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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Rio de Janeiro. We can advise on all legal areas and have focused capabilities and experience in infrastructure, oil and gas, naval industry, mining and insurance.
Brasília. Close to the Supreme Court and regulators, our lawyers are on the ground and actively involved in a wide range of regulatory issues, antitrust and competition matters, and high-level litigation.
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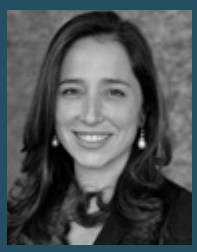

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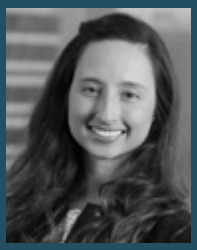

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01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

In Brazil there authorities are the National Health of 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 Statue is the Federal Law 6,360/1976 and the Federal Decree No. 8,077/2013, which provides for the sanitary 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 sanitary legislation, establishes their respective penalties, and makes other provisions.

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

Also, there are a large number of regulations issued by ANVISA related to the products of its inspection. See below a list we prepared with the most important regulations.

OPERATING AUTHORIZATION:

- Resolution RDC No. 16/2014: Operating Authorization ("AFE") authorizes the 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. 1/2017, pro-vides for the registration/licensing of facilities that develop activities subject to the sanitary legislation.

PRODUCT REGISTRATION:

- Resolution RDC No. 200/2017: provides for the synthetic drugs, including generic and similar;
- 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 dinamyzed drugs;
- Resolution RDC No. 26/2014 provides for phytotherapic drugs;
- Resolution RDC No. 73/2016: provides for post-registration changes and cancellation of drugs registration (this resolution is applicable for synthetic and semisynthetic drugs, including generic and similar).

GOOD PRACTICES CERTIFICATE:

- Resolution RDC No. 17/2010: provides for the requirements for the issuance of the Certificate of Good Manufacturing Practices of drugs. Note that the activity of Manufacture of drugs is subject to the compliance of the Good Practices. Importer companies must request the certification of the manufacturing plants located abroad;
- Resolution RDC No. 39/2013: provides for the procedure to obtain the Certificate of Good Manufacturing Practices and the Certificate of Good Practices for Distribution and Storage of drugs.
- Resolution RDC No. 16/2013: provides for the requirements for good manufacturing practices of medical devices and in vitro diagnostic devices.

TECHNICAL RESPONSIBILITY CERTIFICATE

- Federal Law No. 6.360/1976: provides that health companies have to main-tain duly qualified technical personnel, in quality and in quantity, to adequately cover the Company's needs.

PHARMACOVIGILANCE

- Resolution RDC No. 4/2009: provides for pharmacovigilance norms for the holders of registration for drugs for human use.

TECHNOVIGILANCE

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

PROMOTION AND MARKETING

- Resolution RDC No. 96/2008: establishes the general rule regarding advertising of drugs. Note that there are several restrictions on the advertising of drugs (i.e. under prescription drugs may be only advertised in scientific publications, intended for healthcare professionals).
- Resolution RDC No. 60/2009: provides for the distribution of products samples;
- Resolution RDC No. 71/2009: rules the labeling of drugs. However, each specific rule applicable for 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 subjected 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 to a CEP and must describe the trial's purpose and other details. It must also include information about the research participants and the qualification of the

researchers 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 and 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 Company's license before ANVISA (Operating Authorization - AFE) and before the local health authorities (Operating License - LF); (II) maintain a Technical Responsible for the company; (III) apply for Good Manufacturing Practices certification, depending on the product, and (IV) obtain product's registration/enrolment before ANVISA.

4. What are the approximate fees for each authorization?

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

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

Drugs' marketing authorization is valid for 5 years.

Medical devices' marketing authorization is valid for 10 years.

The renewal of both types of marketing authorizations must be requested from 12 up to 6 months before marketing authorizations' expiration date.

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

As a rule, the authorization process will not change. What will differ are the documents and studies to be presented to ANVISA. 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 be attached also with the clinical trial studies (with the studies necessary to prove the quality, safety and efficacy of the product).

Note that there is also the simplified procedure for the registration of generic drugs. This procedure only applies for drugs that have the same production line, same manufacturer, the same technical and clinical reports, the same composition of the drug used as reference, which is already registered by the regular procedure before ANVISA. The differences between the reference drug and the generic one are their name, labeling and packaging. Through this procedure the analysis/review by ANVISA of the documents is faster (when compared with the regular procedure), since the documents were already analyzed by ANVISA on the previous (regular) procedure.

6.B. Are there differences for local manufacturers versus foreign-owned manufacturers?

No, the authorization process is basically the same. However, certain timings may differ (i.e, timings for foreign and local inspection for Good Manufacturing Practices certification are different) and some additional documents will be required in the event of imported products.

Note, however, that only duly licensed Brazilian legal entities may be the marketing authorization holder.