medical devices, whether manufactured domestically or abroad, are subject to health registration for importation, marketing, dispensing, and sale.

Products may only be marketed in accordance with the sales category and classification assigned by ARCSA through health registration.

Classification of medicines in general (chemical synthesis)

The Technical Health Regulations for Obtaining Health Registration, Control, and Surveillance of Medicines in General for Human Use provide for the following classification of medicines:

- 'generic drug' – one that is registered and marketed under the International Non-proprietary Name (INN) of the active ingredient;
- 'new drug' – a drug whose active ingredient is entering the country for the first time;
- 'official drug' – whose active ingredient and pharmaceutical form are included in one of the official pharmacopoeias in force;
- 'over-the-counter drug' – authorised to be sold or dispensed without a prescription.

Biological products

Biological products for human use are regulated by the Technical Regulations for Obtaining Health Registration, Control, and Surveillance of Biological Products, which classify such products as follows:

- vaccines;
- blood products;
- biotechnological and biosimilar products;
- allergens of biological origin;
- immune sera;
- advanced therapy medicinal products – ie, gene therapy, cell therapy, or tissue; and
- engineering.

Medical devices

Medical devices are governed by the Technical Health Regulations for the Control of Medical Devices for Human Use and are classified according to the level of risk and type of medical device:

According to the level of risk:

- I (Low Risk);
- II (Moderate-Low Risk);
- III (Moderate-High Risk); and
- IV (High Risk).

According to the type of medical device for human use:

- active medical device for human use (DMA);

- invasive medical device for human use (DMI);
- non-invasive medical device for human use (DMNI); and
- medical device for in vitro diagnosis for human use (DMDIV).

The classification of biological products, medicines and medical devices has mainly regulatory effects, as the Authority establishes different requirements for granting marketing licences, depending on the type of product. In terms of control and surveillance, the Authority takes a stricter approach to products with high risks to health.

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?

According to the Health Law, establishments subject to health control for their operation must have an operating permit granted by ARCSA. The permit is granted for wholesale distribution in the following categories: representative agencies or pharmaceutical distributors.

Establishments will also need good storage, distribution, and transportation practices, which guarantee compliance with a set of mandatory minimum standards which must be met by establishments that handle the logistics of products. The Authority allows the outsourcing of logistics operations provided that a prior notification of Service Contracting process is completed.

To be granted the licences described above, the establishment must comply with key conditions regarding facilities, equipment, operating procedures, organisation, personnel, and other aspects, designed to ensure that the characteristics and properties of the products are maintained during storage, distribution, and/or transit.

In addition, wholesale distribution establishments must have a technical director who is a professional pharmaceutical chemist, who will oversee quality control, including compliance with procedures by assigned personnel during the receipt, storage, dispatch, distribution, and transport of products, to guarantee their quality.

Finally, pharmaceutical and medical device representative and distribution companies must certify the establishment of a pharmacovigilance and/or technovigilance unit, as appropriate.

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?

Pharmacies are the only establishments which can dispense therapeutic products to end consumers according to the Health Law.

When a private pharmacy is opened, the legal representative must apply for the operating permit within a period not exceeding 60 days.

Once the operating permit has been granted, the pharmacy may be inspected at any time by ARCSA, focusing on the level of health risk, to verify the accuracy of the information provided in the application form.

In pharmacies, the technical responsibility of a pharmaceutical chemist is an important role, as the exercise of their functions must ensure compliance with technical and legal aspects at the time of acquisition, receipt, storage, transport, dispensing, and sale of medicines and other products, and in general, Good Pharmacy and Dispensing Practices.

These types of establishments also have certain special obligations and prohibitions in accordance with the Organic Health Law and other legal and regulatory bodies, for example:

- pharmacies must have official price lists permanently available to the public, a prescription file, a file for narcotics and psychotropic prescriptions, and white aprons for daily use by pharmacy staff;
- prior to opening and subsequent operation of the pharmaceutical establishment, it must have a sufficient stock of the products it is authorised to sell;
- pharmacies must provide uninterrupted service for at least 12 hours a day;
- 60 days before the expiry date of medications, pharmacies must notify their suppliers, who are required to collect and exchange these products;
- pharmacies must implement a staff training programme.

The following practices are banned in pharmacies:

- medical consultations, taking samples, having clinical laboratories or biological sample areas, performing alternative therapies and diagnostics;
- applying treatments, whether invasive or not;
- keeping accumulated empty secondary packaging of medicines or other products;
- storing, delivering, giving away, or marketing medical samples;
- altering the information on the labels of medicines or medical devices;
- the sale or distribution of medications and medical devices containing the labels – 'free medication', 'medical sample', 'sale prohibited', and 'free product';
- the preparation of cannabis-based magistral or officinal preparations that have not been previously notified to ARCSA; and
- agreements between healthcare professionals and pharmacies for the subsequent dispensing and sale of medicines.

