REGISTRATION OF NEW MEDICINES IN BRAZIL

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Abstract:

In view to strictly control the placement of new medicines in the Brazilian market, ANVISA defines the criteria to regulate the registration of these new drugs.

1. Introduction

The National Health Surveillance Agency (ANVISA) is responsible for regulating the placement of medicine, food, cosmetics, sanitation products and other miscellaneous health products in the Brazilian market. In particular, the Manager of Medicines, Research and Clinical Trials (GEPEC), a special department within ANVISA, oversees the registration of new drugs.

In this note, we will discuss the registration process for new medicines, and more specifically, drugs with synthetic and semi-synthetic active principles. The registration process for other types of medicine including vaccines, psychotherapeutic drugs, homeopathic drugs, among others, all follow the same registration process.

2. Registration Process

The discovery or import of a new drug is always followed by expectations for its usefulness. Therefore, before the drug can be sold throughout the country, it must be submitted to a registration process which assesses the product and ensures it has the desired effect.

ANVISA's registration process is divided into three steps: quality analysis, efficiency analysis and safety analysis.

2.1 Quality analysis

The quality analysis is an assessment of the drug's entire manufacturing process. First, ANVISA's pharmaceutical experts look over the drug manufacturer's documents required for registration (Certificate of Correct Manufacturing and Control Practice, Company's Operating License, etc.). After that, ANVISA's experts examine the actual technical report, including the acquisition of the materials to be used in the drug, the drug's production, and finally the storage and shipping process.

2.2 Efficiency and Safety Analysis

The efficiency and safety analysis is performed by external consultants who are capable of delivering unbiased and informed opinions on the proposed drug's suitability for broader sale, through clinical and pre-clinical reviews.

Those external consultants receive a dossier from ANVISA detailing the primary issues to be addressed in their assessment of the proposed drug. Based on this assessment, ANVISA decides whether to approve or deny the registration of the proposed drug.

Even though the external consultants' assessment is crucially important to the registration process, ANVISA is not bound by their decisions, pursuant to Art. 3° of Law 9.782/99.

While this external analysis is being prepared, ANVISA meets with the company hoping to register the new drug to clear up any issues that may impede registration. These meetings are intended to accelerate the release of ANVISA's opinion on the drug, which must be issued within 90 days of the filing of the application, pursuant to Art. 7°, §1° of Law 8.077/13.

3. Conclusion

ANVISA's ultimate goal is to create a system of institutional procedures and safeguards that raises its quality analysis to the same standard of other agencies such as the Food and Drug Administration. In light of this goal, ANVISA has begun standardizing its decisions by publishing all of its opinions on proposed drug applications.

ANVISA has also strengthened its relationship with the private sector and food and drug agencies in foreign countries to improve the speed and quality of Brazil's registration process.

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ALMEIDA ADVOGADOS is placed at your disposal to provide any further clarifications related to the matters addressed in this study.