The Pharma Legal Handbook

Panama

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

Panama

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

Prepared in association with AFRA (Alfaro, Ferrer & Ramírez), one of the leading law firms in Panama, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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AFRA
ALFARO, FERRER & RAMÍREZ
Abogados / Attorneys at Law

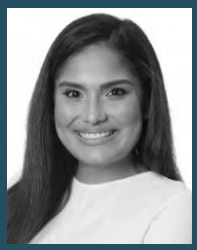
The origins of Alfaro, Ferrer & Ramírez (AFRA) can be traced back to the 1940's, when Dr. Horacio Alfaro, a successful Panamanian lawyer, politician and diplomat, established his own law firm. Soon his son, Eduardo Alfaro, joined in to create Alfaro & Alfaro.

In 1965 Eduardo Alfaro merged his legal practice with that of lawyers Alejandro Ferrer and Alfredo Ramírez, properly founding AFRA on January 21st. Throughout its history, AFRA lawyers have served in various important positions within the public sector, such as ministries and consulting for the writing and designing of laws that still impact the country today. These include Panama's international banking laws, the Panama Canal Administration's
constitutional chapter, various labor laws, special economic regimes, public sector privatizations, among others.

AFRA's practice on the private sector has had a steady growth in clients from local businesses, multinationals, family companies, institutions, as well as small and medium sized entrepreneurs.
Currently AFRA has become one of the country's top law firms, with over 30 lawyers and a staff of 90.

Supported by over 55 year's-experience and growth, AFRA provides a solid commitment from its lawyers, who focus on ethics, integrity and a personalized service.

THE AUTHORS



MARYCARMEN GONZALEZ

Marycarmen Gonzalez is an Associate at the firm's Intellectual Property Department. Marycarmen specialises in work involving industrial property, intellectual property and information technology, and has also gained experience attending consumer protection matters and health regulatory & compliance cases.

Her experience in these areas is broad and includes trademarks and patent prosecution, industrial designs and drawings registration, IP judicial protection, and trademark protection actions with the Customs Authority and the Colon Free Trade Zone Authority. Marycarmen also advises on cosmetics and pharmaceuticals health permits and registrations, and guides clients on regulatory legislation in this area. She also represents clients in consumer protection claims.

Before joining AFRA, Marycarmen was a trainee at Baker & McKenzie in Madrid in their Industrial Property Department.

Marycarmen is also the Co-Chair and Founding Member of the United Way Panama's Young Emerging Leaders in Panama.

MONIQUE FERRER

Monique Ferrer is a partner at our Intellectual Property Department and also the Head of the Regulatory & Compliance Department of our firm.

Monique represents local and foreign companies and individuals on the prosecution of intellectual property rights before the Ministry of Trade and Industries of Panama, as well as the protection and enforcement of such rights before the Courts of Justice, specialized in intellectual property.

Her regulatory and compliance work includes representing and advising companies on advertising and labelling compliance for pharmaceutical products, cosmetics, agrochemicals, medical devices, biomedical equipment and food and beverages. She also has extensive experience obtaining marketing authorization for these products.

Her expertise is recognized by the legal community who acknowledge her level of skill with recommendations and rankings as leading practitioner by Chambers and Partners Latin America who describe her as "very professional and with good knowledge of IP matters" and has also been ranked as an IP Starby the Managing Intellectual Property publication.

Monique is an active member of the International Trademark Association (INTA); the Inter-American Association of Intellectual Property (ASIPI) -where she is currently the National Delegate for Panama and President of the Regulatory Affairs Committee (2021-2023); Board member of the Panamanian Association of Industrial Property (APADEPI) and the Panama Bar Association.

*Co-author: Marissa Lasso de la Vega Ferrari

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is our promise to every client.

With over 50 years of experience, Alfaro, Ferrer & Ramirez (AFRA) holds the distinction of being one of the longest-established Panamanian law firms.

AFRA has wide experience in areas of corporate law, intellectual property, banking, insurance, telecommunications, international trade, energy, environment, hydrocarbons, immigration, labor, commercial, litigation, arbitration, public procurement, infrastructure, administrative law, energy and telecommunications law. The firm also offers corporate and trust services, through its subsidiaries, AFRA TRUST and AFRA BVI.

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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 that regulates drugs, biologicals and medical devices in Panama is the Ministry of Health through the following authorities:

- National Direction of Pharmacy and Drugs
- National Medical Devices Department
- National Bioethical Committee.

See the Chapter: **Directory of Local Institutions** below for more information available on the website.

