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This issue covers the following topics:

I. Lessons from the Beirut Explosion – Understanding Hazardous Substance Control in Thailand

Background

A massive explosion at the port of the Lebanese capital, Beirut, on 4 August 2020 killed hundreds of people, thousands were severely injured and millions have lost their homes and property. It was confirmed that the cause of the explosion was the detonation of 2,750 tons of highly explosive ammonium nitrate which was unsafely stored in a warehouse at the port.

In Thailand, there were similar cases where accidents were primarily caused by inappropriate handling of hazardous substances. In one of the case studies in March 1991, a chemical fire and explosion at the Klong Toey port of Bangkok caused an estimated hospitalization of 1,700 chemical-exposed patients, 642 houses were on fire and 5,000 people became homeless. The most recent case is the fire in a cargo ship containing chemical substances at Laem Chabang port of Chonburi province in May 2019 resulting in many injured people and damaged property.

This article aims to describe certain important requirements for legal compliance applicable to the management of hazardous substances, in order to understand and to mitigate the risks caused by possible accident and to prevent government and legal sanction against your business.

General Concepts of Hazardous Substance Control

The key regulation governing the management of hazardous substances is the Hazardous Substance Act of 1992("**HSA**"). Under the HSA, the definition of hazardous substances broadly covers substances including explosives and inflammable substances.[1]

[1] Section 4 of the HSA, "Hazardous Substances" means the following substances:
(1) Explosives;
(2) Inflammable substances;
(3) Oxidizing agent and peroxide substances;
(4) Toxic substances;
(5) Disease causing substances;
(6) Radioactive substances;
(7) Mutagenic substances;
(8) Corrosive substances;

In addition, certain substances may also be subject to other specific laws, for example, (i) petroleum, which is controlled by the Fuel Control Act of 1999, (ii) radioactive materials, which is controlled by the Nuclear Energy for Peace Act of 2016, and (iii) chemicals substance, biological substances and radioactive substances which can be used in combat or warfare including ammonium nitrate, the underlying chemical which caused the Beirut explosion, which is controlled by the Arms Control Act of 1987.

Under the HSA, hazardous substances are divided into 4 types based on the degrees of hazards, risks and needs for control.[2]

- Type 1 is the lowest impact hazardous substances so that, upon their production, importation, exportation and possession, the business is required to only comply with the specified criteria and procedures such as labelling, safety procedure, etc.;
- Type 2 is substances for which notification must be provided upon their production, importation, exportation and possession to the Department of Industrial Works ("**DIW**") or relevant authorities;
- Type 3 is the substances for which licenses must be obtained upon their production, importation, exportation and possession from the DIW or relevant authorities; and
- Type 4 substances have the highest degree of hazards so their production, importation, exportation and possession thereof are prohibited.

Besides, in order to monitor all substances used in Thailand, the HSA also requires the business to register the substances manufactured or imported into Thailand with the DIW or relevant authorities under specific conditions.

There are subordinated regulations governing the notification and license requirement and procedures including compliance for each type of the hazardous substances. Samples of the compliance requirement involving the hazardous substances under the DIW's control are as follows:

- Appointment of a specialized personnel responsible for the safety of hazardous substance storage and notify such appointment to the DIW under specific criteria and conditions;[3]and
- Submission of a safety report on the storage of hazardous substance to the DIW every year for the business operator who has appointed the specialized personnel as aforementioned.[4]

Official Manual in Relation to the Hazardous Substance Control Standard

To ensure safety in relation to the storage of hazardous substance, classification of the hazardous substance for the purpose of storage and measurement to prevent the danger arising from the hazardous substances, the DIW has issued the Notification of the Ministry of Industry Re: Storage of Hazardous Substance under Authorization of the DIW of 2008 dated 10 March 2008 for the business of production, importation, exportation and possession of hazardous substance to comply with the DIW Notification Re: Manual for Storage of Chemical and Hazardous Substance of 2007 dated 27 November 2007 ("**DIW Manual**") or international standards approved by the DIW. In principle, Thailand adopts the global standard chemical material treatment system for hazardous substances management, for example, the substances will be identified by CAS registry number and the classification of substances including preparation of label and material safety data sheet (MSDS) or safety date sheet (SDS) are referred to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

The DIW Manual contains the guidelines for the control of hazardous substances for (a) technical aspects, e.g. construction of storage facility, building, floor, wall, emergency doors and air ventilation, and (b) the prevention measures aspect, e.g. first aid, personal protective equipment (PPE), warning signs, and handling of chemical leakage, etc. More importantly, the DIW Manual stipulates that the classification of chemical and hazardous substance based on the risk assessment level will help the business operator and the responsible person to understand how to properly deal with them.

