ANVISA'S Role in Regulating Pharmaceuticals: Key Challenges and Opportunities for Improvement

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ABSTRACT

The Brazilian Health Regulatory Agency, or ANVISA (Agencia Nacional de Vigilancia Sanitaria), is essential to protecting public health since it monitors the effectiveness, safety, and quality of a variety of goods and services. It was founded in 1999 and is responsible for food, cosmetics, tobacco products, pharmaceuticals, and Medical Devices (MD). ANVISA has many obstacles in carrying out its duty as Brazil's population increases and its healthcare system changes. By conducting health monitoring on goods and services that present health concerns, ANVISA aims to safeguard and advance public health. Being an integral component of the unified health system in Brazil, it seeks to become accepted by society and become a benchmark for health monitoring and management both domestically and internationally products and services are thoroughly examined as part of ANVISA's regulatory procedures to make sure they adhere to safety and effectiveness requirements. Each of the agency's medicine and device departments has its own set of policies and approval procedures. Additionally, ANVISA works with the Federal District, states, and municipalities to enhance the standard of living for the populace.

Keywords: *ANVISA, Brazil, regulatory, surveillance, federal*

INTRODUCTION

Brazil has a strict health regulatory body and is the seventh most populous country in the world. This tropical country is a prominent player in the global pharmaceutical industry, being the only South American country with one of the world's largest pharmaceutical marketplaces. Since 2016, the organization was accepted as a member of the Management Committee in 2019 after serving as a regulatory member of the International Council of Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH)[1]. In 2021, the generics industry in Brazil grew by over 9.67% year over year and now accounts for approximately 29.4% of the market. By regulating and authorizing goods and services that can be harmful to health, ANVISA seeks to safeguard the population's health in Brazil.

- **Products**: Products deemed to pose a health risk are granted pre-market approval by ANVISA. Pre-market approval is not required for all products.
- **Services**: ANVISA oversees the development, promotion, and utilization of services that are under the purview of health regulation.
- **Sanitary standards**: Sanitary standards are governed by ANVISA.
- **Food industry**: This sector is governed by ANVISA.
- **Ports, airports, and borders** are under the jurisdiction of ANVISA

ANVISA is associated with the Ministry of Health and is a component of the Brazilian National Health System (Sistema Unico de Saude, or SUS). To control medicine prices, ANVISA collaborates with the Chamber of medicine Market Regulation, the Health Ministry, and other ministries. An Ethics Committee associated with the Health Ministry regulates ethical human clinical research[2].

TIMELINES[3]

Timelines period of ANVISA are given below in the Figure 1

Figure 1. Timeline period of ANVISA

ROLES AND RESPONSIBILITIES

ANVISA modulates a variety of medications, such as:

- **New synthetic and semi-synthetic drugs:** These are brand-new medications that have never been sold before.
- **Generic medications:** These are replicas of name-brand medications for which the patent has expired.
- **Similar medications:** These are brand-name generic medications. Homeopathic, anthroposophic, and antihomotoxic medications are examples of potentized medications.
- **Specific medicines:** These are medications prescribed for particular patient groups or medical conditions. Low-risk medications that don't need complete regulatory approval are known as "notified medicines."
- **Over-the-counter (OTC) drugs:** These are medications that are available without a prescription.
- **Herbal medicines:** These are medications made with components derived from plants.
- **Medical gases:** These are gases that are employed in healthcare.
- **Biological products:** These comprise blood products, vaccinations, and other items made from living things.

- **Radiopharmaceuticals:** These are radioactive medications used for both medical and diagnostic applications.

In collaboration with states and local governments, the agency conducts factory inspections, keeps an eye on drug quality, conducts post-marketing surveillance, implements pharmacovigilance measures, and controls drug promotion, and marketing[4].

OPERA PROGRAM

The Optimizing Efficiencies in Regulatory Agencies (OpERA) program aims to improve the performance and efficacy of regulatory agencies, including ANVISA. Introduced in 2013, OpERA provides benchmarking information to help focus on performance improvement and set performance goals.

METHODOLOGY

OpERA uses a combination of using both quantitative (performance metrics) and qualitative (process mapping) data, a comprehensive picture of regulatory assessment activities[5]. It entails gathering particular milestone data, including review phases, time periods, and data points for items that have regulatory agency approval. Objectives of ANVISA given below in the Figure2

Figure 2. Objectives of ANVISA

APPROVAL TIME PERIOD

The intricacy of the medication, the completeness of the regulatory dossier, and the application's priority status are some of the variables that can affect the approval time for drug registration with ANVISA.

Overall Timetable:

- 120 days priority review
- 365 days standard review

It is crucial to remember that these are the legally mandated regulatory timeframes.

However, a number of circumstances, including the following, may cause the actual review process to take longer:

- Completeness of the dossier: The review procedure could take longer if the dossier lacks important material or is not full.
- Drug Complexity: More thorough analysis may be necessary for complex medications, such as biologics or orphan pharmaceuticals.
- Additional information requests: Throughout the review process, ANVISA may ask for more details or explanations.
- Application backlog: It could take longer to assess each submission if ANVISA is dealing with a large number of applications.

