THE LIFE SCIENCES LAW REVIEW

Ninth Edition

Editor
Richard Kingham

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PREFACE

The ninth edition of *The Life Sciences Law Review* covers a total of 28 jurisdictions, providing an overview of legal requirements of interest to pharmaceutical, biotechnology and medical device companies. The chapters are arranged so as to describe requirements throughout the life cycle of a regulated product, from discovery to clinical trials, the marketing authorisation process and post-approval controls. Certain other legal matters of special interest to manufacturers of medical products – including administrative remedies, pricing and reimbursement, competition law, special liability regimes and commercial transactions – are also covered. Finally, there is a special chapter on international harmonisation, which is of increasing importance in many of the regulatory systems that are described in the national chapters.

The past year has been dominated by the covid-19 pandemic, and this will undoubtedly be true of 2021 as well. Manufacturers of healthcare products have expedited the development and testing of drugs, biologics, diagnostics and personal protective equipment. Vaccines, many making use of novel technologies, have moved from the laboratory to the clinic and then to patients in record times; a matter of months rather than years or decades. Regulatory agencies have reviewed marketing applications with unprecedented speed and efficiency and international organizations have taken measures in an effort to ensure equitable access to medicines and vaccines in all countries.

In times such as these, it is vitally important that lawyers who advise companies in the life sciences sector and the business executives whom they serve have a working knowledge of the regulations and policies that govern drugs, biologics and medical devices. It is equally important to keep up to date with developments in the regulatory systems that govern access to the market, pricing and reimbursement, advertising and promotion, and numerous other matters that are essential to success. It is our hope that this year's publication will be especially helpful in this respect.

All of the chapters have been written by leading experts within the relevant jurisdiction. They are an impressive group, and it is a pleasure to be associated with them in the preparation of this publication.

Richard Kingham
Covington & Burling LLP
Washington, DC
February 2021

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Chapter 25

THAILAND

Jessada Sawatdipong, Pranat Laohapairoj, Suphakorn Chueabunchai and Noraseth Ohpanayikool[1]

I INTRODUCTION

The Food and Drug Administration (FDA), established by the Ministry of Public Health (MOPH), is the government administrative and regulatory body governing consumable products in Thailand. Consumable products include foods, drugs, psychotropic substances, narcotics, medical devices, volatile substances, cosmetics and hazardous substances available in the country.[2] To ensure the safety, quality and efficacy of consumable products, the FDA controls, regulates and administers the manufacture, distribution, advertisement and other matters in relation to the consumable products through five main divisions: the Bureau of Foods, the Bureau of Drug Control, the Medical Device Control Division, the Cosmetic and Hazardous Substance Control Division and the Narcotics Control Division.[3]

The FDA's five main roles and responsibilities are pre-marketing control, post-marketing control, development of a surveillance programme for consumers' safety, consumer education and provision of technical support and cooperation with other agencies.

By law, certain important issues are decided by committees, whose members – all experts in their respective fields – are appointed by the Minister of Public Health. Currently, there are seven committees, for: foods, drugs, psychotropic substances, narcotics, medical devices, cosmetics and hazardous substances. In addition, to support the development of drugs, foods and chemical substances, the Cabinet has appointed three additional committees, which are the National Drug Committee, the National Food Committee and the National Chemical Safety Committee.[4]

1 Jessada Sawatdipong is a managing partner, Pranat Laohapairoj is a partner, and Suphakorn Chueabunchai and Noraseth Ohpanayikool are associates at Chandler MHM Limited.

2 Food and Drug Administration, 'The Roles and Responsibilities of Thai FDA' (Food and Drug Administration 2016), www.fda.moph.go.th/sites/FDA_EN/SitePages/Roles.aspx, accessed 2 December 2019.

3 Ministerial Regulation Re: Determination of Organisation Structure of the Food and Drug Administration, Ministry of Public Health B.E. 2552 (2009).

4 Food and Drug Administration, 'Structure' (Food and Drug Administration 2019), www.fda.moph.go.th/SitePages/Structure.aspx, accessed 2 December 2019.

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II THE REGULATORY REGIME

i Classification

The consumable products under the responsibility of the FDA are each governed by eight specific Acts:[5] (1) the Drug Act BE 2510 (1967); (2) the Psychotropic Substance Act B.E. 2518 (1975); (3) the Food Act B.E. 2522 (1979); (4) the Narcotic Act BE 2522 (1979); (5) the Emergency Decree on Prevention of Abuse of Volatile Substances BE 2533 (1990); (6) the Hazardous Substance Act BE 2535 (1992); (7) the Medical Device Act BE 2551 (2008); and (8) the Cosmetic Act BE 2558 (2015), issued specifically for the enforcement, supervision and control over the use, manufacture, distribution, import, export, advertisement, suspension or revocation of required licence, imposition of penalties in case of violation of the act, and determination of governmental fees of the consumable products under the responsibility of the FDA. Each specific Act provides a definition and classification (if any) in its introductory section.

