Thailand

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REGULATORY OVERVIEW

1. Please give a broad overview of the structure and funding of the national healthcare system.

Thailand has witnessed progressive developments in many sectors of its society. Health is no exception as is evidenced by the fact that during recent years, Thailand has spent up to THB300 billion (US$6.8 billion) on health expenditures with an average 10% increase each year.

On 18th November, 1999 with the objective of establishing a national healthcare system, the Health Systems Research Institute Committee proposed the creation of a National Health System Reform Office (HSRO) to the Cabinet. A National Health System Reform Committee (NHSRC) was also established. The NHSRC is now in the process of drafting a National Health Act.

2. What is the definition of a pharmaceutical product?

Pharmaceutical products are defined as substances (*section 4, the Drug Act, B.E. 2510 (1967)*):

- Recognised by pharmacopoeias (books containing an official list of medicinal drugs) notified by the Minister.
- Intended for use in the diagnosis, treatment, relief, cure or prevention of human or animal disease or illness.
- Notified by the Minister as being intended to affect the health, structure or function of the human or animal body.

3. For each of the key regulators (pharmaceutical, medicinal, medical device, GMO) please give:

- Their name.
- Contact details (including website address).
- A summary of their areas of responsibility.

- **Name.** Food and Drug Administration of Thailand (FDA).
- **Contact details.** Food and Drug Administration Ministry of Public Health,
  Tiwanont Rd.,
  Amphur Muang,
  Nonthaburi 11000
  Thailand
  Tel: +66 2 590 7000
  Fax: +66 2 590 7116
  Website: *http://www.fda.moph.go.th*
- **Areas of responsibility.** These include:
  - licensing the production, importation and sale of drugs in Thailand;
  - ensuring that health products (food, drugs, cosmetics, medical devices, narcotic substances and hazardous substances) available to consumers are of standard quality, efficacy and safety; and
  - controlling and monitoring both pre and post-marketing phases of manufacture, import, transport, storage and sale.

MARKETING APPROVAL AND STATE FUNDING

4. Is authorisation required for marketing approval of pharmaceutical products? If so, please give a broad overview of the authorisation process, in particular:

- To whom should the application be made?
- What are the key stages and timing of the process?
- Is there an abridged procedure?
- What fee is payable?
- Is authorisation given for a fixed period? If so, for how long and what is the renewal procedure?
- In what circumstances can authorisation be revoked?

- **Application.** Companies and individuals wishing to place a drug product on the market must obtain a licence from the FDA in order to import or manufacture and sell products in Thailand.
- **Key stages and timing.**
  - registration of a generic drug:
    - step I – submit an application with the Drug Control Division of the FDA for permission to manufacture or import a drug sample into Thailand. Estimated timing: two weeks;

- step II – file an application with the FDA for a Certificate of Drug Quality and Standard Control Method. The FDA will transfer the application to the Drug Analysis Division of the Medical Sciences Department (MSD), which will assume responsibility for reviewing and approving the application. Estimated timing: three to four months; and
- step III – file an application with the Drug Control Division of the FDA for a drug registration. Estimated timing: three to four months.

- registration of a new drug (new chemical entities, new indication, new combination and new route of administration):
  - step I – submit an application with the FDA for permission to import a drug sample into Thailand. Estimated timing: two weeks; and
  - step II – submit an application with the FDA for registration of the drug. Estimated timing: eight to 12 months.

- **Abridged procedure.** It is the policy of the FDA to provide for "fast track" registration of certain types of drug products and certain emergency situations, such as HIV and AIDS vaccines and war.
- **Fee.** The fees payable for applications to the FDA for product registration licences depend on the category of product for which the application is being filed. The current FDA fees are as follows:

Product	Fee
1. New drug	THB2,000 (about US$46)
2. Generic drug	THB2,000 (about US$46)
3. Traditional drug	THB500 (about US$12)
Medical device (MD)	
1. General MD	-
2. Notified MD	-
3. Registration MD	THB2,000 (about US$46)
Cosmetic product (CP)	
1. General CP	-
2. Controlled CP	-
3. Specially controlled CP	THB1,000 (about US$23)
4. Annual Fee	THB2,000 (about US$46)
Food product	
1. General food	-
2. Controlled food	THB5,000 (about US$115)
3. Medical food product	THB5,000 (about US$115)

- **Period of authorisation and renewals.** The FDA issues a licence for a drug product for an indefinite period.
- **Revocation.** The FDA can revoke the licence for a drug product if there have been no imports of the drug product for a two-year period. The FDA can also revoke a licence when the FDA determines that a licensee has not complied with the Drug Act.

