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Medicinal product regulation and product liability in Thailand: overview

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REGULATORY OVERVIEW

1. What are the main legislation and regulatory authorities for pharmaceuticals in your jurisdiction?

Legislation

The key piece of legislation regulating drugs in Thailand is the Drug Act 1967, as amended (Drug Act), together with ministerial regulations and notifications.

Regulatory authorities

The regulation of medicinal drugs in Thailand is overseen by the Ministry of Public Health (MOPH). The Drug Control Division of the Food and Drug Administration (FDA) (*www.fda.moph.go.th/sites/Drug/EN/Pages/Main.aspx*), a department of the MOPH, handles the four main aspects of drug regulation:

- Pre-marketing control (including licensing and registration).
- Post-marketing monitoring and surveillance.
- Consumer education and dissemination of information.
- Promotion of technological development and research for export.

Licences are required for the manufacturing, importation, or selling of pharmaceuticals. Separate licensing regimes exist for "modern medicines" and "traditional medicines".

2. Briefly outline how biologicals and combination products are regulated in your jurisdiction.

All pharmaceutical products, including chemical, biological, and combination products, are regulated by the FDA in accordance with the Drug Act. Before launching any pharmaceutical products in Thailand, companies must first obtain a licence from the FDA to produce, sell, or import the products into the country. In addition, companies must also obtain marketing approval, that is, by registering their product for actual sales.

The marketing approval procedure and post-approval regulations of chemical, biological, and combination products are largely the same. The FDA requires an applicant to follow the Association of Southeast Asian Nations (ASEAN) Common Technical Dossier (ACTD), as the technical document template for submission of both biological and chemical drugs.

In particular, the approval process and requirements for new biological products are similar to those of new chemical (low-molecular-weight) drugs. Electronic dossier registration for new chemical drugs and new biological drugs has been effective since January 1, 2016, wherein the applicant can submit its dossier in the format of an electronic Common Technical Document Specification of International Conference on Harmonisation (ICH e-CTD). For other drug registrations, such as biosimilar and new combination drugs, the Thai FDA still accepts the hardcopy dossier submissions, wherein the ACTD format is the preferred version.

The approval process for follow-on biological products (that is, biosimilars) is more stringent than the approval process for generic chemical drugs. For a biosimilar product, the application dossier must include:

- Administrative and product information.
- Information regarding drug quality (drug substance and manufacturing process).
- Non-clinical and clinical trial data.
- A risk management plan.

For a combination product, if the combination is new, the FDA classifies it as a new drug. An application dossier must contain documentation similar to that of a new chemical or a new biological product.

3. Briefly outline how medical devices and diagnostics are regulated in your jurisdiction. Is there any specific regulation of health IT issues and mobile medical applications?

The key legislation that regulates medical devices and diagnostics is the Medical Device Act B.E. 2551 (2008), together with ministerial regulations and notifications of the Ministry of Public Health (MOPH).

A place of business registration (an establishment licence) by a local company is required, for both importers and manufacturers of medical devices/diagnostics.

Currently, medical devices are divided into three classes, depending on the level of control by the FDA.

Class 1 Licensed Medical Devices

This is the most rigorously controlled class, comprised mainly of condoms, HIV diagnostic kits, contact lenses, and so on. The following details for these medical devices, among other things, must be submitted to the FDA:

- Certificate of free sales.
- Certificate of quality system of manufacture, for example, the relevant International Organisation for Standardisation (ISO) certificate.
- Essential Principles of Safety and Performance of Medical Devices and Method Used to Demonstrate Conformity.
- Preclinical studies.

- Clinical evaluation.
- Sterility.
- Stability.
- Raw material and finished product specifications.
- Device labels and Instructions for Use.
- Product photo.
- Risk analysis.
- Manufacturing process and information.

The FDA requires an applicant to use the ASEAN Common Submission Dossier Template (CSDT) for the technical document requirements for submission of licensed medical devices.

Class 2 Notification Medical Devices

The level of control in this class is less stringent than class 1. Examples of medical devices in this class include physical therapy products, silicone breast implants, amphetamine diagnostic test kits and alcohol detectors. The documents required for submission to the FDA are similar to those of class 1. An applicant must prepare the dossier according to the CSDT.

Class 3 General Medical Devices

This class is subject to the least stringent control by the FDA. All medical devices which are not classified as class 1 or class 2 fall in this class. The required documents are:

- Certificate of free sales.
- Catalogue/product photo.
- Specifications.
- ISO 13485 (in some human use product categories, for example implant products and sterile products).

There are no specific regulations regarding health IT issues and mobile medical applications. According to the Medical Device Act, software and IT systems are also classified as medical devices. Normally, an importer will register it together with the main medical device.

PRICING, STATE FUNDING AND REIMBURSEMENT

4. What is the structure of the national healthcare system, and how is it funded?

There are three main schemes relating to the healthcare system in Thailand.

Social Security Scheme. This is administered by the Social Security Office and covers employers with one or more employees. However, this scheme is not applicable to:

- Government employees in the central, provincial and local administrations.
- Employees of foreign governments or international organisations.
- Employees stationed abroad, despite their employers' office being in Thailand.
- Private school teachers and headmasters.
- Students, including undergraduate students, nursing students and apprentice doctors who are employees of schools, universities or hospitals.
- Employees of other undertakings as prescribed by royal decree.

