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This issue covers the following topics:

I. Thailand's New Regulation on Telemedicine Service Standards in Medical Facilities

1. Background

Telemedicine services have become one of the alternative care options for patients during the COVID-19 pandemic. More and more services are being offered by private hospitals and clinics with support from digital healthcare applications. Now, anyone can access healthcare services at the touch of their finger. Previously, telemedicine services were not specifically regulated. Hence, issues concerning healthcare service safety, standards and quality have arisen, which demand discussion on the solutions to such issues by the relevant authorities.

In our previous article "*Launch of the Practical Guideline on Telemedicine in Thailand*" in NO&T Thailand Legal Update No. 4 (August 2020) (please click here), we provided an update in respect of the Telemedicine Guidelines, which focused on the guidelines for licensed medical practitioners to provide telemedicine services and briefly mentioned a draft Notification of Ministry of Public Health Re: Standard of Service in respect of Medical Facility via Telemedicine System from the Ministry of Public Health to further regulate and legalize the telemedicine business in medical facilities. Earlier this year, the Ministry of Public Health published the Notification Re: Standards of Service in respect of Medical Facility via Telemedicine System dated 18 January 2021 in the Royal Gazette (the **"Telemedicine Notification"**), which came into force on 2 February 2021, further legalizing telemedicine in Thailand.

2. Key Takeaways of the Telemedicine Notification

Principally, the Telemedicine Notification prescribes the standards for private medical facilities that use telemedicine systems as part of their services to ensure the safety of healthcare receivers in such medical facilities under the Medical Facility Act of 1998. The key takeaways are as follows.

- The Telemedicine Notification applies to i) telemedicine services and ii) telemedicine service systems, which are defined as follows:
  1) "**telemedicine services**" means the medical and public health services of medical facilities provided to service receivers by practitioners via telemedicine services in order to exchange information that is beneficial for consultation, examination, diagnosis, treatment, nursing, prevention, health reinforcement and recovery and beneficial for continuous education of medical and public health

personnel;[1] and

2) "**telemedicine service systems**" means systems using digital platforms for providing medical and public health services to those who are in different places by transmitting visual and audio information or other methods[2].

- In order to operate a telemedicine business via a medical facility, the licensee[3] and the medical facility operator (manager)[4] shall have:
  1) a sufficient number of practitioners who possess skills, education and training meeting the relevant standards in their particular fields for providing telemedicine services without affecting main medical service operations, i.e., offline medical services, pursuant to the list of available practitioners submitted thereby to the Bureau of Sanatorium and Art of Healing, Department of Health Service Support;[5] and
  2) a telemedicine service system that has telecommunication devices and technology that a service provider and a service receiver can use to clearly communicate in relation to telemedicine services as well as standards on information security measures.[6].
- Regarding the results of providing telemedicine services, the licensee, the medical facility operator and the medical practitioner providing the services to service receivers shall be liable for any results that may occur due to the provided services[7].
- The Telemedicine Notification shall not apply to any consultations between medical practitioners that do not involve service receivers. Such internal consultations shall not be deemed to constitute telemedicine services under the Telemedicine Notification[8]. This is because information exchanges between medical practitioners, i.e., teleconsultations, are not for the purpose providing telemedicine services under the Telemedicine Notification.
- If the licensee and the medical facility operator wish to provide additional telemedicine services, the licensee and the medical facility shall:
  1) submit an application to add telemedicine services to the Bureau of Sanatorium and Art of Healing, Department of Health Service Support;[9]
  2) ensure that systems for registrations, data records, service reports, inspections and verification processes in respect of telemedicine are sufficiently applied in every step;[10]
  3) ensure that practitioners who provide telemedicine services in medical facilities comply with laws relating to such practitioners' practices and other relevant laws;[11]
  4) provide service receivers with clarification in respect of all of the processes in detail before providing the services, the results that may occur due to the provided services in every aspect and the risks thereof;[12] and
  5) provide sufficient and appropriate technology systems, medical devices and communication devices, including risk management and error controls in technology communications according to the relevant laws[13], e.g., the Personal Data Protection Act of 2019, Electronic Transaction Act of 2001, Medical Device Act of 2008, Act Governing Commission of Offences Relating to Computers of 2007, etc.
- Medical facilities that already provided telemedicine services prior to the effective date of the Telemedicine Notification shall submit an application for additional services following this notification within 90 days from the effective date thereof.

