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 · Orphan Drugs and Rare Diseases · Biosimilars and Biologics

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.

CAVELIER
ABOGADOS

BOGOTÁ
Carrera 4 No. 72 A-35, Edificio Siski
Bogotá 110221 - Colombia
Teléfono (57-1) 347 3611
Fax (57-1) 211 8650

*** THIS REPORT WAS ORIGINALLY PUBLISHED IN JUNE 2018 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**
**** LAST UPDATE: NOVEMBER 2022**

THE AUTHORS

ANDRES RINCON

Andres Rincon is a partner and head of the Patents & Life Sciences Department. His main fields of practice are innovation, patent prosecution and enforcement of pharmaceutical products and processes, life sciences and regulatory affairs, test data protection and freedom to operate analysis. He has 18 years' IP experience, ten focused on patents and regulatory affairs related to chemical synthesis and biologic pharma and agrochemical products, and has successfully intervened in the most important validity, infringement and compulsory license cases before Colombian and Andean Courts.

Andres is a member of the Asociación Interamerica de la Propriedad Intelectual (ASIPI) (Patent Committee member), the American Intellectual Property Law Association (AIPLA) (Latin American and Biotech Committees), and the International Association for the Protection of Intellectual Property (AIPPI) (Colombian Delegate before the Biotech Committee).

LINA DÍAZ

A lawyer from Externado University with a Master's Degree in Intellectual Property and Competition Law from the London School of Economics (LSE) and a Master´s Degree in Applied Economics from Los Andes University. She has more than 7 years of experience in administrative and judicial proceedings in the field of intellectual property, data protection, consumer protection, and competition law.

LINA CAAMAÑO

IP Attorney with 15 years' experience acquired either from government entities (INVIMA), law firms as from corporations in multinational pharmaceutical industry. Her practice is primarily focused on regulatory affairs, health regulation, compliance policies, drug prices, marketing authorizations among others. Graduated from Pontificia Universidad Javeriana of Bogotá with post-degrees studies in Industrial Property, copyright, and new technologies from the University Externado de Colombia.

Some just might
see a blank sheet

We see
Beyond

CAVELIER

INNOVATION FOR BUSINESS

ANDRES RINCON

PATENT & LIFE SCIENCES HEAD

andresrincon@cavelier.com

BOGOTA

65 years

www.cavelier.com

CONTENTS

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?

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.

Additionally, according to Article 132 of Law 1438/2011, the Superintendence of Industry and Commerce (SIC) is the entity in charge of investigating and sanctioning infringements against the price control regulations of medicines and medical devices. The same authority is competent regarding the omission, reluctance to or inaccuracy in the provision of price information to the Medicines Price Information System - SISMED.

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

In Colombia there are two types or regimes of price control for drugs and medical devises:

i) Price report, under which prices are set freely but it has to be reported to SISMED

ii) Direct Price control which the authority sets the maximum price.

The regulatory framework for the authorization of drugs, biologicals and medical devices is framed through Decree 677/95 for chemical synthesis drugs Decree 1484/12 for biologicals, and Decree 4725/05 is applicable to medical devices. Each of these Decrees has been subject to 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, established 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. However, FOSYGA was substituted in its functions by the Administrator of the Resources of the General System of Social Security in Health (ADRES) since August 1, 2017, as established by Act 1753 of 2015.

2.C. Price control over drugs and medical devices is determined by National Medicines and Medical Device´s Prices Commission (CNPMD in Spanish) according to Act 100/1993, Act 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 price control system (fixed price control) if: I) It has a higher 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.

The methodology for setting the price of new medicines based on the evaluation carried out by the Institute of Technological Assessment in Health (IETS in Spanish) was set by Circular No. 013 of 2022 which was issued by the National Commission of Medicines and Medical Device´s scope (CNPMD). Circular No. 13 establishes the maximum sales price, the price per unit for the regulation of unavailable vital medicines and other provisions issued on July 25, 2022, Circular No. 014 of 2022. This new piece of law regulated the supervised freedom regime for some products and created the system to report information on prices of medical devices.