5. Is a distinction made between over the counter drugs and drugs that can only be obtained on prescription? If so, how is the distinction made and what impact does this have on the process for authorisation?

As indicated above (*see Question 4*), the filing procedures at the FDA for generic drugs and new drugs are different. Over the counter (OTC) drugs can be sold in drug stores directly to patients. Prescription drugs are distributed only to patients in hospital, medical units and/or in drug stores in which prescriptions are required before dispensing this kind of drug.

Generic drugs are not necessarily OTC drugs. Some of them are prescription drugs such as specially controlled drugs, for example cancer drugs.

All new drugs (*see Question 4*) are prescription products that can be sold in hospitals and medical units only. The label for these drugs must contain terms such as "hospital use only".

Moreover, for a two-year period after the issue of a registration licence for a new drug product, it can be obtained by prescription-only.

6. Is there a mutual recognition procedure? (For EU countries only.)

N/A

7. Is there a separate procedure for determining whether the cost of a pharmaceutical product will be funded/reimbursed by the state? If so, please give details (including how pricing is determined in these circumstances).

There is no such procedure in Thailand.

MANUFACTURE AND CLINICAL TRIALS

8. Is authorisation required to manufacture pharmaceutical products? If so, please give a broad overview of the authorisation process, in particular:

- To whom should the application be made?
- Are there any specific restrictions on foreign ownership?
- What are the key stages and timing of the process?

- What fee is payable?
- Is authorisation given for a fixed period? If so, for how long and what is the renewal procedure?
- In what circumstances can authorisation be revoked?

- **Application.** Applications are made to the FDA (*see Question 3 for contact details*).
- **Restrictions on foreign ownership.** Only Thai individuals or companies can file an application with the FDA for a manufacturing licence.
- **Key stages and timing.** First, an application for a manufacturing licence and GMP certificate must be filed with the FDA. Secondly, an application must be filed with the FDA for a registration licence for the manufactured product:
  - step I - submit an application at the Drug Control Division of the FDA for permission to manufacture a drug sample for registration. Estimated timing: two weeks;
  - step II - file an application with the FDA for a Certificate of Drug Quality and Standard Control Method. The FDA will transfer the application to the Drug Analysis Division of the Medical Sciences Department that will assume responsibility for reviewing and approving the application. Estimated timing: three to four months; and
  - step III - file an application with the Drug Control Division of the FDA for a drug registration. Estimated timing: three to four months.
- **Fee.** See *Question 4* for fees for new, generic and traditional drugs.
- **Period of authorisation and renewals.** The FDA grants a manufacturing licence for an indefinite period.
- **Revocation.** The FDA can revoke a licence when it determines that a licensee has not complied with the Drug Act.

9. Are clinical trials regulated? If so, please give an overview of necessary consents, authorisations and procedural requirements.

Regulatory authorities for clinical trials. The following six regulatory authorities have jurisdiction over clinical trials:

- The FDA.
- Department of Medical Services (DMS) of the Ministry of Public Health (MOPH).
- Department of Communicable Diseases Control (DCDC) of the MOPH.
- Ethical Review Committee for Research in Human Subjects (ERC) of the MOPH.
- National Sub-Committee of HIV Vaccine (NSCHIV) of the MOPH.
- Specific regulations of medical schools and hospitals.

Required procedures. Before a clinical trial can begin, certain filing procedures must take place at the regulatory authorities set out above. These procedures depend on the type of drug that is being studied.

Drugs. The protocol must be submitted to the DMS of the MOPH so that it can be reviewed by the ERC of the MOPH. When the protocol has been approved by the ERC of the MOPH, if a medical school is involved, the protocol must then be reviewed by the ERC of the medical school.

After an approval has been received by the ERC of the MOPH (and the ERC of the medical school, if applicable) then an application must be submitted to the New Drug Division of the FDA for permission to import a drug in order to conduct a clinical trial. Once the FDA has granted permission, the clinical trial can begin.

AIDS vaccine. If the proposed clinical trial involves an AIDS vaccine, the first submission must be made at the DCDC of the MOPH. This submission is made so that the protocol can be reviewed by the NSCHIV of the MOPH. When the protocol is approved by the NSCHIV, it is then submitted to the ERC of the MOPH. When the protocol has been approved by the ERC of the MOPH, if a medical school is involved, it must then be submitted to the ERC of the medical school.

