The Pharma Legal Handbook

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Asia

Regulatory, Pricing, and Reimbursement Overview

PHARMA BOARDROOM

Regulatory, Pricing and Reimbursement Overview

This Pharma Legal Handbook answers essential questions about the legal and regulatory environment in 8 countries.

Prepared in association with leading local and international law firms and consultancies, it is a must-have for any company operating in/or looking to enter these niches in any of these countries.

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China

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Our service to clients is premised on the dual foundations of strong local law capabilities and a global business outlook. Our lawyers are qualified in many jurisdictions, including the People's Republic of China, Hong Kong SAR, England and Wales, the United States, Singapore and Australia.
Our understanding of the laws and processes in major jurisdictions around the world enables us to advise our clients effectively on the largest and most complicated cross-border matters in China and elsewhere. Our strengths have been widely recognized by our clients and peers. Chambers has commented on our cross-border capabilities in the following terms – "outstanding quality of its lawyers", "high level of service that is comparable to international firms", and "strong global outlook".

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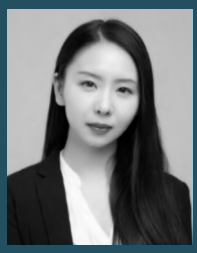

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REGULATORY, PRICING AND REIMBURSEMENT OVERVIEW

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

Several governmental agencies are responsible for the administration of drugs (including biologicals) and medical devices, including the following key players:

- The National Medical Product Administration ("NMPA"), formerly known as the China Food and Drug Administration, which is responsible for issuing marketing authorizations of drugs and medical devices and monitoring product quality.
- The National Health Commission ("NHC"), which is responsible for the overall guidance of healthcare reform, administering China's Essential Drug List ("EDL") and managing the drug tendering and procurement policies.
- The Ministry of Human Resources and Social Security ("MOHRSS"), the authority that takes the lead in formulating the National Drug Reimbursement List ("NRDL").

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

Drugs

Key Regulations

The fundamental pieces of legislation for the pharmaceutical industry are the Drug Administration Law and the Implementing Rules of Drug Administration Law. In addition, the NMPA has issued a wide range of other regulations and implementing measures to regulate the pharmaceutical industry.

Authorization

Steps to obtain the marketing authorization for drugs are mainly set out in the Drug Registration Administrative Measures. In general, all new drug candidates must go through four steps before being marketed: pre-clinical research, application for clinical trial of an investigational new drug, clinical trials and new drug application.

- Pre-clinical research of a drug candidate must be conducted in accordance with the Good Laboratory Practices ("GLP").
- After completing the pre-clinical research, a clinical study sponsor must obtain approval for clinical trials from the NMPA's Centre for Drug Evaluation ("CDE") to conduct clinical trials on the investigational new drug. In July 2018, the NMPA promulgated a new rule that if an applicant for clinical trials does not receive any negative opinions from the CDE within 60 days after the date on which the application was accepted, the clinical trials may be initiated and conducted in accordance with the protocols previously submitted to the CDE in the application.

• After obtaining the approval of a clinical trial, the sponsor shall conduct the clinical trial at Good Clinical Practice ("GCP") certified institutions. Clinical trials are divided into Phase I, Phase II, Phase III and Phase IV, of which Phase IV refers to post-marketing clinical trials.
• Upon completion of the Phase III clinical trial, the sponsor may submit a new drug application for approval to manufacture and launch such investigational new drug.

Pricing

• **Terminal Units of Non-Public Hospitals**

The price of drugs was previously regulated under a scheme of maximum retail price ("MRP") of drugs set by the government, which was abolished (except for narcotic and certain psychotropic drugs) in June 2015.

• **Public Hospitals**

- Centralized Drug Procurement Program. Competitive bids shall be used to purchase medications and be carried out by local governmental authorities on a province-by-province basis under the central coordination of NHC. Public hospitals used to be allowed to mark-up drugs by around 15% above procurement prices. This policy has been replaced with the "zero-mark-up" (i.e., no-profit, the drug price that a hospital charges the patient should be the same as it pays to the drug suppliers) policy in July 2017.
- Volume-Based Procurement. The National Healthcare Security Administration ("NHSA") will directly negotiate with pharmaceutical companies about drug supply for public hospitals and strive to get favourable terms by insisting on bulk purchasing. The participant with the lowest tender price will be the bid winner. By securing the purchase price at the terminal end, the cost at each distribution phase upwards will be reduced, which ultimately leads to an end lower price.

Reimbursement

In terms of reimbursement for the cost of drugs, China's medical insurance system was first adopted in 1998 and has now been gradually expanded to provide coverage for most of the population in China. Individual participants of the national medical insurance program and their employers (if any) are required to contribute to the medical insurance funds by paying an insurance premium monthly. Medical insurance program participants are eligible for full or partial reimbursement of the cost of medicines included in the NRDL, which contains over 2,000 Western and Chinese medicines that are divided into Class A and Class B drugs. Class A drugs typically include low-priced and clinically necessary drugs that can be fully reimbursed, and the Class B drug catalogue typically includes higher-priced or new drugs that generally require the patients to assume 10-40% of the drug's total cost.

The latest NRDL issued in 2020 includes a total of 2,800 drug products, of which 1,264 are Western medicines and 1,315 are proprietary Chinese

medicines. Two hundred and twenty-one (221) drug products are NHSA negotiation-based drugs which will be supplied at an agreed low price during the term of the applicable purchase agreement. Each province may formulate its own Provincial Drug Reimbursement List based on the NRDL and subject to certain restrictions and procedures, but it is likely that the provincial version of the Reimbursement Drug List may be abandoned in the future.

Medical Devices

Key Regulations

The fundamental legislation for the medical devices industry is the Medical Device Supervision and Administration Regulations. A wide range of other regulations and implementing measures have been issued by the NMPA to guide the medical devices industry.

Authorization

Under the Medical Device Registration Administrative Measures, devices can be categorized into Class I, Class II and Class III devices. Class I devices are simple devices that are exempted from clinical trials and are administered through a record-filing system. Class II and Class III devices are more complex devices with medium or high risks, and their safety should be evidenced by clinical trials (unless being on the list of devices exempted from clinical trials) and the devices shall be registered with the NMPA before entering the market.

Pricing

There is no MRP scheme in the medical devices industry. Similar to the mark-up policy previously applicable to drugs, public hospitals are still allowed to charge a certain mark-up on the medical devices purchased by them (for example, a maximum of 5% mark-up is allowed in Shanghai, provided that the purchase price for a medical device exceeds RMB4,000 and the mark-up should not exceed RMB200).

Reimbursement

At the national level, there is a negative list that precludes certain devices (such as glasses and massage devices) from governmental reimbursement. Detailed reimbursement coverage and rates for medical devices are subject to local policies in each province.

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

Please refer to **Question 2 of Chapter 1** regarding the authorizations of drugs and medical products.

4. What are the approximate fees for each authorization?

The table below lists the government fees charged by the NMPA for each category of registration:

CATEGORY	SUB-CATEGORY	FEE (RMB '000)	FEE (RMB 10,000)
Domestic drug	New drug	Clinical trial approval	192.0
		Marketing authorization	432.0
	Generic drug	Marketing authorization (clinical trial is waived)	183.6
		Marketing authorization (clinical trial is required)	318.0
	Supplementary registration	Regular registration items	9.6
		Registration items requiring technical review	99.6
	Renewal application		Set by the provinical authority
Imported drug	New drug	Clinical trial approval	376.0
		Marketing authorization	593.9
	Generic drug	Marketing authorization (clinical trial is waived)	367.6
		Marketing authorization (clinical trial is required)	502.0
	Supplementary registration	Regular registration items	9.6
		Registration items requiring technical review	283.6
	Renewal application		227.2
Domestic devices[1]	Class III	Marketing authorization	153.6
		Post-marketing amendment registration	50.4
		Renewal registration	40.8
Imported devices	Class II	Marketing authorization	210.9
		Post-marketing amendment registration	42.0
		Renewal registration	40.8
	Class III	Marketing authorization	308.8
		Post-marketing amendment registration	50.4
		Renewal registration	40.8

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

Marketing authorizations for drugs and medical devices are valid for a term of five years. The applicant must prepare and submit the renewal application documents to the provincial NMPA six months before the expiry of the

[1] Government fees for domestic or imported Class I and Class II medical devices are set by the provincial authority.

marketing authorization. In addition to review of the application documents, the authority may determine that it wishes to conduct a technical review and on-site inspection when it deems necessary.

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

In March 2016, the NMPA issued the Reform Plan for Registration Category of Chemical Drugs which reclassified drug applications as follows:

Category 1 drugs	New drugs that have not been marketed anywhere in the world.
Category 2 drugs	Improved new drugs that are not marketed anywhere in the world.
Category 3 drugs	Drugs that have equivalent quality and efficacy to the brand-name drugs have been marketed abroad but not yet in China.
Category 4 drugs	Drugs that have equivalent quality and efficacy to the brand-name drugs and have been marketed in China.
Category 5 drugs	Drugs that have already been marketed abroad, but are not yet approved in China.

In general, generic drugs follow similar registration pathways to brand-name drugs. The applicant needs to conduct bioequivalence ("BE") tests for generic drugs to demonstrate conformity with the brand-name drugs. BE tests are administrated through the record-filing system, instead of the review and approval process applicable to new drugs. The BE applicant only needs to file a record on the Clinical Trial Management Public Platform designated by the NMPA and can start the clinical trial after obtaining the filing number. In addition, new drugs in Category 1 may be entitled to certain preferential policies that are not applicable to generic drugs, including fast-track approval treatment by the CDE, a monitoring period up to five years (during which the NMPA will not accept any applications for new drugs with the same active ingredient) and more flexible drug manufacturing technology transfer options.

Local drug manufacturers and foreign-owned drug manufacturers in China are subject to the same drug approval procedures.

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

"Drug (including biologics) + device" combination products must obtain marketing authorizations from the NMPA. For such combination products, if the drug plays a major function, the combination products should be registered as a drug; if the device plays a major function, the combination products should be registered as a medical device.

"Drug + drug" combination products can be commercialized in China market after clinical trials have been completed with satisfactory results and the combination therapy has been granted the marketing authorization.

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?

The NMPA and its local counterparts have the jurisdiction to enforce the Drug Administration Law and its implementing rules, the Medical Device Supervision and Administration Rules, and other guidelines and regulations on drugs and medical devices.

In June 2017, China joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) - an international organization founded by drug administrators of the U.S., EU and Japan to facilitate international collaboration in the pharmaceutical industry. Some of the ICH technical guidelines have already been used as the basis of NMPA regulations.

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

Pursuant to the Drug Administration Law and its implementing rules and the Medical Device Supervision and Administration Rules, non-compliance (depending upon the specific illegal activities) could be subject to different administrative penalties, including monetary fines, confiscation of illegal gains, suspension of business activities, and revocation of marketing authorization and other permits and licenses. In the worst scenario, violation of drug and medical device legislations may result in criminal liabilities.

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

Healthcare System Reform

The PRC government has promulgated several healthcare reform policies and regulations to ameliorate and improve the country's healthcare system. On March 17, 2009, the Central Committee of the PRC Communist Party and the State Council jointly issued the Guidelines on Strengthening the Reform of Healthcare System. On December 27, 2016, the State Council issued the Notice on the Issuance of the 13th Five-year Plan on Strengthening the Reform of Healthcare System. On April 25, 2017, the General Office of the State Council issued the Main Tasks of Healthcare System Reform in 2017. On November 29, 2019, the State Council Leading Group for Deepening the Reform of the Medical and Health Systems, a task force of the State Council, issued the Notice on Several Policies and Measures to Further Deepen the Reform of the Medical and Health System with the Centralized Procurement and Use of Drugs as A Breakthrough (the "Notice"). The Notice pointed out that in order to enhance the interplay of healthcare, medical insurance and pharmaceuticals systems, magnify the synergy of the reforms and resolve the problems involving the general public's accessibility to good medical services, measures and policies covering 15 aspects shall be adopted, as follows:

1) Deepening the reform of state-led centralized procurement and use of drugs;
2) Establishing a national public drug procurement market and a multi-party interlocked procurement market structure;
3) Improving the quality of drugs;
4) Ensuring stability of drug supply;
5) Shortening the payment periods of public medical insurance;

6) Promoting the establishment of a nationwide unified and open market for drug manufacturing and distribution;
7) Promoting synergic reformative measures, such as the adoption of a dynamic pricing strategy price for medical services;
8) Reviewing the salary structure for healthcare staff in public medical institutions for their benefit;
9) Strengthening the supervision of good medical prescription practices in healthcare institutions;
10) Enhancing the implementation of uniformed medical insurance compensation standards for drugs;
11) Improving medical insurance payment methods;
12) Ameliorating the regulatory framework of medical insurance funds;
13) Promoting the refined management of medical services;
14) Improving the nationwide drug price monitoring system;
15) Accelerating the informatization construction of the healthcare system.

