The Pharma Legal Handbook

Thailand

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms · Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs · Orphan Drugs and Rare Diseases · Biosimilars and Biologics

PHARMA BOARDROOM

Thailand

**The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Thailand.
It is a must have for any company operating in the country or looking to enter the market.**

Prepared in association with Tilleke & Gibbins, a full-service regional law firm in Southeast Asia, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

*** THIS REPORT WAS ORIGINALLY PUBLISHED IN OCTOBER 2019 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**
****LAST UPDATE: AUGUST 2022**

Tilleke & Gibbins

Tilleke & Gibbins' is a full-service regional law firm in Southeast Asia, with over 190 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.
From research and development, to clinical trials, to registration and market entry, to commercialization and technology transfer, to government relations, Tilleke & Gibbins assists leading and emerging companies through every stage of a product's life cycle, and is proud to be the pharmaceutical industry's go-to legal advisor for Southeast Asia.

Firm Name: Tilleke & Gibbins
Address: Supalai Grand Tower, 26th Floor, 1011 Rama 3 Road, Chongnonsi, Yannawa, Bangkok, 10120, Thailand
Phone: +66 2056 5555
Fax: +66 2056 5678
Email: bangkok@tilleke.com

THE AUTHORS

ALAN ADCOCK

PARTNER AND DEPUTY DIRECTOR, INTELLECTUAL PROPERTY AND REGULATORY AFFAIRS

Alan Adcock is a partner and deputy director of the Tilleke & Gibbins intellectual property and regulatory affairs groups, helping to oversee the firm's client work in these areas across ASEAN. He is recognized as a leading intellectual property lawyer based on his handling of corporate IP matters, including licensing and acquisitions, and his knowledge in life sciences, fluency in Mandarin, and outstanding client service. Since 2005, Alan has received recognition by Asialaw Leading Lawyers Survey as one of Asia's leading business lawyers in the area of intellectual property, and he has been named a top IP lawyer in Thailand by Chambers Asia-Pacific, The Legal 500 Asia Pacific and WTR 1000. Alan is also recognized as a leading IP strategist by IAM Strategy 300, an expert on patents in IAM Patent 1000, one of the world's foremost life sciences practitioners by IAM Life Sciences 250, and a leading life sciences regulatory lawyer by Who's Who Legal. He also co-heads the firm's regional life sciences practice.

Alan represents diverse clients, from pioneers in the life sciences to the biggest IP owners in the world, and helps them achieve the dual goals of profit and protection. He has extensive experience in IP acquisitions, strategic structuring, technology transfer, and IP licensing and securitization agreements and he regularly handles various IP infringements and regulatory infractions involving labeling, advertising, clinical trials, product handling/warehousing, product registration, taxation, and import/export violations across most of Asia.

E: alan.a@tilleke.com | P: +66 2056 5871

DR. ATTHACHAI HOMHUAN

MANAGER, REGULATORY AFFAIRS

Dr. Atthachai Homhuan is a manager of regulatory affairs at Tilleke & Gibbins. He prepares healthcare product dossiers for registration and he helps international companies develop market entry strategies for countries in Southeast Asia. His broad experience allows him to evaluate the feasibility of product registrations, conduct plant audits, and coordinate pre-clinical and clinical trials in accordance with international guidelines and standards. Atthachai also reviews healthcare product labeling for food, cosmetics, medical devices, and drug products in Thailand and other Southeast Asian countries.

He also assists pharmaceutical, chemical, life sciences, and biotechnology companies to draft and review their patent claims and specifications, and advises patent agents on amending claims and providing responses to office actions. Atthachai frequently drafts counterstatements against opposing parties in trademark and patent applications. His practice also includes advising on pre-litigation and litigation matters involving the life sciences, medical devices, and pharmaceuticals. He has presented before the IP&IT Court as a witness in chemistry and life sciences patent litigation.

Prior to joining the firm, Atthachai was a postdoctoral researcher in Japan and Taiwan, focusing on stem cell therapies and vaccine development. He applied his technical expertise to the industry when he became a project manager for a Thai vaccine manufacturing company, where he led the firm's R&D efforts. His industry background also includes serving as a formulation manager at the subsidiary of a well-known American pharmaceutical innovator, where he was a group leader in charge of the company's R&D and production functions. Atthachai holds a PhD in Pharmaceutical Technology from Thailand's Mahidol University.

E: atthachai.h@tilleke.com | P: +66 2056 5610

THE AUTHORS

SAN CHAITHIRAPHANT

ATTORNEY-AT-LAW

San Chaithiraphant is an attorney-at-law in Tilleke & Gibbins' intellectual property group, specializing in patents for life sciences and technological products. Within the firm's Bangkok IP team, San advises clients on a range of complex patent issues, including specification drafting, registration procedures, portfolio management, and more.

