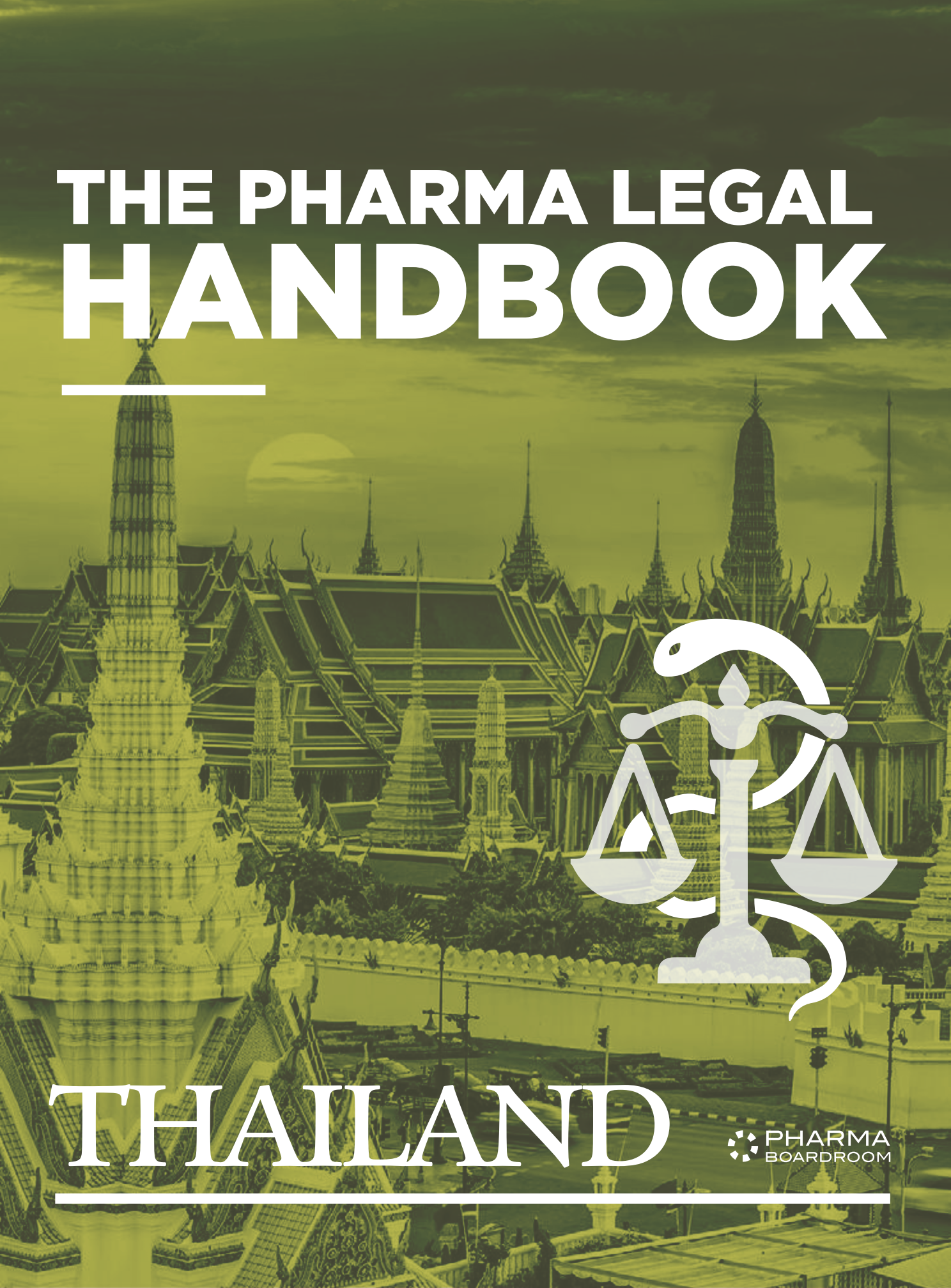
THE PHARMA LEGAL HANDBOOK



THAILAND

PHARMA BOARDROOM

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Tilleke & Gibbins

Tilleke & Gibbins' is a full-service regional law firm in Southeast Asia, with over 180 lawyers and consultants practicing in Bangkok, Hanoi, Ho Chi Minh City, Jakarta, Phnom Penh, Vientiane, and Yangon, and a particularly strong presence in the life sciences sector. With cross-practice life science teams combining corporate and commercial attorneys with decades of government relations experience; patent experts from the IP group holding degrees in medicine, pharmacology, nutrition, chemistry, and biomedical engineering; and licensed pharmacists from the regulatory affairs group with industry experience drawn from decades of working for multinational life sciences companies, Tilleke & Gibbins paves the way for pharmaceutical industry clients to enter and excel in markets throughout Southeast Asia.

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San was ranked among the top of his batch in the Thai Bar Association examinations, and also graduated with distinction with an LLM, focused on intellectual property and digital economy, from the University of Glasgow. He has a multidisciplinary background with advanced degrees in engineering and chemical engineering.