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1 Clause 3 of the Telemedicine Notification
2 *Ibid.*
3 Under Section 3 of the Medical Facilities Act of 1998, "licensee" means a person who receives a license to operate a medical facility business, i.e., the holder of a license for engaging in healthcare services in a medical facility.
4 Under Section 3 of the Medical Facilities Act of 1998, "manager" means a person who receives a license to manage a medical facility, i.e., the holder of a license for operating a medical facility.
5 Clause 4 (1) of the Telemedicine Notification
6 Clause 4 (2) of the Telemedicine Notification
7 Clause 6 of the Telemedicine Notification
8 *Ibid.*
9 Clause 5 of the Telemedicine Notification
10 Clause 7 of the Telemedicine Notification
11 Clause 8 of the Telemedicine Notification
12 Clause 9 of the Telemedicine Notification
13 Clause 10 of the Telemedicine Notification

3. Our Remarks

The Telemedicine Notification sets out stricter standards for private medical facilities regardless of the size and type thereof to ensure the safety and security of telemedicine services as well as boost confidence in medical standards required by laws for digital platforms. It should be noted that the Telemedicine Notification is only applicable to private medical facilities, i.e., private hospitals and clinics. As a result, public medical facilities are not subject to the Telemedicine Notification. However, public medical facilities who wish to provide telemedicine services still need to comply with their own standards.

The Telemedicine Notification clearly indicates that telemedicine services shall be provided by specifically licensed practitioners in healthcare fields and shall be provided under the supervision of a licensed medical facility, which means stand-alone healthcare applications can no longer provide telemedicine services without being partnered with a licensed medical facility.

If the licensee and the medical facility operator fail to comply with the Telemedicine Notification, such failure may be considered a violation of Section 65 of the Medical Facility Act of 1998, which may result in the licensee and the medical facility operator being punished by imprisonment not exceeding one year and/or a fine not exceeding 20,000 THB. In addition, the penalties under the relevant laws may be imposed on violators on a case-by-case basis.

Currently, the relevant authorities for each professional practice field are now preparing specific regulations in relation to telemedicine services in accordance with the principles of the Telemedicine Notification. As of now, telemedicine-related regulations are comprised of the Telemedicine Guideline from the Medical Council of Thailand, the Notification of the Medical Technology Council Re: Standards of Tele-Medical Labs Services of 2020 dated 8 October 2020, the Notification of the Pharmacy Council of Thailand No. 56/2020 Re: Prescription Standards and Processes for Providing Tele-Pharmacy of 2020 dated 2 June 2020, and the Notification of Physical Therapy Council Re: Standards of Tele-Physical Therapy of Medical Facilities of 2020 dated 3 March 2021. Further telemedicine-related regulations are expected within this year and we will provide you with updates on the latest progress thereof.

Please feel free to contact us if you are interested in further details in respect of the laws and regulations of the telemedicine industry or similar industries.

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II. Amendment to the Control Procedures for the Manufacture and Importation of Medical Devices in Thailand

1. Introduction

In Thailand, medical devices are regulated by the Medical Device Control Division of the Food and Drug Administration ("**FDA**"), which is under the Ministry of Public Health ("**MPH**"). Pursuant to the Medical Device Act of 2008 as amended ("**MDA**"), the term "medical devices" is broadly defined to include not only hardware but also software intended to be used for medical purposes[14], for example, according to the FDA's publication, one of the reputable smart watch brands with electrocardiogram (ECG) feature was approved by the FDA as a medical device. Generally, the manufacture, importation or sale of medical devices in Thailand is prohibited unless clearance is obtained through the control procedures required by the FDA under the MDA.

On 21 November 2014, Thailand entered into the ASEAN Agreement on Medical Device Directive and since that date, Thailand has been committed to undertaking all necessary measures regarding medical devices to comply with the provisions stated therein. As a result, in 2019, legislation to amend the MDA was passed. Additionally, the MPH issued a law classifying medical devices based on their risk levels so as to clarify the previous medical device classifications created in 2015[15]. Thereafter, in order to comply with such classifications and to even more efficiently regulate businesses in relation to medical devices, the FDA also significantly revised the control procedures for the manufacture and importation of certain medical devices by enacting a number of regulations earlier this year. The new regulations were recently published in the Royal Thai Government Gazette on 15 February 2021 and currently remain in effect.

This article aims to provide a general summary in respect of the medical device industry in Thailand under those newly issued regulations and the relevant regulations for the benefit of manufacturers and importers of medical devices.

2. Key summary

2.1 Classifications of medical devices

In 2019, the MPH issued the Notification of MPH Re: Classifications of Medical Devices by Risk Level of 2019 ("**MPH Notification of 2019**"). Under the MPH Notification of 2019, medical devices were divided into two groups: (i) in vitro diagnostic medical devices (e.g., reagents, calibrators and equipment to be used *in vitro* for the examination of specimens derived from the human body) ("**IVD Medical Devices**") and (ii) non-in vitro diagnostic medical devices (e.g., surgically invasive medical devices and implantable medical devices) ("**Non-IVD Medical Devices**")[16].