The decisions on classification and categorisation of consumable products into different types or subcategories are undertaken by each responsible bureau or department under the control of the FDA.[6] For instance, the classification and categorisation of drugs is undertaken by authorised officers of the Bureau of Drug Control. If a product is considered as a 'drug' under the definition set forth under the Drug Act, it is then further sub-classified into different categories of drugs (e.g., modern drug or traditional drug).

ii Non-clinical studies

Studies of animals are governed by the Animals for Scientific Purposes Act BE 2558 (2015). The implementation and enforcement of this Act is carried out by the Supervisory and Promotional Committee on the Use of Animals for Scientific Purposes. This Act aims to raise awareness about the ethics of, and impose certain ethical standards on, animal testing, as well as to ensure that the testing will be carried out under proper standards, implementation and monitoring.

The Supervisory and Promotional Committee on the Use of Animals for Scientific Purposes issued a notification determining ethics for the use of animals for scientific purposes. The ethics set forth under this notification clearly promote the value of life of animals, and clearly specify that the use of animals for scientific purposes can be undertaken only when the users have thoroughly considered that the experiment in question shall be for the maximum benefits in respect to the development for mankind, academic progress, or both. After the end of a scientific experiment, the animal subjects shall be put to death in a peaceful manner to ensure animal welfare and humane treatment.[7]

5 ibid.

6 Ministerial Regulation Re: Determination of Organisation Structure of the Food and Drug Administration, Ministry of Public Health B.E. 2552 (2009).

7 Chapter 1 of the Notification of the Supervisory and Promotional Committee on the Use of Animals for Scientific Purposes Re: Determining Ethics for the Use of Animals for Scientific Purposes, announced on 29 February 2016.

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iii Clinical trials

Currently, there is no regulation outlining guidelines for conducting clinical trials. However, according to Section 9 of the National Health Act BE 2550 (2007), if a public health professional practitioner demands to use a service receiver as a subject of an experiment in their research, the written consent of the service receiver shall be granted in advance, and such consent can be revoked by the service receiver at any time.

In addition to the National Health Act, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use and Good Clinical Practice (ICH/GCP) which was translated by the FDA in 2000, is used as guidance for conducting clinical trials in Thailand. Although this guidance does not have legal enforceability in Thailand, the criteria for the independent ethics committee or institutional review board for considering clinical trials relating to drugs shall be in line with such guidance.[8]

iv Named-patient and compassionate use procedures

There are no regulations permitting the distribution of medicines or medical devices without prior issuance of a marketing authorisation or other permission for commercial distribution. Thailand does not have exceptions for the registration of named-patient and compassionate use.

v Pre-market clearance

Under the Drug Act, pre-market clearance covers three main steps: licensing, registration and advertising control.

The Drug Act requires that a person who wishes to sell, produce or import drugs into Thailand obtain a licence from the FDA. The government fee for each licence varies depending on the type of licence and product from between 2,500 and 100,000 baht.[9] The approval process will take approximately 30 days depending on type of licence and product.

In addition, a person who wishes to produce or import drugs into Thailand shall also register the drug formulas with the competent official before producing or importing those drugs into Thailand.[10] The registration procedure for a drug formula is to ensure efficacy, safety and quality of drugs sold in Thailand. Upon receipt of a drug registration certificate, the drug can be lawfully manufactured or imported. Note that the application shall be submitted to the FDA upon making a reservation for the submission via the FDA's website, phone contact or walk-in contact. The evidence, fee and timeline for the registration of a drug formula varies depending on the types of drugs. For instance, the registration of a drug formula for a new drug will require more evidence and longer time for consideration, compared to the registration of a generic or a new generic drug. The submission of the application and supporting evidence can be made via physical delivery or online. However, the registration of new drug formulas (i.e., pharmacopoeia with new chemical entities) shall be submitted using the eCTD (electronic Common Technical Dossier) only.[11] The

8 Clause 6.3 of the Notification of the Drug and Food Administration Re: Rule Method and Criteria for Approving the Ethics Committee for Considering the Clinic Trial Project in Relation to Drugs, dated 10 September 2018.

9 Fee rate, Annex to the Drug Act BE 2510 (1967) as amended by the Drug Act (No. 6) BE 2562 (2019).

10 Section 79 of the Drug Act BE 2510 (1967).

11 Clause 8 of the Notification of Ministry of Public Health Re: the Online Submission of Pharmacopoeia Registration BE 2558 (2015).

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administrative and product information as well as the documents specifying the quality of the drugs shall be in compliance with the guidelines set forth by the FDA, which follows the rules of the Association of Southeast Asian Nations (ASEAN) Harmonization on Pharmaceutical Registration. Upon approval, the newly approved drug formulas for new drugs, new generic drugs, whereby the prototype of such drugs is still under the safety monitoring programme (SMP) and new biological products shall still be monitored and are subject to at least a one-year SMP depending on the risk level of the drugs.[12] Moreover, advertisement of any drug shall be approved by the FDA before being disseminated. The process will take 15 to 80 days.