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

DRUGS AND BIOLOGICALS:

- Law No. 66 of November 10, 1947: Sanitary Code.
- Law No. 419 of February 1, 2024 which regulates medicines and other human health products and the public procurement of drug products, other human health products, health supplies, medical devices and equipment and dictates other provisions.
- Executive Decree No. 13 of March 1, 2023, whereby the Law No. 1 of January 10, 2001, is regulated.
- Executive Decree No. 29 of June 28, 2023, whereby the requirements for the application for sanitary registrations for pharmaceutical products opting for abbreviate procedure and high standard products countries are updated.
- Resolution N°774 of October 7, 2019, establishes the legal requirements regarding the price of drugs basic basket.

MEDICAL DEVICES:

- Law No. 90 of December 26, 2017, which regulates Medical Devices and related products.
- Law No. 92 of September 2, 2019, whereby Law No. 90 is modified.
- Executive Decree No. 490 of October 4, 2019, whereby Law No. 90 is regulated as modified by Law No. 92
- Executive Decree No. 468 of November 7, 2007, whereby is regulated the issuance, renewal and suspension of the Technical Criteria of Medical Devices Certificates.
- Resolution No. 600 of April 23, 2018, whereby is regulated the License and Technical Verification Certificate for Medical Devices and related products.
- Resolution No. 001 of January 10, 2023, whereby the Guidelines for the storage and distribution of medical devices and related products

	and adopts the Form called Guide to Good Practices for the Storage and Distribution of Medical Devices and Related Products are adopted.
3. What are the steps to obtaining authorization to develop, test, and market a product?	DRUGS AND BIOLOGICALS: It is mandatory to obtain previous authorization to import, develop, test and market a drug product by the manufacturer, distributor, and importer (Licensed); to market a product, it must obtain the sanitary registration and obtain a pharmaceutical or non-pharmaceutical License; for testing, all trials must be approved by the Bioethical National Committee. MEDICAL DEVICES: For Importation, Exportation, marketing and use of a medical device on a public or private level can be authorized once the applicant demonstrates with documental evidence that the medical device complies with all the security, efficiency and quality defined by international regulations. Also, the manufacturer and distributor need the authorization (License) to import and market medical devices. Requirements and procedures depend on each product. Please refer to **Chapter 3, Question 22** regarding authorization process.
4. What are the approximate fees for each authorization?	The approximate government and analysis fees vary from between USD 800 and USD 3,500 per product.
5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?	Marketing authorizations (a.k.a Sanitary registrations) for drugs, biological and medical devices products are valid for a period of five (5) years. The renewal for sanitary registration must be requested one (1) month before 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?	The authorization process does not differ between brand-name products and generic product.
7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?	In general terms, the mentioned combination products are regulated under (i) Law No. 419 of February 1, 2024; (ii) the Sanitary Code and (iii) Executive Decree No. 13 of March 1, 2023 as phytopharmaceuticals, biological and biotechnological products, magistral preparations, radiopharmaceuticals, homeopathic medicines, orphan drugs, allergenics and supplements.

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?

The compliance of regulations is monitored and evaluated by the National System of Pharmacovigilance (NSP) which is integrated by the following:

- Ministry of Health
- Public and Private Health Facilities
- Pharmaceutical and Drug Department
- National Centre of Pharmacovigilance
- Regional, Institutional centres and Hospital or Committees Pharmacovigilance units
- Public and Private Pharmaceutical Establishments
- National and foreign pharmaceutical industry and Distribution agencies of the country
- Health Care Providers and Patients
- Universities
- Health Research Scientific Organisms

The NSP uses the International Harmonization Guide and the European Medicine Agency and as a principal source for data (according to Executive Decree No.40) from the following:

1. Health Care Providers:
- Ministry of Health
- Social Security Fund
- Trusts
- Patronage
- Hospitals, Clinics and Private Pharmaceutical Establishments

2. National and foreign Pharmaceutical Manufacturer Laboratories
3. Distribution agencies for pharmaceutical products
4. Universities
- Recognized International Organisms

5. Patients
6. Health Research Scientific Organisms
7. Pharmacovigilance Technologic Platforms

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

The potential penalties for noncompliance of Drugs Regulation ranged between USD 500 to 25,000 including the suspension of sanitary registration, suspension, and cancellation of License for pharmaceutical establishments and temporary or permanent closure of establishments.

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

Yes, in Panama, the National Healthcare System is the Social Security Fund (CSS).

CSS is administered by a Managing Board which include the Ministers from The Ministry of Health, The Ministry of Economy and Finance and several representatives from workers, doctors, retirees. CSS is funded by the contribution of private (affiliations) and public (subsidies).

See the **Directory of Local Institutions** below for more information available on the website.