CHALLENGES

Challenges of ANVISA are listed below

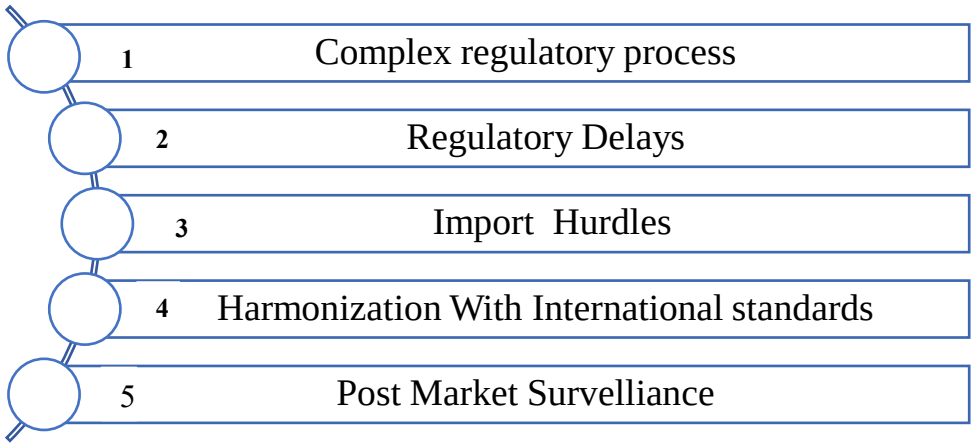

Figure 3. Challenges of ANVISA

As Brazil's health regulator, ANVISA has a number of obstacles to overcome. The following are some of the main obstacles:

1. Intricate Regulatory Procedure

Brazilian regulations are notoriously complicated, making them intimidating for both foreign and native businesses. A thorough awareness of the rules and regulations is necessary to navigate the complex framework, which can be a major barrier to entry.

2. Delays in Regulation

The length of time it takes to approve new medications and medical equipment is one of the main obstacles. Patient care and market competition may suffer if novel therapies and technologies are not promptly made available due to approval procedure delays.

3. Import Obstacles

Due to strict import laws and the requirement for local representation, importing goods into Brazil can be difficult for foreign businesses. The process may become more complicated and expensive as a result.

4. Conformity with International Standards

It is a constant struggle to bring Brazil's regulatory standards into line with those of other countries. In order to improve market access, expedite procedures, and foster innovation in the healthcare industry, harmonization initiatives are essential.

5. Post-Market Monitoring

Assuring the efficacy and safety of products after they have been authorized and placed on the market is another significant challenge. In order to safeguard the public's health, ANVISA must constantly monitor and assess products[6].

DOSSIER SUBMISSION

There are several intricate and nation-specific requirements for drug product registration in ANVISA, both in the administrative and quality components of the dossier. Legalization of the CoPP that was filed is necessary by the government of Brazil. ANVISA will look at and accept the API manufacturer's and API Supplier's factories[7]. Dossier submission process is listed below as table

Table 1. Dossier Submission Process

Step	Description
Preparation	Compile information from manufacturing, quality control, pre-clinical and clinical research, and documentation. Use the Electronics Common Technical Document (eCTD) format for the dossier.
Submission	Use the online ANVISA system to submit. Make careful to incorporate the technical and administrative components. In Brazil, foreign producers designate a licensed importer or distributor.
Review Process	Safety, effectiveness, and quality are evaluated by ANVISA's General Coordination of Evaluation of Products (GEPEC). GMP inspection of manufacturing facilities. The Chamber of Drug Market Regulation (CMED) discusses drug price[8].
Approval	ANVISA authorizes marketing if conditions are satisfied.

Important elements in the dossier	Administrative Information: Local agent information and administrative data. Technical documentation includes manufacturing and quality control data summaries as well as pre-clinical and clinical study summaries.
Additional Considerations	Brazil's National Institute of Metrology, Standardization and Industrial Quality (INMETRO) certification for electro-medical devices. Post-market surveillance for ongoing compliance[9]

RECENT AMENDMENTS

ANVISA made its first step toward strategic positioning in 2010 when it set a long-term goal for the next ten years. From there, ANVISA established particular objectives, programs, and goals that were described in a strategic map. In 2019, ANVISA began a new cycle of strategy updates, and in 2020, the Strategic Plan 2020-2023 was announced, which included 15 Strategic Objectives[10]. The regulatory process is now more efficient and clearer because to clarifications and recent revisions to current legislation, such as Resolution of the Collegiate Board (RDC) 751/2022 and RDC 777/2023.

CONCLUSION

ANVISA is a key component of Brazil's public health protection system, guaranteeing that the country's citizens have access to the safest and most effective food, medications, and medical equipment. which guarantees safe and high-quality medications. To prevent duplication of effort, GMP guidelines and inspection protocols should be harmonized. However, regulatory bodies must also cooperate to ensure pharmaceutical producers are adhering to the correct degree of GMP compliance, which guarantees safe and high-quality medication supply[11]. Notwithstanding the many obstacles it faces, such as resource limitations and legislative complexity, ANVISA keeps improving and modifying its procedures to better serve the public. In addition to protecting Brazilians' health, ANVISA makes a substantial contribution to the global health regulatory environment through its dedication to openness, effectiveness, and international cooperation. ANVISA will surely be better equipped to address public health issues and raise living standards in Brazil as a result of its continuous efforts to innovate and streamline operations.

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