Hospitals

China's hospital system consists of both public and private medical institutions and insurance programs. Public hospitals are owned by the government and funded by out-of-pocket payments by patients, governmental subsidies and various governmental insurance schemes (including Urban Employee Basic Medical Insurance (UEBMI) and Urban and Rural Resident Basic Medical Insurance (URRBMI), both of which managed by the MHRSS).

Private hospitals are controlled and operated by private entities and are mainly funded by out-of-pocket payments by patients and commercial insurance schemes (governmental insurance coverage for private hospitals has been quite low).

Reimbursement

Please refer to **Questions 2 & 13 of Chapter 1** regarding the medical reimbursement system in China.

Essential Drug List

In 2009, the Chinese government launched the National Essential Drug List System, which aims to promote essential medicines sold to patients at fair prices and to ensure that the general public in China has equal access to the drugs contained in the National Essential Drug List. The Ministry of Health promulgated the first National Essential Drug List on August 18, 2009 and the latest version was revised and released on October 25, 2018, which includes a total of 685 drugs.

A new version of the Essential Drug List is being discussed and is expected to be released in 2021.

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

Because of governmental insurance coverage and pricing regime, the public hospitals are of a "non-profit" nature and serve most Chinese patients. Private hospitals can be established either for profit or non-profit, and private hospitals for profit are usually established to attract patients with higher income or with commercial insurance coverage. According to statistics issued by the NHC, as of November 2020, there are 35,000 public and private hospitals across the nation, of which 12,000 are public hospitals and 23,000 are private hospitals. Compared to the statistics by November 2019, there are six fewer public hospitals, while there are 1,146 more private hospitals; the total number of hospital visits over a period from January 2020 to November 2020 is 2.98 billion, a decline of 12.5% compared to that over a period from January 2019 to November 2019, of which public hospitals had 2.51 billion visits, with a year-on-year decrease of 13%, and private hospitals had 0.47 billion visits, with a year-on-year decrease of 9.4%.

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

Please refer to **Question 2 of Chapter 1** regarding the regulation of the price of drugs and device products.

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

At private hospitals, drugs and devices are mainly paid out of pocket by patients or covered by commercial insurance (to the extent available).

At public hospitals, most medical expenditures can be covered by UEBMI or URRBMI (subject to certain exceptions and ceilings) and the patients need to pay out of pocket for the remaining expenditures. For example, the quantity of coverage, reimbursement rates and reimbursement ceiling under URRBMI and UEBMI in Shanghai are as follows:

Urban and Rural Resident Basic Medical Insurance

- Out-patient and Emergency Services
  - Deductibles: If the annual cumulative medical costs of an insured person meet the deductible amount, a certain percentage of the excessive costs will be covered by the medical insurance, and the remaining costs shall be borne by the insured individually.

    Deductible Amount: RMB300 for people aged 60 years or above, the severely disabled, elementary and middle school students, children and infants; RMB500 for people aged 18 years and above and under 60 years.
  - Reimbursement Rates: 70% of covered claims incurred at out-patient and emergency departments of community healthcare centres or primary hospitals; 60% of covered claims incurred at out-patient and emergency departments of secondary hospitals; 50% of covered claims incurred at out-patient and emergency departments of secondary hospitals.

- In-patient Services
  - Deductibles. If the medical costs of the insured person meet the deductible amount, a certain percentage of the excessive costs will be

covered by the medical insurance, and the remaining costs shall be borne individually.

- Deductible Amount: RMB50 for primary hospitals; RMB100 for secondary hospitals; RMB300 for tertiary hospitals.
- Reimbursement Rates:

For people aged 60 years or above, and the severely disabled: 90% of the covered claims incurred at community healthcare centres or at primary hospitals; 80% of the covered claims incurred at secondary hospitals; 70% of the covered claims incurred at tertiary hospitals.

For people aged under 60 years: 80% of the covered claims incurred at community healthcare centres or at primary hospitals; 75% of the covered claims incurred at secondary hospitals; 60% of the covered claims incurred at tertiary hospitals.

Urban Employee Basic Medical Insurance

INSURANCE SCHEME	ANNUAL CONTRIBUTIONS	APPROXIMATE COVERAGE LEVELS FOR MEDICAL SERVICES AND DRUGS	ANNUAL COVERAGE CEILINGS
URRBMI	SHANGHAI · Individual: US$ 16-54 (RMB 110-370) (depending on age)	SHANGHAI · Inpatient: 60%-90% (depending on age and hospital level) · Outpatient: 50%-70% (depending on age and hospital level)	SHANGHAI · No coverage ceiling
UEBMI	SHANGHAI · 11.5% of employee wages: 9.5% from payroll tax on employers and 2% employee contribution	SHANGHAI · Inpatient: 85%-92% (depending on age and working status) · Outpatient: 50%-90% (depending on age and working status)	SHANGHAI · No coverage ceiling

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

Drugs and devices are dispensed by hospitals or retail drug stores. Dispensers are compensated through UEBMI and URRBMI.

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?

Hospitals and drug stores must purchase drugs and devices from qualified manufacturers or distributors, and comply with other legal requirements on acceptance, storage, transport, distribution and dispensing of drugs or device products.

Hospitals and drug stores should monitor and report adverse drug reactions (ADR) to the NMPA within a statutory time period, and take corresponding remediation actions (such as recall of products) to ensure the patient safety.

India

This chapter about Regulatory, Pricing and Reimbursement in India was published in association with:

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LEGAL AND TAX COUNSELING WORLDWIDE

We are an India Centric Global law firm (www.nishithdesai.com) with four offices in India and the only law firm with license to practice Indian law from our Munich, Singapore, Palo Alto and New York offices. We are a firm of specialists and the go-to firm for companies that want to conduct business in India, navigate its complex business regulations and grow. Over 70% of our clients are foreign multinationals and over 84.5% are repeat clients.

Our reputation is well regarded for handling complex high value transactions and cross border litigation; that prestige extends to engaging and mentoring the start-up community that we passionately support and encourage. We also enjoy global recognition for our research with an ability to anticipate and address challenges from a strategic, legal and tax perspective in an integrated way. In fact, the framework and standards for the Asset Management industry within India was pioneered by us in the early 1990s, and we continue remain respected industry experts.

We are a research based law firm and have just set up a first-of-its kind IOT-driven Blue Sky Thinking & Research Campus named Imaginarium AliGunjan (near Mumbai, India), dedicated to exploring the future of law & society. We are consistently ranked at the top as Asia's most innovative law practice by Financial Times. NDA is renowned for its advanced predictive legal practice and constantly conducts original research into emerging areas of the law such as Blockchain, Artificial Intelligence, Designer Babies, Flying Cars, Autonomous vehicles, IOT, AI & Robotics, Medical Devices, Genetic Engineering amongst others and enjoy high credibility in respect of our independent research and assist number of ministries in their policy and regulatory work.

The safety and security of our client's information and confidentiality is of paramount importance to us. To this end, we are hugely invested in the latest security systems and technology of military grade. We are a socially conscious law firm and do extensive pro-bono and public policy work. We have significant diversity with female employees in the range of about 49% and many in leadership positions

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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?

The following authorities are responsible for the regulation drugs, biologics and medical devices in India:

(i) Central Drugs Standard Control Organization **("CDSCO")**, headed by Drugs Controller General of India **("DCGI")** under the Ministry of Health and Family Welfare

The CDSCO regulates import, manufacture, marketing and clinical trials of drugs, biologics and medical devices for the entire territory of India.

(ii) State-level licensing authority **("SLA")**

Each State, through SLAs (who are the state-level Food and Drug Administration), independently regulates manufacture and sale of drugs, biologics and medical devices within the territory of that State.

In certain cases, there is an overlap of function between DCGI and SLAs. In such cases, SLAs operate under the direction of DCGI.

(iii) National Pharmaceutical Pricing Authority **("NPPA")** under the Department of Pharmaceuticals

NPPA fixes prices of certain essential drugs, biologicals and medical devices for entire territory of India. It monitors price movements other drugs, biologicals and medical devices to ensure that the prices do not increase more than 10% year on year. NPPA also monitors the availability of drugs and takes remedial steps to prevent shortage.

(iv) Controller of Legal Metrology

Each State, through its Controller of Legal Metrology, regulates packaging and labelling of medical devices. The Controller of Legal Metrology does not have jurisdiction over drugs and biologicals.

(v) Review Committee on Genetic Manipulation **("RCGM")** under the Department of Biotechnology **("DBT")**

The RCGM, under the Ministry of Science and Technology to evaluate safety related aspects of on-going research involving Genetically Modified Organisms.

(vi) Genetic Engineering Approval Committee **("GEAC")**

The GEAC, under the Ministry of Environment, Forests and Climate Change regulates research, testing, safe use and handling of Genetically Modified Organisms and their products from an environment safety perspective.

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

Authorization/Licensing

The Drugs and Cosmetics Act, 1940 ("**D&C Act**") along with the Drugs and Cosmetics Rules, 1945 ("**D&C Rules**") and the Medical Device Rules, 2017 ("**MDR**") governs the authorization, import, manufacture, distribution and sale of drugs, biologicals of medical devices.

Pricing

The Drugs (Price Control) Order, 2013 **("DPCO")** under the Essential Commodities Act 1954 **("ECA")** regulates the pricing of drugs, biologicals and notified medical devices in India.

Reimbursement

India currently does not have a mechanism for reimbursement of drugs, biologics and medical devices. Out-of-pocket expenditure by patients is the primary means of financing of drugs, biologicals and medical devices. For more details on India's healthcare system, please refer to **Chapter 1 Question 7.**

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

Development

There is no authorization required to develop a product in India. However, once a product starts showing properties that qualify it to be called as drug, then a license is required to import or manufacture it.

A product in development becomes a drug when it starts satisfying the criteria for what is considered a drug for the purposes of the D&C Act, which includes:

(i) "all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

(ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

(iii) all substances intended for use as components of a drug including empty gelatine capsules; and

(iv) such devices* intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board"

Testing

Any processing activity carried out on a drug, biological or medical devices requires a manufacturing license from the CDSCO or SLA, as the case

may be. Testing of product amounts to processing. Therefore, a manufacturing license for the purpose of examination, test or analysis is required to be obtained from the SLA. If a product on which testing is to be carried out is to be imported, then a separate import license for the purposes of test and analysis is required from CDSCO. Please note that the import license is to be obtained in addition to the manufacturing license.

Marketing

If the drug or biological qualifies as a "new drug" or if a notified medical device qualifies as an "investigational medical device" or "new In Vitro Diagnostic Device", then a marketing permission from the CDSCO is required to be obtained in respect of such drug, biological or medical device before its manufacture or import, respectively.

The definition of new drug is as follows:

"new drug" means, -

(i) a drug, including active pharmaceutical ingredient or phytopharmaceutical drug, which has not been used in India to any significant extent, except in accordance with the provisions of the D&C Act and the rules, as per conditions specified in the labelling thereof and has not been approved as safe and efficacious by the CDSCO with respect to its claims; or

(ii) a drug approved by the CDSCO for certain claims and proposed to be marketed with modified or new claims including indication, route of administration, dosage and dosage form; or

(iii) a fixed dose combination of two or more drugs, approved separately for certain claims and proposed to be combined for the first time in a fixed ratio, or where the ratio of ingredients in an approved combination is proposed to be changed with certain claims including indication, route of administration, dosage and dosage form; or

(iv) a modified or sustained release form of a drug or novel drug delivery system of any drug approved by the CDSCO; or

(v) a vaccine, recombinant Deoxyribonucleic Acid (r-DNA) derived product, living modified organism, monoclonal anti-body, stem cell derived product, gene therapeutic product or xenografts, intended to be used as drug;

The drugs, other than drugs referred to in sub-clauses (iv) and (v), are considered to be new drugs for a period of four years from the date of the marketing authorization and the drugs referred to in sub-clauses (iv) and (v) shall always be deemed to be new drugs;

The definition of investigational medical device is a notified medical device:

(i) "which does not have its predicate device as defined in clause (zm); or

(ii) which is licenced under sub-rule (4) or sub-rule (6) of rule 20, sub-rule (1) of rule 25, or sub-rule (1) of rule 36 and claims for new intended use or new population or new material or major design change;

and is being assessed for safety or performance or effectiveness in a clinical investigation."