When an approval has been received from the NSCHIV and the ERC of the MOPH (and the ERC of the medical school, if applicable), then an application can be submitted to the New Drug Division of the FDA for permission to import the vaccine in order to conduct a clinical trial. When this application is approved, the clinical trial can begin.

PACKAGING AND LABELLING

10. Please give a broad overview of provisions relating to the packaging and labelling of pharmaceutical, biotechnology and GMO products.

The label fixed to the container and package of a pharmaceutical product must include the following information (*section 25(2), the Drug Act, B.E. 2510, as amended*):

- Name of drug.
- Number or code of registration of drug ingredients.
- Quantity of drug packed.
- Name and quantity or strength of important active ingredient (as registered).
- Number or character showing the time of production or analysis.

- Name of producer of drug and province where the producer is located.
- Date of production.
- The words "dangerous drug", "specially controlled drug", "external use" or "specific use" must be in red and clearly seen (if necessary to be on the package).
- The term "ordinary household medicine" where it is an ordinary household medicine.
- The word "animal drug" if it is a drug for animal use.
- The word "expiry" and the date of expiry of the drug where it is a drug that the Minister has announced under section 76(7) or (8) of the Drug Act.

The Industrial Products Standards Act, B.E. 2535 (1992) regulates, among other things, the shape, endurance and safety of and the method of manufacture, design and packaging of a product.

The Ministry of Industry may prescribe industrial standards for any industrial product with which the manufacturer or importer may voluntarily comply.

The Ministry of Industry may also prescribe that any industrial product, manufactured or imported, conform to a compulsory industrial standard. Manufacturers or importers of such products cannot manufacture or import the product unless they first obtain appropriate licensing from the Ministry of Industry.

PRICING, MARKETING AND ADVERTISING

11. Are the prices of pharmaceutical products regulated?

Drug pricing is controlled through the following mechanisms:

- Market mechanism allowing free competition among generics and competition among drugs under the same category.
- Direct price control under the Price Fixing and Antitrust Act, enforced by the Ministry of Commerce.
- Medium pricing designated for the sale of essential drugs in public facilities. The medium price list is a price control mechanism established by the government for essential drugs. The medium price list has been effective from 1986 and guides the purchasing committees in price negotiations. The government has also established a new policy for the procurement of drugs, whereby hospitals have to use not less than 80% of the government allocated money to buy the essential drugs.
- Patented drug pricing control designed by the Committee on Patented Drug appointed under the 1992 Patent Act.

12. Are there any restrictions on marketing practices such as gifts or "incentive schemes" for healthcare establishments or individual medical practitioners? Are any such practices commonly used?

There are no such restrictions.

13. How are parallel imports regulated?

Parallel imports are not regulated.

14. Is it possible to market pharmaceutical products online, by email and/or mail order?

It is not permitted to market pharmaceutical products online, by email and/or mail order.

15. Are there any restrictions on advertising pharmaceutical products (available over the counter or on prescription)?

The Ministry of Public Health is authorised to license all advertisements for pharmaceuticals conveyed by audio-visual transmission (*section 88, the Drug Act, B.E. 2510 (1967)*). The content and pictures used in printed advertisements must also be licensed before being released to the public.

Specifically, the Drug Act requires that drug advertisements must not:

- Claim that the drug is capable of miraculous cures or total treatment or cure or prevent disease or illness.
- Exaggerate or make false claims about the drug.
- Create the understanding that the drug contains medicinal substances or ingredients other that those it does contain.

Drug manufacturers whose advertisements violate section 88 of the Act are liable for imprisonment for a term not exceeding six months and a fine not exceeding THB10,000 (about US$230), or both.

PRODUCT LIABILITY AND CONSUMER PROTECTION

16. Please give a broad overview of product liability law. In particular:

- Under what legal provisions can liability arise (eg contract, tort, statutory)?
- Who is potentially liable for a defective product?

- What is the substantive test for liability?
- What defences are available?
- What is the scope of potential liability and sanctions?

- **Legal provisions.** Although there is currently no regulation that directly concerns product liability, there are certain statutes that would support legal claims based on the concept of product liability. Moreover, as a civil law country, the concept of product liability will in many ways be similar to that of other civil law jurisdictions. Thailand also has an established set of tort principles that provide consumers with the ability to sue for damages sustained by defective products.

  The Consumer Protection Act (*B.E. 2522*) which came into effect in 1979 and was amended in 1998 (which established certain committees to deal with consumers' complaints) extends the definition of "consumer" to include a person who uses goods or obtains services even though the person does not pay for the goods. Although the Consumer Protection Act specifically extends the definitions of a consumer to include non-contracting parties, a consumer would have great difficulty enforcing his or her rights. This is largely due to the privity of contract requirements of the Thai Civil and Commercial Code.

