

The Pharma Legal Handbook

Ecuador

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms · Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs · Orphan Drugs and Rare Diseases · Localization · Biosimilars and Biologics

Ecuador

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Ecuador. It is a must have for any company operating in the country or looking to enter the market.

Prepared in association with CorralRosales, a leading Ecuadorian law firm, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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*** THIS REPORT WAS ORIGINALLY PUBLISHED IN OCTOBER 2018 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**

****LAST UPDATE: FEBRUARY 2021**

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01

REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

3. What are the steps to obtaining authorization to develop, test, and market a product?

4. What are the approximate fees for each authorization?

5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?

6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?

7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?

8. How is compliance with regulation monitored and evaluated? Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements?

9. What is the potential range of penalties for noncompliance?

10. Is there a national healthcare system? If so, how is it administered and funded?

11. How does the government (or public) healthcare system function with private sector healthcare?

12. Are prices of drugs and devices regulated and, if so, how?

13. How are drugs and devices used by patients paid for? What roles do public and private payers play?

14. Who dispenses drugs and devices to patients and how are those dispensers compensated?

15. What are the professional and legal responsibilities of those who dispense drugs and devices? What role do they play in providing patient care, information, and safety?

01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

The authority responsible for applying and enforcing the regulatory framework in relation to human medicines, biologicals, and medical devices is the National Agency for Regulation, Control and Sanitary Surveillance (ARCSA), which is a decentralized agency of the Health Ministry (HM).

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

The primary legislation for the authorization, pricing and reimbursement of medicines biologicals, and medical devices is the Health Law (HL) and its regulations, based on the World Health Organization (WHO) guidelines.

ARCSA is the regulating Agency for sanitary control, marketing authorizations are required for imported and domestic products such as medicines, biologicals, and medical devices. As for the approval and revision of pricing, the entity responsible is the National Council for Fixing and Reviewing Drug Prices (CNDP) which is part of the HM.

In Ecuador, the commercialization of medicines and biologicals without a marketing authorization and price determination is prohibited.

3. What are the steps to obtaining authorization to develop, test, and market a product?

Essentially, applicants applying for marketing authorizations must prove the safety and efficacy of their products through clinical trials, according to the rules set out by the HL and its regulations, not only covering the products but also the active ingredients.

Manufacturers must provide all information about the developing, testing, and marketing of their products in the Ecuadorian territory and when applicable, from abroad. The information must include the following:

- Analytical methodology of the active ingredient and the final product.
- Certificate of analysis in drug control tests standards.
- Stability studies to be carried out in Climate Zone IV subtropical with possible high humidity, according to the OMS classification.
- Analysis procedure for identification, quantification, evaluation of the physical, physicalchemical, biological, chemical, microbiological, pharmacological characteristics of the finished product.
- Preclinical studies (where appropriate)
- Toxicity report.
- Pharmacological report.
- Immunogenicity report.
- Pharmacokinetics Studies.
- Pharmacodynamics Studies.
- Clinical Trials.

- Certificate of Pharmaceutical Product (CPP)
- Certificate of Analysis (CoA)
- Colindex by FDA (where appropriate)
- Product specifications.
- Manufacturing process description.

Research and Development companies can benefit from an approval procedure for medicines, when they have been previously approved by:

- The European Medicines Agency (EMA)
- The US Drug and Food Administration (FDA)
- Health Canada

It is the responsibility of the investigating laboratory to issue a responsibility letter, stating:

- Certification of the research plan (according to international references)
- Certificate of experimental phase conclusion of the medicine
- Pharmacovigilance programs (3 years after the marketing authorization granting date)

4. What are the approximate fees for each authorization?

Since there is no research and development of new molecules (medicines) in Ecuador, the Government has not established official fees for this purpose. However, there is a homologation process to obtain marketing authorizations applicable to foreign countries amounting to US\$ 2258.41.

5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?

Marketing authorizations must be renewed every five years for medicines, biologicals and medical devices. The renewal process does not involve official fees and is the procedure through which the marketing authorization is updated once its validity period has ended. The renewal process is carried out in ARCSA's electronic system; however, it only applies to products that have not changed their characteristics since approval. If the product or any of the legal information changes, the process to follow is the same as for a new marketing authorization, if these changes were not notified prior to the renewal date.

6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?

There is no differing process between brand name products and generic products, however for brand name products it is necessary to prove safety and provide efficacy parameters. For generic products, it is necessary to prove interchangeability and bio-comparability of the medicine. Labeling requirements also differ, since generics have to declare the International Common Denomination (ICD) and include "Generic Medicine".

The only difference between local and foreign manufacturers is the applicable government fees, which are less for local manufacturers.

7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?

Combination products will be registered under the same marketing authorization when in their commercial presentation, another medication or medical device whose purpose is to supply medication is included.

These combination products are regulated by ARCSA which will require a classification process prior to applying for the marketing authorization. Given their particular features, these products can be classified as: medicines (medicines/ biologics) and/or medical devices (drug/device). Requirements and application timeframes differ in each case, depending on the nature of the combination product.

8. How is compliance with regulations monitored and evaluated? Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements?

Compliance is monitored and evaluated by ARCSA. Compliance with GMP, GSP and GTP and standard operating procedures, is comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements.

ARCSA is in process of strengthening the pharmacovigilance program that will ensure all procedures are controlled from manufacturing until post registration control.

9. What is the potential range of penalties for noncompliance?

ARCSA is empowered to make on-site visits at any time to inspect premises and verify compliance and can initiate ex-officio legal proceedings to sanction non-compliance. Penalties include the revocation of the marketing authorization, ordering temporary or definitive closure of facilities and/or fines amounting to approximately US\$ 4000.

10. Is there a national healthcare system? If so, how is it administered and funded?

The healthcare system comprises public (social security) and private insurers, out-of-pocket payments and informal arrangements.

The major public segment is The Ecuadorian Institute of Social Security (IESS). This entity provides health services for the self-employed and employees in public and private companies. There are other systems with special structures, for example, for members of the military and police.

The public health sector normally faces financial problems and implements measures to limit costs, for example, by pressing for price reductions in public bids and encouraging competition and the use of generics.

11. How does the government (or public) healthcare system function with private sector healthcare?

Private health insurance generally covers higher economic levels of the private sector. Enrolment in private health insurance has increased considerably over the past few years.

The public and private health sectors function separately. There is no interaction between them.