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An overview of the medical device regulatory requirements in Thailand

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An overview of the medical device regulatory requirements in Thailand

Introduction

Around the world, medical devices have become an integral part of modern healthcare and even daily life. These advancements are largely due to an influx of innovative, digital technology that has changed the medical device environment. Telephones, watches and other wearable items now feature built-in functions far beyond their traditional designs, even offering basic medical functions (e.g. heart rate monitoring). This trend is expected to continue, as newer and more advanced medical devices are made increasingly available to the public through similar avenues.

More importantly, medical devices are steadily becoming easier to use, allowing untrained individuals—not just healthcare professionals—to use and read medical technology effectively. With that, regulatory agencies around the globe are faced with a challenging situation to determine whether their existing regulatory frameworks for medical devices are effective enough to ensure device performance, qualify and safety, even when used by untrained users.

The medical device regulations in Thailand have recently improved to provide a better safeguard for public health and to ensure that high-quality and effective devices reach Thai patients and consumers. This article provides an overview of Thailand's regulatory requirements, including pre-market controls, post-market surveillance, clinical trials for medical devices, labelling and language requirements, and future changes.

Regulatory authority[1]

In order to produce, 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. Such regulations are controlled by the Medical Device Control Division (MDCD) of the Thai Food and Drug Administration (TFDA).

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Legislative framework

Before 1988, there was no specific medical device legislation in Thailand. Instead, the Ministry of Public Health (MoPH) generally resolved medical device issues by referring to provisions of the *Drug Act*, B.E. 2510 (1967), as amended. However, this practice was thought to be unsuitable due to major differences in the nature of the products (e.g. instruments versus medicinal products) and the rapidly advancing technology of medical devices. In 1988, the control of medical devices under provisions of the *Drug Act* was officially deemed inadequate and inefficient[1].

To resolve this issue and establish suitable regulatory controls, the Thai government devised the *Medical Device Act*, B.E. 2531 (1988) (the old Act), which was enacted on 23 May 1988 and established the MDCD as the governing authority for medical devices within the TFDA. A total of 20 years later, an amended *Medical Device Act*, B.E. 2551 (2008)[2] (the new Act) replaced the old Act in an attempt to improve legal enforcement of medical devices and to ensure that the legislative framework kept up with the fast-paced changes in medical device technology.

Since 2008, the medical device industry in Thailand has been mainly regulated by the new Act and the subsequent laws and regulations enacted by the MoPH or the TFDA. However, it is important to note that certain MoPH Notifications issued under the old Act are still enforceable.

The most significant Ministerial Regulations and Notifications on medical devices are as follows:

- Regulation of the Ministry of Public Health *Re: Rules, Procedures and Conditions for Business Place Registration as a Medical Device Manufacturer* (2009);
- Regulation of the Ministry of Public Health *Re: Rules, Procedures and Conditions for Business Place Registration as a Medical Device Importer* (2009);
- Notification of the Ministry of Public Health *Re: Forbidden Medical Devices, either for Importation or Sale* (2006);
- Notification of the Ministry of Public Health *Re: Devices or Instruments for Physical Therapy* (1996);
- Notification of the Ministry of Public Health *Re: Condoms* (2002);
- Notification of the Ministry of Public Health *Re: Rules, Procedures, and Conditions for Reporting Adverse Events or Malfunctions of Medical Devices, and Reporting the Field Safety Corrective Actions* (2016);
- Notification of the FDA *Re: Rules, Procedures and Conditions for Advertisement of Medical Devices* (2010);
- Notification of the FDA *Re: Risk Classifications for In Vitro Diagnosis Medical Devices* (2015).

Copies of the new Act and its bylaws can be accessed (in Thai) via the website of the MDCD of the TFDA (http://www.fda.moph.go.th/sites/Medical/Pages/Main.aspx).

Pre-approval of all medical devices is required before the commencement of any commercial activities or clinical studies. It is also important to note that only locally established companies can import, manufacture or register medical devices in Thailand[3,4].

