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COUNTRY OVERVIEW: THAILAND

By Rarana Phanudulkitti

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Introduction

Now more than ever, the benefits and importance of healthcare have become more evident to Thai citizens. With the emergence of extensive research and development, rapidly advancing medical technology, and an overall improvement in awareness and education in the relevant field of law, the Thai population demands better standards of regulatory enforcement, an improvement in medical device provision and thus, in the long run, an overall increase in life expectancy.

Market research carried out in 2010[1] showed that the value of medical equipment imported into Thailand amounted to over THB 25 billion (around US$853 million) that year. The research also projected a likely average increase of 9% per year, or to THB 38 billion (around US$1.3 billion) in 2015.

Regulatory authority

In order to manufacture, import or sell a medical device in Thailand, it is crucial for medical device companies (manufacturers, importers and sellers) to understand fully the applicable local regulations. These are controlled by the Medical Device Control Division (MDCD) of the Thai Food and Drug Administration (TFDA).

Thai Food and Drug Administration, Ministry of Public Health
Medical Devices Control Division
Tiwanon Road, Nontaburi, Thailand
Tel: +66 2590 7244, +66 2590 7247, +66 2590 7249
Fax: +66 2591 8479, +66 2591 8480
Email: medical@fda.moph.go.th

Legislative framework

The MDCD regulates and monitors the quality, standards, efficiency and safety of medical devices that are manufactured, imported and sold in Thailand, in accordance with the *Medical Device Act of 2008* (B.E. 2551), related Ministerial Regulations, and Notices of the Ministry of Public Health. Important Ministerial Regulations are as follows:

- No 1 B.E. 2533 (A.D. 1990), *Licence for production - application requirements*;
- No 2 B.E. 2533 (A.D. 1990), *Licence for importation - application requirements*;
- No 3 B.E. 2533 (A.D. 1990), *Licence for distribution - application requirements*;
- No 4 B.E. 2533 (A.D. 1990), *Production, importation or distribution of notification medical devices*;
- B.E. 2552 (A.D. 2009), *Fees for medical devices*;
- B.E. 2552 (A.D. 2009), *Terms and conditions for registering a place of business for medical device production*;
- B.E. 2552 (A.D. 2009), *Terms and conditions for registering a place of business for medical device importation*.

Copies of the *Medical Device Act of 2008* and all the Ministerial Regulations may be accessed (in Thai) via the Government Gazette's database (http://61.19.241.70/rkjnew/Front/ShowList.aspx?LawGroupID=53123&rkjTypeID=1).

Pre-approval of all medical devices is required before any commercial activity begins. It is also important to note that only locally established companies can import and register medical devices in Thailand.

Regulatory controls

Definition of a medical device

Contrary to popular belief, the definition of a medical device under Thai law is very similar to, and combines elements of both, the definitions used in the USA and the European Union (EU). The

only difference is that the EU definition is narrower, as it is more detailed and excludes medical devices for animals, while the US definition does not include software. Section 4 of the *Medical Device Act of 2008* defines medical devices as:

> '(1) Instruments, apparatus, implements, machines, appliances, implants, *in vitro* reagents or calibrators, software, material or other similar or related articles, intended by the producer to be used alone, or in combination, for human beings or animals for one or more of the following specific purpose(s):
>
> (a) Performing treatment in the medical profession, the nursing and midwifery profession, the dentistry profession, the medical technology profession, the physical therapy profession, and the veterinary profession, as prescribed by legislation related to performing other medical professions and public health as prescribed by the Minister;
> (b) Diagnosing, preventing, monitoring, treating or alleviating disease in humans or animals;
> (c) Diagnosing, monitoring, treating, alleviating or compensating for an injury to a human or an animal;
> (d) Investigating, replacing, modifying or supporting the anatomy or the physiological process of the human body or in an animal;
> (e) Supporting or sustaining the life of a human or animal;
> (f) Controlling conception or helping with reproduction in a human or an animal;
> (g) Helping, or helping to compensate for, a disability or infirmity in a human or an animal;
> (h) Providing information for medical or diagnostic purposes, by means of an *in vitro* examination of specimens derived from the body of a human or an animal; *and*
> (i) Destroying or disinfecting a medical device.
>
> (2) Accessories or constituents in the instruments, appliances, machines, products, or articles under (1);
>
> (3) Instruments, apparatus, machines, products or other articles prescribed by the Minister as a medical device.
>
> Any of the outcomes as stipulated in the statement in (1), as they occur in a human body or animal, must not be derived from any pharmacology, immunology, or oxidation reaction aimed at creating energy as its main element.'