Next, depending on whether the product will be importer or manufactured in India, appropriate license is required to be obtained from the CDSCO or SLA.

The said marketing permission is give only when the DCGI is satisfied about the safety and efficacy of the product. Where the safety and efficacy of the product cannot be established with available data, then a clinical trial (in case of drugs) or clinical investigation (in case of medical devices) is required to be conducted in India to generate safety and efficacy data of the product on Indian population. A permission is also required to undertake clinical trial/ clinical investigation in India.

Thus, for a product which qualifies as a new drug or investigational medical device, the steps needed to be taken to start manufacturing or import of the product in India are:

1) Obtain permission to conduct clinical trial from DCGI
2) Obtain permission to market product from DCGI on the basis of safety and efficacy data generated from the clinical trial
3) Obtain import/manufacturing license to start import/manufacture of the product.

If the drug or biological does not qualify as a "new drug" or if the notified medical device does not qualify as an "investigational medical device", then the product may be marketed in India after obtaining import/manufacturing license.

4. What are the approximate fees for each authorization?

The fees for each authorization are summarized in the table below:

		FEE (IN INR)
Clinical Trials (Drugs)	Phase I	300,000
	Phase II	200,000
	Phase III	200,000
	Phase IV	200,000
Manufacture of New Drug	Original application	500,000
	Subsequent application by same applicant for the drug (but with modified dosage/new claims)	300,000
Import of New Drug	Original application	500,000
	Subsequent application by same applicant for the drug (but with modified dosage/new claims)	300,000
Clinical Investigation (Medical Devices)	Pilot investigation	100,000
	Pivotal investigation	100,000
Clinical Performance Evaluations		25,000
Import or manufacture a medical device which does not have a predicate device (i.e. if the device is first of its kind).		50,000

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

Marketing authorizations for new drugs, investigational new drugs investigational medical devices and new IVDs are valid in perpetuity. Therefore, they do not need to 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?

The drug and medical device regulatory framework does not make a distinction for authorizations between generic and brand name products or between local and foreign owned manufacturers.

In certain cases, there may be relaxations granted based on approvals/authorizations received from a foreign jurisdiction. For more information on the status of foreign marketing authorizations see **Chapter 3 Question 27** (available in **The Pharma Legal Handbook India**)

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

Combination products introduced into the Indian market for the first time are deemed to be 'new drugs', which means that a permission of the DCGI is required before they can be marketed in India. This deeming fiction continues for a period of four years, which means that any other importer or manufacturer of the combination product during the four-year period would also be required to obtain the permission of the DCGI for marketing of the said combination product.

After expiry of period of four years, combination products may be sold in India with appropriate manufacturing or import license from DCGI or SLA, without the requirement of obtaining a marketing permission from DCGI.

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?

The CDSCO along with the SLAs is responsible for ensuring compliance with the requirements of the D&C Act. The CDSCO is primarily responsible for regulating and monitoring clinical trials and import of drugs, biologics and medical devices. The SLAs primarily deal with licensing for manufacture, stocking and sale of drugs. They also carry out pre-licensing and post-licensing inspections and oversee the manufacturing process for drugs manufactured in their respective state units. The CDSCO and the SLA can inspect the premises of any manufacturing license holder without giving prior notice to ensure compliance with applicable laws. If non-compliance to any condition of the license or provision of the D&C Act is observed, the license can be suspended or cancelled, after providing an opportunity for the manufacturer to show cause as to why the license should not be cancelled or suspended.

With respect to clinical trials, the DCGI and Ethics Committee are the primary bodies exercising control over monitoring and enforcement. Any change in clinical trial protocol or serious adverse events occurring during the clinical trial must be notified to the Ethics Committee and the CDSCO.

Though the Indian regulatory framework is broadly comparable with U.S. Food and Drug Administration or the European Medicines Agency, India

has its own unique and independent legislations governing the drug and medical device sector.

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

Penalties for non-compliances with the requirements of the D&C Act have been summarized in the tables below:

Import related contraventions

OFFENCE	PENALTY FOR FIRST OFFENCE		PENALTY FOR SUBSEQUENT OFFENCE		COMMENTS
	Imprisonment	Fine (in INR)	Imprisonment	Fine (in INR)	
Import of adulterated or spurious drugs	Up to 3 years	5,000	Up to 5 years	10,000	The penalties can be imposed individually or together.
Import of prohibited drugs or import of drugs in contravention of the D&C Act	Up to 6 months	500	Up to 1 year	1,000	The penalties can be imposed individually or together.
Import of drug or cosmetic in contravention of a notification issued by the Central Government which prohibits import of drugs and cosmetics in public interest	Up to 3 years	5,000	Up to 5 years	10,000	The penalties can be imposed individually or together.

Manufacture/sale related contraventions

OFFENCE	IMPRISONMENT	FINE
Manufacture or sale of adulterated and spurious drugs which may cause grievous hurt	Up to 10 years	Between 10,00,000 to three times the value of the drugs confiscated, whichever is more
Manufacture or sale of adulterated drugs (not causing grievous hurt) or manufacture of drugs without a valid license	Between 3 to 5 years	INR 1,00,000 to three times the value of the drugs confiscated, whichever is more.
Manufacture or sale of drugs in contravention of any other provision in the D&C Act	Between 1 to 2 years	INR 20,000

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

India does not have a national healthcare system on the lines present in the United Kingdom and other developed countries. The government operates a fair number of primary, secondary and tertiary healthcare centres around the country. However, a majority of health care providers in India operate privately.

The government operates several schemes under which beneficiaries can avail care facilities from private healthcare providers. For example, the Central Government Health Scheme ("**CGHS**") extends medical coverage to central government employees, pensioners and their dependents. The Employee State Insurance Scheme ("**ESI Scheme**") makes it mandatory for employers who employ more than a certain number of employees in the organized sector, to participate in an insurance scheme for employees that covers the employees against the events of sickness, maternity, disablement and death due to

employment injury and to provide medical care to the insured employees and their families.

Having said that, it is a fact that a major chunk of Indian population does not have a health insurance. To address the situation, A National Health Policy was introduced in 2017, with the objective of providing health insurance coverage to poor and backward population of India the tune of INR 500,000 per year. Any healthcare provider who wishes to participate and offer its services under the National Health Policy is required to register itself with the concerned department. As a precondition of registration, the service provider has to agree to a fixed set of charges for its services that are pre-determined by the government. In furtherance of the policy, the Government in the Union Budget of 2018 announced 'Ayushman Bharat', a National Health Protection Mission funded through Union Budget allocations. INR 12 billion (approximately USD 1.8 billion) was allocated to set up one hundred and fifty thousand Health and Wellness Centres as well as hospitalization cover for approximately 100 million poor and vulnerable families with INR 500,000 (approximately USD 7,700) per family, for secondary and tertiary care hospitalization.

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

For the most part, public healthcare and private healthcare systems function within their own spheres. The cost of care at Government hospitals is fixed by the Government while the market determines cost in the private sphere. However, it has been observed that an increase in quality of public hospitals is concomitant with a decrease in cost of care at private hospitals. Certain primary health and secondary centers run by the Government provide free treatment to patients who are otherwise unable to afford it.

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

The prices of all drugs and notified medical devices are regulated in India. All drugs and notified medical devices have been identified as "essential commodities" and their prices are regulated like prices of other essential commodities under a law called Essential Commodities Act, 1955 ("**ECA**") and an order called Drugs (Prices Control) Order, 2013 ("**DPCO**").

The ECA and DPCO segregate drugs and notified medical devices under two categories – scheduled formulations and non-scheduled formulations, depending on whether the drug or notified medical device appears in the schedule of the DPCO. The prices of scheduled formulations are fixed by an agency called National Pharmaceutical Pricing Authority ("**NPPA**"). The schedule to the DPCO is based on the National List of Essential Medicines, which is amended from time to time. The NPPA uses a formula to fix prices that essentially averages the prices of the same drug or medical device sold under various brands in the market. The government does not fix prices for non-scheduled formulations. However, government has mandated that the price of non-scheduled formulations should not increase by more than 10%

between any 12-month period. The NPPA is tasked with the duty of monitoring prices of non-scheduled formulations.

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

There are three main modes of financing available to patients— out of pocket, beneficiary of government scheme or insurance. Out-of-pocket payment methods, however, remain the primary means of payment as India suffers from low insurance penetration. Reportedly, nearly 30% of the Indian population is devoid of any health insurance. There are also certain Non-Governmental Organizations that provide free medication to patients who are otherwise unable to afford them.

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

Licensed pharmacies and pharmacists are the only persons permitted to dispense drugs to patients in India. The pharmacists are usually compensated by way of salary for their services as part of employment. It is unethical for pharmacists to charge commission from pharmaceutical and medical device companies for sale of drugs and 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?

Pharmacists are governed by the Pharmacy Act, 1948 ("**Pharmacy Act**") and Pharmacy Practice Regulations, 2015 ("**PPR**") issued under the Pharmacy Act. The Pharmacy Act lays down minimum qualifications and mandatory registration requirements for any person intending to practice the profession of pharmacy in India. The role and responsibilities of pharmacists are laid down under the PPR. The PPR defines the practice of pharmacy to mean:

i. "Interpretation, evaluation and implementation of medical orders; dispensing of prescriptions, drug orders
ii. Participation in drug and device selection, drug administration, drug regimen reviews and drug or drug
iii. Provisions of patient counseling and the provision of those acts or services necessary to provide pharmaceutical care in all areas of patient care including primary care; and
iv. Responsibility for Compounding and labeling of drugs and devices (except labeling by a manufacturer, redistributor of non-prescription drugs of drugs and devices and maintenance of proper records for them."

The responsibilities of registered pharmacists include:

- Dispensing medication only on the basis of the prescription of a registered healthcare practitioner, and not substituting the prescription;
- Compounding, preparing, mixing, dispensing and/or supplying medication on the basis of the prescription of a registered medical practitioner.
- Counselling patients by personally initiating discussion on matters that will enhance or optimize drug therapy with each patient. The topics for the discussion may include special directions or precautions for administering the drug, common side effects of the drug and its proper storage.

• Reviewing patient record history and prescription for identifying drug-disease interactions, drug-drug interactions and drug-allergy interactions;
• Maintaining records of drugs dispensed and records of prescriptions for a minimum period of 5 years;
• Maintaining confidentiality of information received;

Indonesia

This chapter about Regulatory, Pricing and Reimbursement in Indonesia was published in association with:

As Indonesia's longest-established law firm (founded 1967), ABNR pioneered the development of international commercial law in the country following its reopening to foreign investment after a period of isolationism in the early 1960s.

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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?

The regulatory authorities with specific jurisdiction over drugs, biologicals, and medical devices in Indonesia are:

a) Ministry of Health of the Republic of Indonesia (Kementerian Kesehatan Republik Indonesia, "MOH"); and

b) Indonesia National Agency of Drug and Food Control (Badan Pengawas Obat dan Makanan "BPOM").

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

The basic regulation on health (including drugs, biologicals, and medical devices) is Law No. 36 of 2009 on Health ("Health Law"), as amended by Law No. 11 of 2020 on Job Creation ("Omnibus Law").

DRUGS AND BIOLOGICALS

• Authorization

The authorization of drugs and biologicals is primarily regulated under BPOM Regulation No. 1010/MENKES/PER/XI/2008, as amended by BPOM Regulation No. 1020/MENKES/PER/XII/2008 on Drug Registration. Further, details on the requirements, criteria, category, as well as registration procedures of drugs and biologicals are further regulated under BPOM Regulation No. 24 of 2017 on Criteria and Management of Drug Registration, as last amended by BPOM Regulation No. 13 of 2021 ("BPOM Regulation 24/2017").

Worthy of note is that at the end of June 2018, the Indonesian government launched the Online Single Submission ("OSS") system, which serves as the main gateway for business licensing for the licenses previously handled by different line ministries, regional governments, and quasi-government bodies, including the Ministry of Investment/ Indonesian Direct Investment Coordinating Board (Badan Koordinasi Penanaman Modal or "BKPM"). The Indonesian government is continuously upgrading the OSS system, lastly into a Risk-Based Approach ("RBA") OSS system as the implementation of Government Regulation No. 5 of 2021 on Risk-Based Business Licensing ("GR 5/2021"). The RBA OSS system is effective since August 2021.