Civil Servant Medical Benefit Scheme (CSMBS). This is administered by the Social Security Office and covers government officials and their dependants (parents and up to three children).

National Health Insurance (THB 30 Scheme). This is administered by the MOPH and covers the remaining population not covered under either the Social Security Scheme or the CSMBS.

5. How are the prices of medicinal products regulated?

Prices of medicinal products are regulated when they are sold to government hospitals. The National Drug Development System Committee has been empowered to establish a median drug price, wherein public hospitals will purchase medicinal products not over the median price. Normally the drugs to be purchased are listed in the National List of Essential Drugs (NLED), a "maximum list" from which government hospitals are expected to select their individual hospital formulary. The prices of the drugs on this list are subject to a median price policy.

In addition, the Ministry of Finance has implemented a notification which sets prices for government hospitals. However, these prices only apply to persons under the CSMBS. The MOPH has implemented a notification on how much government hospitals are allowed to charge patients.

6. When is the cost of a medicinal product funded by the state or reimbursed? How is the pharmacist compensated for his dispensing services?

Medicines are reimbursed by the state when the drugs are listed in the NLED (*see Question 5*). However, this list is only available to government hospitals.

Government hospitals generally provide drugs from the NLED to civil servants under the CSMBS and to all other persons under the THB 30 Scheme. In this case, the patient either pays nothing to the hospital or, for people under the THB 30 Scheme, a maximum of THB 30 in certain circumstances. The hospital is reimbursed completely by the government. Medical devices are not listed on the NLED. However, in 2005 the Ministry of Finance began allowing the reimbursement of some medical therapy equipment and artificial organs for civil servants.

For persons under the Social Security Scheme, reimbursement is partially covered if the medicinal product was administered by a doctor in a government hospital. Persons under the Social Security Scheme can also acquire private health insurance to cover the remainder of the cost.

CLINICAL TRIALS

7. Outline the regulation of clinical trials.

Legislation and regulatory authorities

There is no centralised regulation for clinical trials. However, a draft bill covering human research has progressed to presentation to the National Legislative Assembly (currently no parliament is sitting in Thailand and such activities are undertaken by the National Legislative Assembly pending the next general election). At least six regulatory authorities have jurisdiction over various aspects of clinical trials:

- FDA of the MOPH.
- Department of Medical Sciences of the MOPH.
- Department of Communicable Diseases Control of the MOPH.

- Ethical Review Committee for Research in Human Subjects of the MOPH.
- National Sub-Committee of HIV Vaccine of the MOPH.
- Medical schools and hospitals with specific regulations and/or ethics committee.

The FDA does not have a direct mandate to regulate clinical trials in humans. Instead, the FDA's authority to control the import of drugs for research purposes is frequently used to indirectly allow the FDA to regulate clinical trials of drugs in humans.

Although Thailand has not yet ratified the following treaties on the conduct of clinical trials, it follows them:

- World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects 1964.
- International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use, Guidelines on Good Clinical Practice 1996 (ICH GCP). This sets out a standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials. It ensures consistency in relation to the quality of data and ethics.

Authorisations

To obtain approval for clinical trials in Thailand, the drug developer/sponsor must first select a research facility and a team of physicians to conduct the study. The facility is usually a hospital or university medical centre. The sponsor must then obtain approval to conduct a study in humans from the Ethical Review Committee for Research in Human Subjects of the MOPH (ERC) and/or the ethics committee of the research institute or university that will conduct the trial. This can take two to three months. If an approval is obtained from the ethics committee of the research institute or university conducting the trial, an approval from the ERC is usually optional (unless it is further required by the internal rules and regulations of that research facility).

Once the drug developer/sponsor receives approval from the relevant ethics committee, it can apply to the FDA for a licence to import investigational drugs into Thailand for research purposes. To obtain this licence, the drug developer/sponsor must submit approval from an authorised (or FDA approved) ethics committee, together with documentation, including:

- Details of the drugs to be imported.
- Pre-clinical trial reports.
- A complete clinical trial protocol.
- The estimated amount of drugs required.
- A power of attorney.

The licence is valid for four years from the approval date. If the clinical trial is not complete within four years and the number of investigational drugs is not adequate, a new import licence must be obtained.

Consent

There is no specific legislation governing clinical trials in Thailand. This area, including issues relating to consent, is regulated by the Civil Code, the National Health Act 2007, and the Mental Health Act 2008. Trial subjects are required to sign an informed consent form before commencement of clinical trials. The consent forms must emphasise that participation is voluntary and, therefore, subjects have the right to withdraw from the trial at any time.

To be valid, the consent form must be signed and dated by the volunteers. However, if they are unconscious, an authorised legal representative can sign the form on their behalf. Participants in the study cannot act as witnesses to the signature. The consent of volunteers or patients who are not capable/authorised to give consent can be provided by their legal representatives.

Trial pre-conditions

The trial pre-conditions and recruitment of the participants are in the protocol submitted to IRB/EC. A sponsor must have a local representative (that is, an investigator or co-investigator) to fulfil the appropriate local responsibilities. A sponsor is also responsible for the appropriate selection of investigators.

An import licence must be obtained for samples to be used in the trial.

Insurance is not always a mandatory requirement. The Ethics Committee determines whether insurance is required on a case by case basis, depending on the level of risk involved in the trial.

