

Thailand

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REGULATORY OVERVIEW

1. Please give a brief overview of the regulatory framework for medicinal products/pharmaceutical products/drugs (as they are called in your jurisdiction), including the key legislation and regulatory authorities.

The regulation of medicinal drugs in Thailand is overseen by the Ministry of Public Health (MOPH). The Office of Food and Drug Administration (FDA) (*see box, the regulatory authority*), 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.

The FDA includes the Drug Control Division, which manages the licensing of medicinal drugs for import, manufacture, and sale.

The key piece of legislation regulating medicinal drugs in Thailand is the Drug Act 1967, which has been subsequently revised four times. The Drug Act (including its four amendments), along with ministerial regulations and notifications, form the legislative framework for drug regulation in Thailand.

PRICING AND STATE FUNDING

2. Please give a brief overview of the structure and funding of the national healthcare system.

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 administration.
- 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 dependents (parents and up to three children).

National Health Insurance (THB 30) Scheme. This is administered by the Ministry of Public Health and covers the remaining population not covered under the Social Security Scheme or the Civil Servant Medical Benefit Scheme.

3. In what circumstances are the prices of medicinal products regulated?

Prices of medicinal products are regulated when they are listed on 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 setting prices for government hospitals. However, these prices only apply to those under the CSMBS.

The MOPH has implemented a notification on how much government hospitals are allowed to charge patients. A revision of the Drug Act is in progress which may include cost-effectiveness as an element for drug registration.

4. When is the cost of a medicinal product funded or reimbursed by the state? Please briefly outline the procedure and pricing for state funding or reimbursement (for example, is the reimbursement paid to the producer, pharmacist or end-user)?

Medicines are reimbursed by the state when the drugs are listed in the NLED (*see Question 3*). However, this list is only available to government hospitals.

Government hospitals generally provide drugs from the NLED to civil servants and to persons under the THB 30 Scheme. In this case, the patient pays nothing to the hospital or, for people under the THB30 Scheme, a maximum of THB30 (about US\$0.9) in certain circumstances. The hospital is reimbursed completely by the government.

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 may also have private health insurance to cover another part of the cost.

MANUFACTURING

5. Please give an overview of the authorisation process to manufacture medicinal products. In particular:

- To which authority must the application be made?
- What conditions must be met to obtain authorisation?
- Are there specific restrictions on foreign applicants?
- What are the key stages and timing?
- What fee must be paid?
- How long does authorisation last and what is the renewal procedure?

Application

Applications are made to the Drug Control Division of 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, among other conditions:

- Is the owner of the business and has sufficient property or status to be able to establish and operate the business.
- Is no less than 20 years of age.
- Is resident in Thailand.
- Has not been convicted for an offence against certain laws, such as laws on narcotics and laws on substances having effects on the mind or nerves.
- 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 prescribed in ministerial regulations.
- Uses a trade name which is not a repetition of or similar to the trade name used by a licensee whose license is suspended or has been revoked for less than a full year.

Restrictions on foreign applicants

The foreign applicant must be resident in 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. The applicant’s buildings and facilities are then inspected by the MOPH, to assess compliance with World Health Organisation Good Manufacturing Practices (GMP) and decide whether the applicant has adequate facilities and the appropriate personnel to manufacture such medicines.

Fee

The fees are as follows:

- Licence to manufacture modern medicines: THB10,000 (about US\$297).
- Licence to manufacture traditional medicines: THB5,000 (about US\$149).

Period of authorisation and renewals

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

6. What powers does the regulator have to:

- Monitor compliance with manufacturing authorisations?
- Impose penalties for a breach of a manufacturing authorisation?

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 knowledge of the order.

Further, authorities can impose fines and imprisonment for manufacturing without a licence. Manufacturing modern medicines without a licence can lead to imprisonment up to five years, and a fine up to THB10,000 (about US\$297). Manufacturing traditional medicines without a licence can lead to imprisonment up to three years and a fine up to THB5,000 (about US\$149).

CLINICAL TRIALS

7. Please give an overview of the regulation of clinical trials. In particular:

- Which legislation and regulatory authorities regulate clinical trials?
- What authorisations are required and how is authorisation obtained?
- What consent is required from trial subjects and how must it be obtained?
- What other conditions must be met before the trial can start (for example, the requirement for a sponsor and insurance cover)?
- What are the procedural requirements for the conduct of the trial (for example, using certain medical practices and reporting requirements)?