The following dispensing-related actions are also prohibited:

- recommending the use of medications which require a prescription or changing the prescribed active ingredient without the written authorisation of the prescriber;
- the dispensing of RX medications without the corresponding prescription;
- dispensing medications with expired or postdated prescriptions; and
- dispensing psychotropic and narcotic drugs without a special prescription issued by a specialist HCP.

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

No specific laws or regulations have been issued in Ecuador aimed at regulating the sale of therapeutic products via the internet or marketplace platforms.

Nevertheless, this is not a prohibited activity, so to carry it out, websites must be related to a duly licensed physical pharmaceutical establishment. It is not possible to have a dark store pharmacy, which refers to an entity that does not serve the public on-site and only ships product purchased through digital platforms.

In accordance with the above explanation, the sale of therapeutic products to consumers via virtual channels may only be carried out by pharmacies that comply with the provisions of Resolution ARCSA-DE-2024-048-DASP and have obtained an operating permit before beginning commercial activities.

This type of marketing must also comply in its publications with the provisions of the Law on Consumer Protection, which specifically requires the inclusion of basic commercial information, in addition to prices, weight, measurements, and whatever else is relevant according to the nature of the product.

Although there are no specific regulations regarding the content of online sales publications, the following is suggested as basic commercial information:

- images should be restricted in the case of Rx products so as not to be confused with advertising;
- product price per commercial presentation;
- benefits and uses indications, dosage, side effects, and contraindications;
- technical data sheet – composition;
- disclaimers regarding prices, benefits, deliveries, prescriptions, and personal data protection.

In the case of online sales, whether through social media, websites, or marketplaces, it is worth reiterating the importance of complying with advertising regulations. the Authority may impose sanctions in the event of non-compliance in the marketing and advertising of medicines.

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)?

The importation of therapeutic products into Ecuador is subject to a system of prior and subsequent control, coordinated between the ARCSA and the National Customs Service (SENAE).

The two authorities use the same platform, called *Ventanilla Única* VUE, to issue health registrations, prior permits, customs declarations, and nationalisation authorisations. The main requirement for importing therapeutic products is that they have a health registration approved by ARCSA.

There are exceptional cases in which ARCSA may authorise the importation of therapeutic products without health registration, if they are included in any of the following cases:

- a health emergency;
- specialised treatments not available in the country;
- people suffering from catastrophic, rare, or orphan diseases;
- human clinical research purposes; or
- the supply of the public sector through international organisations.

The importer must be the holder of health registration or have explicit authorisation. The company importing this type of product must have a valid operating permit issued by ARCSA.

Health regulations do not contemplate the need for other prior authorisations for the importation of therapeutic products, except in cases of medicines containing controlled substances, in which case the importing establishment will be required to obtain prior qualification for each substance and an individual licence per importation.

SENAE is the customs control authority responsible for verifying documentation, value, origin, and tariff classification. Therapeutic products are classified according to the National Import Tariff, which must be followed for the purposes of the Customs Import Declaration:

In general, pharmaceutical products are imported under the following tariff headings:

Subheading	**Ad valorem tariff**	**VAT**	**FODINFA**
3004.90.20.00 (Other medicines for human use)	5%	0%	0.5%
9018 (Medical devices)	0 to 5%	15%	0.5%

Regarding the payment of taxes/tariffs, Ecuador has signed several international agreements that establish tariff exemptions or reductions for imports, the main ones are:

- multiparty trade agreement with the European Union;
- agreement with the European Free Trade Association (EFTA);
- Cartagena Agreement; and
- preferential trade agreements with MERCOSUR.

To apply this benefit, it is essential that the customs declaration be accompanied by the certificate of origin or the exporter/importer's declaration of origin.

Documentary controls are applied at border inspections and, where appropriate, physical measurements are based on risk management. ARCSA may intervene as a border control authority to verify sanitary conditions and prevent illicit trade, which may include counterfeiting, adulteration, or smuggling.

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?

As a rule, medicines can only be imported by pharmaceutical establishments with valid permits and in compliance with the prerequisite of obtaining health registration, as stipulated in the Health Law.

The SENAE may allow the direct entry of medicines into Ecuadorian territory in the following cases: (1) travellers entering Ecuador legally, with a medical prescription; (2) via courier through the 4x4 regime.