Classification

When introducing new products to the Thai market, many importers have important concerns about product classification. This is particularly because of the rapid pace of technological progress, which has advanced beyond the current TFDA regulations relating to medical devices. In addition, medical devices are complex and have many uses and benefits. Therefore, some medical devices, which are classified as such in other countries, may not necessarily be classified as medical devices in Thailand.

Although many countries rely on the US or EU classification systems, Thailand uses a different type of classification. Companies need to be aware that Thai classifications may be more or less stringent than their US/EU counterparts.

In Thailand, medical devices are classified into three classes based on the level of risk associated with the use of the device. This is a local Thai regulatory classification system, which appears to be applied in reverse order compared with the US/EU classification systems. The TFDA subjects Class III devices to the least stringent controls, and Class I devices to the most stringent controls.

Class I - Licensed Medical Devices

A Licensed Medical Device is the most strictly controlled class. Class I devices are usually those

that support human life, are of substantial importance in preventing the impairment of human health, or prevent a potential or unreasonable risk of illness or injury. Examples of these devices include condoms, examination gloves, surgical gloves, contact lenses, and human immunodeficiency virus (HIV) test kits (for *in vitro* diagnostic use).

The Licensed Medical Device category requires the most information to be submitted for approval including, but not limited to, a Certificate of Analysis from the Department of Medical Sciences (DMSc), stability data, clinical study and/or evaluation data, a mandatory Thai label and leaflet, product formulae, and production processes. Such medical devices must meet the quality standards set out in the Notice of the Ministry of Public Health[2] for each type of medical device.

Class II - Notification Medical Devices

A Notification Medical Device is subject to a less intensive review procedure than a Licensed Medical Device. As the name implies, the TFDA must be notified of Class II devices. Examples of Notification Medical Devices include HIV test kits (for investigational use and for research use), physical therapy products, alcohol detectors, implanted silicone breast prostheses, and equipment or instruments typically used for breast enhancement.

The information requirements for Notification Medical Devices are the same as those applicable for a Licensed Medical Device, except for some requirements such as the test results from the DMSc.

Class III - General Medical Devices

The requirements for General Medical Devices are the least stringent. Only the product description/information, product catalogue, and the Certificate of Free Sale need to be submitted to the TFDA for approval prior to marketing in Thailand. For some General Medical Devices, such as sterile products and laser equipment products, an ISO 13485 Certificate and technical data specifications are also necessary for approval.

Borderline products

Sometimes a healthcare product may overlap with, or be on the borderline between, the medical device, pharmaceutical and cosmetics legislation. If an applicant wishes to ensure that a product can be classified as a medical device under the *Medical Device Act of 2008*, the applicant may ask the TFDA to assess the product classification. The original documents from a manufacturer of the product which are required for the TFDA's consideration are as follows:

- details of the product (product name, the name and address of the manufacturer, product description, principle of operation/mechanism, component material of the product, product specification, intended uses and indications, and instructions for use);
- product catalogue;
- product leaflet; *and*
- supporting academic documents and/or government certificates from the manufacturing country showing the controlled status of the product (if needed).

The timeframe for the product classification process is officially 10 working days. However, for some difficult cases, the TFDA will need to forward the case to the Medical Device Committee for their consideration and determination. This additional review process may take more time.