  As noted above (*see Question 15*), the Food and Drug Administration protects consumers through its power to regulate advertising.

- **Who is liable?** Claims are brought against those who infringe the rights of consumers. It is usually the manufacturer of the product who is liable or importers who bring products into the country for sale.
- **Substantive test.** In order to bring an action for product liability, it is necessary to show causation. In order to show contractual liability, the element of privity of contract must be present.
- **Defences.** The Consumer Protection Act does not refer to defences. However, it does state that as long as judgment has not been reached by the Consumer Protection Commission, companies against which consumers claims have been brought can continue to engage in business activities.
- **Scope of liability.** In the event of violation of the Consumer Protection Act, the Board of Consumer Protection is empowered by the Consumer Protection Act to revoke or suspend the licence of the manufacturer or importer. Penalties for violation also include prison sentences and fines.

  In 1999, the FDA also initiated procedures that provide for cash rewards to consumers who identify manufacturers that violate consumer protection statutes. Consumers who file complaints are entitled to 35% of any court fines reviewed against manufacturers that are found liable.

17. Are class actions permitted for product liability claims? If so, how common are they?

Class actions are not permitted.

18. Does any regulatory body monitor compliance with authorisation and/or consumer protection regulations? If so, what are its powers?

The Consumer Protection Act of 1979 provides for the creation of a Board of Consumer Protection (*see Question 16*). The Board of Consumer Protection is entrusted with a wide range of functions, which includes considering complaints from consumers who suffer hardship or injury resulting from acts of business persons.

As noted above (*see Question 16*), the FDA and the Ministry of Industry also are authorised to engage in consumer protection activities.

INTELLECTUAL PROPERTY

19. What is the test for a pharmaceutical product to be capable of patent protection? Are there separate tests for biotechnology, medical device or GMO products?

In order to be patented, an invention must:

- Be new (novel).
- Involve a higher inventive step.
- Be capable of industrial application.

20. What is the procedure for obtaining patent protection? In particular:

- To whom should the application be made?
- What are the key stages of the process and timing?
- What fee is payable?
- For how long is protection given?
- What is the renewal process?
- In what circumstances can a patent be revoked?
- Is your country a party to any international conventions on patent protection?

- **Application.** Patents effective in Thailand are granted by the Intellectual Property Department. Protection under the Patent Act is only available to a patentee for whom a patent has

been granted in Thailand. A foreign patent has no protection under law unless it has been granted in Thailand.

Address: Intellectual Property Department,
Ministry of Commerce,
44/100 Sanambin Nam Nonthaburi Road,
Nonthaburi 11000
Tel: 02 547 4692 5
Fax: 02 547 4691
Website: *http://www.ipthailand.org*

Pharmaceutical Patents. The Patent Act creates the Board of Pharmaceutical Patents (the Board) to monitor monopoly practice for pharmaceutical patents. The Board is authorised to trace and compare prices between patented pharmaceuticals and non-patented pharmaceuticals with the same qualification of treatment or remedy and to report to the Price Fixing and Anti-Monopoly Committee or the director if any patented pharmaceutical product is not being distributed or is being distributed at an unreasonably high price. Before taking any measure, the Board must provide the opportunity for the patentee or interested person to present information and statements.

- **Process and timing.** After filing and preliminary examination of an application, it is published in the official Patent Journal in Thai. Any opposition must be made within 90 days from the date of publication.

  In order to file a patent application, a patent specification must be prepared, which should include drawings or photographs if necessary for a better understanding of the invention. Claims and an abstract may also be included.

  In general, it takes:

  - three to five years for an invention patent to be issued;
  - one to two years for a design patent to be issued; and
  - three to six months for a petty patent to be issued.

- **Fee.** The fees payable are listed in the Intellectual Property Department website (*http://www.ipthailand.org/Ministerial_patent.html*).

- **Duration of protection.** The Patent Act, as amended in 1992 and 1999, provides protection for patents of inventions, designs and petty patents. The term of protection (counted from the filing date of the application) is:

  - 20 years for an invention patent;
  - ten years for a product design patent; and
  - six years for utility models.

- **Renewal process.** A petty patent is an invention that has novelty and is capable of industrial application but does not involve an inventive step. A petty patent is valid for six years but it may be renewed twice. The first renewal is for two years and the second for an additional two years (for a total of ten years).