GR 5/2021 has introduced a new paradigm in permits and licenses; company licenses are now determined by a risk-based analysis. The risk assessment is classified into 4 levels: Low, Medium-Low, Medium-High and High, each with its own characteristics, and assessed using various criteria, including safety, health, the environment, resource utilization and management. GR 5/2021 generally sets out the risk-level, validity, requirements, obligations, and timeline related to the licensing. Higher risk imposed higher license requirements.

All licenses and permits must be applied for through the OSS system, including licenses related to drugs and biologicals. Although, in some cases, verification and assessment by the relevant ministries are still required.

- **Pricing**

Pharmaceutical industries in Indonesia are required to provide information on the highest retail price on the relevant drug's label under MOH Regulation No. 98 of 2015 on the Provision of Information on Highest Drug Retail Price ("MOH Regulation 98/2015"). The MOH Regulation 98/2015 also grants authorization to the MOH to determine from time to time the retail price of generic drugs that are not included in the e-catalogue (an electronic system on procurement of goods/services by government).

MEDICAL DEVICES

- **Authorization**

The authorization of medical devices is primarily regulated under MOH Regulation No. 62 of 2017 on MA of Medical Devices, In Vitro Diagnostic Medical Devices, and Household Health Products ("MOH Regulation 62/2017").

Upon the launch of the RBA OSS system, the risk-level, validity, requirements, obligations, and timeline related to the licensing of medical devices are as regulated under GR 5/2021.

- **Pricing**

There is no specific regulation on the pricing of medical devices.

There is no regulation on reimbursement of drugs, biologicals, and medical devices in Indonesia. The Government, however, manages a public healthcare system via an independent authority. Please refer to Question No. 10 below.

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

Drugs

Marketing Authorization ("MA") of drugs, including imported drugs, must be obtained by Indonesian pharmaceutical manufacturing companies.

The Development and testing of drugs differs between generic and new drugs. For generic drugs, applicants may conduct development of formula/testing in the laboratory without any authorization. Once the applicant is sure of the result of the development/testing, the applicant must register the drugs and obtain an MA.

Development and testing of new drugs, on the other hand, must adhere to the regulations on pre-marketing clinical trials. If the new drugs are to be imported from overseas (meaning that they are already marketed and distributed overseas but not in Indonesia), the development and testing may be conducted overseas. The BPOM will accept result of clinical and non-clinical trials conducted overseas as part of the MA application as below.

Prior to distribution of drugs, an MA issued by the RBA OSS System on behalf of BPOM must first be obtained. The application of an MA is divided into 2 steps, namely: (i) pre-registration and (ii) registration phase. The application is conducted online through the RBA OSS System.

In general, the following are the steps for obtaining an MA:

a) The applicant must be registered at the RBA OSS System.

b) Pre-registration phase

The timeline for pre-registration phase is 40 days.

c) Registration phase

The timeline for registration phase is ranging from 5 days up to 300 days, subject to the condition of the registration and the type of drugs being registered.

In both Pre-registration and Registration phases, the applicant must adhere to:

1) Standard and requirement for criteria and procedure of drugs registration;

2) Indonesian Pharmacopoeia Standard and/or analysis method, standard and/or other requirements; and

3) Bioequivalence testing guidelines.

MEDICAL DEVICES

Similar to drugs, development and testing of medical devices prior to distribution shall adhere to the regulations on pre-marketing clinical trials.

In general, medical devices in Indonesia are divided into 4 classifications based on the risk of use against patients:

a. **Class A:** low risk;

b. **Class B:** low to medium risk;

c. **Class C:** medium to high risk;

d. **Class D:** high risk.

Prior to distribution of medical devices, an MA issued by the RBA OSS System on behalf of MOH must be obtained. In general, the following are the steps for obtaining an MA:

a) Prior to applying for an MA, the applicant must first obtain a Medical Devices Manufacturing Certificate (for a local manufacturer) or Medical Devices Distribution Certificate (for importer) via the RBA OSS System.

b) Registration for MA must also be done through the RBA OSS System. Pursuant to GR 5/2021, the applicant will be required to comply with the following requirements:

1) Administrative requirements;

2) Technical requirements; and

3) Payment of Non-Tax State Revenue.

The timeline for new registration of MA is ranging from 10 days up to 45 days, subject to the type of medical devices being registered.

4. What are the approximate fees for each authorization?

Drugs and Biologicals

The applicable fees vary for each authorization, as stipulated under Government Regulation No. 32 of 2017 on Types and Tariffs of Non-Tax State Revenue Applicable at BPOM.

As an illustration, a pre-registration costs up to IDR 1 million per item, and a registration of drug with new active substance, biologicals, and combination costs up to IDR 30 million per item.

Medical Devices

The applicable fees vary depending on the classification of the medical devices and the type of application (new or renewal), as stipulated under Decree of the Director General of Pharmaceutical and Medical Devices No. HK.02.03/I/767/2014 on Guidelines of Medical Devices MA Services. As an illustration, an application for new MA for Class D medical devices costs IDR 5 million per item.

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

Drugs and Biologicals

MA for drugs and biologicals are valid for 5 years, to the extent that they comply with the prevailing laws.

Re-Registration

The timeline to submit re-registration application for renewal of MA depends on whether or not there is an alteration to the product. In the event of any alteration to the MAs (e.g., change of ingredients, manufacturer, etc.), the holders of MAs must submit re-registration applications to the BPOM at the earliest 12 months and latest 2 months prior to the expiration thereof. If there is no alteration, the application may be submitted within 1 month prior to the expiration of the MAs.

Should a holder of a MA fail to re-register within the required time period, a new registration application (not re-registration) must be submitted.

Medical Devices

MA for medical devices are valid for maximum 5 years. Application for renewal of the MA shall be submitted at the earliest 9 months prior to the expiration thereof. Should a holder of a MA fail to apply for renewal after the expiration, a new registration application (not a renewal) must be submitted.

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

Drugs and Biologicals

Drugs regulations do not differentiate the authorization process between brand-name products and generic products. The regulation however differentiates between registration of: **(i)** domestically produced drugs; **(ii)** imported drugs; **(iii)** licensed drugs; **(iv)** patent-protected drugs; **(v)** new development drugs; **(vi)** generic drugs; and **(vii)** orphan drugs.

The authorization process also differs between local manufacturers (whether 100% local or foreign-owned) and foreign manufacturers (import). As the application is made online, the system differentiates between an application for locally made medical devices and imported medical devices by providing different menus/options. Subsequently, different details will be required for each option.

Medical Devices

Medical device regulations also do not differentiate the authorization process between brand-name products and generic products. If the medical devices are branded, the brand certificates shall be provided during the registration.

Similar to drugs, the authorization process also differs between locally-made medical devices and imported medical devices.

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

There is no specific regulation on combination products, as such, the applicant must adhere to each regulation relating to the products combined. For example, for drug and medical devices, the applicant must take into account the prevailing regulations on drugs and medical devices.

However, during the application for MA for drugs, the applicant should be able to select the type of the products to be registered, as follows:

a) Single Product, if the product only consists of drug;
b) Combination Product, if the product consists of drug and solvents or drug use aids (e.g., syringe, aerosol, spray, implant); or
c) Combipack Product, if the product consists of two or three drugs packed into one package to be given to patients simultaneously.

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?

In general, the requirements of U.S. Food and Drug Administration or the European Drugs Agency are informally used as benchmark by the Indonesian authorities, thus certain aspects are comparable. Nevertheless, Indonesia has a set of unique regulations that govern drugs and medical devices sectors.

Drugs

Under Presidential Regulation No. 80 of 2017 on BPOM, BPOM is generally authorized to conduct intelligence and investigation activities in the drugs and foods sector as well as impose administrative sanctions, in accordance with the prevailing laws and regulations. The regulation also stipulates the establishment of a specific Investigation Deputy under BPOM, which is tasked to carry out the formulation and implementation of investigation policies against violations in the drugs and foods sector.

Medical Devices

Under MOH Regulation No. 10 of 2018 on Monitoring in the Health Sector, a functional position of a Health Supervisor is established to implement monitoring and supervision in the health sector. The object of monitoring includes the public and each organizer of activities related to health resources

(including medical devices) and health efforts (e.g., health services). Health Supervisors work at central level (appointed by the MOH), provincial level (appointed by the Head of Provincial Health Agency) and regency/municipal level (appointed by the Head of Regency/Municipal Health Agency).

A Health Supervisor is authorized to, among others, examine licensing related to the health resources and health efforts. If based on the monitoring and supervision activities, it is proven that a health personnel and/or a health services facility violates any regulation in the health sector, they may be imposed with administrative sanctions.

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

Drugs and Biologicals

Under GR 5/2021, noncompliance or violation of business licensing in the drugs and foods sub-sector, including licensing related to drugs and biologicals, is subject to administrative sanctions, ranging from written warning, temporary suspension of business activity through freezing of business licensing, administrative fine, coercion (i.e., withdrawal from distribution, compensation, extermination, closing or blocking of electronic system and/or other internet media used for online distribution of drugs and foods, and/or closing of access for business licensing application), and/or revocation of business licensing (e.g., MA).

Medical Devices

Under GR 5/2021, noncompliance or violation of business licensing in the medical sub-sector, including licensing related to medical devices, is subject to administrative sanctions, ranging from written warning to revocation of business licensing (e.g., MA). Additionally, there is also administrative sanction in the form of government coercion, covering: **(i)** discontinuation of ad service **(ii)** product recall order, and/or **(iii)** product extermination order.

Despite the foregoing, the Health Law provides criminal sanctions for: **(i)** any person who intentionally produces or distributes pharmaceutical supplies and/or medical devices that contravene the standard and/or requirements for safety, efficacy or expedience, and quality in the form of imprisonment for a maximum of 10 years and penalty for a maximum of IDR 1 billion, **(ii)** anyone who intentionally produces or distributes pharmaceutical supplies and/or medical devices without proper business licensing in the form imprisonment for a maximum of 15 years and penalty for a maximum of IDR 1.5 billion.

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

In 2011, Law No. 24 of 2011 regarding Social Security Management Board ("**Law No. 24/2011**") was enacted. The regulation is the basis of establishment of the Social Security Management Board (Badan Penyelenggara Jaminan Sosial or "**BPJS**"), which consists of 2 different bodies: **(i)** Health BPJS – which manages health security program; and **(ii)** Manpower BPJS – which manages manpower related programs such as pension fund. Both BPJSs are responsible to the President of the Republic of Indonesia.

The health social security program was formerly known as the Public Health Care Insurance (Jaminan Pemeliharaan Kesehatan Masyarakat) which was managed by PT Askes (Persero). Following the enactment of Law No. 24/2011, it transformed into the Health Security program and is managed by Health BPJS.

Any person, regardless of whether they already have another health insurance policy, is obligated to become a participant in the health security program managed by the Health BPJS. The Health BPJS will charge periodical contribution fees to the members. The Indonesian Government will provide contribution aid to the Health BPJS as an additional source of funding for the purpose of sponsoring the poor and less fortunate so that they can be covered by the health security program.

The Health BPJS will cover health services expenses of its participants in accordance with the health security program regulations.

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

Under MOH Regulation No. 71 of 2013 on Healthcare Services at National Health Security, as amended several times, lastly by MOH Regulation No. 7 of 2021, Health BPJS may cooperate with healthcare facilities managed by the government, regional government, and/or public. These include: **(i)** health centre (locally known as Puskesmas) or its equivalent; **(ii)** doctor's practice; **(iii)** dentist's practice; **(iv)** primary services doctor's practice; **(v)** pratama clinic or its equivalent; **(vi)** pratama class D hospital or its equivalent; **(vii)** primary clinic or its equivalent; **(viii)** general hospital; and **(ix)** special hospital. The cooperation shall be carried out by a cooperation agreement between the Health BPJS and each health facility. The agreement must be valid for a minimum of 1 year.

On 28 March 2018, the MOH Regulation No. 4 of 2018 on Obligations of Hospitals and Obligations of Patients was enacted. The regulation stipulates that each hospital (whether public or private) must fulfil certain obligations, including, to provide facilities and services for the less fortunate and poor. It is further explained that this obligation shall be carried out by providing Class III care beds for the less fortunate and the poor, and/or for the health social security participants.

