



International Guide on Health Industry Laws

A Global Practice Guide prepared by the Lex Mundi Health Care and Life Sciences Practice Group

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About this Guide

Because each nation of the world faces unique challenges with respect to health care that must be addressed using that nation's resources, the health care systems around the world are as varied as the nations themselves. Medical advancements and technological improvements are rapidly changing the face of health care in many places, yet the cost of those advancements and improvements put them out of reach for many.

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This publication is not intended to represent a comprehensive guide nor legal advice on the matters covered, but rather provide a general overview on the subject. They may only be used as an indication and advice should always be sought from the appropriate Lex Mundi member law firm.

Please note that each response was provided on a different date, and therefore the answers to the survey refer to laws and regulations in force on that specific date.

Thailand

Prepared by Lex Mundi member firm Tilleke & Gibbins International Ltd.

1. Provide an introduction on health law in your jurisdiction.

The health care industry is subject to a wide range of laws and regulations, including those related to healthcare reimbursement, social security, hospital, pharmaceuticals, medical devices, and laws regulating the practices of medical professionals. The National Health Act B.E. 2550 (2007) is considered the principal healthcare law in Thailand. The Act codifies important rights and duties on health that are not prescribed in any other laws, such as the right to live in a healthy environment, the right to receive sufficient health information to make an informed decision to accept or refuse any health service, etc. This is an important turning point in the Thai health system, as the National Health Act extends the concept of health from medical and public health sectors to include other sectors, abiding under the principle of “all for health and health for all.” This leads to a health governance system with greater participation and better health policy decision-making.

The key turning point in the Thai healthcare system was in 2001, when the introduction of a universal healthcare program, known as the THB 30 (USD 1) scheme, was initiated. Under this scheme, patients may visit public hospitals and pay only THB 30 per visit, with the remaining costs of the treatment being subsidized by the government. Apart from the THB 30 scheme, there are three main schemes relating to the healthcare system in Thailand.

Social Security Scheme (SSS). This is administered by the Social Security Office. This scheme was initiated to assure benefits for insured employees to relieve their difficulties, including sickness, maternity, physical disability, unemployment, death, old-age pension, etc. This scheme is financed by tripartite contributions from the government, employers, and employees.

Civil Servant Medical Benefit Scheme (CSMBS). This is a medical service welfare system for civil servants and state enterprise employees and their dependents (including spouses, up to three children, and parents). The budgets of the government and state enterprises are the sources of funding.

Personal payment. People who have no other benefits or do not intend to use the benefits described above pay medical expenses himself/herself or via private voluntary health insurance.

Thai legislation regulating pharmaceuticals and medical devices primarily serves to enforce consumer protection, which aims to ensure that the public has access to safe and efficacious products of high standards and to prevent product abuse. In order to be distributed, sold, and marketed, the products must be registered with the appropriate government authorities. A marketing authorization (MA) product registration dossier must be filed following the ASEAN Harmonization requirements. In addition, a Certificate of Pharmaceutical Product or Certificate of Free Sale is required for the registration of said products. For other health industry aspects, Thailand imposes a variety of laws, regulations, and announcements in such diverse fields as the social security scheme, sanatorium and hospitals, laws regulating the medical profession, and pharmaceuticals and medical devices law.

Relevant Authorities and Associations:

The Ministry of Public Health (MoPH)

- The MoPH is the principal agency in the Thai public health system. Its role is to manage Thai healthcare and formulate national health policies. The main functions of the MoPH include promoting, supporting, controlling, and coordinating all activities related to physical

and mental health, as well as the well-being of people. Within this ministry, there are four separate departments including the Office of Permanent Secretary, Cluster of Medical Services Development, Cluster of Public Health Development, and Cluster of Public Health Services Support.

Office of Permanent Secretary

- This Office deals with strategic development, translation of the Ministry's policies into operational plans, the allocation and management of resources, the monitoring and evaluation of program implementation of agencies under the Ministry, international cooperation, and the amendment of relevant laws. Provincial Administration, which consists of the Provincial Public Health Office and District Health Offices, also operates under this Office.

