Requirements for Registering Pharmaceutical Products
EL SALVADOR 2014

El Salvador requires all pharmaceutical products to be registered with the National Medicine Directorate (Dirección Nacional de Medicamentos- DNM). A U.S. company must identify a local legal representative or importer, and a pharmaceutical chemical representative (a power of attorney must be in Spanish or translated into Spanish if necessary and notarized or apostille).

Article 20 of the Salvadoran Medicine Law requires the following documents:

1. Application form. If signed by the local representative, a Power of Attorney needs to be submitted.

2. Original or certified copy of the Power of Attorney or document that names the pharmaceutical chemical representative.

3. Certificate of the Pharmaceutical Products, determined by World Health Organization (WHO). In case the certificate is not available, the following documentation should be submitted:

    a. Certificate of Free Sale issued by the country of origin. In the case of a shared origin, the CFS will be admitted from the country of precedence as long as the product is commercialized in that country.

    b. Certificate of Good Manufacturing Practices of each of the establishments that have intervened in the manufacturing and packaging of the product, issued by the regulatory/authorized institution of the country or countries where the manufacturing process takes place.

4. Qualitative and quantitative formulas signed by the manufacturer. If these formulas are included in the Certificate of Free Sale, it won't be necessary to submitted in any other document.

5. Product Analysis Certificate issued by the quality control laboratory of the manufacturer (original and copy).

6. Stability Study for climate zone IV, signed by the pharmacist responsible for the study or the technical professional assigned by the company.

7. External Analysis Certificate (original and copy).

8. Chemical monograph of the active principles or pharmacognosic monograph, in the case of natural products.

9. Labeling of the primary and secondary packaging, as it will be sold in the country.

10. Additional technical scientific information, when required by the Regulatory entity.

11. Validated method of analysis of the finished product.

12. Sample of any insert, prospect or instructive, when needed.

13. Pharmacology information of the finished product.

14. Receipt showing payment of the registration fee.

Registration process is processed by the Registry and Certification Unit (Unidad de Registro y Visado) of the DNM. Foreign pharmaceutical products registration fee is US$500 which can take between 3-6 months. Registration is valid for 5 years, after that period, renewal fee is US$86.

In addition, when selling foreign pharmaceutical products the local importer needs to pay an importer license fee of US$86, and an annual sales license of US$75. All documentation must be submitted in Spanish and be Apostille. Samples will be required (number of samples depends on the product).

In addition to the above requirements, established in the Salvadoran Medicine Law, companies need to comply with all the Central American Technical Regulations (RTCA's) related to pharmaceutical products such as: (a) Stability Studies for Pharmaceutical Products for Human Use; and (b) Labeling for Pharmaceutical Products for Human Use.

Upon receipt of all documentation, the DNM will assign a registration code to the product that will be composed of a letter that will determine the type of pharmaceutical product. The classification is as follow:

F: Pharmaceutical
H: Homeopathic
N: Natural
SN: Nutritional supplements
BT: Biotechnology
BL: Biological

The letter will be followed by the month, day, and year of approval. To do any change in documentation or formula after a registration has been approved, the company needs to pay additional fees.

A Users Guide (Guia de Usuarios Registro), which describes in detail the registration process for pharmaceutical products; and the application form (in Spanish) are available at:http://www.medicamentos.gob.sv/index.php?option=com_phocadownload&view=category&id=6:unidad-de-registro&Itemid=115

In February 2013, the Salvadoran government approved the decree "Special Regulation for the Mutual Recognition of Foreign Sanitary Registration". This mutual recognition only applies to pharmaceuticals (drugs) that have a registration from a Sanitary Regulator that have a certification level IV from the Pan American Health Organization (PAHO), and from Regulators from the United States of America, Canada, Australia, Switzerland, Japan, and the Medicine European Agency (EMA).

For biotechnological and biological products, the mutual recognition is allowed only if the countries mentioned above have specific regulations for this type of pharmaceutical products. To apply for a mutual recognition registration process, companies need to supply all documentation determine by Article 20 of the Salvadoran Medicine Law (listed above). If all documentation is correct and complete, the National Medicine Directorate will issue a sanitary registration for the pharmaceutical product in 10 business days.

REGULATORY INSITUTION:

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