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

Drugs

MOH Regulation 98/2015 requires pharmaceutical industries to provide information on the highest retail price on the label of the drug concerned. The information may be provided in the form of a nominal value (in IDR) or formula (as relevant). The price information differs in accordance with the type of the drugs:

- non-generic drugs,
- generic drugs listed in the e-catalogue for government procurement; and
- generic drugs that are not listed in the e-catalogue.

Price information based on the formula must be provided for generic drugs listed in e-catalogue. Specifically, for generic drugs not listed in the e-catalogue, the highest drug retail price must comply with the price determined by the MOH based on its decree. The MOH last issued an MOH Decree on this in 2015.

For non-generic drugs, the information must be provided in the form of a nominal value based on pharmacies' nett price (i.e., retail price from pharmaceutical wholesaler to the pharmacies, including VAT) plus pharmaceutical services fee of 28% on the pharmacies' nett price.

The pharmacies, drug stores, and hospital/clinic pharmaceutical installations may only sell drugs at an equal or lower price than the highest retail price, unless the price provided on the label is no longer valid.

Medical Devices

There is no specific regulation on pricing for medical devices.

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

Patients pay for drugs and devices out-of-pocket or financed by private insurance or the Health BPJS. Some also enjoy the benefit of medical allowances provided by their employers.

Although currently the majority of Indonesians have been registered as participants of Health BPJS, due to the limitation of coverage provided by the Health BPJS, a good portion of the participants either elect to pay for drugs and devices entirely out-of-pocket or pay for the excess not covered by the Health BPJS.

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

Drugs

Drugs dispensing and services based on prescription must be carried out by licensed pharmacists.

In remote areas where no pharmacist is available, the MOH may assign licensed pharmacy technical personnel to primary health services facilities to compound and dispense drugs to patients. Furthermore, in more remote areas where no pharmacy is available, licensed doctors or dentists may compound and dispense drugs to patients.

Drugs dispensers (i.e., pharmacists) are compensated either by way of salary or on their own account. Pharmacists are allowed to establish pharmacies using their own and/or their investors' capital (individual/company).

Medical Devices

There is no general regulation on medical device dispensing.

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?

Main responsibilities of pharmacists in dispensing drugs consist of 3 stages, namely, preparation, delivery and providing information on the drugs. In general, the main duties of the pharmacists include:

a) Dispensing drugs in accordance with the prescription, including compounding if necessary;
b) Ensure correct labelling and packaging of the drugs;
c) Ensure that the drugs are given to the correct patients or their families;
d) Providing information to the patients on the use and dosage of the drugs, as well as its side effects and list of consumables that must be avoided during consuming the drugs;
e) Maintaining records of dispensed drugs; and
f) Educating patients who require OTC drugs for mild disease.

Japan

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Mariko Mimura is an Of Counsel of Nishimura & Asahi. She rejoined Nishimura & Asahi in 2018 and serves as leading counsel for the Life Science and Healthcare practice group of N&A.

Following registration with the Japanese Bar Association in 1992, Mariko joined Nishimura & Partners (currently Nishimura & Asahi) in 1995, with expertise in intellectual property, entertainment, general corporate, bankruptcy, and civil rehabilitation. During her tenure at Nishimura & Partners, she was seconded to Gibson, Dunn & Crutcher LLP, a US law firm, as well as working at a US medical device company as Vice President & General Counsel. After returning to Nishimura & Partners, she became a partner in 2003 and served until she became an in-house counsel of GE Healthcare Japan Corporation until 2005.

She leads N&A Life Science and Healthcare Practice Team, which recently published a book detailing a Japanese law designed to secure the quality, efficacy, and safety of pharmaceutical, quasi-pharmaceutical, cosmetic products and other medical stuff. This book provides basic and detailed explanations of these matters, as well as a minute description of relevant laws and regulations, ministry notifications and industry rules, making it one of the most comprehensive and aspirational illustration of pharmaceutical affairs in Japan to date. She was the editors' representative for this book and was responsible for its overall supervision based on her accumulated experience in this area.

Thus, she is an in-house counsel pioneer in the Japanese healthcare industry. She was selected as one of the top 100 Corporate Counsel in Asia Pacific in the GC Powerlist of the Legal 500 in 2014.

In 2019, she received an award as a Corporate and M&A lawyer by Best Lawyers® 10th Edition of The Best Lawyers in Japan (2020).

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He also has rich experience in Japanese pharmaceutical industry cases, such as handling whistleblower hotlines for pharmaceutical company employees and handling corporate scandal cases involving advertising regulations for pharmaceutical companies.

REGULATORY, PRICING AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?	The Ministry of Health, Labour and Welfare (the "MHLW") and the Pharmaceuticals and Medical Devices Agency (the "PMDA").
2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?	Authorization is governed by the Pharmaceuticals and Medical Devices Law (the "PMD Act") of Japan. Pricing of drugs and biologicals is governed by the National Health Insurance. Drug Pricing Standards are established by the MHLW under the Health Insurance Act. The method of calculation of drug pricing and the price of each drug are announced by the MHLW after consultation with the Central Social Insurance Medical Council. Pricing of medical devices is included in the Medical Fee, which is also established by the MHLW under the Health Insurance Act, and the calculation method and price thereof are announced by the MHLW after consultation with the Central Social Insurance Medical Council. Reimbursement is governed by the Health Insurance Act.
3. What are the steps to obtaining authorization to develop, test, and market a product?	To develop and test a product, it is necessary to obtain a manufacturing/marketing business license, depending on the type of business. To market a product, in addition to the above, the license holder must obtain marketing authorization for each such product.
4. What are the approximate fees for each authorization?	The fee for a manufacturing/marketing license varies depending on the type of license, but is approximately 100,000 to 150,000 yen. The fee for marketing authorization for each product varies depending on the product.
5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?	Manufacturing/marketing licenses are valid for five years, and the license holder must renew the relevant license(s) every five years. Marketing authorizations are valid until and unless withdrawn by the government for appropriate reasons or abandoned by the authorization holder, both of which are rare.
6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus	Clinical trial data is required to obtain authorization for brand-name products. Normally, product creators spend more than 10 years from basic research to obtaining authorization. For generic products, only stability tests and bioequivalence tests are required, as opposed to clinical trials. Thus, generic products can obtain

foreign-owned manufacturers?	authorization in a short time, normally 2 years from the start of testing. Currently, applications for authorization of generic products are accepted only twice a year, in February and August.
7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?	Basically, the same rules apply to combination products. To ensure the safety of combination products, the single drugs used in combination products must be in the market for one year or more, with exceptions for some special combination products (such as HIV drugs).
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?	Compliance with regulations is monitored and evaluated by the PMDA and the local government of each prefecture. Basically, compliance with regulations is harmonized with the FDA and EMA.
9. What is the potential range of penalties for noncompliance?	Potential penalties include suspension of part or all of a business, cancellation of authorizations, or up to 3 years imprisonment or a fine of up to 3 million yen or both, depending on the type of noncompliance/misconduct.
10. Is there a national healthcare system? If so, how is it administered and funded?	There is a national healthcare system. Japan's universal insurance system began with introduction of the Health Insurance Act in 1961. This system ensures that all people's healthcare costs are covered by public insurance and that people have free access to any healthcare provider. People have to pay insurance fees to the health insurance program they join, and then, when the individual goes to a healthcare provider, the cost is covered by the National Health Insurance (other than a portion the individual patient must pay). The portion an individual must pay varies from 10% to 30% depending on the individual's age; in addition, if an individual's total payments exceed a certain amount, which is decided based on his or her income, the residual amount is covered by the National Health Insurance. People have an obligation to join a health insurance program. Company employees join the health insurance program their employer has joined. Most other people join the national health insurance program, although there are also several special insurance programs such as the public employee union program. The national healthcare system is funded primarily by insurance fees paid by the program members. For example, a company employee has an obligation to pay half of his/her insurance fee to the insurance program; the other half is paid by the employer. However, current healthcare costs are far beyond the total of insurance fees. Thus, there is an added public expense. Most recently, approximately one half of the total healthcare costs was covered by insurance fees, approximately 40% was covered as a public expense, and approximately 10% was covered by individual payment by the patients.

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

Most of the hospitals in Japan belong to the private sector (approximately 80%).

The basic functions of public sector and private sector hospitals are the same, but public sector providers have special missions, such as providing healthcare in remote places where no other hospitals exist, assisting patients as a safety net, and providing advanced healthcare based on advanced research and study.

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

Prices of drugs and devices are regulated under the Health Insurance Act.

Pricing of drugs and biologicals is governed by the National Health Insurance Drug Pricing Standard which is regulated by the MHLW under the Health Insurance Act. The methods of calculation of drug pricing and the prices for each drug are announced by the MHLW after consultation with the Central Social Insurance Medical Council.

The pricing of medical devices is included in the Medical Fee, which is also regulated by the MHLW under the Health Insurance Act, and the calculation methods and prices thereof are announced by the MHLW after consultation with the Central Social Insurance Medical Council.

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

Drugs and devices prescribed by doctors and used by patients are covered by the National Health Insurance, other than the portion individual patients must pay under the Health Insurance Act.

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

Doctors prescribe the drugs and pharmacies dispense the drugs to patients. When a pharmacy dispenses a prescribed drug, the patient has to pay a portion of the total cost, and the other portion is reimbursed to the pharmacy by the National Health Insurance payer.

The cost of devices used by doctors for patients is reimbursed to the doctor by the National Health Insurance payer. Patients only pay the hospital a portion of the doctor fees, including service fees.

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?

Under the Health Insurance Act, a doctor must register as an insurance doctor. Only registered insurance doctors can prescribe drugs and dispense devices covered under the national insurance system.

Also, only a pharmacy that is designated as an insurance pharmacy under the Health Insurance Act can dispense drugs.

Insurance doctors and insurance pharmacies have obligations under the Health Insurance Act, and non-compliance may result in cancellation of their licenses.

Malaysia

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Besides contentious matters, Pei Yee regularly advises clients on transactions involving IP subject matters. Her work in this area include drafting and reviewing agreements relating to assignment, licensing, research and development, brand endorsement and others. She also assists clients in refining their IP protection strategies and policies.

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Shi Wen and her team have provided a wide range of corporate services to GLCs, MNCs and trade associations in various industries in Malaysia. She was also engaged by the Malaysian Energy Commission for the drafting of the Competition Law Guidelines. Her practice focuses on industries including pharmaceutical, insurance, banking and shipping. Shi Wen's key clients in the pharmaceutical industry include Servier (M) Sdn Bhd, Merck Sharp & Dohme (Malaysia) Sdn Bhd, Aspen Medical Products Malaysia Sdn. Bhd. and Boehringer Ingelheim.

Shi Wen has been ranked in Band 3 in Competition/Antitrust in Chambers Asia-Pacific 2020 and 2021, and recognised as a stand-out lawyer by Acritas Stars Independently Rated Lawyer 2020 and 2021.

REGULATORY, PRICING AND REIMBURSEMENT OVERVIEW

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

The Ministry of Health (MOH) is the primary governmental body responsible for the health of the people and the overall healthcare system in Malaysia. Its key governmental agencies responsible for the administration of drugs and medical devices are as follows:

a) National Pharmaceutical Regulatory Agency (NPRA), formerly known as the National Pharmaceutical Control Bureau (NPCB), is tasked with implementing quality control on pharmaceutical products and meeting the requirements for testing and quality control activities. NPRA also implements and manages regulatory, licensing and product recall schemes as well as carries out research on methodology and training for pharmaceutical and professional officers.[1]

b) Drug Control Authority (DCA) regulates combination products and is tasked with ensuring the safety, quality and efficacy of pharmaceuticals, health and personal care products marketed in Malaysia. The DCA oversees the registration of pharmaceutical products and cosmetics, licensing of premises (for importers, manufacturers and wholesalers) and monitoring the quality of registered products and Adverse Drug Reactions (ADR).[2]

c) Malaysian Adverse Drug Reaction Advisory Committee (MADRAC) is established under DCA to carry out pharmacovigilance for registered drugs in Malaysia. All ADR reports received and assessed by MADRAC are forwarded to central World Health Organization (WHO) Global ICSR database. MADRAC works to promote ADR reporting in Malaysia and provide reliable information and advice to DCA, doctors, pharmacist and other healthcare professionals on drug safety.[3]

d) Medical Device Authority (MDA) controls and regulates medical devices in accordance with the Medical Device Act 2012 for registration of the medical devices, issuance of licences, training and awareness. The MDA also issues licences to establishments who import, export and place medical devices in the Malaysia market, surveillance and vigilance of medical devices and usage of medical device.[4]

e) Malaysian Pharmaceutical Services Programme (Pharmaceutical Division), is the enforcement agency of the MOH responsible for ensuring that safe, efficacious and quality pharmaceutical products are made available to the public, protecting their interest via enforcement of relevant legislations

1 NPRA, MOH website, 02.07.2015 https://www.npra.gov.my/index.php/en/about/addons-list-6/vision-mission-and-objective.html
2 NPRA, MOH website, 03.07.2015 https://www.npra.gov.my/index.php/en/about/drug-control-authority-dca/about-the-dca
3 NPRA, MOH website, 20.03.2019 https://www.npra.gov.my/index.php/en/about/malaysian-adverse-drug-reactions-advisory-committee-madrac/madrac-introduction
4 MDA, MOH official portal, background pg. https://portal.mda.gov.my/introduction/background.html

and ensuring rational use of medicines by both healthcare providers and patients.

