# Medical Device Regulatory Requirements for The Philippines

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## INDUSTRY DEFINITION

The Philippines uses the Global Harmonization Task Force (GHTF) Study Group 1 guidance document as the basis for its definition of medical devices, which:

refers to any instrument, apparatus, implement, machine, 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, alleviation of diseases,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement or modification or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical or diagnostic purposes by means of in vitro examination of specimen 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 their intended function by such means.

## INTRODUCTION TO THE PHILIPPINES REGULATORY SYSTEM

The principal medical device regulatory authority in the Philippines is the Bureau of Food and Drug Administration (BFAD), under the auspices of the Department of Health (DOH). Importation of medical devices does not require prior approval of BFAD or the Bureau of Product Services, unlike drugs, food supplements and disposables. In addition, there are no import quotas for this sector, including used and refurbished medical equipment.

In the Philippines, all foreign medical devices are required to undergo the same registration procedure, regardless of whether they have been previously registered in

other countries. Medical equipment does not require pre-registration with BFAD, except for radiation-emitting equipment, which must first undergo local testing and is regulated by the Bureau of Health Devices and Technology (BHDT) within DOH. BHDT will issue a pre-registration certification for radiation-emitting devices. Detailed registration guidelines for these products can be found through the following website: http://www.doh.gov.ph/bhdt/mprdtld.htm. However, registration applications are required for distributors of invasive medical devices to receive a license to operate in the Philippines; a detailed list of requirements appears immediately below.

## REGISTRATION WITH THE BUREAU OF FOOD AND DRUG ADMINISTRATION (BFAD)

BFAD has issued the following checklist of requirements for invasive medical device registration. Applicants for registration must provide:

1) A letter of application from the manufacturer or trader or distributor;

2) A valid License to Operate (to be procured by the local representative agent in the case of a foreign manufacturer);

3) A governmental certificate of product clearance and free sale (or registration) for the product from its country of origin. The Philippine consulate in the country of origin must also authenticate this certificate (e.g., the USFDA's CFG).

4) A certificate of agreement between the manufacturer and local Philippines distributor/importer regarding the product involved;

5) The product's suggested retail price;

6) A list of amounts and technical specifications of all raw materials of which the product is composed;

7) A brief description of the methods used, the facilities and control in the manufacture, processing and packaging of the product;

8) Complete quality control procedures for the finished product;

9) Technical specifications and physical description of the finished product;

10) Stability studies of the product, establishing the claimed expiration date (where applicable);

11) Unattached labels or proposed labels and other labeling materials to be used for the product in the Philippines;

12) A representative sample or commercial presentation of the product as marketed in the Philippines; and

13) Proof of payment of the registration fee (i.e., official receipt from the BFAD cashier).

A Good Manufacturing Practices (GMP) certificate is sufficient to meet a requirement attesting to the status of a manufacturer selling in the Philippines.

A certificate for a Non-Registerable Product may be obtained if the medical device in question falls outside the scope of BFAD regulations. However, companies must submit the product description and brochure to BFAD in order to assess whether the product can be registered at all.

The validity period for initial registration of a medical device is one year. Under BFAD Circular #05-1998, medical device renewal registrations are now valid for five years.

In October 2006, the Philippines House of Representatives approved a bill transferring the responsibility for medical device regulation from the BFAD to the BHDT. A hearing in the Senate is under consideration, with the hope that legislation enabling the transfer to occur will pass the legislature before the end of 2006.

## REGIONAL MEDICAL DEVICE HARMONIZATION UNDER DEVELOPMENT THROUGH ASEAN

The Philippines are one of ten members of the Association of Southeast Asian Nations (ASEAN). BHDT is representing the Philippine medical device sector at meetings of the ASEAN Consultative Committee on Standards and Quality-Medical Device Product Working Group (ACCSQ-MDPWG—hereafter ACCSQ), which has met four times over the past two years, most recently in Brunei in July 2006. The working group is focusing on three main activities:

- A comparative study of medical device regulation across all ASEAN countries;
- Developing an ASEAN Common Submission Dossier Template (more on this initiative below); and
- Formulating a Post Market Alert System for unsafe and defective devices.

The objective of ACCSQ is to facilitate efforts to remove technical barriers to trade and implement the Common Effective Preferred Tariff to create an ASEAN-wide FTA in the next few years. ACCSQ is attempting to fast-track integration within eleven priority areas, including pharmaceutical products and medical devices, over the next few years.

Both the ACCSQ and the Asian Harmonization Working Party (AHWP—a subgroup of GHTF) intend to introduce a Common Submission Technical Dossier for application and approval of medical device products in each member country in the next few years (ACCSQ has committed to implementing this system by calendar year 2008). The two

groups have also separately adopted the GHTF medical device definition and classification system for regulating medical devices.

## IMPORT LABELING

The Philippines currently do not have any regulations specifically addressing import labeling for medical devices.

## IMPORT PACKAGING

The Philippines currently do not have any regulations specifically addressing import packaging for medical devices.

## IMPORT DOCUMENTATION

Import documentation requirements are limited to registration of medical device firms and radiation-emitting products; these requirements have been summarized above.

## CONTACTS

In the Philippines, foreign suppliers usually appoint a local distributor to represent their interests. The distributors normally handle all aspects of importation, from registration (if required) of products and/or services, to obtaining a license. Distributors often make sales calls, perform product demonstrations, present exhibits, and advertise to promote their products. Distributors prefer exclusive contracts with foreign manufacturers, and must register with BFAD before beginning operations.

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

Department of Health (DOH)
Bureau of Food and Drugs (BFAD)
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City PHILIPPINES 1781
Email Address: bfad@bfad.gov.ph
Telephone: (632) 807-07-21
Fax: (632) 842-56-06
Contact Person: Prof. Leticia Barbara B. Gutierrez, MS., Director

Department of Health (DOH)
Bureau of Health Devices and Technology (BHDT)
Building 24, San Lazaro Compound
Rizal Avenue, Sta. Cruz, Manila PHILIPPINES
Telephone: (632) 743 8301 locals 3402; 3408

Fax: (632) 711 6016; 711 6824
E-mail: apperalta@co.doh.gov.ph
Contact Person: Ms. Agnette P. Peralta, Director IV, CESO III

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