The importation of products in general, including medicines or medical devices, through the simplified type B import category, known as the 4x4 regime, is regulated by SENAE and the Foreign Trade Committee COMEX.

This modality allows the importation of packages weighing up to 4 kg and with a maximum value of US$400, provided that they are presumed to be for personal use, for which a medical prescription issued by a health professional authorised to prescribe in Ecuador must be presented. There is an annual limit of US$1,600 per person.

COMEX recently reformed the regulations applicable to 4x4, establishing a fixed tariff of US$20 per package to be paid by the recipient.

If the product exceeds the weight or value indicated above, SENAE will require compliance with the regular import process, which involves the presentation of the health registration or the 'import by exception' permit for cases in which the product does not have health registration.

Regardless, the product cannot be marketed and is subject to strict health controls to ensure compliance with this condition.

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?

As explained in the response to Question 7, direct shipping from international suppliers to consumers is possible under the 4x4 (Courier) modality. Products shipped via Courier do not require the presence of a local representative, and the labelling may correspond to that of the product's place of origin.

Outside of this modality, it is mandatory to comply with the regular importation regimes for medicines. The first, under the general rule, is that all medicines, medical devices, or biological products, that are marketed or distributed in Ecuador must have a valid health registration issued by ARCSA. This means that there must be a natural or legal person domiciled in Ecuador who is legally and technically responsible for the product through ownership of the health registration. Product labels must comply with the requirements applicable in Ecuadorian regulations as approved by ARCSA.

The second regime that could be applied to products that exceed the 4x4 rule and do not have health registration in Ecuador is personal importation, with a prescription, in limited quantities and under the control of ARCSA and SENAE. This allows the product to be imported with its labelling in the country of origin.

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?

Parallel importation in Ecuador is understood as the entry into the market of products which may be medicines, biologicals, or medical devices, through a natural or legal person other than the holder of the health registration and without prior authorisation from the latter.

It should be emphasised that, according to the Health Law, the holder of the health registration is the only party authorised to import or delegate to third parties the importation of a product subject to health control and surveillance. Without a formal delegation from the health registration holder, the product cannot be imported and will be detained by the National Customs Service.

This criterion is reinforced by the current sanitary regulation, which establishes that therapeutic products for importation must comply with the information approved by ARCSA on their labels. Relabelling (unless authorised in the health registration), alteration, or local remarking is not permitted.

Ecuadorian regulations allow limited local marking. Health registration and marketing labels are permitted for medical devices; and retail price and labels such as 'medical sample, sale prohibited' for medications.

In the case of medicines (including biologicals), information not covered by the previous items must be printed by the product's manufacturer.

In this regard, the regulation does not explicitly ban parallel imports, but the specific conditions of control and surveillance prevent them from being carried out without the knowledge and specific authorisation of the official local distributor and/or holder of the health registration.

The health registration holder is legally and technically responsible for the product in Ecuador and is also responsible for the quality control and pharmacovigilance of pharmaceutical products. It is not possible to comply with this condition if the import is made outside the local licence holder's exclusive distribution channel.

There are, however, cases in which, despite the existence of valid health registration, the product is not available in the country. In such cases, ARCSA may authorise an exceptional import through parallel channels, provided that a certificate of stock shortage is provided by the holder of the health registration.

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?

To date, there are no quantitative quotas, permits, or other measures which restrict or condition the export of therapeutic products.

Nevertheless, for reasons of emergency duly declared by the President of the Republic or MSP, temporary and duly justified, restrictions may be placed on the export of therapeutic products. This could be based on constitutional provisions on the right to health and access to medicines in order to prevent risk of domestic shortages as a result of the emergency. Should this occur, clear, prior, and general regulations will need to be issued in a coordinated manner between ARCSA, the Ministry of Health, and COMEX.

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?

Compliance with health surveillance and control regulations is mandatory for all public and private institutions, engaged in the production, import, export, distribution, and sale of products for therapeutic products.

As a result of the above, it is important to emphasise that therapeutic products manufactured for export must originate in a duly certified plant that complies with quality standards: GMP in the case of medicines and ISO 13485 for medical devices.

Ecuadorian law allows the manufacture of therapeutic products exclusively for export, even if they do not have national health registration. In these cases, ARCSA issues the Export Health Certificate (CSE), document which certifies that products meet quality, safety, efficacy, and/or harmlessness conditions.

To obtain a CSE, the applicant must declare that the product complies with the specifications of the exporting country, does not conflict with the laws of the country of export, is labelled in accordance with the requirements of the country of destination, and is not sold or promoted for sale on the domestic market.