Procedural requirements

The following procedure must be complied with during the conduct of a clinical trial (*ICH GCP*):

- **Investigator brochure.** This brochure will gather the clinical and non-clinical information of the drug intended to be studied. The aim is to provide information to the investigator and the relevant persons in order to understand the Research Protocol (such as frequency/interval of drug administration, route of administration and safety monitoring). Only the sponsor and the investigator have access to the entire brochure and it is not made available online. This brochure must:
  - be regularly updated and contain all the essential information in relation to the product;
  - be prepared by the investigator (from the literatures/product leaflet/FDA registered number or from the reports of Investigational New Drug).

  The brochure should be attached with the project proposal and submitted to IRB/EC. There is no formal time limit for submission.
- **Source data.** Original documents must be archived for at least 15 years and include:
  - signed and dated consent forms;
  - patient OPD cards;
  - doctor's notes (or any other medical professional's note);
  - lab tests;
  - study evaluation tests; and
  - any other documents related to the research.
- **Monitoring by the sponsor and ethics committee.** To ensure the study does not raise any ethical or other issues, the sponsor and ethics committee must:
  - check all source data;
  - verify the quantity of medication delivered; and
  - prepare a report on any adverse effects.
- **Safety report.** This report must list any adverse events, serious adverse events, adverse drug reactions, or suspected or unexpected serious adverse reactions, and should be submitted to the ethics committee. According to the ICH guidelines, the sponsor should report the serious/unexpected adverse drug reactions (ADRs) to the investigator/medical centre and IRB/ECs as early as possible. The report should conform with the ICH *Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.*
- **Auditing.** This step ensures that the trial is conducted in accordance with the GCP guidelines.

MANUFACTURING

8. What is the authorisation process for manufacturing medicinal products?

Application

Applications are made to the FDA for Bangkok and its territories. Applications are made to the appropriate provincial public health offices for other provinces.

Conditions

A licence from the FDA is required for the manufacture of "modern medicines". The FDA issues a licence to manufacture, sell or import modern medicines, or order them into Thailand, if the applicant:

- Is the owner of the business and has sufficient property or status to be able to establish and operate the business.
- Is at least 20 years of age.
- Is resident in Thailand.
- Has not been convicted for an offence against certain laws, such as laws concerning narcotics and psychotropic substances.
- Has premises to produce, sell, import or store drugs and equipment for use in the production, sale or storage of drugs, and the control or maintenance of drug quality and quantity as prescribed in ministerial regulations.
- Uses a trade name that is not a repetition of, or similar to, the trade name used by a licensee whose licence is suspended or has been revoked for less than a full year.

All of the above conditions must be met to obtain a licence to manufacture in Thailand.

Restrictions on foreign applicants

A foreign applicant must have an appropriately authorised business in Thailand or be a resident of Thailand to obtain a licence to manufacture, sell or import drugs.

Key stages and timing

An application for a licence to manufacture is submitted to the Drug Control Division of the FDA. The applicant's buildings and facilities are then inspected by the FDA to assess compliance with Pharmaceutical Inspection Cooperation Scheme (PIC/S) Good Manufacturing Practices (GMP). The FDA then determines whether the applicant has adequate facilities and the appropriate personnel to manufacture these medicines.

Fee

The fees are listed on the Drug Control Division's website, but are only available in Thai. They are as follows:

- Licence to manufacture modern medicines: THB8,500.
- Licence to manufacture traditional medicines: THB1,500.

Period of authorisation and renewals

Licences for manufacturing medicines are valid up until 31 December of the year in which they are issued. An application for renewal must be submitted before expiration of the current licence.

Monitoring compliance and imposing penalties

Regulators can inspect manufacturing sites for GMP compliance, and monitor manufacturing process changes to ensure that there are no adverse effects on the safety or efficacy of the medicines being produced.

The regulator can suspend or revoke the manufacturing licence if the licensee violates any provision of the Drug Act. Licensees can appeal to the Minister of Public Health within 30 days of notification of an order to suspend or revoke a licence (*section 99, Drug Act BE 2510 (AD 1967)*).

According to the Drug Act, the decision of the Minister is final. The Minister can either dismiss the appeal or amend the order. However, in practice, companies can also contact relevant officials and the head of each relevant group if a licence cannot be obtained.

Another official remedy against a licensing decision is an action via the Thai Central Administrative Court. Thailand's Act on Establishment of Administrative Court and Administrative Court Procedure, B.E. 2542 (1999) gives the Administrative Court jurisdiction to issue an order in relation to any unlawful act by an administrative agency or state official, on a number of specified bases:

- By reason of acting without or beyond the scope of powers and duties (that is, ultra vires).
- In a manner inconsistent with the law (that is, conflict of laws), or the form, process, or procedure which is the material requirement for such act (that is, procedural impropriety).
- In bad faith.
- In a manner indicating unfair discrimination.
- Causing unnecessary process or excessive burden to the public.
- Amounting to an undue exercise of discretion.

Further, the authorities can impose fines and terms of imprisonment for manufacturing without a licence. Manufacturing modern medicines without a licence can lead to up to five years' imprisonment and a fine of up to THB10,000. Manufacturing traditional medicines without a licence can lead to up to three years' imprisonment and a fine of up to THB5,000.

MARKETING

Authorisation and abridged procedure

9. What is the authorisation process for marketing medicinal products?

Application

Applications are made to the FDA.