Under the Medical Device Act, medical devices are categorised into three subcategories, each with different prerequisite obligations.[13] Generally speaking though, any person wishing to import medical devices is required to either obtain a prior licence, notify the relevant authorities, or notify and register the medical device prior to the manufacturing or importation, as the case may be.[14]

vi Regulatory incentives

The Trade Secrets Act contains a provision governing the duties of the state to maintain trade secrets of drugs, which are in the form of testing results or information on drugs which is prepared, discovered or created by an applicant, and such applicant has requested the state agencies to maintain the information as trade secrets.[15] However, under such provision, only one notification has been issued. This notification specifically aimed to protect pharmacopoeia information on modern drugs, which use new chemicals that have never been registered in Thailand.[16] The notification provides guidelines on the safe keeping of the approved and registered pharmacopoeia information as trade secrets for five years from the approval date.[17]

Thailand has no special provisions to encourage the development of products for rare diseases, diseases that are prevalent in developing countries, or paediatric use.

vii Post-approval controls

The Post Marketing Bureau of Drug Control, under the control of the Drug Control Bureau, is mainly responsible for the control and supervision of post-approval controls. The Post Marketing Bureau of Drug Control has two main duties: to monitor manufacturing facilities and drug safety and quality after the applicant has obtained the required approval from the FDA. Manufacturing facilities that have been approved are inspected in accordance with the relevant Ministerial Regulations and Notifications. Facilities must be in compliance with the

12 Notification of the Food and Drug Administration Re: the Criteria on the Risk-Based Approach Safety Monitoring Program BE 2560 (2017).

13 Section 6 of the Medical Device Act BE 2551 (2008).

14 ibid.

15 Section 15 of the Trade Secrets Act BE 2545 (2002).

16 Clause 3 of the Rule of the Ministry of Public Health Re; the Keeping of Trade Secrets of Pharmacopoeia Registration Information BE 2550 (2007).

17 Clauses 18 and 19 of the Rule of Ministry of Public Health Re: the Keeping of Trade Secrets of Pharmacopoeia Registration Information BE 2550 (2007).

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Pharmaceutical Inspection Co-operation Scheme (PIC/S).[18] For the monitoring of product safety and quality, officers of the Post Marketing Bureau of Drug Control are vested with the authority provided by the relevant Act, Notifications or Ministerial Regulations to conduct certain actions are to ensure that drugs approved for distribution are safe and comply with the required standards under the law. For instance, a notification issued under the Medical Act allows the officers to order the manufacturer, importer or distributor to recall unsafe drugs, or provide such drugs to the officers for further inspection and disposal.[19] In relation to medical devices, the Medical Device Act imposes obligations on manufacturers, distributors and importers.[20] Post-market controls on medical devices involve surveillance of medical devices to prevent injury that may be the result of the use of the medical device, as well as to allow the users the opportunity to file a complaint in relation to the medical device for the FDA's further inspection.[21] In addition, a notification was issued to provide procedures for the submission of a device defect report or adverse event report as well as the ensuing field safety corrective report.

In 2020, notifications were issued in relation to quality and safety to ensure consumer protection. In this regard, a notification[22] was issued to impose an obligation on any person who has registered a place for manufacture of a medical device, authorised person, person who gave notice about the manufacture or importation of a medical device or person who gave notice of and registered the manufacture or importation of a medical device, as the case maybe. The notification requires the preparation of academic documents certifying that such medical device manufactured or imported is up to acceptable standards, has the required capacity, as well as being safe for use. In this regard, the aforementioned persons are required to provide these academic documents to officers when the documents are requested.

To monitor and control medical device quality and to ensure the safety of consumers, a notification[23] was issued to govern and regulate medical devices, whereby any person who registered a place for manufacture of a medical device, authorised person, person who gave notice about the manufacture or importation of a medical device or person who gave notice and registered the manufacture or importation of a medical device shall arrange for a channel for customer's complaints, recording of such complaints, as well as a system to manage complaints in relation to the medical device manufactured, imported or sold, as the case may be. The summary of the aforesaid information shall be provided to officers for further inspection when such information is requested.

In addition, for the purpose of allowing end-users of any medical device to receive the required information in relation to the usage and maintenance of that medical device, and to

18 Ministerial Regulation Re: Modern Pharmaceutical Manufacturing BE 2546 (2003) and Notification of the Ministry of Public Health Re: Good Manufacturing Practice Requirements for Modern Medicines and Amendments of Good manufacturing Practice Requirements for Traditional Medicines in accordance with the Drug Act BE 2559 (2016).

19 Ministerial Regulation No. 20 (BE 2525) (1982), issued under the Drug Act BE 2510 (1967).

20 Section 41 of the Medical Device Act BE 2551 (2008).

21 ibid.

