LEX MUNDI
PUBLICATION

Medical Devices

THAILAND
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1. **Definition of medical devices**
What is the definition of a medical device in your jurisdiction?

According to the Medical Device Act of 2008, a medical device is defined as a:

Tool, appliance, machine, or object used for insertion into the body of a human or animal, a solution in a laboratory, software product, or other object, intended by the manufacturer for its specific use in a particular purpose, whether in its use solely or jointly or in compositing with other element:

- Performing treatment in the medical profession of nursery and midwifery, dentistry, medical technology, physical therapy, or veterinary medicine under such law or performing in medical professions and other public health as announced by the Minister;
- Diagnosis, prevention, follow-up, treatment, mitigation, or curing of disease or injury in human or animal;
- Examining, replacing, correcting, changing, supporting, or maintaining the anatomy or a physical process of a human or animal body;
- Sustaining or helping human or animal life;
- Human or animal birth control;
- Helping or helping compensate for disability or infirmity in a human or animal;

- Giving information from examination of a specimen of a human body or animal for medical purpose or diagnosis; and
- Destruction or disinfection of medical devices.

Accessories or components in the tool, appliance, machine, or object described above; and Any tool, appliance, machine, product, or other object as announced by the Minister of Public Health to be a medical device.

2. Combination products

i. Which legal regime (on medicinal product or on medical devices) applies to combination products incorporating both medicinal products (drugs/biologics) and medical devices?

None.

ii. Are combination products (combining drugs and medical devices) subject to separate regulation in your jurisdiction?

Yes, they are separately controlled.

iii. If the answer to (i) is negative, what is the scope of application of the legal regimes: evaluating both the drug and device components of the combination product?

In Thailand, there are medicinal regulations and medical device regulations for evaluating and registering drugs and medical devices respectively.

iv. What are the general conditions for review, approval and marketing the combination product?

The general conditions of the combination product have to be in comply with each product category regulations.

3. Borderline products

Are there any official and binding criteria for determination whether the product is a medicinal product or medical device, or whether a product is a device requiring pre-review or a non-medical device?

No. The Thai FDA will concern most with the purpose of use of the product. If it falls into the definition of a medical device as the answer no.1, the product shall be a medical device product and needs to be registered.

i. Are there any legal and binding criteria for determination whether the product is a medical device or medicinal product?

None, it will be considered on the purpose of use as the principle.

ii. If the answer to (i) is positive, what are the main principles for differentiation?

N/A.

iii. Are there any significant court or administrative judgments demonstrating the rules of product differentiation?

None, but there is the considering subcommittee of each medicinal product and medical device product sat up to judge the borderline product case by case.

If an applicant is not sure whether a product is a medicinal product or medical device, an applicant can submit a Classification Letter to the considering subcommittee of medicinal product and/or the considering subcommittee of medical device for clarification.

iv. How is software that may have some related-medical applications regulated in your jurisdiction?

The software is a medical device according to the Medical Device Act of 2008 and needs to be registered.

4. Cellular or tissue based products

Are there any official or binding criteria for determination whether a product is a animal or human based tissue or a medical device?

None.

i. How are products composed of cells or animal/human tissue regulated in your jurisdiction?

If an objective of the product itself tends to be a medical device as defined in the Medical Device Act of 2008 and is manufactured from tissue, the product is a medical device.

ii. Are there any legal and binding criteria for determination whether the product is a medical device or cellular/tissue based product?

No.

iii. If the answer to (ii) is positive, what are the main principles for differentiation?

N/A.

iv. Are there any significant court or administrative judgments demonstrating the rules of product differentiation?

None, but there is the considering subcommittee of medical device product sat up to judge the obscure product case by case.

An applicant can submit a Classification Letter to the Thai FDA in order to clarify the classification of the obscure product.

5. Admission to trade of medical devices

What are the requirements for admission (import) of medical devices into trade?

Actually, there are 3 categories of medical devices in Thailand which are general medical device, notification medical device and license medical device. The requirement for admission of each category is different. The basic requirements are a Certificate of Free Sale, a product catalogue including an instruction for use and a Quality Management System Certificate or ISO 13485. However, there are additional required documents for notification medical device and license medical device such as a product specification, a Certificate of Analysis, a Clinical Data etc.

i. Is clinical assessment required for admitting (importing) medical devices into trade?

Yes, the Thai FDA will request a clinical assessment for some notification medical device and license medical device case by case.

ii. If the answer to (i) is positive, are clinical trials required or is there an alternative basis for clinical assessment?

There are no local clinical trial requirements specifically tailored for medical devices at this time. For some stringent control medical devices, however, clinical data or foreign clinical trial is required.

iii. Is certification by an external certifying body required for compliance assessment of medical devices, or is a manufacturer's declaration of conformity sufficient?

A certification by an external certifying body is required for compliance assessment of medical devices. A manufacturer's declaration of conformity is not sufficient.

iv. Is administrative pre-clearance or pre-approval of medical devices required for admission of medical devices into trade, or is post-launch notification sufficient?