Cluster of Medical Services Development

This cluster is comprised of three departments:

- Department of Medical Services
 - This department is responsible for conducting research studies, developing and transferring appropriate medical technologies, and providing complex, specialized, or tertiary medical care.
- Department for Development of Thai Traditional and Alternative Medicine
 - This department is responsible for taking actions with regard to the law relating to the protection and promotion of Thai traditional medicine wisdom and to other relevant laws; establishing and developing standards; making recommendations on consumer protection, promoting, and supporting the provision of Thai traditional medicine, folk medicine, and alternative medicine in the healthcare system.
- Department of Mental Health
 - This department is responsible for conducting research studies, developing and transferring knowledge and technologies relating to the promotion of mental health, prevention, treatment, and rehabilitation of mental health problems, and providing services, especially for serious or complicated cases of mental disorders.

Cluster of Public Health Development

This cluster comprises two departments:

- Department of Disease Control
 - This department is responsible for conducting research studies, developing and transferring knowledge and technologies for the surveillance, prevention, control, diagnosis, and treatment of diseases and health risks, coordinating with relevant agencies, international organizations and local administrative organizations in the surveillance, prevention and control of diseases and health risks, as well as other international health problems.
- Department of Health
 - Apart from conducting research studies for health promotion and environmental management that facilitate healthy status, this department also establishes and develops the quality and standards for health impact assessments and supports local administrative organizations, communities, and public/private sector partnerships to participate in health promotion efforts and in environmental management for health.

Cluster of Public Health Services Support

This cluster consists of three departments:

- Department of Health Service Support
 - This department is responsible for promoting and coordinating efforts for the development of the health services system, taking actions with regard to laws relating to medical registration, healthcare facilities, and other relevant laws, supporting the operation of programs on health education and health systems of the people, conducting research studies, and conducting research and disseminating knowledge and transferring appropriate medical technologies relating to health service systems.
- Department of Medical Sciences

- This department is responsible for establishing and developing the standards of laboratory analyses and methods, developing knowledge and technologies relating to health products, herbal medicine, and diagnostic investigations, providing laboratory analysis services and serving as reference laboratories, and developing laboratory quality assurance systems.
- Thai Food and Drug Administration (TFDA)
 - The TFDA is responsible for taking actions according to laws relating to foods, drugs, cosmetics, hazardous substances, psychotropic substances, narcotics, medical devices, and volatile substance abuse prevention and surveillance, monitoring and inspecting the quality and standards of products, business places, and advertisements, as well as adverse effects of health products, conducting research studies and developing knowledge, technologies, and systems for consumer protection relating to health products, and developing the potential of consumers in selecting health products and protecting their rights.

2. Provide a checklist of laws with a short summary of the general requirements of each.

a.) Hospital law

Sanatorium Act B.E. 2541 (1998): (พรบ.สถานพยาบาล พ.ศ.๒๕๔๑)

- i. This is the main Act that governs hospital activities, from operating to managing a sanatorium. This Act classifies two types of sanatoriums: those with overnight facilities (inpatient) and those with no overnight facilities (outpatient).
- ii. This Act requires a person who wishes to engage in a sanatorium business to obtain a license from the grantor (Bureau of Sanatorium and Art of Healing, Ministry of Public Health). Such person must be a qualified person, as specified in this act; for example, he/she must not be less than 20 years old, must be domiciled in Thailand, etc.
- iii. In the consideration of the issuance of a license, the authority will look at the action plan for the establishment, a sanatorium which possesses the qualifications prescribed in the Ministerial Regulation, the medical instruments, and medical supplies or vehicles. In addition, the medical practitioners must meet the requirements of the Ministerial Regulations.
- iv. The license to operate a sanatorium is valid for ten years. Extension and transfer of the license is allowed, subject to the authority's decision. The licensee, manager, and practitioner can be the same person.