22 Notification of the Food and Drugs Administration Re: Rules Conditions and Procedures for the Arrangement of Academic Documents to Certify the Quality Capacity and Safety for Officer Inspection Upon Request BE 2563 (2020).

23 Notification of Ministry of Public Health Re: Rules Conditions and Procedures for the Provision of Complaint Channel, Recording of Complaint, and System to Manage Complaint to Medical Device Manufactured, Imported or Sold for the Inspection of Officer BE 2563 (2020).

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ensure safe usage of that medical device, the Notification of the Ministry of Public Health[24] was issued to govern the details provided on the device label. In essence, the notification provides specific requirements in relation to the language used and other contents of the label (i.e., name of the product, details of that product, components, method of use, type and kind, objective and purpose, name and place of the manufacturer or importer, licence number, or details on notification receipt, notification or registration receipt, caution, as well as the details for the maintenance of that medical device). The notification also provides details in relation to the medical device documentation and the details required thereto. In this regard, the notification allows the medical device documentation to be presented in a paper or other form, which is included in the packaging of the medical device. The medical device documentation also covers the medical device manual guide. Certain types of medical devices are exempt from having to comply with the labelling and medical device documentation details requirement pursuant to the above-mentioned requirements. Nonetheless, certain details determined under this notification are still required to be presented. The notification also requires any authorised importer of a medical device to present a label in compliance with the details set forth in the notification to the medical device inspection zone, as well as to arrange for a label to be prepared in compliance with the requirement set forth in this notification within 180 days after the officer of the medical device inspection zone has permitted the importation of such medical device, before such product is sold.

viii Manufacturing controls

As mentioned in Section V, the Drug Act requires that any person who wishes to manufacture drugs in Thailand obtain a licence from the FDA.[25] In this regard, the applicant shall provide the required evidence (i.e., the floor plan of the manufacturing facility, which is approved by the FDA, evidence of ownership over the assets and properties, affidavit if the applicant is a juristic person, and other required evidence, such as factory licence or building construction permit if the facilities fall within the size and manufacturing power as required under the relevant laws).[26] After obtaining a licence for the manufacture of modern drugs, the manufacturer must have at least two pharmacists to manage the operations and to monitor drugs at the premises during business hours.[27]

In 2020, a guideline for good distribution practices was issued to govern and provide standards for the wholesale distribution of drugs, covering drug manufacturers, distributors and importers. Specifically, the guideline was issued to cover the management of drug quality, personnel, place of business operation and equipment, document system, operation, inspection, delivery, etc.

In this regard, the Ministerial Regulation Re: The Determination of Rules Conditions and Procedures for the Manufacturing of Modern Drugs BE 2563 (2020) was issued to impose additional obligations for the authorised drug manufacturers. In this regard, the

24 Notification of Ministry of Public Health Re: Rules Conditions and Procedures on Labelling and Documents Regulating Medical Device BE 2563 (2020).

25 Section 12 of the Drug Act BE 2510 (1967).

26 Thai Government, 'Application for Obtaining License to Manufacture Modern Drugs' and 'The Application for the Consideration of Floor Plan of the Modern Drug Manufacturing Facility and Traditional Drug Manufacturing Facility' – www.fda.moph.go.th/sites/drug/SitePages/Zone_manual.aspx?Name=%E0%B%A2%E0%B8%B2 assessed 10 December 2019.

27 Section 20 of the Drug Act BE 2510 (1967).

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obligation to manufacture and distribute drugs in accordance with rules, conditions and procedures for the manufacture and distribution of drugs is determined by the Ministry of Public Health.

Any person wishing to manufacture any category of medical device in Thailand must have its place of business operation registered with the FDA[28] and obtain a manufacturing licence.[29] A Notification of the Ministry of Public Health[30] was issued to categorise medical devices to let the operators know when the manufacture or importation of the medical device requires notification to be sent to the FDA and the device needs to be registered with the FDA. This notification represents a continuation to the amendment of the Medical Device Act made during 2019, specifically for the determination and grouping of medical devices or a group of medical devices into different categories based on the level of risk of harm to health, body, or life of humans or animals or impact on public health in general.

In addition, a notification of the Ministry of Public Health[31] was issued to determine the standards of medical devices listed in the notification, requiring the manufacturer or importer to comply with such standards to provide safety for consumers.

ix Advertising and promotion

The Consumer Protection Act generally governs the content of advertisements as well as labelling requirements. However, the Drug Act and Medical Device Act specifically contain chapters governing the advertisement of drugs and medical devices, respectively.[32] Both acts set forth two fundamental requirements for advertising drugs and medical devices.

