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

Alfaro, Ferrer & Ramírez (AFRA) was established in 1961, and since then has grown into one of Panama's leading full service law firms.

The firm is recognized by its solid integrity, ability to successfully address legal issues in sophisticated deals, and the reliability and trust offered to its clients by its lawyers and professional staff.

Most of the lawyers at AFRA have obtained masters education at top academic institutions in the United States, South America and Europe, which makes it easy for them to adjust to virtually any cultural approach required by its international clients.

The firm is sensitive about the clients' needs to obtain straightforward and practical solutions to their legal concerns, and is focused in delivering a high quality on time service.

AFRA has a strong local practice, and is focused primarily on international companies coming to Panama to carry out business operations. In addition to that, it has a representative group of local companies engaged in important sectors of the economy. The firm's offshore practice is complemented by the services offered through its BVI office.

Some of the Firm's lawyers continue to attain experience by serving important posts outside of their ordinary legal work. Partner Alfredo Ramírez Jr. has been a member of the Board of Directors of the Panama Canal Authority since 1999, when he was appointed by the President of the Republic of Panama and ratified by the National Assembly. Partner Enna Ferrer de Carles is a member of the Board of Directors of the International School of Panama, a non-profit international group of schools that seeks to enroll highly qualified children of expatriates. Partner Rodrigo Moreno serves as board member of Panama´s first private and only catholic university (USMA) and is a member of the Economic Council of the National Catholic Archdiocese. Partner Marissa Lasso de la Vega F. was appointed again last year as member of the Board of Directors of the American Chamber of Commerce in Panama. Narciso Arellano serves as Alternate Judge in the First Superior Court for the Province of Panama, which is the appellate body that reviews all decisions issued by judges in the cities of Panama and Colon.

Due to the consistent increase in clients and work in recent years, the Firm is steadily growing, being 2012 the tenth year in a row in which it has continue to add new associates to its team. As such, AFRA continues to serve its clients with utmost care. AFRA main international areas of practice are Intellectual Property, Banking & Finance, Public Contracting & Infrastructure, Labor & Immigration, Taxation and Franchise.

THE AUTHORS

MARISSA LASSO DE LA VEGA FERRARI

Marissa Lasso de la Vega Ferrari is a Partner at the Firm and Head of the Intellectual Property Department which includes Regulatory, Compliance and Data Privacy. She also plays an active role in our Litigation Department regarding antitrust and consumer protection disputes, and intellectual property enforcement.

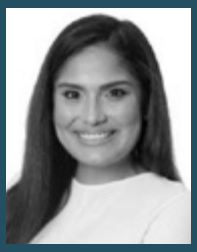
Marissa has a Law and Political Sciences degree and a Master of Commercial Law, both from the Universidad Católica Santa María La Antigua. She also completed the Studies in U.S. Legal Methods at the George Washington University Law School.

Described by Chambers and Partners Latin America as "a very talented IP lawyer" and in Latin Lawyer 250 as "one of the best IP lawyers in the country". She has also been voted by corporate counsel as a leading practitioner in LACCA for her work in Intellectual Property.

Member of the Panama Bar Association and the Panamanian Association of Industrial Property (APADEPI) where she occupied a place on the Board of Directors from 2008-2012 and currently acts as President (2017-2019).

She is a member of the International Trademark Association (INTA) and has acted in various committees and offices there since 2005. Marissa is a member of the American Chamber of Commerce and Industry of Panama (AMCHAM) where she has been both a member and the Secretary of the Board of Directors and also the Chair of the Legislation and Taxation Committee. Finally, she is a member of the Chamber of Commerce and Industry where she has continuously acted as legal counsel to the board of directors since 2009.

Marissa is a member of the International Association of Privacy Professionals (IAPP), where she is since 2018 chair of the KnowledgeNet in Panama City.



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.

Personalized service and integrity
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:

- Pharmaceutical and Drug Department
- Medical Devices National Department
- Bioethical National Committee.

See the Chapter: Directory 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. 1 of January 10, 2001 which regulates Drugs and other Human Health related products.
- Executive Decree No. 40 of February 15, 2019 whereby the Law No. 1 of January 10, 2001 is regulated.
- Resolution No. 367 of September 4, 2013 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.
- 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.

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 (License); 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 are valid for a period of one (1) year and the renewal must be done one (1) month before the renewal date.

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. 1 of January 10, 2001; (ii) the Sanitary Code and (iii) Executive Decree No. 40 of February 15, 2019 as phytopharmaceuticals, biological and biotechnological products, magistral preparations, radiopharmaceuticals, homeopathic medicines.

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 Center of Pharmacovigilance
- Regional, Institutional centers 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 Local Institutions** below for more information available on the website.

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

The public healthcare system it is not linked nor functions with the private sector healthcare.

Executive Decree No. 40 of February 15, 2019 contemplates a special process for public acquisitions of drugs from private sector through the National Offerors Committee, which is in charge of creating the National Offerors Registry of all those contractors that are interested in participating in drugs public tenders.