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

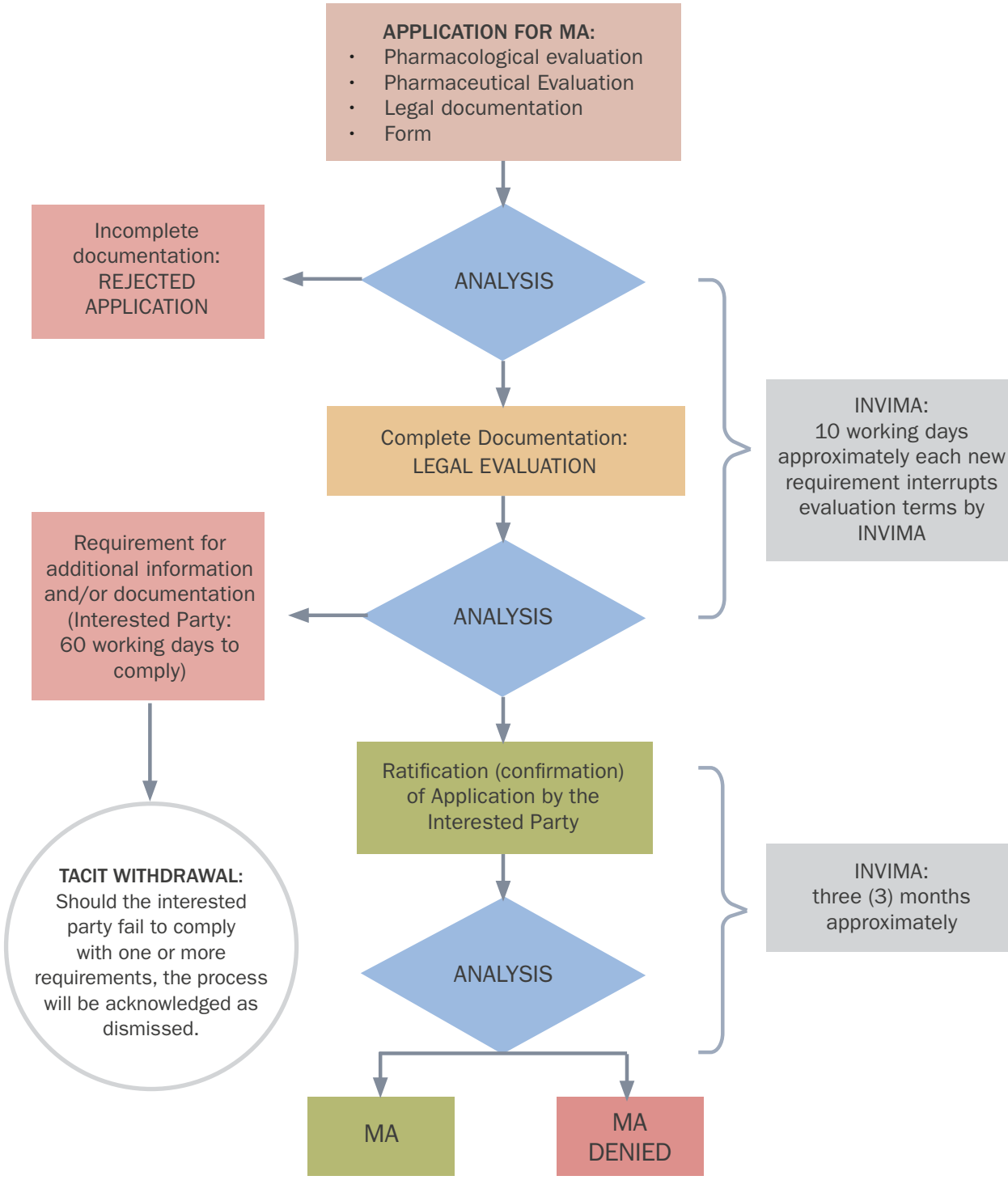
Usually, the marketing authorization for drug products included in Official Pharmacological Regulations may take from 4 months to 9 or 12 months depending on the product supporting information. In practice INVIMA takes more time than the legally established limits.

4. What are the approximate fees for each authorization?

GOVERMENT FEES IN USD FOR MARKETING ATHORIZATION FOR A:	
DRUG PRODUCT INCLUDED IN THE PHARMACOLOGICAL CODE	$3,200
NEW DRUG	$7,000
BIOLOGICAL PRODUCTS	$7,238
GOOD MANUFACTURING PRACTICE CERTIFICATE	$12,035

Note: Resolution No. 2022018438 of June 2022 and Resolution No. 2022021123 of July 8, 2022 establishes new fees that will be implemented by

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



1= TACIT WITHDRAWAL: Should the interested party fail to comply with one or more requirements, the process will be acknowledged as dismissed.