First, a party must obtain prior approval for the content of the advertisement before that advertisement can be disseminated.[33] In addition, there is also an obligation to obtain an advertising licence for the purposes of advertisements that contain information related to medical devices.[34]

Second, both acts provide guidelines set forth by the FDA, whereby the content of an advertisement shall not contain information that is false, exaggerated, misleading, or different from the details approved by the FDA.[35]

In addition to the Drug Act and the Medical Device Act, other rules and Ministerial Regulations issued under both acts provide additional requirements as to the advertisement of drugs and medical devices. For instance, the FDA issued a rule governing presentation of drug names, drug properties, and recommendations for usage and warnings.[36] The FDA also issued

28 Section 15 of the Medical Device Act BE 2551 (2008).

29 Section 17 of the Medical Device Act BE 2551 (2008).

30 Notification of the Ministry of Public Health Re: Group of Medical Devices or Medical Device where the Manufacturer or Importer shall Notify and make Registration BE 2563 (2020).

31 Notification of the Ministry of Public Health Re: Standards of Medical Device for the Compliance of the Manufacturer or Importer BE 2563 (2020).

32 Chapter 7 of the Medical Device Act BE 2551 (2008) and Chapter 11 of the Drug Act BE 2510 (1967).

33 Section 88 *bis* of the Drug Act BE 2510 (1967), and Section 57 of the Medical Device Act, BE 2551 (2008).

34 Section 57 of the Medical Device Act BE 2551 (2008).

35 Section 88 of the Drug Act BE 2510 (1967), and Section 59 of the Medical Device Act BE 2551 (2008).

36 Rules of the Food and Drug Administration Re: Rules on Advertisement of Drugs BE 2545 (2002).

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a notification that provides details regarding prohibited content and other requirements in the advertisement of medical devices, and rules and guidelines for the references to academic studies or research to support information in advertisements related to medical devices.[37]

In 2020, the notification[38] was issued to exempt certain methods of advertisements for medical devices from having to apply for prior approval. In this regard, the advertisement containing only a trade name, a trademark or a trade logo, without specifying the properties, benefits, qualities, standards, components or origin of the medical device to incentivise the viewers to purchase the product shall be exempt from having to apply for prior approval for making advertisements from the FDA.

Another notification[39] was issued to exempt advertisements made directly to medical professionals and the public health sector. In this regard, these advertisements shall not contain details or wording that are in violation of the Medical Device Act, and shall clearly contain a statement that the advertisement is made only for medical professionals and the public health sector. If so, an application for prior approval for making the advertisement would not be required. Advertisers who are exempt from having to obtain prior approval under this notification shall notify the FDA of the advertisement using the form contained in the notification.

x Distributors and wholesalers

The sale of modern drugs is prohibited unless a licence has been granted by the FDA.[40]

The Notification Re: Permission and Issuance of a License to Sell Modern Drugs BE 2556 (2013) prescribes the application form and other obligations that an applicant must comply with to receive a distributing licence or a wholesaler licence. Generally, depending on the type of licence, the facilities for distribution or storage of drugs must follow the notification. A distributor or wholesaler is also required to produce purchase reports, as well as to generate sales reports for submission to the FDA as required. There are also other obligations that must be complied with (i.e., the distributor shall have a pharmacist present during business hours to distribute drugs and monitor activities). In addition, the drug distributors and wholesalers shall comply with the guidelines for good distribution practices in relation to the transportation, storage, personnel and document standards and requirements set forth under such guidelines as mentioned in Section II.viii.

Distribution of medical devices is prohibited unless a licence for the distribution of such medical device has been granted.[41] The Notification Re: the Permission and the Issuance of Medical Device Distribution Licences BE 2555 (2012) was issued to govern the issuance of licences and imposition of obligations on the applicant.

37 Notification of the Food and Drug Administration Re: Rules Conditions and Procedures on Advertisement of Medical Device BE 2553 (2010).

38 Notification of the Ministry of Public Health Re: Exemption of certain Characteristics of Advertisement from having to Apply for Prior Approval BE 2563 (2020).

39 Notification of Ministry of Public Health Re: Rules Conditions and Procedures for Advertisement directly to Medical Professional Practitioner and Public Health that is Exempted from Prior Approval BE 2563 (2020).

40 Section 12 of the Drug Act BE 2510 (1967).

41 Section 6 and Section 24 Paragraph 2 of the Medical Device Act BE 2551 (2008).

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xi Classification of products

Drugs are categorised as modern, traditional, dangerous, specially controlled, external-use, site-specific, household, packaged, and herbal.[42] The MOPH, with advice from the Drug Committee, has the authority to classify drugs into one of these categories by making an announcement in the Royal Gazette.[43]

The Medical Device Act classifies medical devices into different categories each with different restrictions and requirements.[44] The MOPH, with advice from the Medical Device Committee, has the authority to classify medical devices based on risk and safety characteristics.

xii Imports and exports

An import licence, granted by the FDA, is required to import drugs into Thailand.

Any person wishing to import medical devices is required to register a place of business operations with the FDA.