Authorisation conditions

Companies and individuals wishing to place a drug on the market must:

- Obtain a licence from the FDA to manufacture, sell or import drugs in Thailand.
- Then obtain FDA registration for the medicine to market and sell the drug in Thailand. Registration requirements differ for modern drugs (which include generics, new medicines and new generics) and traditional drugs. Registration of a modern drug requires an application to the Drug Control Division of the FDA for permission to import a drug sample into Thailand or, less frequently, permission to manufacture a sample.
- Then submit a full marketing approval application, together with samples, to the FDA for review and registration (*see below, Key stages and timing*).

Key stages and timing

The FDA review of a marketing approval application can take at least nine months, depending on the type of drug, with different timelines for new drugs and generic drugs. The review can take up to two years for a new drug that has never applied for a marketing licence in Thailand. The timeline also depends on the credibility and comprehensiveness of the information submitted along with the application. Before 4 August 2017, the FDA did not charge an evaluation fee for drug registration dossiers. Currently, the fee for

reviewing a drug registration dossier is THB185,000 for a new chemical drug or a new biological drug.

Once the review has been passed, the new drugs must undergo a two-year safety monitoring period, during which the product can only be prescribed in hospitals and clinics. Safety reports must then be submitted to the authorities for consideration as to whether general marketing will be permitted.

For generics, see *Question 11.*

Fee

The fees are not listed on the FDA's website. The fee for a licence to market a drug is THB2,000.

Period of authorisation and renewals

Once approved, the certificate of product registration is valid as long as the product marketing remains active. If the product is not on the market for longer than two consecutive years, the FDA will automatically cancel the registration.

Monitoring compliance and imposing penalties

To further ensure quality, safety, and efficacy of approved drugs, the Thai FDA, together with the drug analysis laboratory of the Medical Sciences Department under the MOPH is the main authority responsible for testing approved drugs on the market in Thailand. Samples are regularly tested at its laboratories to monitor the quality and safety of new and generic drugs.

The Thai FDA can, if necessary, remove drugs from the market. The authorities can also suspend or revoke a licence. A breach of a marketing authorisation is considered a criminal offence and is subject to both imprisonment and a fine. Licensees can appeal to the MOPH within 30 days from the date of notification of an order to suspend or revoke a licence.

10. What commitments and pharmacovigilance obligations apply after a company has obtained marketing authorisation? Are there further conditions concerning how the drug is distributed and accessible to patients?

Just before the licence for a new drug is issued, the licence holder must submit a protocol of Safety Monitoring Programme (SMP) to the FDA for review. After receiving the licence, the pharmaceutical product must follow the safety monitoring protocol of the FDA for at least two years. During the monitoring process, the new drug can only be used and sold in clinics and hospitals.

Some drugs can only be dispensed by hospitals during the SMP. In 2012, the FDA issued an announcement to set out guidelines for the SMP. The announcement provides a specific time frame for a licensee to submit the monitoring report. For instance, a report of a death that relates to use of the new drug must be reported verbally within 24 hours, and the completed written report must be submitted within seven days after first knowledge of the death. In 2017, the FDA has implemented a risk-based SMP approach, wherein a new drug is categorised into one of four classes, based on its risk. Class 1 is the highest risk, and includes drugs with teratogenicity. Class 4 is the lowest risk drug. The specific timeframe for a licensee to submit a monitoring report for class 1 to 3 remains the same as for the 2012 regulation. The safety monitoring period for class 1 and 2 drugs is two years and the period for class 3 drugs is one year.

If there is no report of serious events or side effects, the committee will consider the regularly submitted report, and release the drug from the SMP, so that the drug can be sold in any clinics, hospitals, and pharmacies throughout Thailand. In addition, the said drug is eligible to be further listed in the NLED.

11. Which medicinal products can benefit from the abridged procedure for marketing authorisation and what conditions and procedure apply? What information can the applicant rely on?

Generics enjoy an abridged registration process. To benefit from the streamlined procedures, the product must meet the criteria for a generic. Generics are pharmaceutical products with the same active ingredients and the same dosage forms as those of the original products, but they are made by different manufacturers.

To register generics, an applicant must submit an application for permission to import or manufacture drug samples. The requirement is similar to that for registration of new drugs (*see Question 9, Key stages and timing*).

The applicant then submits various details about the drug production process to be used including Part I Administration and Product Information, and Part II Quality in which the key parameters are:

- Manufacturing methods.
- In-process controls and process validation.
- Specifications of the active ingredients.
- Excipients used in the production process.

Information about the drug storage conditions and details about the stability of the drug according to ASEAN stability guidelines are also required.

The applicant then submits a formal application for a drug registration certificate. The entire process can take six to 12 months.

There are also "new generics", or medicines with the same active ingredients, doses and dosage forms as those of new compounds registered after 1992. To register new generics, the FDA only requires dossiers of bioequivalence studies, in addition to the required documentation for a generics submission (*see above*).

While a marketing authorisation application for a new drug requires disclosure of any patent covering that drug, generic drug applications do not require patent disclosure. The requirement for disclosure of any patent covering a new drug has been effective since 23 April 2013.

12. Are foreign marketing authorisations recognised in your jurisdiction?

An existing market authorisation issued in a foreign jurisdiction does not provide fast-track approval for an application filed with the FDA. However, the application requires the applicant to inform the FDA of any approved and pending marketing authorisation for the product in other countries.