As per Table 1 below, both IVD Medical Devices and Non-IVD Medical Devices are further separated into four classes (Class 1 to Class 4) and are assigned risk levels. Each of these four classes are subject to one of three types of control procedures: (a) notification, (b) declaration of specifications and (c) permission for the manufacture and importation of medical devices. The manufacturer or the importer shall follow such control procedures depending on the classification of the medical device[17] as illustrated in Table 1 below.

Table 1: Classifications of both IVD Medical Devices and Non-IVD Medical Devices and applicable control procedures

[14] Section 4 of the MDA
[15] Two Notifications of FDA were previously issued on 1 April 2015, which classified IVD Medical Devices and Non-IVD Medical Devices based on their risk levels. The new law, which is the MPH Notification of 2019, was issued to clarify such two existing Notifications of FDA without revoking them and to additionally specify the control procedures for their manufacture and importation.
[16] Clause 1 of the MPH Notification of 2019
[17] Clauses 2, 3 and 5 of the MPH Notification of 2019

Classifications of medical devices	Risk levels[18]	Control procedures for manufacture/importation
1	Low risk	Notification
2	• Low risk to public health or moderate risk to individuals in the case of IVD Medical Devices • Low to moderate risk in the case of Non-IVD Medical Devices	Declaration of specifications
3	• Moderate risk to public health or high risk to individuals in the case of IVD Medical Devices • Moderate to high risk in the case of Non-IVD Medical Devices	Declaration of specifications
4	High risk	Permission

2.2 Updated list of medical devices and details of control procedures

In the past, businesses who wished to manufacture or import medical devices in Thailand were required to carry out the FDA's control procedures, which consisted of either issuing declarations of specifications or obtaining permission, unless the medical devices thereof were not in the list of medical devices requiring declarations of specifications or permission as announced by the MPH from time to time.

However, after the MPH classified medical devices by risk level as explained in 1. above, in 2021, the MPH issued three new notifications and three new ministerial regulations in order to (a) revise the list of medical devices that require declarations of specifications or permission to be in line with the MPH Notification of 2019, (b) update the control procedures for issuing declarations of specifications or obtaining permission from the FDA and (c) introduce the new "notification" control procedure for the manufacture or importation of medical devices and provide a list of medical devices that fall under such notification requirement. Please note that, for the manufacture and importation of medical devices, the notification requirement is the new control procedure from the FDA that finally came into effect after it was roughly mentioned in the amendment to the MDA in 2019.

The updated list of medical devices and the control procedures for the manufacture/importation thereof is summarized in Table 2 below:

Table 2: Updated list of medical devices and details of control procedures for manufacture/importation

[18] There is no definition of low, moderate or high risk under the law. However, under the MPH Notification of 2019, the factors that the MPH uses to consider medical device risk levels are briefly clarified. For IVD Medical Devices, the MPH will consider the risk levels of such medical devices based on factors such as the purposes of use and indicated uses prescribed by the owners of such medical devices, the skill of the users of such medical devices and the importance and effect of the information obtained from such medical devices with respect to individuals and public health. For Non-IVD Medical Devices, the MPH will consider factors such as the level of invasiveness of such medical devices in respect of the bodies of patients, the period of time such medical devices will remain in the bodies of patients, the methods of use thereof and the biological effects thereof.

Control procedures for manufacture /importation	Classifications of medical devices and risk levels	List of applicable medical devices (collectively, "MPH Notifications of 2020")	Details of control procedures (collectively, "Ministerial Regulations of 2020")	Examples of medical devices
Notification	Class 1	Notification of MPH Re: Medical Device Groups or Medical Devices where Manufacturers or Importers Must Provide Notification of 2020	Ministerial Regulation Re: Notification and Issuances of Notification Certificates for the Manufacture or Importation of Medical Devices of 2020	Non-invasive medical devices intended to be used as mechanical barriers for wounds, specimen receptacles and medical devices intended to be used with animals only
Declaration of specifications	Classes 2 and 3	Notification of MPH Re: Medical Device Groups or Medical Devices where Manufacturers or Importers Must Issue Declarations of Specifications (No. 2) of 2020	Ministerial Regulation Re: Declaration of Specifications and Issuances of Declaration Certificates for the Manufacture or Importation of Medical Devices of 2020	IVD Medical devices intended to be used for diagnosis of infective agents in cerebrospinal fluids, IVD Medical Devices intended to be used for diagnosis of fetal genetic disorders (e.g., Down Syndrome or Spina Bifida) and non-invasive medical devices intended to be used as a bypass or a collector for body fluids or body tissue that is connected to an active medical device with high to moderate risk
Permission	Class 4	Notification of MPH Re: Medical Device Groups or Medical Devices where Manufacturers or Importers Must Obtain Permission of 2020	Ministerial Regulation Re: Applying for Permission and Granting of Permission for the Manufacture and Importation of Medical Devices of 2020	Surgically invasive medical devices intended to be temporarily used for diagnosis, tracking or solving of heart impairments