There is no specific ban on double labelling in Ecuador. However, the label for domestic use must be approved by ARCSA through the health registration, and the label for export will be governed by CSE regulations.

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?

Ecuador requires complete traceability from manufacturing, importation, and distribution. This means that batch identification must be carried out, expiry dates must be recorded, and import and distribution records must be maintained. Traceability to consumers has not been regulated.

In the fight against counterfeiting, ARCSA issued the 'Technical Health Regulations for the control of products for human use and consumption subject to health control and surveillance considered counterfeit or substandard', which allows the Agency to require safety measures for products throughout the national territory.

ARCSA has the power to order the withdrawal of products, issue health alerts, and establish enhanced traceability measures.

Ecuador does not require a universal mandatory identification system as the FDA or EU does, but it does require clear identification of the device, batch or serial number.

In the case of therapeutic products intended for export which are not marketed in the domestic market, labelling in Spanish is not required, provided that they comply with the regulations of the destination country. In this case, ARCSA may issue CSE, GMP certificates, certificates of analysis, and free sale certificates.

Regarding traceability for export, the manufacturer/exporter must keep records of manufacturing by batch, destination records, customs documents, and health certificates issued, which are subject to subsequent inspection and control by ARCSA.

Finally, SENAE carries out customs control through the verification of documentation, control of the entry or exit of products, and coordination with ARCSA when there is a possible health risk.

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?

One of the most important factors that substantially influence distribution channels, or the availability of medicines and biological products, is price setting by the government through the Health Law and the Price-Setting Regulation.

The main objective of the Price Setting Regulation is to establish new procedures for setting, reviewing, and controlling the final consumer prices of medicines.

The Price Setting Council establishes a ceiling price for each strategic and new medicine.

In the case of strategic medicines which have already been registered, the ceiling price is set by the Council for the same active ingredient, pharmaceutical form, and concentration, and will be calculated as the equivalent of the median retail price on the private market. No medicine may be sold at a price above the ceiling prices.

As determined in the new Price Setting Regulation, the basis for determining the regime that applies to each medicine is to verify whether it is a strategic medicine.

There is a general criterion issued by the Price Setting Council, which states that the list of strategic medicines is based on the essential nature of the medicines; and on two fundamental principles for price regulation: (1) the importance of the drug from a public health perspective; and (2) an economic perspective and relevant restrictions on competition.

There are specific situations in which the fixed price corresponds to values that do not allow the importation and marketing of medicines and biological products in Ecuador. In such cases, legal challenges may be brought.

There is no state mandated price setting for medical devices.

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?

If ARCSA carries out control and surveillance inspections and determines that the pharmaceutical establishment or product does not comply with the provisions of the Law, the Authority may impose penalties of confiscation, fines, and temporary closure.

To protect the health of the population, the Authority may also adopt provisional protective and/or precautionary measures, including: (1) the suspension of sale activities, the confiscation or immobilisation of products; (2) any other measures established by the relevant regulations, for example, suspension of activity, withdrawal of products, documents, or other goods, and limitations or restrictions to access.

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 first and second debates about the draft Health Code took place in 2020. In the same year, the draft was vetoed in its entirety by the President of the Republic, who considered that it did not guarantee the population's right to health and wellbeing, due to the issues it addressed. On 5 December 2025, the plenary session of the Assembly accepted the total veto applied by the former President.

The abandoning of the bill is based on the need to maintain harmony in the legal system regarding the right to health, therefore avoiding the likelihood of legal contradictions, regulatory duplication, and legal loopholes.

Subsequently, no new laws have been proposed to regulate the importation and distribution of therapeutic products in general.

At the regulatory level, two recently published regulations have made an impact.

The first is the reform of the Replacement Technical Regulation for Authorising the Importation by Exception and Importation by Donation of Medicines, Biological Products, and Medical Devices, issued on 7 November 2025. A single article included general provisions stating that applicants for authorisation to import by exception or import by donation of a drug whose purchase is ordered by a court must detail the court case number in the application so that ARCSA can verify the provision of the drug, as ordered by a constitutional judge.

If the applicant has not notified the Agency that the product was ordered by a court and that it does not have a valid health registration, the import authorisation issued by ARCSA will be null and void.

The second relevant regulation published on 9 December 2025, corresponds to COMEX Resolution No. 017-2025 adopted by the Foreign Trade Committee, which prohibits any form of endorsement, assignment, or transfer of Health Registrations and Health Notifications that have not been processed and authorised by ARCSA.