In 2020, the Ministerial Regulation No. 30 (BE 2563) (2020) issued under the Drug Act imposed additional obligations on authorised drug importers, such as the obligation to only import drugs that are up to the manufacturing standard as determined by the Ministry of Public Health or equivalent standard as determined by the Secretary of the Food and Drug Administration.

Both the Drug Act and the Medical Device Act do not impose an obligation on an exporter to obtain a licence for the exportation of drugs or medical devices. However, in practice, the Thai Customs Department will request an exporter to provide an export certificate. For example, an export of medical device certificate, issued by the FDA, is evidence specifying that the exporter (or the manufacturer) is the owner of the products. This certificate also indicates the market status and shows that this person has already obtained and complied with the requirements of the law in relation to the medical device.[45]

In addition, the notification of the Ministry of Public Health[46], as mentioned above in Section II.viii, was issued to govern medical device standards for medical devices to be imported into Thailand and must be complied with by the medical device importer.

xiii Controlled substances

The Narcotics Control Division has control over import, export, commercial sale and possession of narcotics and psychotropic substances.[47] It is also responsible for the approval, revocation and suspension of licences for import, export, commercial sale, and possession of narcotics and psychotropic substances. For instance, the Narcotics Act provides that no person shall import, export, commence commercial sale of or possess dangerous narcotics such as heroin.[48]

42 Section 4 of the Drug Act BE 2510 (1967).

43 Section 76 and Section 78 of the Drug Act BE 2510 (1967).

44 Section 6 of the Medical Device Act BE 2551 (2008).

45 Food and Drug Administration, 'The Application for Export of Medical Device Certificate', p. 1.

46 Notification of the Ministry of Public Health Re: Standards of Medical Device for the Compliance of the Manufacturer or Importer BE 2563 (2020).

47 Order of Narcotics Control Division No. 4/2562 Re: Determination of Duties and Power of the Narcotics Controls Division.

48 Section 15 of the Narcotics Act BE 2522 (1979).

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xiv Enforcement

One of the main responsibilities of the FDA involves surveillance of products to maintain product quality and standards, and to prevent violations under the Drug Act and the Medical Device Act. In this regard, FDA officers will, from time to time, initiate random spot checks to ensure that the products (i.e., drugs and medical devices) remain in compliance with the law. If a spot check reveals any failure to comply with the law, or in the case of a complaint made to the FDA, the enforcement phase will commence, which could lead to penalties for the violation as provided in the aforementioned acts.

III PRICING AND REIMBURSEMENT

In Thailand, procurement by government agencies, including public hospitals, is subject to the criteria and requirements under the Public Procurement and Management of Supplies Act, BE 2560 (2017). In this regard, drug prices for public hospitals are prescribed by the National Drug System Development Committee. The latest list was announced in the Government Gazette on 22 April 2019.

Regarding reimbursement, Thailand has three types of the public health coverage: the civil service welfare systems for central and local civil officers and their family, social security for eligible employees in the private sector, and the Universal Coverage scheme (UC) for all other Thai nationals.[49]

The benefits packages, payment systems and funding for each programme are different from one another. The civil service welfare system is funded and regulated by the Comptroller General's Department of the Ministry of Finance or the Ministry of Interior (for local officers), social security is funded by the Social Security Office, while the UC is funded by the National Health Security Office under the National Health Security Act, BE 2545 (2002).

It is notable that all three programmes universally use the National List of Essential Medicines (NLEM) as a guideline for reimbursable drugs. The NLEM is a list of reimbursable drugs announced by the Drug System Development Committee, including the conditions (or lack thereof) for medical professionals to prescribe reimbursable drugs under the coverage. The drugs outside of the NLEM can also be reimbursed; however, only with a prescription by medical professionals in charge as necessary to cure the patient of a sickness.

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

Under the Drug Act, in the case that a drug licence is not granted or the authority does not renew an existing licence, an applicant has the right to appeal against that decision to the Ministry of Public Health within 30 days from receipt of notice that the licence will not be issued or renewed. If an applicant does not appeal against that decision within 30 days, the licence will be revoked.

Because there is no specific period for consideration of an appeal under the Drug Act, consideration for such an appeal with be as specified in the Administrative Procedure Act, BE 2539, meaning the consideration process shall be completed within 30 days from the date of receipt of the appeal.

49 '10 Things in Health Security' by National Health Security Office.

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In the case of medical devices, if the authority does not issue an establishment registration certificate, licence or specifications declaration receipt, the applicant has the right to appeal against the authority's order in writing to the Minister of Public Health within 30 days from the date of receipt of notice of the non-issuance of establishment registration certificate, licence or specifications declaration receipt, as the case may be.

When considering an appeal under the Medical Device Act, the Minister of Public Health shall complete the appeal process within 120 days from the date of receipt of the appeal. If, due to necessity, consideration cannot be completed within this time period, written notice shall be sent to the appellant before the expiry of the time period. The period for consideration of an appeal may be extended for not more than 120 days from the expiry of the initial 120-day consideration time period.

