The Pharma Legal Handbook

Brazil

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 · Localization · Biosimilars and Biologics

PHARMA BOARDROOM

Brazil

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

Prepared in association with TRENCH ROSSI WATANABE, one of the largest law firms in Brazil, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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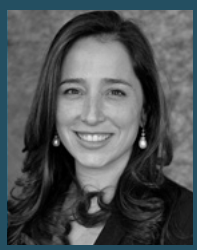

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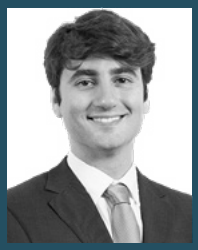

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CONTENTS

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?

In Brazil, the authorities are the National Health Surveillance Agency ("ANVISA"), which is a federal entity linked to the Ministry of Health, and local health authorities in states and municipalities.

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

The main Statutes are the Federal Law 6,360/1976 and the Federal Decree No. 8,077/2013, which provide for the surveillance of drugs, medical devices and related products, and others are subject.

Federal Law No. 6,437/1977 is an important law; it sets forth the violations to federal health legislation, establishes their respective penalties, and makes other provisions.

Also, Federal Law No. 10,742/2003 created the Drugs Market Regulation Chamber (CMED) in order to regulate the prices of the drugs commercialized in the country.

Also, there are many regulations issued by ANVISA related to the products it inspects. See the list with the most important regulations below.

OPERATING AUTHORISATION:

- Resolution RDC No. 16/2014: Operating Authorisation ("AFE") authorizes a company to store, distribute, pack, export, import, manufacture, repack and transport.

OPERATING LICENSE:

- Depends on the State/Municipality in which the operating facilities are established. In São Paulo, for example, the Ordinance CVS No. 1/2020, provides for the registration/licensing of facilities that develop activities subject to health legislation.

PRODUCT REGISTRATION:

- Resolution RDC No. 200/2017: provides for synthetic drugs, including generics and biosimilars.
- Resolution RDC No. 205/2017 provides for orphan drugs.
- Resolution RDC No. 55/2010 provides for biological drugs and biosimilars.
- Resolution RDC No. 238/2018 provides for dynamized drugs.
- Resolution RDC No. 26/2014 provides for phytotherapy drugs.
- Resolution RDC No. 73/2016: provides for post-registration changes and cancellation of drug registration (this resolution is applicable for synthetic and semisynthetic drugs, including generics and biosimilars).

o Resolution RDC No. 505/2021: defines the criteria necessary to develop and to request the marketing authorisation of high technology products based on human cells and genes, called "advanced therapy medicinal products".
o Resolution RDC 465/2021: provides a registration and authorisation waiver authorisationfor emergency use of COVID-19 vaccines purchased by the Ministry of Health.
o Resolution RDC 595/2022: provides for self-tests for detecting the COVID-19 antigen.

BEST PRACTICES CERTIFICATE:

o Resolution RDC No. 301/2019: provides for the requirements for the issuance of the Certificate of Best Manufacturing Practices for drugs. Note that drug manufacturing is subject to compliance to best practices. Import companies must request certification from the manufacturing plants located abroad.
o Resolution RDC No. 497/2021: provides for the procedure to obtain the Certificate of Best Manufacturing Practices and the Certificate of Best Practices for Distribution and Storage of drugs.
o Resolution RDC No. 16/2013: provides for the requirements for best manufacturing practices of medical devices and in-vitro diagnostic devices.
o Resolution RDC 508/2021: provides for the best practices for human cells for therapeutic use and clinical research, and makes other provisions.
o Resolution RDC 606/2022: provides exceptional temporary procedures to obtain the Certificate of Best Manufacturing Practices for active pharmaceutical ingredients and drugs and health products linked to Coronavirus;

TECHNICAL RESPONSIBILITY CERTIFICATE

o Federal Law No. 6.360/1976: provides that health companies must maintain duly qualified technical personnel, in quality and in quantity, to adequately cover the company's needs.

PHARMACOVIGILANCE

o Resolution RDC No. 406/2020: provides for pharmacovigilance norms for the holders of registrations for drugs for human use.

TECHNOVIGILANCE

o Resolution RDC No. 67/2009: requires the implementation of a technovigilance system.

PROMOTION AND MARKETING

o Resolution RDC No. 96/2008: establishes the general rule regarding advertising drugs. Note that there are several restrictions for advertising drugs (i.e. prescription drugs may only be advertised in scientific publications, intended for healthcare professionals).

o Resolution RDC No. 60/2009: provides for the distribution of product samples.
o Resolution RDC No. 71/2009: rules the labeling of drugs. However, rules applicable to each type of drug will provide for specific labeling requirements.

Note that this is not an exhaustive list of the regulations related to drugs and medical devices, but only a list of the main applicable rules.

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

Clinical trials are subject to approval from the Committee for Ethics in Research (CEP) and, in certain cases, from the National Committee for Ethics in Research (CONEP) and ANVISA.

The research protocol document must be submitted to CONEP, or CEP, and must describe the trial's purpose and other details. It must also include information about the research participants and the researchers' qualifications and all responsible parties. One of the documents to be filed with the research protocol is the Informed Consent Form.

After the protocol is submitted to the CEP/CONEP,the relevant authority will analyze the request and if the clinical trial complies with the applicable legislation, the authority will authorize the commencement of the research.

In order to market a product (drugs, biologicals, and medical devices), it will be necessary to **(i)** obtain a company license from ANVISA (Operating Authorisation - AFE) and from the local health authorities (Operating License - LF); **(ii)** maintain a Responsible Technical Party for the company; **(iii)** apply for Best Manufacturing Practices certification, depending on the product, and **(iv)** obtain the product's registration/enrolment before the ANVISA.

4. What are the approximate fees for each authorisation?

The fees vary depending on the type of authorisation, on the product and on the company's corporate size.

5. For how long are marketing authorisations/registrations valid? How are marketing authorizations/registrations renewed?

In general, marketing authorisation for drugs and medical devices authorisationis valid for ten years. In certain cases applicable to drugs, the period can be of three or five years, pursuant Resolution RDC 317/2019.

The renewal of both types of marketing authorisations must be requested from six to twelve months before the marketing authorisation expiration date, as set forth in Resolution RDC 250/2004.

6.A. How does the authorization process differ between brand-name products and generic products?

As a rule, the authorisation process does not change, but the documents and studies to be presented to ANVISA differ. The registration of generics will require studies in order to prove that the product is stable and therapeutically equivalent to the reference drug, with pharmaceutical equivalence and bioequivalence studies, while the registration of a new drug should also be attached to its clinical trial studies (with the studies necessary to prove the quality, safety and efficacy of the product).