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

Drugs

Key Legislation

The key legislations for the drug industry in Malaysia are the Sale of Drugs Act 1952, Dangerous Drugs Act 1952, Poisons Act 1952, Medicines (Advertisement and Sale) Act 1956, and the Control of Drugs and Cosmetic Regulations 1984. Other guidelines and regulations issued by NPRA have also be implemented to provide guidance to the pharmaceutical industry.

Authorization

The drug formulary produced by the MOH contains a list of drugs that has been approved by the MOH hospitals and institutions. Prior authorization and approval by the Director-General of Health is required before the use of any non-formulary drugs. In order to obtain approval for a new drug, an application must be approved in accordance with the following steps: -

- Pre-submission of application: the category of product, method of evaluation and requirements for product registration must be determined;
- Submission of application: applicant must register and submit application via the online QUEST3 system;
- Screening of application: initial valuation carries out to ensure the required data/information of the submitted application are complete. This takes place before payment is made;
- Evaluation of application: Application with the submitted data is evaluated following different categories of products and/or level of claims. Applicant shall be informed via the system if any further supplementary data/information or documentation is deemed necessary by the Authority. Application is rejected if there is no response to the correspondence from NPRA within six (6) months from the first correspondence date. This takes place after payment is made;
- Regulatory outcome: a regulatory decision will be sent via email/official letter to the product registration holder. The Authority may, at any time reject, cancel or suspend the registration if there are deficiencies in safety, quality or efficacy of the product or failure to comply with conditions of registrations. A product registration number shall be assigned to the registered product.
- Post-registration process: registration status shall be valid for five (5) years or a period as specified in the Authority database. Upon approval, the application shall fulfil all commitments and conditions imposed during the approval process and shall be responsible for the maintenance of the product in terms of quality, safety and efficacy throughout the validity of the registration period.

Biologicals

The specific requirements for registration of biologicals are set out in the

Guideline on Registration of Biologics. This comes under Appendix 4 of the Drug Registration Guidance Document (DRDG)

The requirements for registration of biologics/ biopharmaceuticals shall be in accordance to the ASEAN Common Technical Dossier (ACTD) format and in adherence to the general regulatory requirement as described in sections of the main DRGD.

It covers:

- Administrative information
- Product quality data
- Product safety data
- Clinical data, demonstrating clinical efficacy and capacity to meet therapeutic claims, through clinical studies

Biologics include a wide range of products such as:

1) Vaccines;
2) Blood products;
3) Monoclonal antibodies (therapeutics);
4) Recombinant proteins:
   - Insulins
   - Hormones
   - Erythropoetins and other hematopoietic factors
   - Cytokines: interferons, interleukins, colony-stimulating factors, tumour necrosis factors
5) Cell and Gene Therapy Products (CGTPs)

There are specific requirements which exist for the registration of different types of biologics under the DRGD. These include specific requirements for the registration of Vaccines, Biotechnology Products, and Blood Products.

Pricing

The MOH is the largest pharmaceutical spender and indirectly controls and reduces medicine price with bulk purchase. The three procurement methods are 1) Supply by Concession Company 2) National tender and 3) Local purchase.

There are no price control methods in the private sector. Manufacturers, distributors and retailers may offer any prices in the free market without any pricing policy or regulation. However, under the Pharmaceutical Services Programme (PSP), MOH have published and updated a Consumer Price Guide (CPG) as a public reference to purchase medicines in the private sector. The PSP have conducted studies and produced reports with the aim of guiding medicine pricing policy and improving accessibility and affordability of medicine in Malaysia.

Nonetheless, based on publicly available information, the MOH has plans to implement price control measures. The MOH is targeting single-source innovative drugs sourced through public procurement in its first phase of price controls by using external reference pricing to benchmark drug

prices in Malaysia against eight to 12 countries. The average three lowest reference prices will then be chosen to determine the maximum medicine prices allowed in Malaysia at the wholesale and retail levels (clinics, hospitals, pharmacies). However, as of June 2021, this has yet to be implemented and the countries that will be used as part of the references have yet to be decided.

Reimbursement

There is currently no national reimbursement scheme in Malaysia. However, the CPG published by the Pharmaceutical Services Programme is said to provide a comprehensive and reliable price data for consumers and for insurance reimbursement until a systematic nationwide procurement and reimbursement scheme can be implemented.

Medical Devices

Key Regulations

The key legislation for the medical device industry in Malaysia is the Medical Device Act 2012. The First Edition of the Medical Device Guidance Document and Licensing for Establishment produced by the MDA also provides guidance on licensing requirement and establishments dealing with medical devices in Malaysia, to ensure compliance with the Medical Device Act and regulation.

The Medical Device (Advertising) Regulations 2019 and Medical Device (Duties and Obligations of Establishments) Regulations 2019, which were gazetted by the Malaysian Parliament under the Medical Device Act 2012, have officially come into effect as of 1 July 2020.

The Medical Device (Advertising) Regulations 2019 prescribes the matters relating to the contents of and conditions for advertising of medical devices. Meanwhile, the Medical Device (Duties and Obligations of Establishments) Regulations 2019 prescribes the manner, criteria, conditions and procedures of post-marketing activity of medical devices.

Authorization

Medical devices must be registered before they can be used and sold in Malaysia by licensed establishments. In Malaysia, medical devices are classified into 4 risk classes, namely Class A (Minimal), Class B (Low to Moderate), Class C (Moderate to High) and Class D (High). Manufacturers must ensure that their products conform to Essential Principles of Safety and Performance (EPSP) and Good Manufacturing Practices (GMP) standards and that a Conformity Assessment Body (CAB) certification is obtained in order to receive MDA approval for their product registration application. Moreover, a medical device cannot be imported, exported, or placed on the market unless it is registered. A single producer or authorised agent can only register one medical device. Multiple registrations of the same product are not permitted.

The general procedure to register a medical device is to group and classify it in one of the classes abovementioned, following which, a Common Submission Dossier Template (CSDT) must be prepared (including technical information i.e. design input/specification/verification/etc.). Then, a conformity assessment is conducted and assessed by CAB. The manufacturer can then apply to register the medical device and MDA will conduct an evaluation thereafter. If approval is granted, the medical device will be registered upon payment of a prescribed fee.

Notwithstanding the above, in 2016, a Medical Device (Exemption) Order was gazetted which provides an exemption for registration required under the Medical Devices Act 2012 for the following purposes: -

(i) the purpose demonstrating the marketing;
(ii) the purpose of education;
(iii) the purpose of clinical research or performance evaluation of medical device;
(iv) a custom-made medical device; or
(v) a special access medical device.

An importer or manufacturers of the above-mentioned medical devices are also exempted from obtaining the required establishment licence. However, prior to any importation of a device potentially eligible for exemption, a notification must be sent by the manufacturer or importer to MDA.

Pricing

There are currently no laws regulating market prices for medical devices.

Reimbursement

There is no national reimbursement scheme for medical devices in Malaysia.

Combination Products

Key Legislation

The same as that which regulates drugs and medical devices separately. Aside from legislation, reference can also be made to the Guideline for Registration of Drug-Medical Device and Medical Device-Drug Combination Products.

Authorization

There are different registration processes for combination products which are described as products comprising of two or more regulated components combined to produce a single entity i.e. drug/device, biological/device or drug/device/biological or two or more separate products packaged together in a single package or as a unit.

According to the 2020 Guideline For Registration Of Drug-Medical Device And Medical Device-Drug Combination Products: The registration

process of Drug-Medical Device combination product hall undergo the following 2 stages:

(i) Stage 2 – Obtaining Endorsement from MDA
(ii) Stage 3 – Application For Registration to NPRA

Note: All the stages shall be completed, with the exception of low risk medical devices which may proceed directly to Stage 2- Application for Registration to NPRA.

The registration process of Medical Device-Drug combination product shall undergo the following: -

(i) Stage 2 – Obtaining Certification from CAB
(ii) Stage 3 – Obtaining Endorsement from MDA

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

Refer to authorization in section 2 Chapter 1 above.

4. What are the approximate fees for each authorization?

Drugs

No.	Category of Product	*Processing Fees	Laborartory/Analysis Fees	Total Fees
1.	Pharmaceutical a) New Drug Products b) Biologics	RM 1,000.00	Single active ingredient: RM 3,000.00	RM 4,000.00
			Two or more active ingredients: RM 4,000.00	RM 5,000.00
2.	Pharmaceutical a) Generic (Scheduled Posion) b) Generic (Non-Scheluded Poison) c) Health Supplement	RM 1,000.00	Single active ingredient: RM 1,200.00	RM 2,200.00
			Two or more active ingredients: RM 2,000.00	RM 3,000.00
3.	Traditional/Natural Product	RM 500.00	RM 700.00	RM 1,200.00

Certificate fees for any product where such certification is required by any country importing such a product

Certificates	Fee	Validity
Issuance of one (1) Certificate of Pharmaceutical Product	RM 50.00	2 years
Issuance of one (1) Certificate of Good Manufacturing Practice (GMP)	RM 50.00	2 years
Issuance of one (1) Certificate of Declaration (Sijil Deklarasi)	RM 50.00	-
Issuance of one (1) Certificate of Indication (Sijil Indikasi)	RM 50.00	-

Charges for Product Classification

Processing fee	Timeline
RM 300 per product for each application	7-14 working days upon receipt of complete and satisfactory application

Device Classification	Application fee	Processing fee
Class A	MYR 100	n/a
Class B	MYR 250	MYR 1,000
Class C	MYR 500	MYR 2,000
Class D	MYR 750	MYR 3,000
Combination device	MYR 750	MYR 5,000

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

Marketing registration for drugs is valid for a period of (5) years or such period as specified in the registration certificate. Renewal of the product registration shall be done no later than 6 months prior to expiry of the product registration. The product information/amendments/variation can be updated through a proper application. Any changes affecting the quality, safety and efficacy of a registered product cannot be renewed - a new registration shall be required. This is however not applicable to non-medicated and contraceptive devices.

Medical Devices

All establishments importing, exporting or placing on the market any registered medical devices must obtain an establishment licence. This licence is valid for three (3) years but may be renewed no later than one year before the expiry date by paying the prescribed fee and complying with any request for information, particulars or documents as may be required by the MDA.

Additional Licences

In addition to the product registration and establishment licence, any person(s) or company that intends to manufacture, import or wholesale any registered product will have to obtain a Manufacturer's Licence, Import Licence or Wholesale Licence respectively. Each licence is valid for a period of one (1) year and an application must be submitted together with the following documents: -

i) a copy of Company/ Business Registration Certificate
ii) a copy of Business License (Local Authority) for business premise or store (if any)
iii) a copy of Applicant's/License Holder's Identity Card
iv) a copy of Annual Retention Certificate and/or Type A License (This document is necessary if products manufactured/ imported/ wholesale are Scheduled Poison A products or any other products that require a Pharmacist)

Application for these licences must be made to the Drug Control Authority through the QUEST 3+ System. These licences are non-transferable. Compliance with Good Manufacturing Practice (GMP) and Good

Distribution Practice (GDP) is required for the application of a manufacturing licence as well as product registration, whilst GDP compliance is required for the application of a wholesale or import licence.

For the renewal of any of these licences, a new application with the same supporting documents abovementioned must be submitted along with a copy of the previous licence.

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

All medicines, either brand-name ("the innovators") or generic medicines must undergo a scientific evaluation process to establish their quality, safety and efficacy. Generic medicines must have specifications similar to that of the innovators to ensure they are equally effective and interchangeable. Both brand-name and generic medicines' facilities must comply with the same standards of Good Manufacturing Practices (GMP). The regulatory requirements in Malaysia are similar to that of other developed countries.