There is no centralised regulation for clinical trials. At least six regulatory authorities have jurisdiction over clinical trials:

- The FDA.
- Department of Medical Services 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.

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.

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 often 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 from two to three months.

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 sponsor must submit approval from an authorised (or FDA approved) ethics committee, and 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 only valid for one year. If the clinical trial is not complete within a year, a new import licence must be obtained.

MARKETING

8. Please give an overview of the authorisation process to market medicinal products. In particular:

- To which authority must the application be made?
- What conditions must be met to obtain authorisation?
- What are the key stages and timing?
- What fee must be paid?
- How long does authorisation last and what is the renewal procedure?

Application

Applications are made to the FDA.

Conditions

The applicant must register its product (*see below, Key stages and timing*).

Key stages and timing

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. The licensed applicant must then obtain FDA registration for the medicine to market and sell the drug in Thailand. Registration requirements differ for general drugs, (which include generics, new medicines, and new generics) and traditional drugs.

Registration of a new 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 the applicant must submit a full marketing approval application with the samples to the FDA for review and registration. The review can take at least 12 months.

Once the review has been passed, 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 9*, and for traditional medicines, see *Question 17*.

Fee

The fees are as follows:

- Licence to sell modern medicines for pharmacies (Type 1): THB2,000 (about US\$60).
- Licence to sell OTC (ready pack) medicines (Type 2): THB1,000 (about US\$30).

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 in the market for longer than two years, the FDA will automatically cancel the registration.

9. Please briefly outline the abridged procedure for obtaining marketing authorisations for medicinal products. In particular:

- Which medicinal products can benefit from the abridged procedure (for example, generics)?
- What conditions must be met?
- What procedure applies and what information can the applicant rely on?

Generics enjoy an abridged registration process. To benefit from 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 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 8*).

The applicant then submits various details about the drug production process to be used, including:

- Manufacturing methods.
- In-process controls.
- Specifications of the active ingredients.
- Excipients.

Information about the drug storage conditions and details about the stability of the drug 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 dossiers for generics submission.

10. Are foreign marketing authorisations recognised in your jurisdiction? If so, please briefly outline the recognition procedure.

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 approved and pending marketing authorisation of 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 and evidence submitted to the FDA with the application for marketing approval.

11. What powers does the regulator have to:

- Monitor compliance with marketing authorisations?
 - Impose penalties for a breach of a marketing authorisation?
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The Medical Sciences Department under the Ministry of Public Health is the main authority responsible for ensuring the quality and safety of drugs on the market in Thailand. Samples are regularly tested at its laboratories to monitor the safety of new drugs. The Medical Sciences Department can, if necessary, remove the drugs from the market. Authorities can suspend or revoke a licence. The violation is considered a criminal offence subject to both imprisonment and fines. Licensees can appeal to the Minister of Public Health within 30 days from the date of knowledge of the order.

12. Are parallel imports of medicinal products into your jurisdiction allowed? If so, please briefly outline what conditions must be met by the parallel importer. Can intellectual property rights be used to oppose parallel imports?

Generally, most intellectual property laws in Thailand recognise the exhaustion of rights principle. Therefore, parallel imports are not generally regulated in Thailand.

However, parallel imports are not permitted in the pharmaceutical sector. To import a drug into Thailand, a company needs a licence from the FDA. When applying for product registration, the FDA will not accept an application for a product which has a trade mark identical to other products in the Thai market.

13. Please briefly outline the restrictions on marketing practices such as gifts or “incentive schemes” for healthcare establishments or individual medical practitioners.

The Drug Act is silent on this issue. However, for pharmacists or doctors who are government officers, the anti-corruption rules prohibiting gifts or incentives that exceed THB3,000 (about US\$90) apply.

For activities with 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.

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

14. Please briefly outline the restrictions on marketing medicinal products on the internet, by e-mail and by mail order.

It is not permitted to market pharmaceutical products online, by e-mail, and/or by mail order. According to the FDA, most adverts (more than 85%) on the internet are being run without FDA permission. The FDA has made it a priority to focus on this problem.