2.3 Applications for medical devices using the FDA electronic system

Pursuant to the Ministerial Regulations of 2020, the control procedures for (a) notification, (b) declaration of specifications or (c) permission shall be principally conducted through the FDA electronic system[19]. Under the Ministerial Regulations of 2020, a manufacturer or an importer is required to submit via such electronic system certain documents to the Secretary-General of the FDA, e.g. a medical establishment registration certificate number, a document explaining the name

[19] Clause 9 of the Ministerial Regulation Re: Notification and Issuances of Notification Certificates for the Manufacture or Importation of Medical Devices of 2020;
Clause 13 of the Ministerial Regulation Re: Declaration of Specifications and Issuances of Declaration Certificates for the Manufacture or Importation of Medical Devices of 2020; and
Clause 13 of the Ministerial Regulation Re: Applying for Permission and Granting of Permission for the Manufacture and Importation of Medical Devices of 2020.

and details of a medical device, medical device documentation[20] or a document explaining the risks of a medical device or a sale record certificate of a medical device (in the case of declaration of specifications or permission)[21]. The Secretary-General of the FDA will consider an application for a notification, a declaration of specifications and permission within two hundred, two hundred and fifty and three hundred days, respectively[22].

2.4 Preparations that should be taken by manufacturers and importers of medical devices

New or established manufacturers and importers of medical devices should know the classifications of medical devices that they wish to manufacture or import by checking the MPH Notifications of 2020 in order to verify and ascertain the control procedures for such classifications of medical devices since there were material changes thereto. New manufacturers and importers also need to conduct such control procedures as required by the Ministerial Regulations of 2020.

Established manufacturers and importers of medical devices who wish to continue their operations are, according to the MPH Notifications of 2020, required to submit applications for notification, declaration of specifications or permission based on the classifications of medical devices prior to the expiration date of their existing (i) manufacturing establishment registration certificates in the case of manufacturers or (ii) importation certificates in the case of importers[23]. However, for established manufacturers and importers where the required control procedures for their medical devices were changed (e.g., the required control procedures for surgical gloves, contact lenses, condoms and HIV Test Kits for diagnostic use were changed from "permission" to "declaration of specifications" and the required control procedures for Ophthalmic Viscosurgical Devices (OVDs) were changed from "declaration of specifications" to "permission"), they are required to submit applications before the expiration date of any "permission" or "declaration of specifications" they may hold[24].

3. Conclusion

Under these newly enacted regulations, manufacturers or importers of medical devices, whether new or established, should know the new risk classifications of their medical devices, understand the new requirements for such medical devices and comply with the FDA's updated control procedures.

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[20] Medical device documentation means papers or any other objects that are capable of explaining the purpose of a medical device through any statements relating thereto and that are inserted or enclosed in the container or packaging of such medical device and that also include a manual for using such medical device (Section 4 of the MDA).

[21] Clause 2 of the Ministerial Regulation Re: Declaration of Specifications and Issuances of Declaration Certificates for the Manufacture or Importation of Medical Devices of 2020; and
Clause 2 of the Ministerial Regulation Re: Applying for Permission and Granting of Permission for the Manufacture and Importation of Medical Devices of 2020.

[22] Clause 5 of the Ministerial Regulation Re: Notification and Issuances of Notification Certificates for the Manufacture or Importation of Medical Devices of 2020;
Clause 5 of the Ministerial Regulation Re: Declaration of Specifications and Issuances of Declaration Certificates for the Manufacture or Importation of Medical Devices of 2020; and
Clause 5 of the Ministerial Regulation Re: Applying for Permission and Granting of Permission for the Manufacture and Importation of Medical Devices of 2020.

[23] Clause 5 of the Notification of MPH Re: Medical Device Groups or Medical Devices where Manufacturers or Importers Must Provide Notification, of 2020;Clause 6 of the Notification of MPH Re: Medical Device Groups or Medical Devices where Manufacturers or Importers Must Issue Declaration of Specifications (No. 2) of 2020; and
Clause 5 of the Notification of MPH Re: Medical Device Groups or Medical Devices where Manufacturers or Importers Must Obtain Permission of 2020.

[24] Clause 5 of the Notification of MPH Re: Medical Device Groups or Medical Devices where Manufacturers or Importers must Issue Declaration of Specifications (No. 2) of 2020.

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