If the foreign authorisation belongs to a country where regulatory practice is credible and globally accepted, this adds credibility to the authorisation application and the evidence submitted to the FDA with the application for marketing approval.

Additionally, following the Association of Southeast Asian Nations (ASEAN) Harmonisation on Pharmaceutical Product Registration of 1 January 2009, the FDA implemented the ASEAN Common Technical Requirements (ACTR) and ASEAN Common Technical Dossier (ACTD) on quality, safety and efficacy, which provides guidelines on analytical and process validation, stability studies, and bioavailability or bioequivalence. It means that in the ASEAN region, the same requirements exist for all drug products, which facilitates the registration process. However, some local specifics still remain.

Parallel imports

13. Are parallel imports of medicinal products into your jurisdiction allowed?

Parallel imports are not regulated in Thailand, because the exhaustion of rights principle is recognised by most intellectual property laws in Thailand.

However, parallel imports are not permitted in the pharmaceutical sector, because it is mandatory for a company to preliminarily obtain an import licence and product registration locally. Also, the FDA will not accept an application for a product that has a trade mark which is identical to other products in the Thai market, unless this product has the same manufacturer and the manufacturer has given its authorisation to use and sell such product.

For information on pharmaceutical patents, trade marks, competition law, patent licensing, generic entry, abuse of dominance and parallel imports, see *Pharmaceutical IP and Competition Law in Thailand: overview*.

Restrictions on dealings with healthcare professionals

14. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

The Drug Act does not restrict marketing practices. However, a state official can only receive property or any other benefit from any person (other than a relative) if the value of the benefit received from each person, and on each occasion, does not exceed THB3,000 (*section 103, Organic Act 1999 (as amended) and Notification of the National Counter Corruption Commission Concerning the Provisions on the Acceptance of Property or Any Other Benefit on an Ethical Basis by State Officials B.E. 2543 (2000)*). This applies to gifts, entertainment, services, training and so on.

For pharmacists or officers who are not employed by the government, marketing practice is restricted by the Code of Sales and Marketing Practices issued by the Pharmaceutical Research and Manufacturers Association (PReMA) (PReMA Code). The PReMA Code provides detailed marketing restrictions in different situations.

Clinical assessments, post-marketing surveillance and experience programmes, and post-authorisation studies must not be disguised as promotion. Such assessments, programmes and studies must be conducted with a primary scientific or educational purpose. Materials relating to pharmaceutical products and their uses, whether or not they are promotional in nature, which is sponsored by a company, must clearly indicate who it has been sponsored by. Product information furnished to healthcare professionals must be current, accurate, balanced, and cannot be misleading, either directly or by implication, omission, or addition. Scientific data to support the claims and recommendations for use must be made available, on request, to healthcare providers.

Generally, gifts to healthcare professionals and institutions for customary courtesy and traditional occasions are allowed. The gift must not be distributed frequently and the value of any gift must not exceed THB3,000 per healthcare facility or professional on each occasion.

Special requirements and guidelines apply to government purchases of pharmaceuticals, particularly during the procurement process and tender bidding. Pharmaceutical product procurement must generally be conducted with a higher than normal degree of transparency (all quantities and pricings of products must be disclosed).

In addition, the Ministry of Public Health Circular dated 2 March 2018 expressly prohibits the exchange of benefits relating to the procurement of drugs, and is aimed at preventing corruption in the purchasing of drugs and medical devices under the Civil Servant Medical Benefit Scheme. The Circular is aligned with the Cabinet's resolution on Thailand's National Anti-Corruption Strategy. According to the Circular, no discount or free samples will be provided to the welfare fund of the hospitals. The conceptual idea is that the government's payment will be of the net price.

SALES AND MARKETING

15. What are the restrictions on selling medicinal products? Are there specific regulations for the sale of medicinal products on the internet, by e-mail and by mail order?

Modern Drugs are divided into four categories, namely:

- Household remedies which are available in both convenience stores and drugstores.
- Pre-packed drugs that can be sold in drugstores, in which patients can buy these drugs without the need for a pharmacist to dispense the drug.
- Dangerous drugs, which must be dispensed by a pharmacist but do not require a prescription. Most drugs are classified as dangerous drugs under Thai law.
- Specially controlled drugs. These drugs are specifically listed by the MOPH, and may have a potentially harmful effect on health. Sales of these drugs require a prescription.

Marketing pharmaceutical products online, by e-mail, and/or by mail order is not permitted (*see Question 16*). According to the FDA, most advertisements (more than 85%) on the internet are being run without FDA permission. The FDA has prioritised the solving of this problem.

ADVERTISING

16. What are the restrictions on advertising medicinal products?

Legislation and regulatory authority

Sections 88 to 90 of the Drug Act regulate the advertising of medicinal products and are enforced by the FDA. The authorities also take the Consumer Protection Act 1979 into consideration when regulating advertising practice. Further, pharmaceutical companies that are members of PReMA must comply with the PReMA Code. Although the PReMA Code is not considered to be law, and the FDA does not have the authority to enforce it, a violation of the PReMA Code can be reviewed by the PReMA Committee, which can sanction its members.

Restrictions

Advertisements for prescription or pharmacy dispensed medicines can only be targeted to professionals. Drugs in the household remedy category can be advertised directly to consumers and the general public, but that advertising is subject to FDA review and approval before dissemination.

