CONTENTS

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 **Chapter: 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.

12. Are prices of drugs and devices regulated and, if so, how?

In general terms, there is no price control fixed regarding drugs and medical devices.

Nevertheless, according to Law No. 1 January 10, 2001 and Resolution No. 367 September 4, 2013 the Ministry of Health, CSS, ACODECO, Gorgas Hospital has the authority to determine the price cap for some products through an executive decree.

13. How are the drugs and devices used by patients paid for? What roles do public and private payers play?

PUBLIC SECTOR:

CSS provides drugs and medical devices to patients at no cost, when they are affiliated and/or beneficiary.

The Ministry of Health through the clinics named MinsaCapsi, provide available drugs at a low cost to patients without limitations or restrictions.

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

PRIVATE SECTOR:

The patients are in charge to afford their own drugs and devices in pharmaceuticals establishments, which can be also done through private medical insurance.

14. Who dispenses drugs and devices to patients and how are those dispensers compensated?

Each one of the healthcare providers have a special method to dispense directly the drugs and devices, on public sector there is no cost.

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?

All medical professionals that assumes the technical direction or pharmaceutical regency of any pharmaceutical establishment, has the legal and moral responsibility of all technical operations. It is in charge to ensure that all pharmaceutical products that are sold and dispensed preserve the characteristics stated by the manufacturer, in connection with the stability, handling and storage of products. It will also be responsible for repackaging and preparations done at the pharmaceutical establishment. The responsibility of the medical professional does not exclude from liability to the owner of the pharmaceutical establishment.

The healthcare providers are obligated to have a License and/or authorization for the activity they do issued by the Ministry of Health and are obligated to provide patient care, information and safety as well as they must comply with special regulations to reception, storage, distributions and marketing products.