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REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

3. What are the steps to obtaining authorization to develop, test, and market a product?

4. What are the approximate fees for each authorization?

5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?

6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?

7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?

8. How is compliance with regulation monitored and evaluated? Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements?

9. What is the potential range of penalties for noncompliance?

10. Is there a national healthcare system? If so, how is it administered and funded?

11. How does the government (or public) healthcare system function with private sector healthcare?

12. Are prices of drugs and devices regulated and, if so, how?

13. How are drugs and devices used by patients paid for? What roles do public and private payers play?

14. Who dispenses drugs and devices to patients and how are those dispensers compensated?

15. What are the professional and legal responsibilities of those who dispense drugs and devices? What role do they play in providing patient care, information, and safety?

01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

In Thailand, drugs, biologics, and medical devices are regulated by the Thai Food and Drug Administration (Thai FDA), under the supervision of the Ministry of Public Health (MOPH).

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

The Drug Act, B.E. 2510 (1967), as amended, provides the regulatory framework for the marketing authorization and post-marketing surveillance of drugs and biologics in Thailand. The Medical Device Act, B.E. 2551 (2008), as amended, provides legislation governing the marketing authorization and post-marketing surveillance of medical devices in Thailand.

In general, there are no specific regulations related to pricing for drugs and medical devices. The prices of medicinal products are only controlled when they are listed in the National List of Essential Drugs (NLED), a list of medications used by public hospitals and public health services. Under the control of the Ministry of Commerce, drugs on the NLED are subject to a median price policy. However, these pricing regulations only apply to drugs that are listed on the NLED and are prescribed in public hospitals. Private hospitals and drug stores are free to set their own prices for the drugs they sell, but the price must not exceed the sticker price—the maximum price set by the distributor.

The cost of drugs and medical devices on the NLED can be reimbursed by the government. Government hospitals generally provide drugs and medical devices from the NLED to civil servants and other persons under the universal coverage (THB 30 Scheme). Civil servants are not required to pay anything to the hospital, and patients under the THB 30 Scheme will pay a maximum of THB 30 (approximately USD 1). Public hospitals will be reimbursed in full by the government for the cost of the drugs and medical devices used in these cases. Another reimbursement scheme available to Thais is the Social Security Scheme, which is available to employees of private companies. For more information on reimbursements, please see the answer to **question 10** below.

3. What are the steps to obtaining authorization to develop, test, and market a product?

Generally, there are three steps to obtaining market authorization. First, an established company in Thailand must obtain either a drug manufacturing license or a drug importation license from the Thai FDA. After obtaining one of these licenses, the company can submit a request to manufacture or import samples for various purposes (e.g., clinical trials, research and development, etc.). For research purposes, the clinical trial protocol must be approved by

the relevant ethics committee. Once those first two steps are complete, the company can apply for marketing authorization of the particular drug product.

4. What are the approximate fees for each authorization?

The new fee schedule is designed to facilitate the government for levying fees by defining the actual cost for each type of registration. At present, to the best of our knowledge, the fee assessed will not exceed the maximum values provided in the table below.

Pharmaceutical Products		
(1) Modern Drug Manufacturing Licenses	THB 50,000	Each copy
(2) Modern Drug Selling Licenses (Retail)	THB 5,000	Each copy
(3) Modern Drug Selling Licenses (Wholesale)	THB 10,000	Each copy
(4) Modern Drug Import License	THB 100,000	Each copy
(5) Modern Drug Registration License	THB 25,000	Each copy

Medical Devices		
(1) Medical Device Manufacturing Licenses	THB 100,000	Per issue
(2) Medical Device Import License	THB 200,000	Per issue
(3) Medical Device Sale License	THB 10,000	Per issue
(4) Medical Device Advertising License	THB 10,000	Per issue
(5) License Application	THB 1,000	Per issue

5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?

The modern drug manufacturing and modern drug import license are both valid for a period of one year (from January 1 to December 31). Each type of license must be renewed before December 31 each year in order to be carried over to the following year.

Currently, marketing authorization drug licenses are valid indefinitely, as long as the accompanying drug manufacturing or drug import license is still valid. Amendment No. 6 of the Drug Act, which will come into force on October 13, 2019, prescribes that marketing authorization drug licenses have a validity of seven years, and can be renewed.

6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?

There are no significant differences between local and foreign-owned manufacturers. Both types of companies are required to apply for marketing authorization licenses for each drug product they wish to manufacture.

There are, however, major differences between original and generic product registrations. Original drugs are classified as new drugs, meaning the registration dossier must include both non-clinical and clinical documentation. To register a generic product, companies can merely submit the bioequivalence study to prove pharmaceutical equivalence with the original product.

Further, after obtaining a market authorization license, new drugs (original products) must undergo a mandatory Safety Monitoring Program (SMP). During the SMP, new drugs can only be dispensed in hospitals. The company manufacturing the original drug must provide periodic safety updates to the Thai FDA for the first two years. After the committee evaluates these reports over the two-year period, the drug can be released from the SMP and re-classified. SMPs are not required for generic drugs.