In addition to patent work, San advises leading clients in the life sciences industry on a wide range of legal matters including regulatory compliance, product registration with the Thai FDA, and securing intellectual property rights in Thailand.

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.

E: san.c@tilleke.com | P: +66 2056 5640

KITTIYA NOPPARATRUNGROJ

CONSULTANT, REGULATORY AFFAIRS

Kittiya Nopparatrungroj is a consultant in Tilleke & Gibbins' regulatory affairs team in Bangkok and is a licensed pharmacist in Thailand. She advises and assists international and local clients in the pharmaceutical, medical device, and broader life sciences industries on market entry, obtaining and maintaining marketing authorization licenses, advertising and marketing regulations, and other related regulatory affairs matters. She also regularly prepares and reviews registration dossiers, and evaluates the feasibility of product registrations, advertisements, and labeling material for pharmaceutical products and medical devices.

Kittiya regularly authors articles covering updates of Thai laws and regulations applicable to the pharmaceutical and medical device industries. In addition, she has participated in several seminars and webinars on the same topics.

Kittiya graduated with a bachelor's degree in Pharmaceutical Science from Mahidol University. During her studies, she completed internships with a local drug manufacturer and a local cosmetics manufacturer in Thailand. She also received a scholarship to intern at the Analytical Chemistry Institute of Johannes Kepler University in Austria, where she conducted research on steroid hormones from placenta extract.

E: kittiya.n@tilleke.com | P: +66 2056 5750

Tilleke & Gibbins

Tilleke & Gibbins is a leading regional law firm in Southeast Asia

With over 200 lawyers and consultants in Cambodia, Indonesia, Laos, Myanmar, Thailand, and Vietnam, we represent the top investors and the high-growth companies that drive economic expansion in Asia in the key areas of commercial transactions and M&A, dispute resolution and litigation, and intellectual property.

Cambodia
cambodia@tilleke.com

Indonesia
indonesia@tilleke.com

Laos
lao@tilleke.com

Myanmar
myanmar@tilleke.com

Thailand
bangkok@tilleke.com

Vietnam
vietnam@tilleke.com

CONTENTS

01

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).

More precisely, the Drug Division of the Thai FDA is the main regulatory body controlling pre-marketing and post-marketing of Drugs and Biologics in the Kingdom; while the Medical Device Control Division of the Thai FDA is the main regulatory body controlling pre-marketing and post-marketing of medical devices in the Kingdom.

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 and patients under universal coverage are not required to pay anything to the hospital. 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.

Classification of Pharmaceutical Products

Chemical drugs are classified into three categories:

(i) New Drug

A new drug is a drug formulation that has not been registered in Thailand before. New drugs include products of a new chemical entity (NCE), a new combination, a new dosage form, a new drug delivery system, a new indication, a new strength, or a new route of administration.

(ii) New Generic Drug

A new generic drug is a drug formulation that has the same active pharmaceutical ingredient(s), dosage form, indication(s), route of administration, and strength as a reference drug that had previously been approved by the Thai FDA after B.E. 2534 (1991).

(iii) Generic Drugs

A generic drug is a drug formulation that has the same active pharmaceutical ingredient(s), dosage form, indication(s), route of administration, and strength as a reference drug that had previously been approved by the Thai FDA before B.E. 2534 (1991).

Classification of Medical Devices

On February 15, 2021, the risk classification system, as laid out in the ASEAN Medical Device Directive (AMDD), entered into force resulting in significant changes in the classification system and registration scheme of medical devices in Thailand. Under the Medical Device Act, medical devices are classified into three categories, depending on the level of risk of the medical device to individuals and the general public:

(i) Licensed Medical Devices (equivalent to Class 4 Medical Device)

The Licensed Medical Device category is the most strictly controlled class. Prior to importation and production, the applicant must apply for and obtain a license for importation or manufacturing of licensed medical device (or product license). The license for importation or manufacturing of a licensed medical device remains valid for five (5) years and it is renewable. The full Common Submission Dossier Template (CSDT) is required.

Examples of Licensed Medical Devices include SARS-CoV-2 diagnostic test kits, HIV diagnostic test kits (but not HIV self-test kits), methamphetamine test kits, Hyaluronic acid-based filler for correction of skin depressions, silicone breast implants, blood bags, etc.

(ii) Detailed Notification Medical Devices (equivalent to Class 2 and Class 3 Medical Device)

Detailed Notification Medical Devices are subject to a less intensive review procedure than Licensed Medical Devices. Prior to importation and production, the applicant must submit a dossier and obtain an approval certificate for importation or manufacturing of a Detailed Notification Medical Device (or product license). The certificate for importation or manufacturing of a Detailed Notification Medical Device remains valid for five