Malaysia is a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S). Therefore, the code and standards of GMP is the same as that used by PIC/S members such as Australia, Canada, Europe and the United States. Local manufacturers however are subject to licensing and periodic GMP audits. Foreign manufacturers of imported generic medicines are also subjected to GMP conformity assessment whereby the manufacturers are required to provide acceptable evidence that the premise conforms to current GMP requirements. Where the GMP evidence is not available or the documents are insufficient or unsatisfactory to demonstrate equivalence to GMP standards, the DCA may require an on-site audit of the foreign manufacturer. In order to ensure that generic medicines comply with strict registration requirements, all registered generic medicines are subjected to post-market surveillance, complaints and adverse drug reactions monitoring programme.

Local manufactures must ensure that the products meet essential principles of safety and performance (EPSP) and are manufactured in accordance with GMP. Both local and foreign manufacturers must apply for registration of their medical device products. The process of registration of medical devices for foreign manufacturers are as such: -

1. A foreign manufacturer needs to appoint an Authorised Representative (AR) to register their devices;
2. The AR must prepare the registration application Common Submission Dossier Template (CSDT) based on the technical information from foreign manufacturer to be submitted to the MDA;
3. An independent CAB (different from the one engaged by the foreign manufacturer in other countries) is to review the same registration application dossier and issue a CAB certificate to be submitted to the MDA; and
4. The MDA will then review and approve or reject the registration of the medical device under the registration name of the AR for the device to then be marketed in Malaysia.

7. How are combination products

(drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?

In Malaysia, the primary agency for registration of combination products is based on the primary mode of action/the principal mechanism of action by which the claimed effect or purpose of the product is achieved.[5] In short, if the primary function of the combination product is as a drug, that would be its classification. Drug is based on pharmacological, immunological or metabolic action in/on the body.[6] Combination products categorised as drug by the DCA is regulated in accordance with the CDCR 1984 and any other relevant documents published by NPRA.[7]

Medical devices do not achieve their primary mode of action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its intended function by such means.[8] Combination products regulated as medical devices by the MDA is in accordance with the Medical Device Act 2012 and its subsidiary legislation, and any other relevant documents published by the MDA.

Additionally, any drug substances used as ancillary to medical device which is listed as a scheduled poison shall be regulated in accordance with the Poison Act 1952.[9]

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?

Compliance with regulation is monitored by different agencies depending on the relevant products. Before any product is marketed and sold in Malaysia, it must be registered with the DCA even if it has received approvals from other regulatory bodies such as the US FDA.[10] Furthermore, although the International Council for Harmonization (ICH) and European Medicine Agency (EMA) guidelines are generally acceptable in most ASEAN countries, there are additional regulatory requirements as well as enforcement and compliance procedures unique to Malaysia that must be further complied with for the dispensing and marketing of medicines.[11] These are set out in detail below.

The NPRA monitors compliance with regulations on drug related matters. Any pharmacy or individual carrying on the business of manufacturing, whole-selling and/or importing medicines in Malaysia must obtain the respective licences from the NPRA. Upon doing so, the NPRA will conduct various inspection on the premises of the business. In particular, a GMP inspection will be carried out for manufacturers and a GDP inspection for wholesalers and importers. This inspection may be carried out annually depending on the performance of the business. In undergoing the renewal process for each licence, all such manufacturers, wholesalers and importers

5 *Ibid*. pg. 10
6 *Ibid*. pg. 10.
7 Guideline for Registration of Drug-Medical Device and Medical Device-Drug Combination Products, MOH, 1st edn, 15th March 2017, https://www.npra.gov.my/images/Guidelines_Central/MDC/Garis_Panduan_13.3.17.pdf, at pg 2
8 *Ibid*. pg. 10.
9 *Ibid*. pg. 2
10 NPRA, MOH, Frequently Asked Questions (FAQs) Veterinary Medicine, question 2), https://www.npra.gov.my/index.php/en/frequently-asked-questions-faqs-veterinary-medicine/general-regulatory.html
11 Regulatory Affairs Professional Society, Regulatory Focus, News Article, The drug regulatory landscape in the ASEAN region, 2018 https://www.raps.org/news-and-articles/news-articles/2018/1/the-drug-regulatory-landscape-in-the-asean-region

must comply with the current regulations set out by the NPRA.[12] All validly licenced pharmacy or business will be listed on the NPRA website.

The Malaysian Pharmaceutical Division regulates any pharmacy dispensing or marketing medicines and products containing scheduled poisons, (chemicals listed in the First Schedule of the Poisons Act 1952) or non-scheduled poisons (chemicals not found in the First Schedule of the Poisons Act 1952). This body is tasked with enforcing compliance to existing legislation and ensuring that the link of supply and marketing, advertising of the products (including the medical services) and its usage are properly managed.[13] In ensuring continued compliance with all the local legislative provisions, rules and guidelines, the Pharmaceutical Division would carry out its own annual inspection and audit for the renewal of any such licences granted.

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

Failure to submit necessary documentation and reports (i.e. BE studies) will result in a rejection of the application for registration of the product. Additionally, if the DCA finds unsafe or sub-standard medicines, they are authorised to remove such products from the market. According to the CDCR 1984 enforced pursuant to the Sale of Drugs Act 1952, as well as the Dangerous Drugs Regulations 1952, non-compliance by any persons (depending on the nature of the non-compliance) could lead to financial penalties, suspension of business activities, revocation of a product registration or establishment licence. Save in the more serious cases, violations of the legislation and regulations on drugs and medical devices may attract criminal liabilities, including imprisonment.

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

Malaysia has a two-tiered healthcare service sector: a government-based and publicly funded sector and a private sector. The public healthcare services are tax-funded and administered by the Ministry of Health through its central, state and district offices. The policies and programmes are centrally formulated, funded and administered. There are also many active non-governmental organisations providing emergency ambulatory and relief services in Malaysia.

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

To a small extent the MOH also regulates the private sector, i.e. requiring health care professionals to register with statutory professional bodies. In addition, the MOH also regulates the pharmaceutical industry and food safety offering comprehensive services ranging from preventive and primary health care to tertiary hospital care. The private health sector provides health services, mainly in urban areas, through physician clinics and private hospitals with a focus on curative care. The government also works with

12 NPRA, MOH, Frequently Ask Question: Compliance and Licensing, question 1), 5) and 11), https://www.npra.gov.my/index.php/en/faqs-compliance-and-licencing/frequently-asked-questions-faqs-licensing.html?highlight=WyJmcmVxdWVudGx5Il0=

13 Pharmacy Enforcement Division, Official Portal of Pharmaceutical Services Malaysia, MOH, 2018, https://www.pharmacy.gov.my/v2/en/content/pharmacy-enforcement-division.html

private insurance companies to give low-income people with cheap health-care protection and coverage. For example, via the "mySalam National Health Protection Scheme".

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

See Question 2 of Chapter 1 regarding the regulation of price of drugs and device products.

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

Malaysia's public health system is financed mainly through general revenue and taxation collected by the Federal government, while the private sector is funded through private health insurance and out-of-pocket payment from consumers.

Government taxes collected by the Treasury are allocated to the MOH under the framework of five-year plan and annual budgets. The MOH funds its public health care facilities through global budgets based on historical spending, while the private sector funders mainly seek fee-for-service to pay for their facilities and expenditure.

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

Medicines are dispensed by registered medical practitioners, registered dentists and registered veterinarians. Medicines and devices are dispensed by hospitals and pharmacists. Public hospitals are government funded and are therefore compensated by taxpayers whereas pharmacists tend to be privately owned and therefore are paid out-of-pocket of consumers.

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?

Pharmacists are regulated by the Malaysian Pharmaceutical Society (MPS) and must adhere to a code of conduct therefore maintaining the highest professional standard in the discharge of their professional service to patients and clients, in their conduct and professional relations with members of the profession and other allied professions. Various extensive guidelines are available concerning good dispensing practices. These include the "Guidelines for Good Dispensing Practice" adopted by the Malaysian Medical Council on 19 July 2016 and the "Guide to Good Dispensing Practice" issued by the Pharmaceutical Services Division of the Ministry of Health Malaysia in 2016

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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?

The key regulatory authority with jurisdiction over drugs, biological and medical devices in Singapore is the Health Sciences Authority (HSA). It was established on 1 April 2001 as a statutory board of the Ministry of Health under the Health Sciences Authority Act (Chapter 122C).

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

Authorisation

Therapeutic products (including biological therapeutic products)

Subject to certain prescribed statutory exceptions, all therapeutic products including biological therapeutic products that are imported or sold in Singapore must be registered with the HSA.

The HSA will generally register a therapeutic product if it is satisfied that:

- the overall intended benefits to a user of the therapeutic product outweigh the overall risks associated with the use of the therapeutic product; and
- the therapeutic product is suitable for its intended purpose and that any risk associated with its use is minimised, based on its formulation, manufacturing process controls, specifications and shelf life, as well as its stability under the recommended storage conditions.

The company seeking to market the therapeutic product in Singapore is responsible for obtaining product registration. This must be a locally registered company that will be responsible for the quality, safety and efficacy of the product. Therapeutic products must be marketed in accordance with the Health Products Act and the applicable subsidiary legislation.

For instance, the advertising of therapeutic products is subject to statutory and regulatory requirements and restrictions, such as:

- matters that must be excluded from advertisements of therapeutic products;
- restrictions on promoting therapeutic products for certain specified diseases and conditions;
- the general prohibition against advertising prescription-only medicines; and
- restrictions on the advertising of pharmacy-only medicines.

Biological therapeutic products are generally regulated in the same manner as other therapeutic products.

Dealers such as importers and wholesalers will need to obtain the relevant licence(s) from the HSA in order to import or supply by wholesale therapeutic products in Singapore.

Medical devices

In general, all medical devices (including in vitro medical devices) must be registered with the HSA by a locally registered company, before they can be supplied in the Singapore market. This is subject to certain exceptions, such as for the following types of medical devices:

- custom-made medical devices;
- medical devices which have underwent maintenance or repair;
- medical devices for patients' use;
- Class A medical devices; and
- medical devices to be used in clinical research.

The HSA classifies medical devices into four risk level classifications, namely:

- Class A, for low risk devices, such as wheelchairs and tongue depressors;
- Class B, for low to moderate risk devices, such as hypodermic needles and suction equipment;
- Class C, for moderate to high risk devices, such as lung ventilators and bone fixation plates; and
- Class D, for high risk devices, such as heart valves and implantable defibrillators.

The risk classification for a medical device is based on several factors, including the duration of medical device contact with the body, the degree of invasiveness, whether the medical device delivers medicinal products or energy to the patient, whether the device is intended to have a biological effect on the patient, and its local versus systemic effects.

Similarly, in vitro medical devices are classified under one of the four different risk level classifications:

- Class A, for devices with low individual risk and low public health risk, such as specimen receptacles;
- Class B, for devices with moderate individual risk and/or low public health risk, such as Vitamin B-12, pregnancy self-testing, anti-nuclear antibody, and urine test strips; and
- Class C, for devices with high individual risk and/or moderate public health risk, such as blood glucose.

The classification of an in vitro medical device is determined based on a set of rules derived from those features that create risk, such as the intended purpose and indications for use as specified by the product owner; the technical, scientific or medical expertise of the intended user; the importance of the information to the diagnosis, taking into consideration the natural history of the disease or disorder including presenting signs and symptoms which may guide a physician; and the impact of the result to the individual and/or public health.

Pricing and Reimbursementtion

The prices of therapeutic products (including biological therapeutic products) and medical devices are generally not regulated by the Singapore government. However, public sector hospitals in Singapore generally purchase medicinal products through centralised Group Procurement Offices (GPOs) by way of tender contracts, and this operates in some way to regulate the prices of therapeutic products and medical devices.

The national healthcare system in Singapore operates on mixed financing system that provides multiple tiers of financing for its citizens and residents. Apart from direct subsidies for services and drugs at public healthcare institutions, the Singapore government also administers a number of drug subsidy schemes. These include the Medication Assistance Fund (see **Chapter 1, Question 10**) and the Standard Drug List, to ensure that eligible patients have access to effective medications for medical conditions that are common in Singapore.

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

Therapeutic Products (including biological therapeutic products)

Registering a new therapeutic product generally involves the following steps (see the HSA's Guidance on Therapeutic Product Registration in Singapore):

- pre-submission preparation/consultation;
- application submission;
- application screening;
- application evaluation;
- regulatory decision; and
- post-approval changes.

