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.

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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.

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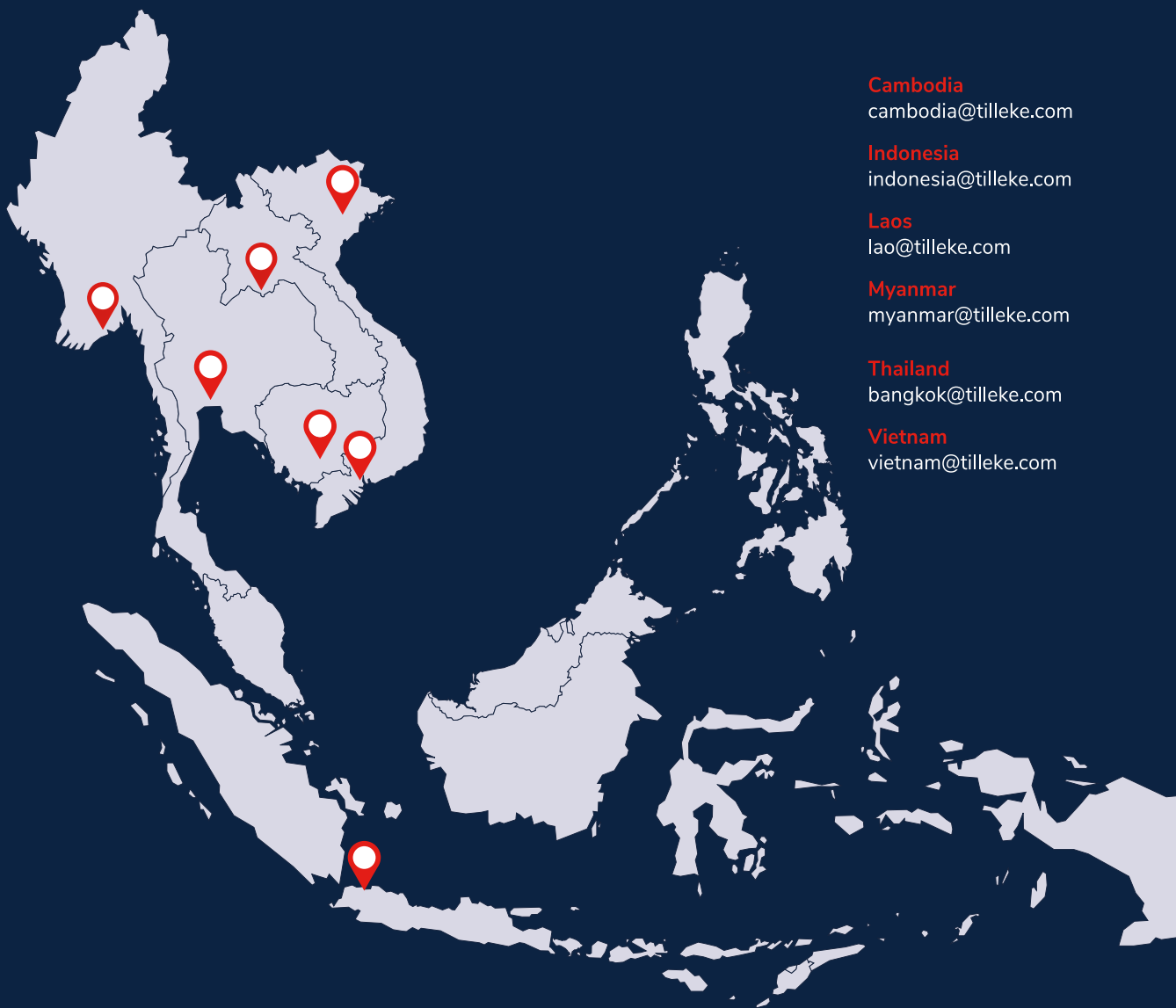

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CONTENTS

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