ADVERTISING

15. Please briefly outline the restrictions on advertising medicinal products. In particular:

- Which legislation applies and which regulatory authority enforces it?
 - What types of medicinal product cannot be advertised?
 - What restrictions apply to advertising that is allowed?
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Sections 88 to 90 of the Drug Act regulate advertising of medicinal products and are enforced by the FDA. The authorities also take the Consumer Protection Act into consideration when regulating advertising practice. Further, pharmaceutical companies which are members of PReMA must comply with the PReMA Code. Although the PReMA Code is not considered a law and the FDA does not have authority to enforce it, violation of the PReMA Code is reviewed by the PReMA Committee, which can punish its members.

Adverts 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 they are subject to FDA review and approval before dissemination.

There is an emphasis on truthfulness and non-exaggeration and adverts must be approved by the FDA before dissemination. Adverts must (*section 88, Drug Act*):

- Not boast that a medicine can miraculously or absolutely treat, cure, or prevent disease or illness.
- Not exaggerate or falsely declare properties of the medicine.
- Not cause to be understood that it has a substance as its chief or component ingredient which it does not have, or has in less than the quantity caused to be understood.
- Not cause to be understood that it is an abortifacient or a strong emmenagogue.
- Not cause to be understood that it is an aphrodisiac or a birth control drug.
- Not advertise specially controlled drugs or dangerous drugs.
- Contain no certification or endorsement of its therapeutic properties by any other person.
- Should not show its therapeutic properties as being capable of curing, mitigating, treating, or preventing diseases or symptoms of them as notified by the Minister of Public Health under Section 77 of the Drug Act.

Further, adverts must (*FDA Internal Rules 2002*):

- Not be contrary to traditions.
- Not persuade patients to consume the product more than necessary or create a misunderstanding that the product should be used regularly.
- Not make a comparison to defame other products
- Not cause a misunderstanding to consumers that the drug is equivalent to other products such as food or cosmetics.
- Not encourage acts or activities contrary to law.
- Meet FDA information requirements (for example, drug name, ingredients, and manufacturing source).

PACKAGING AND LABELLING

16. Please briefly outline the regulation of packaging and labelling of medicinal products. In particular:

- Which legislation applies and which regulatory authority enforces it?
- What information must the packaging and/or labelling contain?
- What other conditions must be met (for example, information being stated in the language of your jurisdiction)?

The label and the size of the packaging are mandatory documents to obtain FDA marketing approval. For labelling, the Drug Act requires a package insert, a Summary of Products Characteristics, and a Patient Information Leaflet. Required information is listed in the FDA Guidelines. If an applicant submits a Patient Informa-

tion 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.
- Pharmacodynamic/pharmacokinetics.
- Indications.
- Recommended dose.
- Instructions for use, including modes of administration, contraindications, general warnings and precautions, interactions with other medicaments, 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.
- Registration certificate number.
- Content.
- Composition or active ingredient with the quantity/potency.
- 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.

All of the above information can be in Thai or English, except for certain information which must be presented in Thai.

TRADITIONAL HERBAL MEDICINES

17. Please briefly outline the regulation of the manufacture and marketing of traditional herbal medicinal products in your jurisdiction.

Manufacture and sales of traditional medicines are regulated by the FDA. Those who wish to produce, sell, and/or import traditional medicines must first apply for a manufacturing licence, a sales licence, and/or an import licence (as the case may be).

A marketing approval (that is, a drug registration certificate) from the FDA is generally required for traditional medicines. However, the Drug Act exempts traditional herbal medicines from this requirement. Traditional herbal medicines do not have to be registered with the FDA. Only a manufacturing, sales or import licence is required.

18. What types of medicinal products and related substances and processes can be protected by patents and what types cannot be patent protected? What are the legal criteria to obtain a patent? Which legislation applies?

The main source of patent law is the Patent Act 1979, as amended by the Patent Act 1992 and the Patent Act 1999 (Patent Act). Ministerial regulations and notifications published by the Department of Intellectual Property also regulate patent law.

Pharmaceutical patents are treated no differently to inventions in other fields. There are no specific guidelines or examination guidelines for pharmaceuticals. A claim for a pharmaceutical innovation must meet the usual criteria of novelty, inventiveness, and industrial applicability.