Occupational Safety in relation to Hazardous Chemicals

There is also a law governing the safety work environment for workers who closely work with hazardous chemicals, so-

(9) Irritative substances; and
(10) Others substances, whether chemicals or otherwise, which may be harmful to people, animals, plants, property or environment.

[2] Section 18 of the HSA and the Notification of Ministry of Industry Re: List of Hazardous Substance of 2013 dated 28 August 2013

[3] Clause 4 of the Notification of the Ministry of Industry Re: Designation of a Specialized Person Responsible for Safety of Hazardous Substance Storage under Authorization of the DIW at the Hazardous Substance Business Facility of 2008 dated 10 March 2008

[4] Clause 5.5 of the Notification of the Ministry of Industry Re: Designation of a Specialized Person Responsible for Safety of Hazardous Substance Storage under Authorization of the DIW at the Hazardous Substance Business Facility of 2008 dated 10 March 2008

called the Occupational Safety, Health and Environment Act of 2011 ("**OSHA**") that we should not overlook when considering the duties applicable to the hazardous substance. The OSHA defines the 'Hazardous Chemicals', which is different from the Hazardous Substance under the HSA, that means the elements, composition or mixture, according to the list prescribed by the Director-General, which takes the states of a solid, liquid or gas, whether it is in the form of fiber, dust, droplets, vapor, or fume, with one or many qualities together, as follows:

(1) Toxic, erosive, irritative, which can cause allergic reaction, cancer, genetic mutation, hazardous to an born baby or causing death; and
(2) Causing an extreme reaction, oxidization or inflammability which can cause explosion or fire.[5]

It seems highly likely that some substances will be subject to both the HSA and the OSHA. However, the OSHA imposes obligations of the possessor of Hazardous Chemicals as an employer to ensure a safe and healthy workplace for the employees.

In general, obligations that the employer shall perform under the OSHA are as follows:

- Notify the Labour Protection and Welfare Office when it takes possession of Hazardous Chemicals under the list of Hazardous Chemicals prescribed under the notification[6] and submit a list of Hazardous Chemicals used in the workplace every year;[7]
- Conduct a test on saturation of the Hazardous Chemicals in the work environment and Hazardous Chemicals storage and submit a test result to the Labour Protection and Welfare Office every year;[8] and
- Arrange for health checkup of the employees working in relation to certain Hazardous Chemicals.[9]

Conclusion

Even there are still fragments in terms of regulatory authorities, which can sometimes be seen as overlapping each other, the Hazardous Substance of and Hazardous Chemicals control law remains systematic. Such regulatory overlaps are also for the ultimate safety benefits of business operators and employees involved, as well as the community at large. Hence, we strongly encourage the business operators to adhere to such legal compliance and restrictions. If you have any question, please contact us.

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[5] Clause 1 of Ministerial Regulation on Prescribing Standard for Administration and Management of Occupational Safety, Health and Environment in relation to Hazardous Chemicals of 2013 dated 22 October 2013.
[6] Notification of the Department of Labour Protection and Welfare Re: List of Hazardous Chemical dated 6 December 2013.
[7] Clause 2 of the Ministerial Regulation on the Prescribing of Standard for Administration and Management of Occupational Safety, Health and Environment in relation to Hazardous Chemicals of 2013 dated 22 October 2013.
[8] Notification of the Department of Labour Protection and Welfare Re: Criteria, Testing Method and Analysis of Testing Result on Saturation of the Hazardous Chemical dated 23 November 2016.
[9] Ministerial Regulation on Prescribing Criteria and Method of Conducting Health Checkup of Employees and Forwarding the Results of Health Check Up to Labour Inspector of 2004 dated 29 December 2004.

II. Launch of Practical Guideline on Telemedicine in Thailand

Background

The World Health Organization ("**WHO**") has described the term 'Telemedicine' as the delivery of healthcare services, where distance is a critical factor, by all healthcare professionals, using information and communication technologies for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of healthcare providers.[10] Examples are: (i) patient-to-healthcare provider communication via webcam or mobile application, (ii) healthcare provider-to-healthcare provider communication via webcam, or mobile application, (iii) store-and-forward telemedicine or the collection of clinical data and sending it electronically to another healthcare provider for evaluation.

