The Pharma
Legal Handbook

Market Access & Health Technology Assessment

Brazil

PHARMA BOARDROOM

Brazil

The Market Access & Health Technology Assessments 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, a leading corporate law firm in Brazil.

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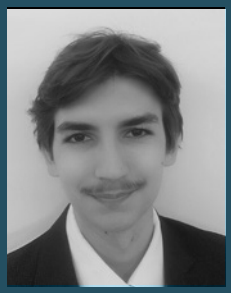

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1. Please make a general introduction to the public health sector in your country and its organization

1. Please make a general introduction to the public health sector in your country and its organization

As set out in the Brazilian Federal Constitution of 1988, health is a right of all and a duty of the state. It must be guaranteed by means of social and economic policies, with the purpose of reducing the risk of illness and other hazards.

The Federal Constitution of 1988 considers the complementary existence of the private sector in health assistance.

The public healthcare system was introduced by the Brazilian Federal Constitution of 1988 and is named the Unified Health System (SUS).

SUS provides free and universal coverage and is funded through the social welfare budget of the Union, the states, the Federal District and the municipalities, as well as from other sources such as fines, fees and donations. The federal government, the states and the municipalities are responsible for the free distribution of medicines and medical devices. The Ministry of Health has a programme for the free distribution of essential and specialised medicines; the list of the medicines and health technologies covered is reviewed periodically. However, whenever the medicine is not available through the SUS system, individuals may file lawsuits against the government in order to force the government to purchase de product and deliver it to the specific individual (based on the argument that health is a right of all and a duty of the state). Such lawsuits are quite common and lead to discussions regarding their impact on government finances.

The SUS also provides financial support to philanthropic and not-for-profit organisations, and to private health institutions by financial grants and reimbursement of medical procedures, devices and medicines upon the signature of an agreement between the private entity and the Ministry of Health. The reimbursement values are listed, along with the types of procedure and therapy that are covered. In the public sector, healthcare is delivered through programmes and plans that are implemented at federal, state and municipal levels. Actions and services must be organised and executed on a regional basis.

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PHARMA MARKET ACCESS MAIN ACTORS




ANVISA

- Corporate operating authorisation
- Approval and registration of products subjected to health surveillance

CMED

- Drug price approval

Conitec

- Incorporation of treatments inthe public healthcare systemfor free dispensation list

ANS

- Incorporation of mandatory treatments in private health insurances formularies
- Transfer of reimbursements owed by health insurance companies to the public healthcare system

SANITARY LICENSING MARKETING AUTHORISATION FLOW

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Corporate operating authorisation by ANVISA (federal level) and by VISA (municipal level).	Corporate operating authorisation by ANVISA (federal level) and by VISA (municipal level).	Corporate operating authorisation by ANVISA (federal level) and by VISA (municipal level).	Corporate operating authorisation by ANVISA (federal level) and by VISA (municipal level).	Corporate operating authorisation by ANVISA (federal level) and by VISA (municipal level).

02 HEALTHCARE ACTORS AND PAYERS

1. Which are the administrations, bodies and institutions in charge of public health in your country and what are their respective responsibilities?

2. Which are the administrations, bodies and institutions in charge of drug approvals in your country and what are their respective responsibilities?

3. Which are the administrations, bodies and institutions in charge of Health Technology Assessment in your countries and what are their respective responsibilities?

4. Which are the administrations, bodies and institutions that qualify as “payers” in your country and what are their respective responsibilities?

5. Which are the administrations, bodies and institutions in charge of pricing decisions in your country and what are their respective responsibilities?

6. Which are the administrations, bodies and institutions in charge of reimbursement decisions in your countries and what are their respective responsibilities?

7. Which are the administrations, bodies and institutions in charge of public procurement and tendering in your country and what are their respective responsibilities?

8. What are the other actors of significance with regards to market access in your country and what are their respective responsibilities?

1. Which are the administrations, bodies and institutions in charge of public health in your country and what are their respective responsibilities?

SUS is managed collaboratively by the Federal Government, the States of the Federation, and the Municipalities.

At the federal level, the SUS is managed by the Ministry of Health, which is responsible for formulating, regulating, inspecting, monitoring, and evaluating policies and actions, in coordination with the National Health Council.

SUS also comprises, among others, the following public entities:

- ANVISA – a regulatory agency responsible for the protection of public health by executing sanitary control over the production, importation, distribution, use and commercialization of a broad category of products such as drugs, medical devices, sanitizers, cosmetics, food, tobacco and services such as licensing conditions for health-related companies and healthcare institutions, among other attributions related to sanitary surveillance.
- Conitec – a multi-disciplinary collegiate formed by government representatives and civil society members, with advisory attributions related to the incorporation, exclusion or alteration of health technologies supplied by the SUS, as well as in the constitution of the protocols and guidelines for treatment in the public sector.
- CMED – entity responsible for regulating the pricing of drugs.
- ANS – a regulatory agency that regulates private health insurances.

2. Which are the administrations, bodies and institutions in charge of drug approvals in your country and what are their respective responsibilities?

The approval of drugs in Brazil is carried out by the National Health of Surveillance Agency ("ANVISA"), which is responsible for granting the product marketing authorisation after the evaluation of the manufacturing process, clinical trial results, stability, safety and efficacy data, as well as by Drug Market Regulation Chamber ("CMED"), which is the entity in charge of pharmaceutical market regulation and price approval of drugs.

3. Which are the administrations, bodies and institutions in charge of Health Technology Assessment in your countries and what are their respective responsibilities?

Organisms that qualify as payers are the federal, state and municipal entities that compose and manage the SUS, such as the Ministry of Health, health secretariats, public hospitals, public health foundations, etc.

Health insurance companies, private hospitals, private health institutions, are also payers.

4. Which are the administrations, bodies and institutions that qualify as "payers" in your country and what are their respective responsibilities?

As mentioned in **Question 2** above, CMED is the public entity responsible for pricing decisions. Among other attributions, CMED sets rules that stimulate competition in the sector, applies penalties when its rules are broken, as well as establishes and monitors the application of the mandatory minimum discount for public purchases.