Pursuant to both Acts, the judgment of the Minister of Public Health is considered to be final. However, if the appellant is not satisfied with the judgment of the Minister of Public Health, the appellant has right to file a case with the Administrative Court.

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYORS

Thai law regulates the purchase of medicines and medical devices by the government. For the most part, the organisations that generally make decisions concerning utilisation or reimbursement of medicines and medical devices in Thailand are the Government Pharmaceutical Organisation (GPO), the Thai Red Cross Society and public hospitals.

These organisations need to comply with a set of rules regarding the procurement of these products.[50] Thus, there should be no financial relationships between product suppliers or prescribers.

Generally, there are three methods for the procurement of products: the general solicitation method, the selection method and the specific method. The general solicitation method can be made through an e-market, e-bidding or examination of price.[51] The e-market method is used when procurement of products will cost more than 500,000 baht, such products do not have complex or specific characteristics and the details and specifications are provided in the e-catalogue system of the Comptroller General's Department.[52] The e-bidding method applies to the procurement of products costing more than 500,000 baht and the specifications are not provided in the e-catalogue system in accordance with the methods specified by the Comptroller General's Department.[53] The examination of price method must be used in the case of procurement of products costing more than 500,000 baht and there is no internet connection within the area of the relevant government organisations.[54] Under the selection method, a government agency will solicit at least three business operators who possess specific qualifications determined by the relevant agency to submit a proposal, unless there are fewer than three business operators who possess such qualifications.[55] Under the

50 Public Procurement and Management of Supplies Act BE 2560 (2017).

51 Ministerial Regulation re: Public Procurement and Management of Supplies BE 2560 (2017).

52 id. Article 30.

53 id. Article 31.

54 id. Article 32

55 Section 55(2) of the Public Procurement and Management of Supplies Act B.E. 2560 (2017).

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specific method, a government agency may solicit a single business operator who possesses specific qualifications determined by the relevant agency to submit a proposal, or offers bargain prices where the cost does not exceed 500,000 baht for a single procurement.[56]

In March 2019, the committee that analysed issues related to public procurement and management of supplies issued guidelines for the purchase of medicines and medical devices for relevant government agencies.[57] Under these guidelines, when a government agency intends to purchase medicines or medical supplies under the NLEM that the GPO or the Thai Red Cross Society produces and distributes, that government agency is required to procure such medicines and medical supplies using the specific method. However, the government agency may purchase such products from any other suppliers when the GPO or the Thai Red Cross Society is not able to produce and distribute the products within the specified period according to the annual plan submitted by the relevant government agency.[58]

On 29 January 2020, the Ministerial Regulation[59] was published in the Royal Gazette to determine the products that the state promotes or supports, as well as the procurement method of these products. Certain types of drugs and medical supplies are also listed as supported and promoted products. In this regard, the Ministerial Regulation provides budget allowed for the procurement of the listed drugs or medical supplies, method of procurement or organisation, and list of promoted or supported supplies.

With regard to the purchase of medicines or medical supplies by the private sector, the authorised private sector entity may purchase these products certified by the FDA from any suppliers without restrictions.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

As there is no specific compensation system for persons injured by medicines or medical devices in Thailand, the general principles of law regarding tort and product liability apply.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

There is no specific rule or law on the settlement of patent disputes between an originator and generic manufacturers provided under intellectual property laws. Also, there is no specific provision targeting drug or medical device markets under the current antitrust law.

ii Transactional issues

There is no specific law governing licensing or strategic collaborations, joint ventures or mergers and acquisitions in relation to medicines and medical devices.

56 id. Section 55(3).

57 The most urgent letter of the committee on analysing the problems on Public Procurement and Management of Supplies the Comptroller General's Department No. GorKor. (GorWorJor) 0405.2/Wor 119 dated 12 March 2019.

58 Clause 3.1.1 of the Most Urgent Letter of the Committee on analysing the problems on Public Procurement and Management of Supplies the Comptroller General's Department No. GorKor. (GorWorJor) 0405.2/Wor 119 dated 12 March 2019.

59 Ministerial Regulation Re: Determination of the Promoted and Supported Products and the Procurement Methods BE 2563 (2020).

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VIII CURRENT DEVELOPMENTS

i Drug Act

A Notification of the Ministry of Public Health Re: Rules, Conditions and Procedures for Drug Distribution is currently being drafted and is expected to be issued in 2021. The intention of the law is to provide good distribution practices to ensure that quality is maintained from the manufacturing and importation stage to the storage and supplying stage.

On a related matter, a general guideline for good distribution practices was issued by the Drug Department, FDA, on 1 October 2020. This guideline (which is a translation of the PIC/S Guide to Good Distribution Practice for Medicinal Products (PE 011-1,1 June 2014)) sets forth general ideas and guidelines for the drug manufacturers and importers to follow. Once the aforesaid draft notification is issued, the operators shall follow the notification and use the guideline as a supplement.