Certain subject matter is specifically excluded from patentability by statute. The following cannot be patented (*section 9, Patent Act*):

- Microorganisms that naturally exist and their components, animals, plants or extracts from animals or plants.
- Scientific and mathematical rules and theories.
- Computer programs.
- Methods for diagnosing, treating or curing human or animal diseases.
- Inventions which are contrary to public order or morality, public health or welfare.

This prohibition is absolute. The most problematic for the pharmaceutical sector relate to biologics and diagnostic methods and methods of treatment.

Generally, the following can be patented if it is novel, non-obvious, and useful:

- Polymorphic forms (such as solvates or different crystalline forms of a known chemical compound).
- Formulations (that is, pharmaceutical compositions).
- New therapeutic use of a known chemical compound.
- Combination and dosage form.
- Methods for preparing medicinal products or related substances.

19. How is a patent obtained? In particular:

- **To which authority must the application be made?**
 - **What fee must be paid?**
 - **What are the key stages and timing?**
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The authority

Patent applications are made to the Patent Office of the Department of Intellectual Property, Ministry of Commerce (www.ipthailand.org).

Fee

Government fees for filing a patent in Thailand depend on the type of patent and number of claims. In general, the government filing fees are minimal. Once the patent is granted, various maintenance fees apply from the fifth year.

Process and timing

An applicant must first prepare a patent specification, including a detailed description of the invention, drawings, and claims. Then the application must be filed with the Patent Office. The Patent Office then conducts a preliminary examination and publishes the patent in the official *Patent Journal* in Thai.

The entire process for an invention patent to be issued can take from three to five years. For pharmaceutical patents, the process can take six to eight years, and in some cases up to ten years. Thailand has recently become a signatory to the Patent Cooperation Treaty.

20. How long does patent protection last? How is a patent renewed or patent protection extended?

A patent for an invention is valid for 20 years from the date of filing (*section 35, Patent Act*). No extensions or renewals are allowed.

21. In what circumstances can a patent be revoked?

The validity of patents can be challenged in the Intellectual Property and International Trade Court (IP and IT Court). The IP and IT Court can revoke a patent if one of the following apply:

- The invention is not new, lacks an inventive step, and/or is not capable of industrial application.
- The subject matter of the invention is not patentable (see *Question 18*).
- The patent applicant did not have the right or was not eligible to apply for the patent.

22. When is a patent infringed? How is a claim for patent infringement made and what remedies are available?

Specific rights of patentees are set out in Section 36 of the Patent Act. They include the sole right relating to patents of products to produce, use, sell, possess for sale, offer for sale or import into Thailand those patented products. The same protection is provided for processes. Any person who violates the patentee's exclusive rights is subject to infringement liability, except where a statutory exemption applies.

Patentees can enforce their patent rights through criminal and/or civil actions in the IP and IT Court, which can issue injunctive remedies, damages, and criminal penalties (fine and/or imprisonment).

TRADE MARKS

23. Can a medicinal product brand be registered as a trade mark? What are the legal criteria to obtain a trade mark? Which legislation applies?

A medicinal product brand can be registered as a trade mark according to the Trade Mark Act 1991, as amended by the Trade Mark Act 2000 (Trade Mark Act). There is no special register of pharmaceutical trade marks. Applicants for drug marketing approval are not required to obtain prior approval from the drug regulatory authorities about trade mark use. There are no guidelines or ministerial regulations requiring stricter levels of distinctiveness for marks used on pharmaceutical products.

A trade mark is registrable if the following requirements are met:

- It is distinctive.
- It is not forbidden under the Trade Mark Act.
- It is not identical or similar to trade marks registered by others.

24. How is a trade mark registered? In particular:

- To which authority must the application be made?
- What fee is payable?
- What are the key stages and timing?

The authority

Applications are made to the Trade Mark Office of the Department of Intellectual Property, Ministry of Commerce (www.ipthailand.org).

Fee

One trade mark or service mark application can be filed per class. Multiple class applications are not available.

The registrar determines the filing fee and registration fee, based on the number of goods to be registered. The filing fee is THB500 (about US\$15) and the registration fee is THB300 (about US\$9) for one item of goods.

If a mark covers more than one item of goods, the cost of registering a mark in one class will increase by THB800 (about US\$25) for each additional item of goods.