Examples of differing classifications

Dermal fillers provide a good example of how the classification system in Thailand differs from other jurisdictions. Dermal fillers are considered to be

Class IIb medical devices (generally regarded as medium risk) in the EU, and Class III (pre-market approval) in the USA. However, in Thailand, as of today, such products are still considered to be drugs. Thus, the process will be more stringent and, depending on the category, the requirements may be more burdensome, especially since companies would not necessarily be able to provide the quality, clinical and non-clinical parts required for new drugs, in accordance with the Association of Southeast Asian Nations (ASEAN) guidelines.

A similar problem exists for blood bag systems, which are currently classified as drugs in Thailand. The TFDA does not take into consideration the product (the bag) itself, but rather the component in the bag (blood) that is provided to the patient; it is this factor that determines the classification. However, the TFDA is in the process of adopting a new regulation that will classify blood bag systems as medical devices[3]. This regulation is expected to be implemented in the near future.

Finally, products such as exercise machines used in hospitals may be classified as medical devices in Thailand, even though they are not classified as such in the USA/EU. This classification decision will depend on the intended use of the products as specified in the relevant product leaflets.

Advertising

It is mandatory to obtain an advertising licence before undertaking any type of advertising or promotion for a medical device.

The concept of advertising has evolved over the past few decades. It no longer merely covers print materials such as publications, brochures, posters, or even television and radio advertisements. Today, on-line marketing of medical devices is also controlled in Thailand, especially via social networks or blogs.

Advertising must meet TFDA information requirements. For example, it must contain the name of the medical device, TFDA mandatory warnings, and the name of the importer and/or manufacturer. Information distributed on the Internet that is intended for customers or patients in Thailand must also meet these requirements.

The TFDA will review and consider an advertising application before issuing a licence. According to Clause 7, Section 59 of the *Medical Device Act of 2008*, advertisements of medical devices must not:

- show benefits, quality, volume, standard, components or the origin of the medical device, in a false or misleading manner;
- show guarantee of benefits or endorsements by any person;
- offer monetary compensation, or any other reward to patients, for the use of a medical device on a trial basis;
- show benefits in respect of preventing, treating, mitigating or the healing of a disease or symptom, which the TFDA prohibits from being advertised; *and*
- show any statements that may cause misunderstanding, in material part, in respect of the medical device.

Examples of words that cannot be used in medical device advertisements in Thailand are 'excellent', 'special', 'the best', 'completely cured', 'holy', 'marvellous', 'safe', 'number one', 'no adverse effects', 'superior', 'most appropriate', etc. These are some of the most well-known words that are prohibited. In order to determine whether particular words or phrases are acceptable, it is necessary to consider the use of the products themselves, and the construction of the messages.

When a licence number has been obtained, it must be included in the advertisement. It is also important to note that an advertising licence for a medical device is only valid for a period of three years from the date of issue.

Vigilance requirements

According to the *Medical Device Act of 2008*, Section 41(4), the registrant of the establishment, licensee or notifier has to prepare a report on the abnormal performance of, or any adverse reaction involving, a medical device, and issue a report on its correction to the licensor, whether the event happened in Thailand or abroad. The report should be made in accordance with the rules, procedures and conditions prescribed by the Minister. Currently, there is no specific Regulation under the *Medical Device Act of 2008* to cover such reporting. Therefore, Ministerial Regulation No 5 B.E. 2533 (A.D. 1990) on production, importation and distribution reporting requirements should be followed[2].

The licensed and notified producer, importer or distributor must submit an adverse event report in the event that the licensed and notified producer, importer or distributor discovers an adverse event associated with the medical device. A report of the incident is required to be submitted to the Secretary General of the TFDA within 15 working days. In addition, if the adverse event is serious or causes death, it must be reported within 24 hours from the time the licensed and notified producer, importer or distributor discovers such an adverse event.

Post-market surveillance

In order to ensure that companies comply with both the TFDA regulations and the advertisement requirements for medical devices, the TFDA conducts random post-marketing audits of companies.

Before product launch, the TFDA conducts a pre-marketing review, and it is highly protective of Thai consumers. As a developing country, Thai consumers rely heavily on the government to protect them. This is quite different from the practice in the USA, where product liability cases and class actions are often filed, which serves to deter companies from marketing harmful products. As part of its post-marketing reviews, the TFDA collaborates with other agencies, including the DMSc and provincial health offices, to monitor, inspect and follow up on pre-marketing controls.

