The Pharma Legal Handbook

Colombia

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

PHARMA BOARDROOM

Colombia

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

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

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Some just might
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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?

Jurisdiction over drugs, biologicals and medical devices is centralized at the Colombian National Food & Drug Surveillance Institute, better known as INVIMA. This is a decentralized agency of the Ministry of Health, created in 1993. More information available at invima.gov.co.

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

The regulatory framework for the authorization of drugs, biologicals and medical devices is framed through Decree 677/95 (chemical synthesis), Decree 1484/12 (biologicals) and Decree 4725/05 (medical devices). Each field has additional regulations:

2.A. Law 1751/2015, regulated by Decree 780/2016, provides the general national framework on health rights and duties in Colombia;

2.B. Resolution 3951/2016, establishes the reimbursement procedure at the Fund of Solidarity and Assurance (FOSYGA) for supplying medicines, medical services and health benefits not included in the Health Benefits Plan;

2.C. Price control over drugs and medical devices is determined under the National Commission of Medicines and Medical Devices' scope (CNPMD) according to Law 1438/2011, Decree 1071/2012 and Decree 705/2016. The CNPMD annually assign a reference price for all medicinal products marketed in the country. This price is considered a regulatory tool to establish the price for each commercial presentation of the medicinal product. A product will enter on a direct control system (price control fixed) if: I) It presents a retail price higher than the reference price of the corresponding homogeneous group and/or II) The class of products do not form a homogeneous group, with at least three or more references of the product.

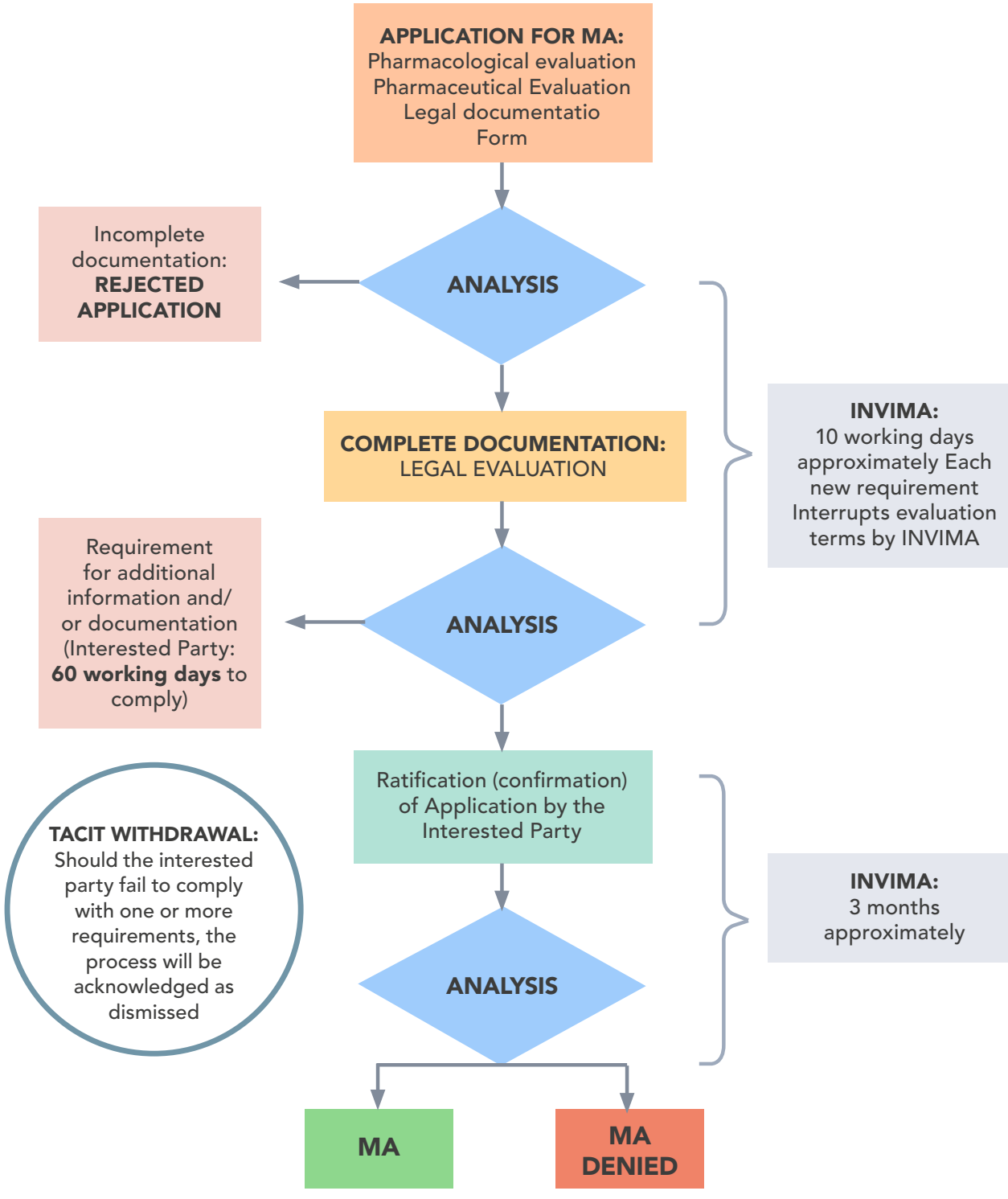
3. What are the steps to obtaining authorization to develop, test, and market a product?

It is mandatory to obtain a marketing authorization (MA) or health registration to manufacture, sell, import or export a drug product. Requirements and procedures depend on the product, its background, indications of use and risks.

3.A. STEPS TO OBTAINING MARKETING AUTHORIZATION OF NEW DRUG PRODUCTS:

Usually, the marketing authorization for a new medicinal product may take from between 9 months to 12 or 20 months depending on the product

supporting information. In practice, INVIMA takes more time than the legally established limits.



3.B. STEPS TO OBTAINING A MARKETING AUTHORIZATION FOR PRODUCTS INCLUDED IN OFFICIAL PHARMACOLOGICAL REGULATIONS

Usually, the marketing authorization for drug products included in Official Pharmacological Regulations may take from 4 months to 9 or 12 months depending on the product supporting information. In practice INVIMA takes more time than the legally established limits.