b.) Laws regulating medical profession

The laws in this area cover the practices and qualifications of medical professions, of which are termed the Professional Practice of the Art of Healing. Since various councils of the medical profession have been established, certain medical professions are regulated under their own specific professional laws. Some examples are the Medical Professionals Act B.E. 2525 (1982), the Pharmaceutical Profession Act B.E. 2537 (1994), the Nursing and Midwifery Profession Act B.E. 2528 (1985), and the Dental Profession Act B.E. 2537 (1994). The following are definitions of Professional Practice of the Art of Healing, Medical Professional Act, and Consumer Case Procedure Act.

Professional Practice of the Art of Healing Act B.E. 2542 (1999) (พรบ.การประกอบโรคศิลปะ พ.ศ.๒๕๔๒)

- This Act defines the practice of the art of healing as a professional practice which is performed or intended to be performed on humans concerning a medical examination, diagnosis, cure, prevention of diseases, health promotion and rehabilitation, and obstetrics, but not including other professional practices in medical and public health governed by laws on such matters.

Medical Professionals Act B.E. 2525 (1982) (พรบ.วิชาชีพเวชกรรม พ.ศ.๒๕๒๕)

- Medical professionals are required to hold a professional medical license. The license is obtained through the Medical Council of Thailand, which is regulated by the Medical Professional Act B.E. 2525 (1982).
- This Act defines the “medical profession” as a profession that performs the following activities on human beings: examination, diagnosis, treatment and prevention of disease, midwifery, insertion of contact lenses for visual correction, and acupuncture for therapeutic or anesthetic purposes, and shall include any act of surgical procedure, the use of radiation, the insertion or injection of medicine or other matter, and the insertion of any matter inside the body for the purposes of birth control, beautification, or physical fitness.

Consumer Case Procedure Act B.E. 2551 (2008) (พรบ.วิธีพิจารณาคดีผู้บริโภค พ.ศ.2551)

- Any damage that occurs to life, the body, or health during the course of medical practice falls under this Act. This is a procedure which allows a consumer or other entity, such as the Consumer Protection Board, to bring a lawsuit on behalf of a consumer who is injured by the wrongful practice of a medical professional to bring a claim against them.

c.) Pharmaceutical law

Drug Act B.E. 2510 (1967) (พรบ.ยา พ.ศ.๒๕๑๐)

- This is the most important Act in pharmaceutical law, as it covers all activities relating to drugs, including importation, sales and manufacturing, marketing, parallel import, advertising, product liability, drug packaging, and labeling.
- The Thai Food and Drug Administration (TFDA) is the authority that is responsible for overseeing all activities related to drugs under the Drug Act B.E. 2510 (1967). A person who wishes to manufacture, sell, or import modern medicine into Thailand is required to obtain a license from the TFDA. Specific requirements are set for the applicant who wishes to apply for the license: such person must be the owner of the business and have sufficient property or status to be able to establish and operate the business, be at least 20 years of age, reside in Thailand, etc.
- Advertising must be approved by the TFDA before dissemination, as several restrictions apply such as prohibitions on exaggerating the advertisement, falsely declaring properties of the medicine, etc.

d.) Medical instrument law

Medical Instrument Act B.E. 2551 (2008) (พรบ.เครื่องมือแพทย์ พ.ศ.2551)

