Medical Device Regulatory Requirements for Malaysia

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Industry Definition

In Malaysia, a medical device is any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article:

a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- controlling conception,
- disinfecting medical devices,
- providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body;

and

b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Medical Device Product Registration System in Malaysia

The Malaysian government has long considered developing a regulatory system to cover medical devices. The Ministry of Health (MOH) is responsible for developing and implementing a regulatory framework to control medical devices. The aims of Malaysia's medical devices regulation are:

- To protect public health and safety
- To allow patients for earlier access to new technology for early detection, diagnosis and treatment
- To facilitate trade and invigorate the medical devices industry

In February 2005, MOH launched their regulatory system, announcing the creation of a voluntary registration system for medical device establishments. Details about this system, called MeDVER (Voluntary Registration Scheme for Medical Devices Establishments), were announced in January 2006, with the following objectives:

- To familiarize all affected parties with the registration process
- To gauge the readiness of medical devices establishments in conforming to the regulatory requirements
- To prepare a smooth transition into the mandatory phase before the full enforcement of medical devices regulation
- To obtain a profile of the Malaysian medical devices industry

MeDVER is a free, web-based registration system consisting of two application forms:

i) Account Application Form (MeDVER-01) (registration form to create an account in MeDVER system), and:

ii) Establishment Registration Form (MeDVER-02), containing the following five sections:

- Establishment Information
- Person Responsible
- Medical Device Information
- Post-Market Requirements
- Application Declaration

The MeDVER website indicates that all applications must be accompanied by relevant supporting documents (as required), and authenticity verification of submitted documents may be necessary with the issuing authority or organization. The website also claims security and encryption features have been incorporated in this registration system to protect the confidentiality of the information provided.

Manufacturers, importers, exporters, distributors and vendors are included in the voluntary registration program. The Ministry of Health notes that the MeDVER system does not denote approval of either a medical device establishment or its products. Drugs, cosmetics, and food supplements are not included in the registration process. The Malaysian government hopes to complete the process of voluntarily registering establishments by the middle of 2007, by which time mandatory registration and product approval of medical devices should be underway. Creation of systems to oversee and enforce the availability of medical devices in the market is scheduled to follow.

USFDA documentation (Certificate for Foreign Government, or "CFG"), CE mark or other international approval must accompany imported devices regarded as experimental in their country of origin. However, while there is no Malaysian governmental requirement medical device documentation approval by the country of origin, a U.S. CFG

(or European CE mark) is often sought by end-users or buyers of even non-experimental devices as assurance of safety and effectiveness.

Import Labeling

In 2006, the Malaysian Deputy Director General of Health, Technical Support, announced that:

"No person shall place on the market, supply or put into service a medical device unless it has been properly labeled."

He added that labeling requirements for Malaysia are based on Global Harmonization Task Force guidance, found in document GHTF/SG1/N43:2005.

Import Packaging

At this time, there are no specific rules regulating packaging for medical devices imported into Malaysia.

Import Documentation

Imported medical equipment is duty-free. Importers of medical equipment, like all importers into Malaysia, are required to fill out the customs declaration form, as part of normal customs procedure.

Import into Malaysia of any apparatus based on the use of lasers, such as X-rays, or other high-technology capital medical equipment purchased for use in public hospitals and institutions is subject to standards-based evaluation and requires a permit issued by the Health Technology Assessment Unit of MOH. In addition, while pre-owned medical equipment is not barred to private purchasers, Malaysian government policy is not to buy used or refurbished medical equipment.

Contacts:

There are three main approaches by which U.S. medical suppliers can sell products in Malaysia:

- setting up partnerships or joint venture arrangements with local firms;
- appointing a local agent or distributor; or
- opening a branch or sales office.

This is especially critical if the medical supplier wants to bid on government-sponsored projects or tenders. The local partner can gather and analyze market information, introduce new technology and equipment to local medical service providers, and train end-users to operate the equipment properly. The local partner can also facilitate after-sales service (if they have trained technical staff available) and develop sales contacts.

U.S. firms wishing to learn more about regulatory issues related to medical devices in Malaysia are encouraged to contact the following agencies and individuals for additional information:

KEMENTERIAN KESIHATAN MALAYSIA
Block E1, E6, E7 & E10, Parcel E
Pusat Pentadbiran Kerajaan Persekutuan
62590 Putrajaya, Malaysia
Tel: 603-8883 3888
Email: **webmaster@moh.gov.my**

Voluntary Medical Devices Establishment Registration (MeDVER)
Engineering Services Division
Ministry of Health Malaysia
Level 2-5, Block E6, Parcel E, Precinct 1,
Federal Government Administrative Centre,
60240 Putrajaya,
Malaysia.
Tel: 603-8883 2267 /68 / 70 / 71 /72
Fax: 603-8888 6184
Email: MeDVER@medicaldevices.gov.my

US Commercial Service Contact:

Natila Ahmad
Commercial Specialist
American Embassy, Kuala Lumpur
Tel: 603-2168-5101 Fax: 603-2142-1866
E-Mail: natila.ahmad@mail.doc.gov
http://www.buyusa.gov/malaysia