Regulatory controls

Definition of a medical device[2]

Under Thai law, the definition of a medical device is largely harmonised with international standards. In general, devices that include software and accessories used for the diagnosis, monitoring, prevention, or treatment of diseases fall within the scope of a medical device, provided such devices do not achieve their primary intended action by immunological, metabolic, or pharmacological means. It is worth noting that the *Medical Device Act* also governs medical devices used for animals. Section 4 of the new Act describes a medical device as:

> '(1) An apparatus, appliance, implant, instrument, *in vitro* reagent, machine, product, software, or other article intended by the manufacturer to be used, alone or in combination or assembled with other things, for any of the following specific purposes:
>
> (a) dental practice, healing arts practice, medical practice, medical technology practice, nursing and midwifery practice, physical therapy practice, and veterinary practice under the relevant specific laws or other medical or public health practices as notified by the Minister;
>
> (b) alleviation, cure, diagnosis, monitoring, prevention, or treatment of human or animal disease;
>
> (c) alleviation, cure, diagnosis, monitoring, or treatment of human or animal injury;
>
> (d) investigation, modification, remedy, replacement, or support of the anatomy or of a physiological process of the human or animal body;
>
> (e) supporting or sustaining life of human beings or animals;
>
> (f) control of conception or promotion of human or animal fertility;
>
> (g) aid or compensation for disabled or handicapped human beings or animals;
>
> (h) providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human or animal body;
>
> (i) disinfection or sterilization of a medical device.

(2) Equipment or a component part of an instrument, apparatus, machine, object, or product under (1).

(3) Other apparatus, instruments, machines, objects, or products prescribed to be medical devices by the Minister.

Any of the outcomes of a device's function(s), as stipulated under (1), which occurs in a human or animal body, must not be derived from any immunological, metabolic, or pharmacological actions.'

Classification

As mentioned above, in the past, the TFDA applied provisions of the *Drug Act* to control medical devices[3]. As a result, a number of products that are medical devices by nature (e.g. medicated plasters and multi-purpose contact lens solutions) were previously registered as drugs in Thailand. In addition to the complications associated with medical devices that were registered as drugs under the *Drug Act*, additional grey areas have arisen with the rapid pace of technological progress and medical device innovation. Newer, more technologically advanced devices are extremely complex and increasingly versatile (e.g. smart phones that are capable of monitoring disease progression), placing them beyond the scope of current TFDA regulations. Therefore, importers have deep and growing concerns regarding product classification when seeking approval for new medical devices for the Thai market.

Currently, the TFDA has its own classification system based on policy and the needs of the country, which includes separate schemes for *in vitro* diagnostic devices (IVDs) and non-IVD devices[3,4]. Foreign companies should be aware that Thai classifications may be more or less stringent than those in the European Union (EU) or USA.

In Thailand, the government classifies medical devices into three categories based on integration of risk analyses of medical devices and any concerns over their potential misuse. The three categories are Licensed Medical Devices, Notification Medical Devices, and General Medical Devices[3,4]. These categories follow the local Thai regulatory classification system, which has a number of significant differences from classification systems in the EU and USA. For example, because driving under the influence of alcohol is significantly linked to road traffic injuries, alcohol detectors are classified as Notification Medical Devices in Thailand. A summary of the requirements for each category can be found below.

Licensed Medical Devices

This is the most strictly controlled class under Thai regulatory law, in that any and all devices specified under this category must obtain a licence and registration from the TFDA before production or importation. Examples of such devices include condoms, contact lenses, and human immunodeficiency virus (HIV) test kits (for IVD use).