- All importation and manufacturing of medical devices require a license from the TFDA. The applicant must have a place of business registration (an establishment license) by a local company.
- The Act classifies medical devices into three classes: Class 1, Licensed Medical Devices; Class 2, Notification Medical Devices; and Class 3, General Medical Devices. Class 1 is the most rigorously-controlled class, and is comprised mainly of condoms, HIV diagnostic kits, contact lenses, etc. Required documents for this class are a certificate of free sale, certificate of quality system of manufacture, such as the ISO certificate, clinical evaluation, sterility, stability, raw material and finished product specifications, Thai label leaflet, product photo, and manufacturing process. Meanwhile, Class 2 and 3 are under more lenient control. Examples of Class 2 devices include physical therapy products, silicone breast implants, and alcohol detectors. Class 3 includes all medical products which are not classified as either Class 1 or Class 2. The required documents for Class 2 are similar to those of Class 1. For Class 3, the following documents are required: certificate of free sale, product catalogue and its photo, specifications, and ISO 13485 certification.
- Currently, there are no specific regulations regarding IT and mobile medical applications. According to the Medical Instrument Act, however, software and

IT systems are also considered as medical devices, and the importer will normally register them together with the main devices.

3. Provide any special issues which arise in your jurisdiction.

a) Compulsory Licensing

In 2006-2008, Thailand's Ministry of Public Health issued the first set of compulsory licenses on six patented drugs. The legitimacy of these compulsory licenses was questioned by the drug originators who own the patents, international legal experts, and other experts in the pharmaceutical industry.

Although the parameters within which a country may legally permit a compulsory license are set out in the WTO's TRIPs agreement, the TRIPs Agreement itself is not Thai Law. In the context of compulsory licenses in Thailand, the relevant law is set out in the Patent Act B.E. 2522 (A.D. 1979), as amended in 1992 and 1999. This legislation permits various types of voluntary and compulsory licenses in Sections 45-47 and 50-52.

The compulsory licenses pursued by the Ministry of Public Health were based on Section 51 of the Thai Patent Act. This section permits government ministries and departments to seek a compulsory license subject to compliance with a number of preconditions.

The dispute regarding the legitimacy or validity of the compulsory licenses pursued by the MoPH stems from the first paragraph of Section 51, which appears to authorize government ministries and departments to exploit a patented invention by way of a compulsory license, but requires the government department to pay a royalty after a period of negotiation with the patent owner. The Ministry has interpreted this to confer authority on the Ministry to unilaterally issue compulsory licenses without prior consultation with the patent owners or the Department of Intellectual Property.

Moreover, the second paragraph of Section 51 specifically states that "... the ministry or bureau or department shall submit its offer setting forth the amount of royalty and conditions for exploitation to the Director-General." Section 50 also sets out the process for negotiations between the parties and the procedures which must be followed before a compulsory license can be issued by the Director-General of the Department of Intellectual Property. Therefore, a careful reading of Section 50 and Section 51 would seem to suggest that the Ministry of Public Health has not taken the appropriate steps required by law when seeking to impose compulsory licenses on patented drugs.

The Compulsory Licensing period was limited to a certain period—mostly until December 31, 2011—but for two patents, the period lasted until the patents had expired. Some patent owners eventually negotiated with the MoPH to offer special programs that expanded public accession to medicine. As a result, in some cases, the MoPH agreed to not import or manufacture generic drugs of the patent owner, who also gave support.

b) Surrogacy

The issue of surrogacy has taken a foothold in the sphere of public debate in 2014 with news of an Australian couple allegedly abandoning their disabled surrogate baby with his Thai surrogate mother. The news has once again highlighted that Thai law has not kept up with advancements in infertility treatments. Assisted reproductive technologies exist and are used in Thailand, but falls into a legal grey area.

A draft piece of legislation, the Surrogacy Bill, seeks to specify the legal bases and clarify the issue. The Surrogacy Bill has been entrenched in the drafting process for several years. It has already been passed by the Cabinet and is currently under review and awaiting parliamentary approval. Under the proposed legislation, legally married couples would be allowed to engage a surrogate mother to carry a pregnancy on their behalf.

The Surrogacy Bill also sets out the rights of the social parents, surrogate mother, and newborn child. Under present law, a child born via surrogacy is considered the legitimate child of the

birth mother, meaning the social parents have no legal parental rights to the child. As a result, the prospective parents have to go through the lengthy process of adoption to obtain the rights to the child, which for foreign couples in particular can be burdensome and expensive. Surrogacy arrangements have also yet to be tested in the Thai courts and an agreement or contract entering into a surrogacy agreement before the Surrogacy Bill takes effect could be deemed a violation of provisions of public order and/or good morals.