Dangerous drugs cannot be advertised directly to consumers and the general public. Most drugs are classified as dangerous drugs under Thai law (*see Question 15*).

Advertising must be approved by the FDA before dissemination (*section 88 bis, Drug Act*). Advertisements must not (*section 88, Drug Act*):

- Boast that a medicine can miraculously or absolutely treat, cure or prevent disease or illness.

- Exaggerate or falsely declare properties of the medicine.
- Give the impression that the drug has a substance as its chief or component ingredient that it either does not have or has in a lower quantity than believed to be present.
- Give the impression that it is an abortifacient or a strong emmenagogue.
- Give the impression that it is an aphrodisiac or a birth control drug.
- Advertise specially controlled drugs or dangerous drugs.
- Contain certification or endorsement of its therapeutic properties by any other person.
- Show its therapeutic properties as being capable of curing, mitigating, treating or preventing diseases (or symptoms of them) as notified by the MOPH under section 77 of the Drug Act.

Further, advertisements must not (*FDA Internal Rules 2002*):

- Be contrary to traditions, for example, local beliefs, norms and morals.
- Persuade patients to consume the product more than necessary or create a misunderstanding that the product should be used regularly.
- Make a comparison that would defame other products.
- Cause consumers to misunderstand that the drug is equivalent to other products, such as food or cosmetics.
- Encourage acts or activities contrary to law.

Advertisements must meet the FDA information requirements (for example, contain the drug name, ingredients and manufacturing source).

No sale of drugs can be advertised by a gift or lottery drawing (*section 90, Drug Act*). The FDA has adopted a broad interpretation of this section, and has determined that free samples or "buy-one-get-one-free" offers are equivalent to advertising by giving a gift.

Internet advertising

There are no particular rules or codes of practice on the use of the internet or social media for drug advertising. Information distributed on the internet which is intended for customers or patients in Thailand must meet the same requirements (*see above, Restrictions*). According to the FDA, most advertisements (more than 85%) on the internet are being run without permission, and the FDA has made it a priority to address this issue.

DATA PROTECTION

17. Do data protection laws impact on pharmaceutical regulation in your jurisdiction?

While Thailand currently has no comprehensive data protection legislation, a draft "Personal Data Protection Bill" and draft "Data Privacy Bill" have been approved by the Cabinet and will be considered by the National Legislative Assembly. These bills are expected to be passed by the National Legislative Assembly in the near future. The bills, as drafted, would dramatically change personal data privacy requirements and would require consent from the subject for some types of data collection. The Draft Drug Bill is also being scrutinised by all interested parties.

This change could have an impact on the distribution and promotion of drugs, as those two aspects rely heavily on patient and more generally consumer data. After the bills are passed, this may be more difficult to acquire.

There is no specific body of law that offers direct protection or mandates specific compliance with regard to data privacy. However, there are other laws that would allow for relief if the use of data or information causes damage to reputation, health, or property of the information owner/subject.

PACKAGING AND LABELLING

18. Outline the regulation of the packaging and labelling of medicinal products.

Legislation and regulatory authority

The Drug Act deals with packaging and labelling. The regulations relating to the packaging and labelling of medicinal products are overseen by MOPH. The Drug Control Division of the FDA handles enforcement. The label and the current size of the packaging are mandatory documents that must be submitted to the FDA to obtain FDA marketing approval.

Information requirements

For labelling, the Drug Act requires that either a package insert, a Summary of Product's Characteristics or a Patient Information Leaflet are submitted. Required information is listed in the FDA Drug Registration Guidelines. If an applicant submits a Patient Information Leaflet, he must also submit the package insert.

Package inserts must contain the following:

- Product name.
- Name and strength of the active ingredients.
- Product description.
- Pharmacodynamics/pharmacokinetics.
- Indications.
- Recommended dose.
- Instructions for use, including modes of administration, contra-indications, general warnings and precautions, interactions with other medical products, warnings and precautions for pregnant and lactating women, undesirable effects, and possible overdose and treatment.
- Dosage forms and packaging available.
- Name and address of manufacturing/marketing authorisation holder.
- Date of revision of package insert.

A package label must include the following mandatory information:

- Product name.
- Dosage form.
- Registration certificate number.
- Composition or active ingredient with the quantity, unit or strength.
- Pack sizes.
- Lot/batch number.
- Manufacturer's name and country of origin.
- Date of manufacture.
- If applicable, and on a red label, a statement that the drug is classified as a specially controlled drug, dangerous drug, or common household drug in Thailand.
- Expiration date and the word "expiry" in Thai.

Other conditions

All of the above information can be in Thai or English, except for the information noted above that must be expressly stated in Thai (*see above, Information requirements*). Further, periodically the FDA will issue ministerial notifications to set out specific required information to be included on the label of specific drugs such as antibiotics, antihistamines, sedatives and hypnotics.

PRODUCT LIABILITY

19. Outline the key regulators and their powers in relation to medicinal product liability.

The key regulator is the Drug Control Division of the Food and Drug Administration (FDA), Ministry of Public Health (MOPH). It directly regulates and monitors all pharmaceutical products in Thailand, including the authority to recall products and impose penalties for non-compliance.

20. Are there any mandatory requirements relating to medicinal product safety?

Product labels must be approved by the FDA (*see Question 18*).

