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主旨：檢送駐泰國代表處經濟組函報泰國醫療器材進口之規定 1 份，請　查照並轉知會員廠商參考。

說明：依據駐泰國代表處經濟組本(97)年 2 月 19 日泰經組字第 09700002870 號函辦理。

正本：台灣區醫療暨生技器材工業同業公會、台北市醫療器材商業同業公會
副本：本局貿易服務組

局長 黃志鵬

依照分層負責規定
授權單位主管決行

MEDICAL DEVICE CONTROL DIVISION Ministry of Public Health Thailand

Detail of Medical Device Control in Thailand

Laws and Regulations

Definitions of terms

The 1988 Medical Device Act has noted a number of significant points (Section 3).

"Medical device" is defined as:

1. an instrument, product, or article that is used for medical practice, nursing, midwifery practice, general medical or veterinary practice, in pursuance of the governing laws;
2. an instrument, product, or article that is used to affect health structure or any physiological function of human or animals;
3. a constituent, component, part, accessory or part of instrument, product or article prescribed in (1) or (2);
4. other instruments, products or articles notified in the Government Gazette by the Minister as medical devices.

Section 36 of the Medical Device Act prohibits manufacture, import or sale of the following devices:

1. fake devices;
2. substandard devices;
3. deteriorated devices;
4. unsafe devices.

A fake medical device , according to Section 37 of the Act, is a device characterized in any of the following categories:

1. a device which is imitatively made or copied, whether in part or as a whole;
2. a device whose name, category, feature, or brand name as shown is inconsistent with its licence or with the details notified to the grantor;

3. a device whose name of producer, place of origin, manufacturing date, or location of production shown is different from the fact.

A substandard device , according to Section 38, is a device whose quality does not comply with the standard requirements as specified by virtue of Section 35(2) of the Act.

A deteriorated device , according to Section 39, is a device whose quality and/or performance is below its standard requirements, or a device that has already expired.

An unsafe device , according to Section 40, is a device characterized in any of the following categories:

1. a device that is designed for being disposed of after use;
2. a device produced or stored unhygienically;
3. a device that is contaminated;
4. a device that consists of decomposed substances that might cause intoxication and do harm to users;
5. a device whose liability or efficacy is doubtful.

Control of Medical Devices

Control of medical devices is categorized into three main levels:

- general control,
- pre-marketing notification, and
- pre-marketing approval.

Pre-marketing Control

General Control of Medical Devices (Category I devices)

Producers, importers or distributors who produce, import, or sell category I devices do not need to have a license, but they need to submit the certificate of free sale (CFS), which is issued by the health authority or relevant government body in the country of origin of the product imported into Thailand. Therefore, the CFS submission must comply with the Ministerial Notification No. 6 for importation.

Pre-marketing Notification (Category II devices)

Under Section 35 and 35(3), the Minister has the authority to declare, as notified in the Government Gazette, what kinds of medical devices require FDA approval with regard to their effectiveness, quality and safety.

Producers, importers or distributors of medical devices in category II (pre-marketing notification) are required to submit details on product descriptions, usage, specifications, labeling, and name of producers and distributors to the FDA. A certificate of free sale in the country of manufacture is also required for importing devices in this category.

Pre-marketing Approval (Category III devices)

Devices that fall under Section 35(1) are required to register with the FDA for approval before they can be manufactured, imported or sold. The operators must comply with the Ministerial Regulations Nos. 1, 2, 3, and 5 of B.E. 2533 (1990).

However, the devices specified under category III must have a licence for production, import, or sale. The licence for production or importation shall be deemed as a licence for production, importation or sale, but it must possess the qualifications imposed in Section 14. The licensee is also required to submit the information on production, import, sale, and adverse reactions of their devices to the FDA in accordance with rules and procedures described in the Ministerial Regulations.

