Regulation Under Health Surveillance

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1. Introduction

In the field of health surveillance, the state uses regulation to protect public health. In pursuit of this goal, the state controls the production and consumption of goods and services which have an impact on public health. These regulations also contribute to the smooth functioning of the economy by creating a predictable, transparent and stable environment for economic growth.

In order to standardize the licensing systems for establishments engaged in health surveillance activities, the National Agency of Sanitary Inspection of Brazil (ANVISA) established criteria for obtaining the company's Operating Permit (AFE) under law 6.360/76 and the company's Special Authorization (AE) under ANVISA Order nº 344/98.

Although these regulations affect a broad list of products, in this note, we will highlight only methods to license the commercialization of medicines, drugs and pharmaceutical inputs.

2. Company's Operating Permit

The granting of AFE is a discretionary act of ANVISA. For each specific company performing activities related to the listed products in Law 6.360/76 - medicines, drugs, pharmaceutical raw materials, toiletries, cosmetics, perfumes, household cleaners, and products for aesthetic correction - there are different procedures for obtaining the AFE.

In particular, the procedure for obtaining an AFE to market medicines and correlates is primarily conducted online. The procedure is based on the Sanitary License issued by the state or municipal health agency where the company is located, containing permission for operation of the establishment. Additionally, ANVISA may require information on the number of employees, conditions of the premises, proceedings involving the products which will be manufactured, distributed, imported or sold, as well as any information it deems necessary to ensure the state-of-art conditions of the company.

In addition to the Sanitary License, regular enrollment in the Regional Pharmacy Council is also required for the validity of AFE, pursuant to Article 15 of Law 5.991/73.

3. Company's Special Authorization

Institutions and agencies that already have the AFE and intend to work with the extraction, production, processing, manufacturing, fractioning, handling, packaging, distribution, transportation, repackaging, import, and export of medicinal products containing the ingredients listed in Order nº. 344/98 of ANVISA must get and AE prior to initiating its activities. Such ingredients include, among others, narcotics, psychotropics and retinoids.

For the AE, the technical officer of the applicant company must file a petition with the local health authority. The local health authority then shall inspect the applicant company's property in accordance with pre-established official roadmaps to assess the technical and sanitary conditions of the establishment.

After assessing, the local sanitary inspector delivers its opinion to ANVISA and, if accepted, ANVISA issues the Certificate of Special Authorization to the company.

Both the AE and the AFE are valid for 1 (one) year from the publication of the act granting the respective authorization in the Official Gazette. Therefore, they must be renewed every year. The renewal proceeding is, in most cases, likely to be an automatic proceeding.

4. Conclusion

Sanitary surveillance is instrumental in protecting the population from individual, collective, and environmental health hazards. The protection of the public health through control of sanitation in both the production and sale of products is fundamental to preserving the public's welfare.

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