7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?

If the drug combination is new, the Thai FDA will classify it as a new drug.

For a combination between a drug and medical device, the classification will be based on the products intended use; therefore, it requires an evaluation by both the Drug Bureau and the Medical Device Control Division. However, the final classification decision will be at the Thai FDA's discretion.

8. How is compliance with regulations monitored and evaluated? Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements?

Thailand's regulatory regime is comparable to that in the U.S. because it is governed by a centralized process through the Thai FDA, and specific subdivisions of the Thai FDA, namely the Drug Bureau and the Medical Device Control Division, are responsible for supervising drugs and medical devices, respectively.

In order to comply with the Thailand's regulatory regime, pharmaceutical companies must follow the provisions laid out in the Drug Act, as amended, and medical device companies must follow the provisions laid out in the Medical Device Act, as amended.

In order to monitor pharmaceutical and medical device companies and ensure that there are no adverse effects regarding the safety or efficacy of drugs, the Thai FDA conducts consistent pre- and post-marketing inspections. These inspections can come in a variety of forms, including on-site inspections for GMP compliance, on-site inspections to explore any aspect of the manufacturing process, and general on-site visits on a yearly basis.

9. What is the potential range of penalties for noncompliance?

Under the Drug Act and the Medical Device Act, penalties for noncompliance by a licensee include suspension of import licenses, revocation of the marketing authorization licenses, a financial penalty, and imprisonment.

10. Is there a national healthcare system? If so, how is it administered and funded?

The national healthcare system is divided into three main schemes:

1. The Social Security Scheme (SSS): This scheme is administered by the Social Security Office and financed by tripartite contributions from the government, employers, and employees. It covers employees, and employers with one or more employees. This scheme is not applicable to those covered by the Civil Servant Medical Benefit Scheme (below) or to employees of foreign entities.
2. The Civil Servant Medical Benefit Scheme (CSMBS): This scheme is administered by the Social Security Office and provides health care benefits

to government officials and their dependents (spouse, parents, and up to three children).

3. The Universal Health Coverage Scheme (UCS): This scheme is administered by the MOPH and covers the remaining population not covered under either the SSS or the CSMBS.

11. How does the government (or public) healthcare system function with private sector healthcare?

In general, private sector healthcare companies are not subsidized by the government. However, some private sector healthcare companies may be partially subsidized by the government if they cooperate with the SSS. Subsequently, these private hospitals are able to provide healthcare services for patients who are registered at their hospital under the SSS.

12. Are prices of drugs and devices regulated and, if so, how?

The prices of medicinal products are only controlled when they are listed in the National List of Essential Drugs (NLED), a list of medications used by public hospitals and public health services. Under the control of the Ministry of Commerce, drugs on the NLED are subject to a median price policy. However, these pricing regulations only apply to drugs that are listed on the NLED and are prescribed in public hospitals. Private hospitals and drug stores are free to set their own prices, but the price must not exceed the sticker price—the maximum price set by the distributor.

In May 2019, the Department of Internal Trade issued Notification No. 52 on the Price Reporting of Drugs, Devices, and Healthcare Services, that requires distributors to set reasonable prices and to report the price of any and all drugs sold to government and private hospitals. Further, government and private hospitals must also report the selling price of medicinal product and medical devices.

13. How are the drugs and devices used by patients paid for? What roles do public and private payers play?

Reimbursement of drugs and devices is only available for those listed on the NLED and prescribed at public hospitals (or private hospitals that cooperate with the SSS). Therefore, the government will ultimately bear the cost (beyond THB 30) of NLED-listed drugs and devices at all public hospitals and a select number of private hospitals. For all other drugs and devices, including those prescribed by private hospitals that do not cooperate with the SSS, the patient will be solely responsible for the total cost.

14. Who dispenses drugs and devices to patients and how are those dispensers compensated?

Licensed practitioners, such as doctors and dentists, are authorized to prescribe the drugs and medical devices to patients. Following prescription for a licensed practitioner, a licensed pharmacist will dispense the prescribed drugs or medical devices to patients.

15. What are the professional and legal responsibilities of those who dispense drugs and devices? What role do they play in providing patient care, information, and safety?

Only licensed practitioners such as doctors and dentists are authorized to prescribe drugs in Thailand, after which such drugs will be dispensed by a licensed pharmacist. Generally speaking, most drugs are available at the hospital and at the pharmacy stores. Unlike the case for drugs, there are no dispensing requirements for medical devices.

Only doctors holding a medical license from the Medical Council of Thailand can practice the medical profession in Thailand, which includes the diagnosing, treating, and preventing diseases. Likewise, only pharmacists holding a pharmacy license from the Pharmacy Council of Thailand can dispense drugs to patients.

Medical professionals who work in hospitals may have additional responsibilities such as investigating a patient's drug allergies, and monitoring drug levels.

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