Ministerial regulations issued under the amended Drug Act

Ministerial Regulation Re: The Determination of Rules, Conditions and Procedures for the Manufacturing of Modern Drugs BE 2563 (2020) was issued to:

a revise the application for manufacture of sample drugs for the registration of drug formula;

b prescribe additional duties of drug manufacturers. For instance, to:
- produce an annual manufacturing report and exportation of drug report;
- manufacture and distribute drugs in accordance with the guideline for good distribution practices; and
- comply with the representations and warranties set forth in the drug registration;

c prescribe additional conditions with regard to the renewal of the licence for the drug manufacture (i.e., provision of the right to reject the renewal of the drug manufacturing licence if the applicant possesses prohibited characteristics under the Drug Act, the place for drug manufacture does not pass the test, or the operator does not pass the drug distribution test); and

d permit the drug manufacturers to apply for the increase of its drug storage facility.

Ministerial Regulation No. 30 (BE 2563) (2020) issued under the Drug Act was issued to:

a permit the Ministry of Public Health to issue characteristics of the drug storage facility, as well as those for the equipment used for storage of drugs;

b prescribe additional duties of drug importers. For instance, to:
- import only drugs of the quality as specified in the notification of the Ministry of Public Health or the equivalent standard;
- comply with the guideline on storage and distribution of drugs;
- comply with the representations and warranties set forth in the drug registration; and
- report the exportation of drugs; and

c prescribe additional conditions with regard to the renewal of the licence for the importation of drugs (i.e., provision of the right to refuse the renewal of the drug importation licence if the applicant possesses prohibited characteristics under the Drug Act or does not pass the requirement on drug storage and distribution test).

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ii Amendment to the Medical Device Act

Several ministerial regulations have been issued under the Medical Device Act (see details aforementioned). In addition to those mentioned above, please see further updates on covid-19-related notifications below.

Covid-19-related notifications

a Notification of the Ministry of Public Health Re: Standards of Medical Device for the Compliance of the Manufacturer or Importer (No. 3) BE 2563 (2020) was issued to provide standards for manufacture or importation of single-use medical masks and N95 masks.

b Notification of the Ministry of Public Health Re: Medical Device being Exempted from Section 6(18) of the Medical Device Act (No.3) BE 2563 (2020) was issued to exempt any operator who manufactures or imports single-use medical masks, N95 masks or masks with better protection and standards from having to comply with regulations regarding notification about the manufacture or importation, or notification about and registration of manufacture or importation, as the case maybe.

c Notification of the Food and Drug Administration Re: Standards for Medical Mask for One-time Usage BE 2563 (2020) was issued to specify the standards for medical mask for one-time usage to be manufactured or imported by the manufacture or importer, as the case maybe.

iii Narcotic Act

Pursuant to the Narcotic Act BE 2522 and latest amendment (No. 7) BE 2563 (the Narcotic Act), the law permits the sale and possession of cannabis, subject to conditions and requirements under the Narcotic Act and the relevant regulations, to allow hospitals to utilise cannabis in the treatment for their patients.

In this regard, a guideline for the permission for sale of narcotics under Category V, Cannabis, for the treatment of patients (modern medicine) (the Guideline) was issued to provide guidelines on the application process, requirements, obligations of permitted persons, and guidelines on prescription of cannabis to patients, to allow patients to have access to treatment using cannabis in an effective and reasonable way, to maximise usage of cannabis for the treatment of patients while the regulation governing sale and the utilisation of cannabis, i.e., the Ministerial Regulation Re: Application and Permission for the Manufacturing, Importing Exporting Disposing or Possessing Cannabis, is not yet effective.

Under this Guideline, the following persons are eligible to apply for the licence to sell narcotics under Category V, Cannabis: (1) governmental organisations whose role is to provide medical or pharmaceutical services or the Thai Red Cross Society; and (2) medical practitioners, pharmacist practitioners or dental practitioners.

If the applicant is a juristic entity, it shall have a medical practitioner, pharmacist or dental practitioner who has passed training for utilisation of cannabis and extraction of cannabis for medical usage hosted by the Ministry of Public Health or other training sessions as approved by the Ministry of Public Health. The practitioner shall also be registered as a cannabis prescriber with the Food and Drug Administration.

After receiving permission to sell cannabis, the licensed person shall be obliged to perform certain duties; for instance, to arrange for a system to control the prescription of cannabis to the patients which complies with and follows the Guideline, to distribute cannabis only within the premises prescribed in the licence, to arrange for a facility to store

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and prevent loss or damage to the drug, to clearly separate such drug from other substances and objects, as well as to arrange for the Special Access Scheme monitoring programme (intensive monitoring) to monitor the effectiveness and safety with regard to the usage of cannabis for the treatment of patients, and report such results to the FDA.

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Appendix 1

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