New drugs must follow the safety monitoring protocol of the FDA for at least two years, which is extendable to a total of four years (*see Question 10*).

Product recall and/or rapid alert notification of a defective medicinal product can be ordered by the FDA, if it is deemed necessary. Public notifications and information regarding product recalls and safety alerts are provided online by the Drug Control Division of the FDA. See *http://newsser.fda.moph.go.th/safetyalert*.

21. Outline the key areas of law applicable to medicinal product liability, including key legislation and recent case law.

Legal provisions

Thailand has adopted the following laws to specifically address product liability.

Unsafe Goods Liability Act 2008. This is a substantive law, also known as the Product Liability Act, which came into force in February 2009. It is designed to protect consumers who incur damage from defective or dangerous products, by imposing strict liability on business operators involved in the manufacture and/or sale of the product. It addresses manufacturing defects, design defects and warning defects (or failure to warn).

Consumer Case Procedure Act 2008. This is a procedural law governing court proceedings for disputes between consumers and business operators, which came into force in August 2008. It was adopted to make it easier for consumers to pursue product liability claims against business operators. It simplifies and expedites the legal process for an injured party to seek redress. For example, consumers can orally file complaints and court fees are waived for consumers who file an action. Further, the court is given considerable discretion to conduct the proceedings and ensure that consumers receive fair treatment.

Substantive test

The Unsafe Goods Liability Act imposes a strict liability standard. A business operator can be liable regardless of whether it was negligent in making or selling the product. An injured party only has to prove that he was injured or suffered damage from the defective product while using the product in the way it was intended to be used. There is no need to prove fault or negligence.

22. Who is potentially liable for defective medicinal products?

A potentially liable "operator" includes a:

- Producer, outsourcer or importer of the defective product.
- Seller who cannot identify the manufacturer, outsourcer or importer of the product.
- Person using a trade name, trade mark, logo, wording, or showing by any means, in a manner that would cause people to understand that he is a producer, an outsourcer or an importer.

In the pharmaceutical context, the following persons can be liable if the product is found defective and/or has resulted in damage to a consumer:

- Drug manufacturers, including contract manufacturers and ingredient producers.
- Local importers and distributors.
- Hospitals, clinics and drug stores that sell the drugs.

Product liability cannot be waived or limited by way of contract, or by any waiver or limitation of liability statement given by a business operator.

23. What defences are available to product liability claims? Is it possible to limit liability for defective medicinal products?

The Unsafe Goods Liability Act provides several defences for a defendant operator. For instance, an operator is not liable if it can prove one of the following:

- The product was not defective.
- The injured party was aware that it was defective but used it anyway.
- The damage was due to improper use or storage of the product.

The Unsafe Goods Liability Act also provides defences for producers of custom-made products and component producers, who are generally not liable if they can show that the defect was due to the specifications or design of the final product provided to them by the outsourcer or producer.

24. How can a product liability claim be brought?

Limitation periods

The right to claim damages expires after three years from the date that the injured person knew of both the injury and the identity of the business operator liable for loss or damage, or ten years after the date of sale of the product.

If the injury occurred to life, body or health as a result of substances accumulated in the body of the injured person, or if it takes time to show symptoms, the injured party (or the person with a right to file a legal action on behalf of the injured party) must bring the claim within three years from the day that he knows of the injury, and can identify the responsible business operator. However, this must not exceed ten years from the date on which the injury was discovered.

Class actions

Thailand has not historically allowed for class actions, but this changed following the National Legislative Assembly's amendment of the Civil Procedure Code to allow class action legal proceedings. The new class action legislation came into force in December 2015. The amended provisions provide for the following:

- Cases involving a group of persons who have the same interests and rights related to tort, breach of contract, and other laws (including environment, consumer protection, labour, securities and stock exchange, and trade competition) can petition to be filed as class actions by a claimant which is a class member, together with the complaint.
- The court has the power to allow, define the scope or characteristics of a class, inquire into, and terminate a class action.
- Class members can opt-out of the class action and pursue individual claims.
- A judgment binds all parties and members of the group. A claimant (or attorney) has the power to proceed with execution of the judgment on behalf of all members of the group.
- Defendants can be held liable for claimants' attorneys' fee awards up to 30% of the judgment amount. Historically, the lawyers' fees assessed by Thai courts have been very low.

25. What remedies are available to the claimant? Are punitive damages allowed for product liability claims?

Damages under the Unsafe Goods Liability Act consist of two components:

- Damages for a wrongful act as provided for in the Civil and Commercial Code.
- Additional categories of damages specially provided under the Unsafe Goods Liability Act, including:
  - compensation for mental damage as a result of damage to the body, health or sanitation of the injured party; and
  - punitive damages.

A court can award punitive damages on top of actual damages if it can be shown that the defendant either:

- Produced, imported or sold the product, despite being aware that it was defective, or was unaware that the product was defective due to gross negligence.
- Became aware of its defect after production, importation or sale, but failed to take proper action to prevent any damage, for example by failing to recall a defective product.

In these cases, the court can award punitive damages in an amount that the court deems appropriate (with a maximum limit of no more than twice the amount of the actual damages).