Before the arrival of the COVID-19 pandemic in Thailand, telemedicine was rather viewed as an optional path to physical contact with healthcare professionals and patients. Since then, telemedicine has reached a level of unprecedented growth owing to the necessity of having 'contactless' safety requirements and overcoming 'long-distance' obstacles. This article provides the latest legal update and trends in relation to the said medical technology business.

Practical Guideline on Telemedicine

Owing to the previously unregulated business of telemedicine in Thailand, issues concerning professional ethics and legal liability have arisen. There are many obstacles and exposures which a hospital or clinic, as a health facility, and a doctor, as a healthcare provider, should be aware of while providing telemedicine services. For example, there could be unlicensed persons claiming to provide telemedicine services, which will affect the standard and quality of healthcare. Further, there could be medical negligence and error of judgment should doctors rely solely on telemedicine without physical treatment.

On 21 July 2020, the Medical Council of Thailand issued the Notification of the Medical Council on Guideline in respect of Telemedicine and Online Clinics No. 54/2563 dated 21 July 2020 ("**Telemedicine Guideline**"). The Guideline shall come into effect 90 days after its date of issuance of 21 July 2020, i.e. 20 October 2020. This Telemedicine Guideline is considered as a pioneering official guideline for the telemedicine business in Thailand and aims to set standards – particularly safety and professional standards for healthcare providers and healthcare receivers.

Key concepts of the Telemedicine Guideline are as follows:

- "Telemedicine" is defined as the transmission or communication of data on modern medicine from a medical practitioner, including from a health facility, in the public and/or private sector, from one place to another place by electronic means in order to provide advice, recommendations to other medical practitioners, or any other person, for a medical procedure within the scope of the medical profession, according to the state and existing circumstances of such medical data.[11]
- "Healthcare Provider" is limited to licensed medical practitioners, and they shall also be responsible for any negative effect occurring from such Telemedicine service, while "Healthcare Receiver" can be anyone who receives a Telemedicine service.[12]
- In order to provide a Telemedicine service, Healthcare Provider shall be subject to the professional medical standards as prescribed by the Medical Council of Thailand, i.e. the Professional Standards for Medical Practitioners of 2012, Criteria of Knowledge and Skills for Assessment of License to Practice as Medical Personnel of 2012 (as amended in 2020) and other criteria or guidelines stipulated pursuant to the Medical Profession Law.[13] Given the foregoing, Healthcare Provider must strictly adhere to all criteria above and is advised to learn all necessary techniques as well as limitations of Telemedicine technology to ensure patient safety.[14]
- Provision of a Telemedicine service is subject to certain technological and electronic limitations, and therefore Healthcare Provider and Healthcare Receiver are to be informed of their certain rights:[15]
  (1) A patient has the right to know information concerning their medical treatment, e.g. any medical facts concerning the treatment provided under the Telemedicine service as well as any other subsequent medical

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[10] Brief summary of WHO's 'A health telematics policy in support of WHO's Health-For-All strategy for global health development: report of the WHO group consultation on health telematics, 11-16 December, Geneva, 1997'
[11] Clause 3 of the Telemedicine Guideline
[12] *Ibid.*
[13] Clause 4 of the Telemedicine Guideline
[14] Clause 5 of the Telemedicine Guideline
[15] Clause 6 of the Telemedicine Guideline

facts, e.g. expert opinion from other medical schools;

(2) Both Healthcare Provider and Healthcare Receiver must be made aware that not all diseases or conditions are fit for Telemedicine, i.e. face to face treatment would be more efficient;

(3) Both Healthcare Provider and Healthcare Receiver are entitled to reject the use of Telemedicine; and

(4) In the case of the use of Artificial Intelligence (AI) with the Telemedicine, the Telemedicine must comply with specific laws, e.g. medical device laws and pharmaceutical laws.

