Requirements for Registering Medical Equipment and Medical Devices
EL SALVADOR 2014

U.S. exporters looking for opportunities in El Salvador should be aware of the multi-step registration process required by the National Medicine Directorate (DNM- Direccion Nacional de Medicamentos). U.S. companies must carefully select a local partner who will ultimately be responsible, along with a pharmaceutical chemical representative, for registering the product/equipment. A common practice is for U.S. companies to process the registration under their name and not under the local distributor name.

The Registry and Certification Unit (Unidad de Registro y Visado) part of DNM requires the following documents:

1. Application form signed by the owner, legal representative or legally recognized attorney (as the case may be), and by the pharmaceutical chemical representative. Documents needs to be notarized or apostille from the United States.

2. Certificate of Free Sale (document needs to be apostille). If the CFS includes more than one product, a certified copied can be submitted.

3. Good Manufacturing Practices Certificate (document needs to be apostille). If the certificate includes more than one product, a certified copied can be submitted.

4. Product literature or technical information of the product must be in Spanish.

5. Receipt showing payment of the registration fee.

Once all the documents have been submitted, the Registry and Certification Unit will proceed with the codification of the sanitary registration of the medical devices. The identification of the medical devices will be an alphanumeric codification, which will contain the initials “I.M.” (abbreviation of medical devices in Spanish); an internal correlative number; and the month, day, and year that the registry is given. The registration process takes maximum 60 business days. All documents must be submitted in Spanish.

Once all of the requirements have been fulfilled, the sanitary registration of the medical devices will be approved. Registration is valid for 5 years, with a renewal option. Fee for registration is US$75.00, renewal fee US$ 25.00.

In addition, the local importer needs to pay to the National Medicine Directorate (DNM), an importer license fee of US$ 25.00 and an annual sales license fee of U$S25.00.

Registration forms and a medical device registration guide is available in Spanish at the DNM website:http://medicamentos.gob.sv/index.php?option=com_phocadownload&view=category&id=6:unidad-de-registro&Itemid=115

If the registration is granted and there is a need to make changes, additional fees will apply.

The National Medicine Directorate does not have a list of medical devices, however they define "medical device" according to the World Health Organization (WHO). The five categories of medical devices are:

1. Medical equipment
2. Prosthesis, Orthotics, and equipment for functional assistance
3. Diagnostic agents
4. Devices or supplies of odontology use
5. Surgery materials

In additional, medical equipment that it is considered an ionizing radiation device or equipment needs an import permit from the Ionizing Radiation Advisor and Regulatory Unit (UNRA) at the Ministry of Health.

REGULATORY INSITUTIONS:

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