Pre-approval of medical devices is required for admission of medical devices into trade.

6. Processing of personal data (privacy)

What are the rules of processing of personal data in a number of activities performed by manufacturer/s distributors/ healthcare units with the use of medical devices.

i. Are there any specific rules protecting the privacy of personal data of consumers purchasing medical devices, by manufacturer/distributors?

No FDA regulations on this matter.

ii. Are there any specific rules of processing of personal data sourced by means of medical devices containing software, by healthcare units?

No FDA regulations on this matter.

iii. Are there any specific rules of processing of personal data by manufacturers/distributors in case of collecting reports on medical incidents from customers?

No FDA regulations on this matter.

iv. What is the standard for reporting adverse events, and is reporting of events in foreign countries required, and using what standards?

The Thai FDA has an ADR form and a system called "Voluntary Spontaneous Reporting" for entrepreneurs, practitioners, consumers reporting any ADR occurred either in Thailand or foreign countries to the Thai FDA. For ADR that has an effect on health should be informed within 15 working days whereas very serious ADR have to be informed within 24 hours.

7. Reimbursement

What is the optimal model of reimbursement of medical devices?

i. What are the rules of granting reimbursement of medical devices in your jurisdiction?

Medicines/Medical devices are reimbursed by the state when the drugs/medical devices are listed in the NLED (the National List of Essential Drugs). However, this list is only available to government hospitals.

Government hospitals generally provide drugs/medical devices from the NLED to civil servants and to persons under the THB30 Scheme. In this case, the patient either pays nothing to the hospital or, for people under the THB30 Scheme, a maximum of THB30 (as at 1 November 2010, US$1 was about THB30.2) in certain circumstances. The hospital is reimbursed completely by the government.

For persons under the Social Security Scheme, reimbursement is partially covered if the medicinal product/medical device was administered by a doctor in a government hospital. Persons under the Social Security Scheme can also acquire private health insurance to cover the remainder of the cost.

8. Distribution

Is distribution and promotion of medical devices subject to legal regulation?

Yes.

i. Are there any specific regulations determining mode of business activity of medical devices distributors?

No.

ii. Is administrative permit for medical devices distribution required?

Yes. A manufacturer or importer has to get an FDA approval for manufacturing or importing before distributing a medical device in the Thai market. However, Medical Device Sale License is needed for HIV test kit only.

iii. Are there any specific limitations in distributing medical devices in your jurisdiction?

Yes, according to section 43 in the Medical Device Act of 2008, there are some special medical devices which shall be sold specifically to consumers having purchase orders of a person engaged in medical and public health professions or specifically to a clinic or a person engaged in medical and public health professions.

iv. Are obligations of distributors of medical devices specifically legally regulated?

All manufacturers and importers which can be distributors of medical devices must register their place of business with the Thai FDA before manufacturing, importing or distributing a medical device in the Thai market.

v. What specific rules exist for advertising and promoting medical devices?

The advertising of medical devices is regulated by the Medical Device Act of 2008 and enforced by the Thai FDA. Therefore, it is a mandatory to have an advertising license before advertising and promoting all kinds of medical devices.

9. Manufacturing

How are manufacturing practices regulated?

i. Are there any specific standards or regulations determining the quality of manufacturing practices?

Yes, there are GMP certificate and ISO 13485.

ii. If the answer to (i) is positive, how are these good manufacturing practices or quality system regulations reviewed and enforced?

GMPs are currently being implemented on a voluntary to eventually mandatory basis to ensure safe and effective products. However, if a local manufacturer would like to get GMP certificate from the Thai FDA, the Thai FDA will review and inspect all systems of the manufacturer and then grant a GMP certificate. For import medical devices, Healthcare providers in Thailand are being encouraged to purchase medical devices that have GMP certified.

iii. Are establishments manufacturing medical devices, or components of medical devices, required to be registered with a government regulator?

Yes. According to Section 15 of the MDA of 2008, In order to manufacture medical device in Thailand, the registrant of the business place must apply for and be granted a license by the Thai FDA before production can commence.

iv. Are these establishments inspected regularly by government regulators or authorized bodies, and what is the mode of such inspections?

Yes, government regulators usually inspect the manufacturer who applied GMP with the Thai FDA at least once a year.

The modes of such inspections are as follows:

1. Quality management system
2. Management responsibility
3. Resource management
4. Manufacturing
5. Inspection Testing and Corrective action

10. Regulatory Guidance

How are the requirements communicated to medical device manufacturers?

i. In what form do the laws and regulations appear that are applicable to medical device manufacturers?

- Published In the Government Gazette;
- Announced through the Thai FDA website and;
- Announced directly by post or email.

ii. Are informal guidance or the opinions of regulators available to device makers, and in what form?

Yes, it is verbal consulting between manufacturers or importers and regulators by a meeting or phone call.