In order to apply, a registration dossier template, which must comply with the format of the Common Submission Dossier Template (CSDT) as outlined in the Association of Southeast Asian Nations (ASEAN) Medical Device Directive (AMDD)[5], needs to be submitted along with the government fee of THB 20,100 (approximately US$ 670) or THB 10,100 (approximately US$ 337) for each type of imported or domestically-manufactured Licensed Medical Device, respectively. Once granted, a product licence is valid for five calendar years. Before the licence expires, the applicant can apply for a renewal of the licence. The Minister of the MoPH is authorised to require specific devices in this category to obtain a sales licence, in addition to a licence for production or importation, in order to legally sell the product.

Notification Medical Devices

Devices in this category are subject to a less intensive review procedure than Licensed Medical Devices. Examples of devices classified within this category include, among other things, alcohol detectors, methamphetamine test kits, physical therapy devices, and prosthetic silicone breast implants.

In order to apply, a submission dossier that follows the CSDT needs to be submitted along with the government fee of THB 10,100 (approximately US$ 337) or THB 5,100 (approximately US$ 170) for each type of imported or domestically-manufactured Notification Medical Device, respectively. Once granted, the product licence is valid for five calendar years. Before the licence expires, the applicant company can apply for a renewal of the licence. Companies are not required to obtain a licence to sell or distribute medical devices in this classification.

General Medical Devices

Devices that are not listed under either of the preceding categories will fall under this classification. Only imported devices in this category must receive an approval licence prior to importation. Applications to the TFDA are not required for products manufactured in Thailand.

There is no need to submit a dossier to the TFDA for medical devices in this classification; however, certain requirements do need to be met. The basic requirements are a Certificate of Free Sale (CFS), issued by the health authority in the country of origin, and product information

(e.g. instructions for use and product brochures). For implantable devices, laser equipment products, and sterile devices, an ISO 13485 Certificate is also required. The government fee for a product licence for an imported medical device is THB 2,100 (approximately US$ 70). Unlike the other two categories, product licences for General Medical Devices cannot be renewed. Following the expiration of the licence, a new application must be submitted to the TFDA. Companies are not required to obtain a licence to sell or distribute medical devices in this classification.

IVD and non-IVD medical devices: future classification

On 1 April 2015, the Secretary-General of the TFDA announced several Notifications regarding risk classification for both IVD and non-IVD medical devices, which have been implemented to comply with the AMDD[5]. According to the Notifications, medical devices are to be classified into four classes based on their risk assessment:

- Class A (low-risk devices);
- Class B (low-moderate risk devices);
- Class C (moderate-high risk devices);
- Class D (high-risk devices).

Importers or manufacturers must be able to determine the risk classification of their medical device. Classification of a device is dependent on whether it is an invasive or non-invasive medical device, or whether or not the device is an active medical device. In the future, the TFDA will require all medical devices in Classes B, C and D to submit registration dossiers in accordance with the CSDT, but this requirement is not currently in force. Medical devices in Class A will follow a similar procedure, and require a similar list of documents, as required for General Medical Devices. The TFDA plans to implement a new electronic system (the e-Listing Scheme) to facilitate Class A and General Medical Device registrations by allowing online submission of necessary documentation. This new risk classification system, in accordance with the AMDD, will likely be implemented in the near future.

Borderline products

At times, a device may be on the borderline between being classified as a 'medical device' or as an 'uncontrolled device' (e.g. laboratory devices and simulation devices). In addition, certain medical devices (e.g. a head massager for migraine treatment) may be scrutinised by the TFDA Registrar in relation to product efficacy, performance, or safety[4]. In some cases, the TFDA Registrar may ask the company to consult the Medical Device Classification Working Group before proceeding further.

Home care devices that patients/users can use without the involvement of healthcare professionals are often referred to the Medical Device Classification Working Group for its opinion before the devices are allowed to proceed to registration.

The TFDA requires several documents from the overseas product owner or manufacturer to consider registration. These documents include the following:

- details of the product (components/materials of the product, instructions for use, intended uses and indications, name and address of the manufacturer, principles of the device's operation, product description, product name, and product specification);
- product catalogue or brochure;
- supporting academic documents, preferably published in peer-reviewed journals; *and*
- 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 more complicated devices, the examining TFDA official will need to consult with the Medical Device Subcommittee for its consideration and determination. This additional review process may add on up to three months of additional processing time[4].