- To mitigate the risks from telecommunication or from technical error, Telemedicine shall be conducted under a safe IT system standard that conforms with international standards and shall be materially available and ready for inspection, including the following procedures:[16]
  (1) Identification and confirmation as regards the Healthcare Provider's being a licensed practitioner and providing his or her Telemedicine service under an IT system standard in respect of hospitals or health facilities pursuant to the specific laws;
  (2) Identification and confirmation in respect of the Healthcare Receiver's existence according to the IT system standard as stipulated by the responsible authorities; and
  (3) Confirmation that the IT system used for Telemedicine complies with the standards set out in the Electronic Transactions Act of 2001 and the Personal Data Protection Act of 2019 ("**PDPA**").
- "Online Clinic" is also recognized by the Telemedicine Guideline as being health facilities as prescribed by the laws.[17] Provision of an Online Clinic and Telemedicine under the Telemedicine Guideline shall be conducted only from/via a licensed health facility which belongs to the public and/or private sector and is established pursuant to the relevant laws.[18] As a result, once the Telemedicine Guideline comes into force, private sector enterprises such as startup companies who are currently engaging in the business of Healthcare Provider providing Telemedicine services outside a heath facility, may no longer freely operate a Telemedicine business.
- The Telemedicine Guideline shall not apply to any consultation among licensed medical practitioners or other public health personnel who have already been regulated specifically by other regulations.[19] This is because communication via electronic means among medical practitioners, other public health practitioners, or nurses can – of its nature – be regular communication for the purpose of information exchange and is not communication directly to the Healthcare Receiver.

Further Legislative Developments

Recently, the Department of Health Service Support, of the Ministry of Public Health, one of the emerging regulators of the Telemedicine field, began preparing a draft Notification of Minister of Public Health re: Standard of Service in respect of Health Facility via Telemedicine System. This draft aims to further regulate the Telemedicine business such that any health facility wishing to operate a Telemedicine business may have to apply for a license prior to operating. This draft, once finalized and promulgated, could drastically affect Telemedicine business operations in general. We will keep you informed of further developments once it is legislated.

This Telemedicine Guideline issuance represents a pivotal point for further legislative reform by other supporting mechanisms of Telemedicine, which would require multi-disciplinary efforts from both public and private sectors, i.e. health insurance and medical practitioner license for Telemedicine. We expect that there will be future regulations to support insurance claim and coverage for Telemedicine. Moreover, Telemedicine may ideally lead to future relaxation of medical practitioner license requirements regionally and/or globally, ensuring that doctors in Thailand can assist other countries' patients in need of healthcare. This overseas service would require international level of co-operation among the governments to overcome the practical barriers and ensure that patients can access quality healthcare at affordable price in a timely manner through Telemedicine. This would contribute to further growth in the usage and popularity of Telemedicine, domestically and globally.

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[16] Clause 7 of the Telemedicine Guideline

[17] Section 4 of the Health Facilities Act of 1998, a "Health Facility" means a place including a vehicle provided for healing arts practices under the law on healing arts practices, medical profession practices under the law on medicine profession, nursing and midwifery practices under the law on nursing and midwifery profession, dental profession practices under the law on dental profession, physical therapy profession practices under the law on physical therapy profession, technological medicine profession practices under the law on technological medicine, or traditional Thai medical profession practices and applied traditional Thai medical profession practices under the law on the traditional Thai medicine profession, or other medical and public health profession in accordance with such law, in which the relevant activity is normally conducted regardless of payment or non-payment.

[18] Clause 8 of the Telemedicine Guideline

[19] Clause 9 of the Telemedicine Guideline

Our Remarks

Prior to the issuance of this Telemedicine Guideline, a lack of regulations for Telemedicine meant that many problems had been caused in terms of security, safety and quality of healthcare services, which was likely to endanger patients. Further, since there were many laws that did not directly address the Telemedicine business, legal implementation and enforcement was rather inconsistent and fragmented.

The Telemedicine Guideline constitutes a set of initial guidelines and criteria to supervise Telemedicine business, in order to prevent legal loopholes in relation to the Telemedicine business and to ensure patients are given a high quality of healthcare. Although the Telemedicine Guideline prescribes no direct penalty against Telemedicine business operators, such operators might be subject to the penalties under other relevant laws and regulations, e.g. Medical Profession Act of 1982; Public Health Act of 1992; Health Facilities Act of 1998; Electronic Transactions Act of 2001; National Heath Act of 2007; Medical Device Act of 2008; Computer Crimes Act of 2007; PDPA, etc. Apart from the aforementioned laws, failure to comply with the Telemedicine Guideline may lead to the imposition, by the Medical Council of Thailand, of disciplinary actions against healthcare providers for legal and/or ethical breaches,[20] on a case by case basis.

It is anticipated that the regulations in respect of Telemedicine will have to keep up with the borderless nature of Telemedicine and ensure patients are treated safely and securely. In the near future, telemedicine could soon become the 'new normal' form of medical and health services, with less traveling and waiting time, as well as the lowering of costs to patients.