REFORM

26. Are there proposals for reform and when are they likely to come into force?

The Thai Trade Mark Act has recently been amended. According to the Trade Mark Act 2016, the registration of trade marks through the Madrid system is now applicable in Thailand. In addition, the Act has changed the trade mark regime as follows:

- Sounds trade marks are acceptable for registration.
- The definition of a distinctive trade mark has been broadened to include shapes or three-dimensional objects that are not the natural shapes of the applied goods.
- Multiple-class applications are allowed.
- A licence agreement will not be terminated as a result of the transfer or inheritance of rights to the underlying mark.
- Government fees for certain transactions have been revised.

The Department of Intellectual Property is currently preparing a draft Ministerial Regulation that will provide clear guidelines and practices about these changes.

There are currently two bills under review that concern the pharmaceutical industry, which are the Patent Bill and the Drug Bill.

The Patent Bill is currently under review and final revision by the Department of Intellectual Property. It is expected that the Bill will be passed soon. The Bill's amendments aim to address the long periods of pendency for patent registration and to update Thai patent law according to international agreements and standards. Areas for amendment include:

- Reducing the long periods of pendency for patent registration and improving the patentability and enforceability of petty patents.
- Accepting the Protocol Amending the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) regarding Thailand's public health.
- Facilitating Thailand's accession to the Hague Agreement regarding design protection.

The Drug Bill has been drafted and revised many times in recent years, but it is not currently high on the government's legislative agenda. The contentious issues, among others, are civil liability and price controls.

For information on pharmaceutical patents, trade marks, competition law, patent licensing, generic entry, abuse of dominance and parallel imports, see *Pharmaceutical IP and Competition Law in Thailand: overview.*

ONLINE RESOURCES

Thai Food and Drug Administration, Ministry of Public Health

W *www.fda.moph.go.th/eng/drug/index.stm*

Description. The Food and Drug Administration website, Ministry of Public Health, contains official versions of the Drug Act, in Thai only.

W *www.ipthailand.go.th/ipthailand*

Thai Department of Intellectual Property

Description. The Department of Intellectual Property website. It contains unofficial English translations of the Patent Act and the Trade mark Act.

W *www.ipthailand.go.th/ipthailand/index.php*

Thailand Office of Consumer Protection Board

Description. The website of the Office of Consumer Protection Board. It contains unofficial translations of product liability legislation, including the Unsafe Goods Liability Act 2008.

W *www.ocpb.go.th/*

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Areas of practice. IP and regulatory affairs; IP commercialisation

Recent transactions

- Advising leading life sciences companies on pharmaceutical, food and beverage, medical device, veterinary, cosmetic, agrichemical and biotechnology regulatory matters.
- Advising innovator pharmaceutical companies in patent infringement litigation against local generic companies.
- Advising companies on plant variety protection, enforcement and commercialisation in Thailand.
- Registering products with the Food and Drug Administration and Ministry of Agriculture in Thailand and throughout Southeast Asia.

Languages. English, Mandarin

Professional associations/memberships. Member INTA Emerging Issues Committee; Member INTA Global Advisory Council Asia Pacific; AIPPI Thailand National Group Reporter; President of LES Thailand

Publications

- *Distribution and Marketing of Drugs Global Guide - Thailand Chapter, Practical Law, 2015 (with Siraprapha Rungpry).*
- *Life Sciences Global Guide – Thailand Chapter, Practical Law, 2015 (with Dr Atthachai Homhuan and Siraprapha Rungpry).*

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Areas of practice. Intellectual property; regulatory affairs.

Recent transactions

- Implemented a quality system and GMP-related topics for the manufacturing of vaccines. This involved working closely with the Department of Medical Sciences of the Thai FDA in regard to biohazard manufacturing, ex-plan audit, in order to obtain approval.
- Participated in conducting clinical trials and bioequivalence studies for new drugs and conventional products, and ensured the trials/studies and protocols were in accordance with the Good Regulatory Practices and Good Clinical Practices.
- Co-invented several pharmaceutical products regarding liposomal vaccines and stem cell therapy, each of which is patented in Japan.

Languages. Thai, English

Professional associations/memberships. Regulatory Affairs Pharmacy Association (Thailand); European Association for Business and Commerce; International Association for the Protection of Intellectual Property.

Publications

- *Life Sciences Global Guide – Thailand Chapter, Practical Law, 2015 (with Alan Adcock and Siraprapha Rungpry).*
- *Allow Case-by-Case Patent "Evergreening" of Pharmaceuticals, Bangkok Post, 3 October 2014.*
- *Expediting the Patent Examination System in Thailand: Recent Developments, Informed Counsel, 3 March 2014.*
- *Electronic Data Linkage Between Thai FDA and Customs, Informed Counsel, 26 August 2013.*

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Areas of practice. Intellectual property; regulatory affairs; technology, media, and telecommunications.

Recent transactions

- Advised pharmaceutical clients on various IP and regulatory issues, product liability, government advocacy on new regulations, and compulsory licences.
- Advised multinational pharmaceutical companies in patent infringement litigation against local generic companies.

Languages. Thai, English

Publications

- *Distribution and Marketing of Drugs Global Guide - Thailand Chapter, Practical Law, 2015 (with Alan Adcock).*
- *Life Sciences Global Guide – Thailand Chapter, Practical Law, 2015 (with Alan Adcock and Dr Atthachai Homhuan).*
- *Patent Litigation in Thailand: Know Your Rights and Duties, Bangkok Post, 7 February 2014.*