Examples of differing classifications

Multi-purpose contact lens solutions provide a good example of how the classification system in Thailand differs from other jurisdictions. Under the EU and US classification systems, contact lens solutions are considered to be Class II. However, in Thailand, such products are currently still considered to be, and registered as, drugs. Thus, the registration process for contact lens solutions in Thailand will be more stringent and, depending on the category, the requirements may be more burdensome, especially as some companies would not necessarily be able to provide the dossier containing chemistry, manufacturing and control parts, or the clinical and non-clinical parts required for drug registration, in accordance with the ASEAN drug registration guidelines.

A similar problem exists for dermal fillers, which are also currently classified as drugs in Thailand, even though the product falls under the definition of a medical device (i.e. a dermal filler does not exert its action via immunological, metabolic, or pharmacological means, but is administered via injection). Regardless, such filler products have been registered as drugs in Thailand for a long time, although this is set to change. The TFDA is in the process of adopting a new

regulation—expected in the near future—that will classify dermal fillers as medical devices, based on the product's true definition.

Finally, certain products, such as exercise machines used in hospitals, may be classified as medical devices in Thailand even though they are not classified as such under the EU or US systems. The reason for this difference is because the classification decision in Thailand depends on the intended use of the products, as specified in the relevant product leaflets.

Advertising

Over the last decade, the TFDA has found and resolved numerous illegal advertisements for medical devices on cable TV and public radio channels. Over time, these advertising media have lost their attractiveness for a number of reasons, including increased costs, and a shrinking, unresponsive audience. Since then, advertising methods have changed quickly and drastically to adapt to the market. Nowadays, medical device advertising is largely conducted via online platforms such as social media and e-commerce. While these new strategies have proven to be effective, they are drawing heavy scrutiny from the TFDA.

In order to use advertising material for communication with either healthcare personnel or laypersons, an advertiser of medical devices must first receive an approval licence from the MDCD[6]. Gimmicks or giveaway items for marketing purposes that bear the trademark of a medical device are also considered advertisements, and therefore an advertising licence must also be obtained before any such promotion is started. Any and all claims made on advertisements must be factual, and supported by sufficient scientific evidence (e.g. research papers).

The TFDA will thoroughly review and consider an advertising application before issuing a licence. According to Section 59 of the *Medical Device Act*[2], advertisements of medical devices must not:

- show benefits, component parts, origins, quality, standards, or volume of the medical device in a false or misleading manner;
- show a 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 healing, mitigating, preventing, or treating a disease or symptom, which the TFDA prohibits from being advertised; *or*
- show any misleading statement that may cause misunderstanding, in material part, in respect of the medical device.

In addition, the advertising must meet the requirements as announced in the Notification of the FDA *Re: Rules, Procedures and Conditions for Advertising of Medical Devices* (2010). This Notification provides that medical device advertisements must contain the name of the medical device, mandatory warnings (if any), and the name of the importer and/or manufacturer. Additionally, advertisements are not permitted to use specific terminology including, among others, 'excellent', 'special', 'the best', 'completely cured', 'holy', 'marvellous', 'safe', 'number one', 'no adverse effects', 'superior', and 'most appropriate'. In order to determine whether particular words or phrases are acceptable, it is necessary to consider the actual use of the products themselves and structure the messages in accordance with factual evidence.

Vigilance requirements

According to Section 41(4) of the *Medical Device Act 2008*, medical device importers and domestic manufacturers have a duty to report the defects of a medical device or adverse effects on consumers by submitting a Field Safety Corrective Action (FSCA) form to the TFDA[2]. Problems related to medical devices that occur either in Thailand or outside the country must also be reported to the TFDA. On 31 October 2016, the Notification of the Ministry of Public Health *Re: Rules, Procedures, and Conditions for Reporting Adverse Events or Malfunctions of Medical Devices, and Reporting the Field Safety Corrective Actions* was implemented.