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[20] Sections 8 (2) and 39 of the Medical Profession Act of 1982

III. Update on Personal Data Law – Standard of the Security Measures and Our Remarks

Background

Despite the postponement of the Personal Data Protection Act of 2019 ("**PDPA**") to 1 June 2021 by virtue of the 'Royal Decree Prescribing the Data Controller's Organizations and Businesses to which the Personal Data Protection Act of 2019 shall not be applied of 2020' ("**Royal Decree**"), which generally applies to the data controllers operating in certain businesses ("**Data Controllers**") (see details *here*), the Data Controllers are still subject to compliance with the security measures for the protection of personal data ("**Security Measures**") in accordance with the standard prescribed by the Ministry of Digital Economy and Society.

On 24 June 2020, the 'Notification of Ministry of Digital Economy and Society Re: Standard of Security Measures on the Personal Data of 2020' ("**Notification**") was issued with a limited effective period from 18 July 2020 to 31 May 2021. As a result, the Data Controllers, shall still provide the Security Measures in accordance with the minimum standard per the Notification, as elaborated below.

Duties of the Data Controllers under the Notification

Under the Notification, the duties of the Data Controllers are as follows:

1. Duty to provide the Security Measures in accordance with the standard provided[21]

   The Data Controllers are required to provide the Security Measures which should cover the administrative safeguard, technical safeguard, and physical safeguard in respect of the access and control of the use of the personal data. The Security Measures must at least comprise of the following undertakings:
   (1) Controlling the access to the personal data and the tools for the storing and processing of the personal data by taking into account the usage and security;
   (2) Prescribing the permission or the right to access the personal data;
   (3) User access management so as to limit the access to those who are authorized;
   (4) Prescribing the user responsibilities in order to prevent any unauthorized access to the personal data, disclosure, knowledge of or unlawful copying of the personal data, theft against equipment for storage or processing of the personal data; and
   (5) Providing the methods for the inspection of the history of access, changes, deletion or transfer of the personal data which must be appropriate according to the methods and media used in collection, use or disclosure of the personal data.

   In any event, the Notification allows the Data Controllers to provide the Security Measures based on the standards which are different from that of the Notification, provided that such standards are not lower than that prescribed under the Notification.[22]

2. Duty to notify employees and relevant persons regarding the Security Measures

   The Data Controllers are required to notify the staff, employees, workers, or relevant persons regarding their own Security Measures and must promote the awareness to strictly comply with the protection of the personal data protection amongst those persons to strictly comply with.[23]

   In practice, the Data Controllers may choose to draft the Security Measures separately from or incorporate the Security Measures into existing internal policies and thereafter announce them to such persons.

Possibility of Having Different Standards of the Security Measures upon the Future Enforcement of the PDPA

Upon future enforcement of the PDPA from 1 June 2021, different standards for the Security Measures may be issued. According to the PDPA, the standard thereof is supposed to be issued under legal source of Section 37(1)[24]and issued by

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[21] Clause 5 of the Notification
[22] Clause 6 of the Notification
[23] Clause 4 of the Notification
[24] Section 37 of the PDPA, "The data controller shall have the following duties:
(1) Provide appropriate security measures for preventing the unauthorized or unlawful loss, access to, use, alteration, correction or disclosure of personal data, and such measures must be reviewed when it is necessary, or when the technology has changed

the Personal Data Protection Committee ("**Committee**") – which is still in the process of being formed. Currently, there is only an interim standard of the Security Measures applicable until 31 May 2021 issued under the PDPA Section 4 paragraph 2 via the Notification and the Royal Decree and is issued by the Minister of Digital Economy and Society.

Nevertheless, it can be reasonably assumed that the standard issued by the Committee should not substantially deviate from that which is already provided under the Notification.

Liability for Non-Compliance with the Notification

It can be reasonably interpreted that there is no direct legal liability prescribed under the PDPA for the non-compliance with the Notification which happens prior to the future enforcement of the PDPA. This is because the Royal Decree has effectively postponed the enforcement of the PDPA including its provisions relating to civil, criminal and administrative liabilities. Nonetheless, it should be noted that the Royal Decree does not exempt liabilities which may arise under other relevant laws.

Conclusion

Prudent business operators should view such Notification as a guideline to preparing the minimum standard of Security Measures and ensure that necessary preparations to design and provide Security Measures to meet the standard as may be required under the PDPA in the future, and further seek compliance support from a professional legal advisor.

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in order to efficiently maintain the appropriate security and safety. It shall also be in accordance with the minimum standard specified and announced by the Committee…"

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