According to the MDCD's website, the main purposes for undertaking post-marketing audits are:

- to protect the quality, safety and efficiency of medical devices for Thai people;
- to monitor and follow up on trading, and indicate improper trends relating to medical devices;
- to identify and punish whoever breaks the relevant medical device laws or regulations; *and*
- to protect and persuade entrepreneurs to operate a legal business, and promote fair competition.

All registered medical device entrepreneurs also have mandatory duties to record and prepare a report for TFDA inspection relating to the quantities of medical devices manufactured, imported and sold in the Thai market, for a period of not less than five years from the manufacturing, importation or sales dates, and not less than one year from the expiry dates (if any). This requirement is set forth in the Notification of the Ministry of Public Health on the terms and conditions for the preparation of records, and for manufacturing, importing and selling reports[4], which has been effective since 7 February 2012.

All product registration holders also have to prepare and submit an annual report in respect of manufacturing, importing or selling medical devices, according to the TFDA's report forms, as mentioned in the above Notification.

If a company does not comply with the TFDA requirements, the penalties are imprisonment not exceeding six months, or a fine not exceeding THB 50,000 (around US$1705), or both.

In practice, the TFDA has rarely issued public

punishments for non-compliance in respect to advertising licences. However, companies need to be aware that random audits still occur. If inspected, employees should report the inspection immediately to their supervisors, prior to agreeing to sign any report from the TFDA.

Clinical trial requirements

There are no specific regulations on clinical trials in Thailand. Thus, no clinical trial requirements are specifically tailored for medical devices. For clinical trials in general, the government relies on the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Good Clinical Practices guidelines.

Labelling and language requirements

According to the *Medical Device Act of 2008*, Section 44, the registrant of an establishment, licensee or notifier who produces or imports medical devices shall provide a label and its accompanying document. This document should not include any false statement or overstate the truth.

However, the specific requirements for labels and/or accompanying documents (e.g. product leaflet) for each type of medical device are different. The requirements in regard to the label and/or leaflet for Licensed Medical Devices and Notified Medical Devices are mentioned in the Notification of the Ministry of Public Health for each medical device[2].

Currently, there are no specific labelling requirements for General Medical Devices. However, the TFDA has announced a draft regulation on this matter[5].

Future changes

Thailand and the other nine ASEAN Member States are moving toward implementation of the ASEAN Economic Community (AEC) in 2015. The formation of a single market and a single production base in the region will permit companies within the AEC to move their capital freely, and will serve to break down effectively existing trade barriers that currently stunt intra-regional trade within the 10-member trading bloc.

The implementation of consistent standards within the ASEAN countries for each product, including related rules and regulations that conform to international standards, will in theory ensure the removal of trade barriers or obstacles. This process has already started for drugs and cosmetics.

With regard to the harmonisation rules for medical devices, each ASEAN Member State has until 2014 to implement the new requirements established by the Medical Device Working Group, and to finalise the harmonisation process for all medical devices. This includes formulating a common definition for medical devices (derived from the Global Harmonization Task Force definition), harmonising the classification of products (five classes based on the assessed risk of the products), formulating a common list of international medical device standards in order to obtain similar quality assurance, and implementing a Common Submission Dossier Template (CSDT)[6], among other requirements.

The TFDA has announced that is considering using the CSDT by 2012-2013, and preparations are underway for the implementation of the ASEAN Medical Device Directive[7] within the next two years. Additionally, the TFDA is currently forcing local manufacturers to obtain Good Manufacturing Practice Certificates for their facilities, which are equivalent to international ISO 13485 certificates, for example.

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Rarana Phanudulkitti is a consultant in the regulatory affairs group at Tilleke & Gibbins, a leading Southeast Asian law firm with offices in Bangkok, Hanoi and Ho Chi Minh City. Rarana can be contacted at rarana.p@tilleke.com.