In 2018, the TFDA issued its Guidance for Industry report to support the above Ministerial Notification[7]. Entities that are responsible for the submission of reports and performance of any remedial actions (e.g. FSCAs) include:

- medical device businesses that have registered as a manufacturer or importer of a medical device;
- market authorisation holders of a Licensed Medical Device, whether a domestic manufacturer or an importer; *and*
- market authorisation holders of a Notification Medical Device, whether a domestic manufacturer or an importer.

According to this list of entities, all medical device businesses in Thailand have the duty to report to the TFDA. The law also mentions that the Thai Red Cross, and other state agencies that may manufacture or import medical devices, are also required to report the defects of their medical devices and remedial plans to the TFDA.

The TFDA Guidance for Industry report follows the AMDD with respect to the timeframes for reporting adverse events[7]. The following list contains medical device defects or adverse effects that must be reported to the TFDA:

- any defect or adverse effect that would cause a serious threat to public health;
- any defect or adverse effect that would cause death or endanger life severely;
- any defect or adverse effect where the information or evidence has indicated that, if it happens again, it may lead to serious harm or death to the patient, user, or others.

Reporting timeframes

In the case of a serious threat to public health, a report should be made immediately or, at the latest, within 48 hours from the date of awareness. In cases that would cause death or endanger life severely, a report should be made immediately or, at the latest, within 10 days from the date of awareness. In cases where the information or studied evidence has indicated that, if the event happens again, it may lead to death or serious harm to the patient, user, or others, report within 30 days from the date of awareness.

The format that the report should follow is provided in the Ministerial Notification from 2016. The importer or domestic manufacturer will be required to provide general information about the company, contact details, the medical devices to be reported, a description of the event, and the proposed FSCA. The report will then be sent to the Health Product Vigilance Centre (HPVC) of the TFDA, online or in person. Next, the HPVC will publish the case report, vigilance news, and product recall of the medical devices on its website (http://thaihpvc.fda.moph.go.th/thaihvc/index.jsf).

Post-market surveillance

In addition to vigilance requirements, all registered medical device companies are required to record and prepare a report for TFDA inspection relating to the quantity of medical devices manufactured, imported, and sold in the Thai market, for a period of no less than five years from the manufacturing, importation, or sales dates, and no less than one year from the expiry dates (if any). This requirement is set forth in the Notification of the MoPH on the terms and conditions for the preparation of records, and for manufacturing, importing and sales reports, which became effective on 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 reporting forms, as

mentioned in the above Notification. The annual report must be submitted each year before 31st March.

In order to ensure that the medical devices distributed to consumers or patients meet quality standards and are safe for use, the post-marketing surveillance control group of the MDCD thoroughly monitors devices in the market. This surveillance process includes a regular inspection of manufacturing sites throughout Thailand, together with sampling select products for further analysis and testing. If non-compliance issues are found, the TFDA will take legal enforcement action against those companies that are in violation of the law and regulations. In addition, the post-marketing surveillance control group also monitors advertisements and labels for medical devices. Any and all claims included in advertisements or printed on the labels of medical devices must have supporting evidence readily available when requested by the medical device control officers. In the event that an advertisement is made public without an approval licence, the Secretary-General of the TFDA will send a complaint letter to the importer or domestic manufacturer which will include the penalties of the offence. Advertising a medical device without an approval licence from the TFDA incurs penalties of imprisonment of no more than six months, a fine of no more than THB 50,000 (around US$ 1,667), or both.

As mentioned above, before a product launches, the TFDA must conduct a pre-market review, through which the Agency is highly protective of Thai consumers. As a developing country, Thai consumers rely heavily on the government to ensure their protection. This is a stark difference from the medical device practice in the USA, where product liability cases and class action suits are filed often, and serve to deter companies from marketing harmful products.