Based on the current draft wording of the Surrogacy Bill, all of the legal parental rights and duties will be conferred to the social parents without the need to go through the adoption process. In addition, the Juvenile and Family Court is granted jurisdiction to hear cases involving any disputes related to parenthood as a result of surrogacy. The Bill allows a married husband and wife to seek surrogacy, and it can be viewed that surrogacy under this Bill is not allowed for same-sex couples.

As it stands, commercial surrogacy is not explicitly illegal under Thai law. The practice is, however, regulated by the Thai Medical Council, which controls the medical practitioner, not the surrogacy mother and prospective parents. The pertinent regulation provides that the physician may perform the surrogacy under conditions. For instance, no payments or compensation of any kind would be allowed to be made to the surrogate mother, with the exception of those related to health maintenance costs at the time of pregnancy, delivery, and post-delivery. Surrogacy mothers must have a blood (familial) connection with the couple whose medical records confirm their infertility problems.

Under the new law, engaging in commercial surrogacy and brokering and advertising would be strictly prohibited and would incur heavy penalties.

c) Clinical Trials

Another health-related issue in Thailand that is worth mentioning is the regulation of clinical trials in Thailand. Currently, there is no centralized regulation for clinical trials. At least six regulatory authorities have jurisdiction over various aspects of clinical trials, including:

- 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 Ministry of Public Health; and
- Medical schools and hospitals with specific regulations and/or an ethics committee.

To conduct a trial, drug developers/sponsors must obtain approval for clinical trials from the Ethical Review Committee for Research in Human Subjects of the MoPH or from the ethics committee of the research institute or university that will conduct the trial. Once the developer receives approval from the relevant ethics committee, it can apply to the FDA for a license to import investigational drugs into Thailand for research purposes.

Although the FDA does not have a direct mandate to regulate clinical trials in humans, 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.

Moreover, Thailand follows the World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects 1964 and the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use, Guidelines on Good Clinical Practice 1996 (ICH GCP), even though Thailand has not ratified them.

A draft bill covering human research is currently undergoing public hearing and will most likely progress to the Cabinet and then to the Council of State and finally the parliament for promulgation.

d) Stem Cell Research

In Thailand, stem cell research and use for therapy is currently regulated by the Medical Council's Regulation on Medical Ethics Regarding Stem Cell Research for Human Treatment B.E. 2552 (2009).

Persons who conduct stem cell research or persons who use stem cells for disease treatments must be registered with the Medical Council of Thailand. The objective of this is to check and stop persons who are not capable and have no experience with the proper training from performing stem cell treatments. Additional draft regulations to further control the use of stem cells in Thailand are pending approval at the MoPH.

4. Are mobile health applications regulated under the law of your jurisdiction? If so, provide a brief summary as to how they are regulated.

Mobile health applications are new in Thailand and, generally speaking, mobile health applications are used mainly by health professionals as a reference guide. The public does not yet use mobile health applications as an alternative to consulting a health professional due to the prevalence of medical facilities in all parts of the country and access to a Universal Healthcare System. As a result, no issues have arisen from the use of mobile health technologies. The most commonly used mobile health applications among the general public in Thailand are fitness and training aids. Neither is regulated by any specific piece of legislation or regulation.

Contact Information

Alan Adcock

Alan.A@tilleke.com

Areeya Pornwiriyangkura

Areeya.P@tilleke.com

Atthachai Homhuan

Atthachai.H@tilleke.com

Tilleke & Gibbins International Ltd.

Supalai Grand Tower, 26th Floor, 1011 Rama 3 Road, Chongnonsi, Yannawa, Bangkok 10120, Thailand

Tel +66 2653 5555

Fax +66 2653 5678

www.tilleke.com

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