Process and timing

After filing an application with the Trade Mark Office, it takes at least six to nine months for the registrar to examine an application. After the examination, if the application is accepted for registration, it is published in the *Trade Mark Gazette*. If no objections are filed within 90 days after publication, registration is granted dated as of the application filing date. The registrar issues a notification requesting payment of the registration fee. The certificate of trade mark registration is issued within two months after the registration fee has been paid. Barring any problems, it normally takes about ten to twelve months for a trade mark to be registered.

25. How long does trade mark protection last? How is a trade mark renewed?

A trade mark is protected for ten years from the filing date, and can be renewed every ten years. A renewal application can be filed within 90 days before the expiry, for an additional ten years from the date of expiry of the original registration, or from the date of the previous renewal.

26. In what circumstances can a trade mark be revoked?

A trade mark can be revoked if it does not comply with the legal requirements, that is, it must be distinctive, not forbidden under the Trade Mark Act, and not identical or similar to trade marks registered by others.

27. When is a registered trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

The person registered as the trade mark owner has the exclusive right to use the goods for which registration has been granted (*section 44, Trade Mark Act*). Infringement of the rights of a registered trade mark owner is a criminal offence leading to penal remedies. Penalties for forgery of a registered trade mark can include fines up to THB 400,000 (about US\$12,000) and prison sentences up to four years (usually reduced or suspended for first-time offenders). Penalties for imitation of a registered trade mark can include fines up to THB200,000 (about US\$6,000) and prison sentences up to two years (usually reduced or suspended for first-time offenders).

A trade mark owner can bring criminal charges against an infringer by submitting a complaint directly to a court or, more commonly, lodging a complaint with police authorities.

The owner of a registered trade mark that has been infringed can file an action claiming compensation from the infringer under sections 420 and 421 of the Civil and Commercial Code. The owner of a trade mark not yet registered in Thailand but registered elsewhere can receive protection under the passing off theory (*section 46, Trade Mark Act*). Proof of damage is required for monetary recovery.

28. Is your jurisdiction party to international conventions on patent and trade mark protection?

Thailand is party to the:

- WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994.
- WIPO Paris Convention for the Protection of Industrial Property 1883.
- Patent Cooperation Treaty (this will enter into force in Thailand on 24 December 2009).

PRODUCT LIABILITY

29. Please give an overview of medicinal product liability law, in particular:

- Under what laws can liability arise (for example, contract, tort or statute)?
- What is the substantive test for liability?
- Who is potentially liable for a defective product?

Legal provisions

Thailand recently adopted the following new 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 to govern court proceedings for disputes between consumers and business operators, which took effect 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 file complaints orally, and court fees are waived for consumers who file an action. Further, a court is given considerable discretion to conduct the proceedings and make sure 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 needs 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.

Liability

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 the trade name, trade mark, logo, wording, or showing by any means in a manner to 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 has resulted in damage to a consumer:

- Drug manufacturers, including contract manufacturers and ingredient producers.
- Local importers and distributors.

THE REGULATORY AUTHORITY

Food and Drug Administration

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Main areas of responsibility. These are:

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

- Hospitals, clinics, and drug stores which 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.

30. What are the limitation periods for bringing product liability claims?

The right to claim damages expires after three years from the date that the injured person knew of 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 he knows of the injury and could identify the responsible business operator. However, this must not exceed ten years from the date on which the injury was discovered.

31. What defences are available to product liability claims?

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.

32. What remedies are available to the claimant?

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

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

A court can award punitive 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 such damage, such as by failing to recall a defective product.

In such cases, the court can award punitive damages in an amount the court may deem appropriate, but no more than twice the amount of the actual damage.

33. Are class actions allowed for product liability claims? If so, are they common?

There is no legal basis for bringing product liability class actions.

REFORM

34. Please summarise any proposals for reform and state whether they are likely to come into force and, if so, when.

A draft proposal calls for legislation to define and distinguish the dissemination of useful information on new drug discoveries and innovations from drug advertising. For such information, the proposal would relegate the FDA to a supervision and monitoring role, similar to the Consumer Protection Board's role under the Consumer Protection Act (in contrast to the FDA's command and control over drug advertising). Further, the draft proposal would allow drug manufacturers and companies to appeal an FDA ruling on advertising. However, the draft has not progressed since it was proposed in 2006.

CONTRIBUTOR DETAILS

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