With regard to post-market surveillance, the TFDA collaborates with other agencies, including the:

- Department of Medical Sciences for testing of medical devices;
- Public Health Provincial Offices in each province of Thailand to collect any suspect samples in the market; *and*
- the Customs Department to monitor any suspect devices that are being imported without an approved licence.

A mandatory medical device recall is enforced by the TFDA when it appears that the efficacy, quality, or standards of a medical device do not conform with the registration dossier previously submitted to the TFDA, or if the medical device is unsafe for use or is potentially harmful to health. The

Secretary-General will publish the results of an analysis or inspection of the medical device to the public and contact the importer, manufacturer, or vendor to recall the unsafe products.

Clinical trial requirements

Currently, there are no specific laws or provisions governing clinical trials in Thailand, and registration of a medical device does not require a clinical study to be conducted. For clinical trials in general, the Principal Investigator and sponsor must adhere to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Harmonised Tripartite Guideline for Good Clinical Practice. The Principal Investigator of a clinical trial is responsible for submitting the Clinical Trial Protocol for review and approval by the Ethics Committee of the study site hospital. The TFDA indirectly controls the clinical trial by approving the importation of the investigational device into Thailand for clinical trial purposes.

Labelling and language requirements

According to the Section 44 of the *Medical Device Act 2008*, the registrant of an establishment, a licensee, or a notifier who produces or imports medical devices, shall provide the label and its package insert for inspection. This document should not include any false statements or overstate the truth[1,2].

However, the specific requirements for labels and accompanying documents (e.g. product leaflets) for each type of medical device are different. The requirements with regard to the label and/or leaflet for Licensed Medical Devices and Notification Medical Devices are set out in the Notification of the MoPH for each medical device. Currently, there are no specific labelling requirements for General Medical Devices. However, the Medical Device Committee is reviewing the final draft of a Notification prescribing labelling requirements for *all* medical devices, which may be enacted in the near future[8].

Future changes

Thailand and the nine other ASEAN Member States have ratified, or are in the process of ratifying, the AMDD to standardise medical device classification, registration requirements, and documentation for the registration of medical devices among ASEAN members. The formation of a single market and a single production base in the region will permit companies within the ASEAN Economic Community (AEC) to move their products freely, and will serve to break down existing trade barriers that currently stunt intra-regional trade within the 10-member trading bloc. In addition, the implementation of consistent standards within the ASEAN countries for both IVD and

non-IVD medical devices, including related rules and regulations that conform to international standards, will in theory ensure the removal of trade barriers or obstacles.

Although Thailand has moved towards harmonising the classification of products according to a risk-based approach (A, B, C, D), as announced in the TFDA Notification 2015, the registration of medical devices still relies on the policy-based control of the TFDA. This means that Licensed and Notification Medical Devices require the submission of full registration dossiers in the CSDT format. However, almost all medical devices are classified as General Medical Devices and, thus, do not yet require a full dossier submission. It is expected that the new classification system and new requirements for medical device registration will enter into force once the draft *Medical Device Bill* is implemented, which has been under the review of the National Legislative Assembly since January 2019.

Another area of the medical device regulations that may impact the medical device industry in the future is a proposal from the TFDA for the implementation of Good Distribution Practice (GDP) of medical devices. The TFDA published the draft *Guidance on Good Distribution Practice for Medical Devices* on 24 April 2018[9]. This final version of this Draft is currently pending approval. Once the final version is published and implemented, medical device companies will have to ensure that they remain in compliance with GDP requirements.

Finally, innovation of medical devices is often closely correlated with data collection and processing. The use of cloud technology and artificial intelligence for facilitating the storage and processing of patient information has particularly raised concerns over patient privacy with regard to personal data protection. The *Personal Data Protection Act 2018* has been approved by the National Legislative Assembly; however, the law will have a grace period of about one year before it enters into force. This means that there will be no enforceable personal data law in Thailand until 2020. Nonetheless, medical device companies must ensure that they are equipped with proper mechanisms and control tools in order to legally collect, use, and transfer personal data.

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