- **Revocation.** The Intellectual Property and International Trade Court (IP/IT Court) was established in December 1997 under the International Property and International Trade Court Establishment Act, October 1996. The IP/IT Court is responsible for ensuring justice in case of intellectual property right violations. The IP/IT Court is also empowered to issue criminal rulings. The validity of patents can be challenged in proceedings brought in the IP/IT Court.

- **International conventions.** According to the Patent Act, the right to apply for patent protection is also extended to nationals of countries that are parties to international patent treaties or conventions to which Thailand is also a party. Since Thailand is a member of the World Trade Organisation (WTO) and the Agreement of Trade Related Aspects of Intellectual Property Rights (TRIPS), nationals of WTO member countries will receive the same protection as Thai nationals.

21. Are drug patents commonly infringed? What is the process for enforcement?

It is not uncommon for infringements of drug patents to occur. A person using a patented product, process or design without authorisation is subject to a term of imprisonment not exceeding three years or a fine of not more than THB400,000 (about US$9,300), or both.

In addition, a person selling or having in possession for sale any product made under a patented product or design with the knowledge that such product is produced by a person not having authorisation is subject to a term of imprisonment not exceeding two years or a fine of not more than THB20,000 (about US$460) or both.

22. Can the brand of a pharmaceutical/medical device/GMO product be protected by registration as a trade mark? If so, what is the test for obtaining trade mark protection?

To be registrable, a trade mark must:

- Be distinctive.
- Not be forbidden by law.
- Not be identical with, or similar to, those registered by others.

23. What is the procedure for obtaining registration of a trade mark? In particular:

- To whom should the application be made?
- What are the key stages of the process and timing?
- What fee is payable?
- For how long is protection given?

- What is the renewal process?
- In what circumstances can a trade mark be revoked?
- Is your country a party to any international conventions on trade mark protection?

- **Application.** Applications for registration of trade marks are filed with the Intellectual Property Department of the Ministry of Commerce under the Trade Mark Act B.E. 2543 (*2000*) (*see Question 20 for contact details*).
- **Process and timing.** Applications must contain a specimen of the trade mark as well as a detailed list of the goods or services to be covered by the application.

  After an application is filed and processed, it is published in the official Trade Mark Gazette. If there is no objection within 90 days of publication, registration is granted in due course, dated as of the day of application.

  It takes about ten months for a trade mark application to be registered.
- **Fee.** A fee of THB500 (US$12) is charged for each trade mark.
- **Duration of protection.** A trade mark registration is valid for ten years from the application date.
- **Renewal process.** After the expiration of the initial ten-year period, a trade mark registration is renewable for successive ten-year periods.
- **Revocation.** A trade mark can be revoked if :
  - it appears to the Registrar that the proprietor of the registered mark has violated the conditions or limitations imposed on the registration; or
  - the proprietor has abandoned or ceased to use the mark or the mark is no longer distinctive.
- **International conventions.** An application for a trade mark filed in Thailand within six months of a corresponding application filed in a foreign country will be considered to have been filed in Thailand on the same date on which the foreign application was filed, provided that the corresponding country provides reciprocal treatment to Thai nationals. As noted above (*see Question 20*), Thailand is a member of WTO and TRIPS.

24. What is the process for enforcing brand or trade mark infringement?

The law provides both civil remedies and criminal sanctions for unauthorised use of another person's marks:

- Civil suit. Legal proceedings can be instituted in court to prevent use or recover damages for infringement of a trade mark.
- Criminal suit. The Trade Mark Act and Penal Code both provide for criminal sanctions against any person who forges or imitates any other person's trade mark.

HOMEOPATHIC PRODUCTS

25. Are homeopathic products specifically regulated? If so, please give details.

The FDA does not specifically regulate homeopathic products. Homeopathic products must be registered as traditional drug products at the FDA.

DEVELOPMENTS

26. Please summarise any impending developments in the field of life sciences (regulatory/legal/popular).

Developments that should be mentioned are:

- Electronic submissions of applications to regulatory authorities. These are permitted in the US and are becoming accepted in Europe. Electronic submissions are also gradually becoming accepted in Thailand. At the present time, the FDA permits electronic submissions of applications for import licences and for the registration of medical devices and cosmetic products.
- There has been progress toward supporting and developing the harmonisation schemes of pharmaceutical regulations of the Association of Southeast Asian Nations (ASEAN) member countries in order to complement and facilitate the objectives of the ASEAN Free Trade Area (AFTA), in particular the elimination of technical barriers to trade posed by regulations, without compromising the quality, efficacy and safety of drugs.

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