THE PHARMA LEGAL HANDBOOK

ECUADOR

PHARMA BOARDROOM

THE PHARMA LEGAL HANDBOOK ANSWERS ESSENTIAL QUESTIONS ABOUT THE LEGAL AND REGULATORY 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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- Spanish

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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?

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 or notifications 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. 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, physical-chemical, 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)
- Coloindex 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.