Labeling of Medical Devices

Every medical device sold or possessed for sale must bear a label on its container or package with Thai texts. The following information must appear on the label:

1. name, category, and type of the medical device;
2. name and location of producer or importer; in case of importer, the name of producer and place of origin of such device must also be shown;
3. quantity contained therein;
4. number or letters indicating a lot number of production;
5. licence number;
6. purpose of use, instructions for usage and storage;
7. a medical device for single use must display the words "disposable" or "for single use" in clearly visible red color;

8. warnings and precautions;
9. an expiry date, if any.
10. other messages as notified by the Minister in the Government Gazette.

Control of Advertisement

The Act also prohibits advertisements with false or exaggerated statements regarding the purpose of use, quality, quantity, standard or place of origin of any devices.

Any means of advertisement, messages, audio, or videos for beneficial purposes must be approved by the FDA. The grantor has the authority to issue a written order to terminate any advertisement that is a breach of the Act (see Sections 41, 42 and 43).

Post-marketing Control

The purpose of Post-Marketing Control is to ensure that medical devices distributed to consumers are wholesome and have quality that complies with the medical device standards. As a result, this measure deals primarily with the activities of enforcement. Inspection of all medical device factories and premises throughout the country is conducted regularly, together with the sampling of products for analysis and assaying to ensure compliance with legal requirements. Market surveillance is performed in an all-year-round manner, including the investigation of product labeling and the collection of marketed product samples at the inspecting place. All claims imprinted on the labels of medical device products must have the support evidence kept in a ready-to-be-delivered manner when inquired by the medical device control officer.

In case of violation, actions like seizure, recall, and prosecution will be executed. In general, there are two types of inspections:

Regular Inspection. This is a planned inspection to ensure that the FDA annual plan on medical devices has been implemented successfully.

- Plant Set-up Inspection. This is a comprehensive check of newly established firms or the modified ones for compliance with laws or regulations, prior to issuing a license.
- Routine Inspection. This is a periodic inspection particularly at the premises that have received licences.

- Follow-up Inspection. This is to confirm that the certain correction of the licence holders or firms after the former inspection has indicated.
- Ports of Entry Inspection. This is done by medical device inspectors at the checkpoint to ensure the safety of medical devices entering into the country in compliance with the relevant regulations.

Suspected or Petitioned Inspection. This is a particular type of inspection with the specific aim to investigate or gather necessary evidence for taking legal action. It includes an inspection to find out the cause of the complaint or rejected medical devices from the importing country, so as to solve the problems of manufacturers and medical device exports.

Plant inspections and import inspections are performed periodically as planned. The inspection is undertaken in conjunction with the collection of product samples. It is usually carried out in response to the complaints or reports of adverse reactions or as part of the surveillance. The collected product samples are sent to the Department of Medical Sciences, Ministry of Public Health, for testing for fraudulent characteristics or harmful effects to human health. Any products found to be harmful to human health will be recalled or confiscated under the jurisdiction of the Medical Device Control Division and will eventually be destroyed in order to ensure that such products will not be re-marketed. Consequently, the responsible persons will be charged with placing the hazardous medical device products on the market.

Manufacturing Development

One of the objectives of all manufacturers in engaging in medical device business is to deliver the standard-quality and safe-for-use products to customers. This objective is in line with that of the Medical Device Control Division, i.e. to ensure that the medical device products placed on the market are safe for use. Yet, the manufacturers' practices play a major role in manufacturing such products. Without appropriate guidelines for manufacturing practices, the manufacturers will hardly be able to develop their manufacturing practices.

Hence, the objective of this activity is firstly to provide basic steps for medical device manufacturers to correctly practice and further improve the rapidly-developing medical device manufacturing industry within the country. The coverage of this guidelines ranges from the building or facilities where productions are to take place, to the equipment or instruments, personnel, raw materials, and all the processes relating to the production of medical devices.

The production of good-quality medical devices requires close supervision, thorough monitoring and inspection in every step of the manufacturing