Pre-submission preparation

An application for new product registration can either be in respect of a new drug application (NDA) or a generic drug application (GDA). The GDA is generally available for a therapeutic product that contains one or more chemical entities that is essentially the same as a current registered product, in terms of its qualitative and quantitative composition of active ingredients, pharmaceutical dosage form and clinical indication. Follow-on biologic products, or biosimilar products, are not eligible for a GDA and are required to be submitted via a NDA.

The registration must undergo one of the following evaluation routes:

- Full route: applies to any new product that has not been approved by any drug regulatory agency at the time of submission.
- Abridged route: applies to any new or generic product that has been evaluated by at least one drug regulatory agency.
- Verification route: applies to any new or generic product that has been evaluated and approved by one of the HSA's reference drug regulatory agencies, including Australia's Therapeutic Goods Administration, the European Medicines Agency, Health Canada, the UK Medicines and Healthcare Products Regulatory Agency and the US Food and Drug Administration.

- Verification-CECA route: applies to any generic product manufactured in India that has been evaluated and approved by one of the HSA's reference drug regulatory agencies, including Australia's Therapeutic Goods Administration, the European Medicines Agency, Health Canada, the UK Medicines and Healthcare Products Regulatory Agency and the US Food and Drug Administration.

Application submission

Application submission involves: (i) an online sub-mission of the relevant application form through the HSA's PRISM web portal; and (ii) the sub-mission of the technical dossier.

Application screening

The application will be screened to ensure that the correct application type has been selected and that the submitted dossier is complete. Where the HSA identifies deficiencies in the dossier, it will send a query stating the same to the applicant and put in place a stop-clock, which ends when the HSA receives a complete and satisfactory response.

Application evaluation

Upon acceptance of the application, the HSA will begin its evaluation. Similarly, a stop-clock starts when the HSA issues a query to the applicant and ends when the HSA receives a complete and satisfactory response.

Where necessary, the HSA may involve external evaluators (whose identities will be kept confidential), experts (such as scientists and clinicians from both local and overseas institutions) and advisory committees. The external evaluators and experts will be contractually bound to protect information provided to them.

Regulatory decision

The HSA will make a regulatory decision following the conclusion of its benefit-risk assessment, based on the data submitted in support of the application.

The regulatory decision issued by the HSA will be one of the following:

- Approval, i.e., the application satisfies the registration requirements for quality, safety and efficacy. This is a final decision issued by the HSA.
- Approvable, i.e., the application can be approved subject to adequate response to minor deficiencies. The HSA will inform the applicant of the approval conditions, and the applicant will need to satisfy these conditions within a specified time period.
- Non-approvable, i.e., the application has major deficiencies. The HSA will inform the applicant of the deficiencies. Should the applicant wish to proceed with the application, it should respond within the specified time period based on the original data set submitted to the HSA.
- Rejection, i.e., the response provided by the applicant fails to address the major deficiencies specified in the HSA's non-approvable decision. This is a final decision issued by the HSA.

Further, the HSA may register the product subject to post-approval commit¬ments, in which case the applicant will have to furnish a letter of commit¬ment setting out the undertakings concerned.

Post-approval changes

Following product registration, product registrants are responsible for ensuring the product's quality, efficacy and safety throughout its life cycle, and must notify the HSA of any changes to the same.

Medical Devices

The risk classification of a medical device (**see Chapter 1, Question 2**) will affect its registration requirements and the evaluation route that applies to such registration. The relevant product evaluation route will also depend on whether the medical device has received reference agency approvals (if any) and the prior safe marketing history of the medical device (if applicable).

For instance:

- Class A medical devices are generally exempt from product registration requirements.
- Class B, C and D medical devices may have a complex registration process, especially if the abridged, expedited, or immediate route is not available for the device. Any medical device which has not obtained prior approval from any of the HSA's reference agencies at the point of application is subject to a full evaluation.
- Class B medical devices may qualify for immediate registration if the device has obtained prior approval from any two of the HSA's independent reference agencies for an intended use identical to that being submitted for registration in Singapore and has been marketed for at least three years in two of the independent reference regulatory agencies' jurisdictions without quality, performance, efficacy or safety concerns.
- Class C standalone medical mobile applications which are medical devices may qualify for immediate registration if it has obtained prior approval from at least one of the HSA's independent reference agencies at the point of application and has been marketed for at least three years in the independent reference regulatory agency's jurisdiction without quality, performance, efficacy or safety concerns.

The medical device registration applications must be made as online sub-missions through the HSA's MEDICS web portal. All information and documents submitted in support of the registration of Class B, C and D medical devices must be compiled in the ASEAN Common Submission Dossier Template format.

The processing of the application differs depending on the product evaluation route. For instance, Class B medical devices that qualify for immediate registration can be registered immediately and listed on the Singapore Medical Device Register within an hour.

4. What are the approximate fees for each authorization?

The product registration fees for therapeutic products and medical devices vary, depending on the type or risk classification of the product and the evaluation route.

For therapeutic products, the product registration fees comprise a screening fee of between S$500 and S$2,750, and an evaluation fee of between S$3,850 and S$82,500, depending on whether the application is an NDA or GDA, and the evaluation route used.

For medical devices, the application fee is S$500, and the evaluation fees (depending on the evaluation route) range from S$900 to S$75,000. Additional fees apply where the application is submitted for a full evaluation under the priority review scheme.

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

For both therapeutic products and medical devices, registration is generally valid for one year, and may be renewed upon paying an annual retention fee, unless the registration is suspended by the HSA, or cancelled by the HSA or the product registrant.

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

A generic product is a therapeutic product that has the same qualitative and quantitative composition in active substances and is of the same pharmaceutical form and dosage as a currently registered product in Singapore. Such product must demonstrate bioequivalence to the Singapore reference product via appropriate bioequivalence studies.

A generic drug application (GDA) can apply for the registration of generic products (see **Chapter 1, Question 3** above). The fees for a GDA are generally lower compared to that for a new drug application (NDA), and the evaluation processing time is generally also shorter.

The application for therapeutic product or medical device registration can only be submitted by a locally registered entity.

Overseas manufacturers that intend to register their therapeutic products in Singapore are subject to a Good Manufacturing Practice (GMP) Conformity Assessment by the HSA. Overseas manufacturers must comply with Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP standard and can submit a valid GMP certificate or other evidence of GMP compliance from a PIC/S member authority. If such evidence is found to be acceptable, an audit by the HSA would not be necessary. Otherwise, the HSA will conduct an on-site GMP compliance audit of the applicant manufacturer.

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

Biological therapeutic products are subject to the same regulations as other therapeutic products. These regulations would similarly apply to combination products consisting of multiple biological and/or other therapeutic products.

Where a combination product comprises a medical device as well as a medicinal product, whether it will be regulated as a medical device or a therapeutic product is determined based on its primary mode of action (PMOA),

i.e., the mode of action that makes the greatest contribution to the overall intended therapeutic purpose of the combination product.

The combination product will be regulated as a medical device under the Health Products Act where it does not achieve its PMOA in or on the human body by pharmacological, immunological or metabolic means. Examples of such products include drug eluting stents and dermal filler incorporating analgesic.

Medical devices incorporating registrable medicinal products are Class D medical devices. The Medical Devices Branch and the Therapeutic Products Branch of the HSA will jointly evaluate the product registration applications for such devices. Medical devices incorporating non-registrable medicinal products will be classified according to the risk class applicable to the medical devices.

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?

The HSA has broad powers of investigation and enforcement under Part X of the Health Products Act, including the right to enter, inspect and search premises, as well as take samples for testing, examination or analysis without payment.

A person who furnishes to the HSA false or misleading information in a product registration application shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

The US Food and Drug Administration and the European Medicines Agency are reference agencies of the HSA. Prior approval for a therapeutic product or medical device by the HSA's reference drug regulatory agencies does not oblige the HSA to approve the application for product registration in Singapore, but such prior approval may allow an applicant to submit its application via a more simplified evaluation route for the Singapore registration.

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

Penalties for non-compliance with the regulatory requirements under the Health Products Act, which includes requirements on the manufacture, import, supply and advertisement of therapeutic products and medical devices in Singapore and the licensing of dealers of such products, include fines and/or imprisonment.

For instance, the failure to keep proper records relating to the manufacture, import, supply, use or administration of a therapeutic product (where applicable) is an offence which can attract a fine of up to S$10,000 and/or imprisonment for a term of up to 6 months. The supply of an unregistered therapeutic product or medical device is an offence which can attract a fine of up to S$50,000 and/or to imprisonment for a term of up to two years. A person who manufactures a counterfeit therapeutic product can be liable upon conviction to a fine of up to S$100,000 and/or imprisonment for a term of up to 3 years.

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

Yes. Singapore's national healthcare system is funded by a mixed financing system, comprising multiple tiers of financing for Singaporeans' healthcare expenditure.

There are broadly four tiers of healthcare funding, namely:

- Direct subsidies from the Singapore government for all Singaporeans, of up to eighty per cent (80%) of the total bill in acute public hospital wards;
- Medisave, which is a compulsory individual medical savings account scheme under which every working Singaporean as well as his employer must contribute a portion of his monthly wages into the account to save for his future medical needs;
- Insurance plans such as MediShield Life, which is a basic, lowcost medical insurance scheme for all Singaporeans and permanent residents, which helps to pay for large hospital bills and specified costly outpatient treatments, including dialysis and chemotherapy; and
- MediFund, which is a medical endowment fund established by the Singapore government to further aid needy Singaporean patients who are unable to pay for their remaining medical bills even after using other means of payment (including the abovementioned tiers of financing).

In addition, the Singapore government also administers several other subsidy schemes, such as:

- Community Health Assist Scheme: Common outpatient medical treatment and basic dental services are provided at subsidised rates to needy elderly or disabled patients by general practitioners and dental clinics that have agreed to partner with the MOH.
- Interim Disability Assistance Programme for the Elderly: Financial help is provided to certain disabled elderly Singapore citizens.
- Medication Assistance Fund: Subsidies are provided for certain drugs at public hospitals, specialist outpatient clinics and polyclinics.

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

Singapore adopts a mixed delivery healthcare model, with primary healthcare services, acute hospital services and step-down care services being offered by healthcare providers in both the public and private sectors. Briefly, the distribution of services provided by the public and private sectors is as follows:

- Primary care sector: Private sector providers account for around 80% of the market.
- Acute care sector: Public sector providers account for around 80% of the market.
- Step-down care sector: Voluntary welfare organisations, most of which are funded by the government for services provided, account for a majority of the market.

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

The prices of therapeutic products (including biological therapeutic products) and medical devices are generally not regulated by the Singapore government,

how?

though prices in the public sector may be indirectly regulated through the purchasing of drugs and devices through centralised Group Procurement Offices (GPOs) by way of tender contracts.

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

The national healthcare system in Singapore operates on mixed financing system that provides multiple tiers of financing for its citizens and residents (see **Chapter 1, Question 10**). Government subsidies are available for certain drugs at public sector healthcare institutions, for instance, drugs under the Standard Drug List. Private insurers may provide reimbursement for the cost of drugs and medical devices, depending on the specific terms of the relevant policies.

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

The persons who can dispense drugs and sell medical devices to patients depends on the relevant classification of the drug or device.

For therapeutic products:

- prescription-only medicines (POMs) can only be supplied by a doctor or dentist, or by a pharmacist at a retail pharmacy according to a prescription by a doctor or a dentist;
- pharmacy-only medicines (P-Medicines) can be supplied by or under the supervision of a pharmacist without a prescription; and
- general sales list (GSL) medicines can be purchased from any retailer;

For medical devices:

- "professional use only" medical devices can only be supplied to a licensed wholesaler of medical devices or a qualified medical or dental practitioner; and
- "trained user only" medical devices can only be supplied to a person who has been provided with training on the safe and efficacious use of the medical device as the manufacturer of the medical device determines is necessary.

The Singapore Government provides subsidies for certain drugs, such as those on the Standard Drug List, dispensed through the public sector hospitals.

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?

Under regulation 17 of the Health Products (Therapeutic Products) Regulations 2016, a qualified practitioner or collaborative prescribing practitioner (or a person acting under the supervision of the same) or a qualified pharmacist (or a person acting under the supervision of the same) may dispense a therapeutic product only if the package or container of the therapeutic product is labelled with all of the following information in English:

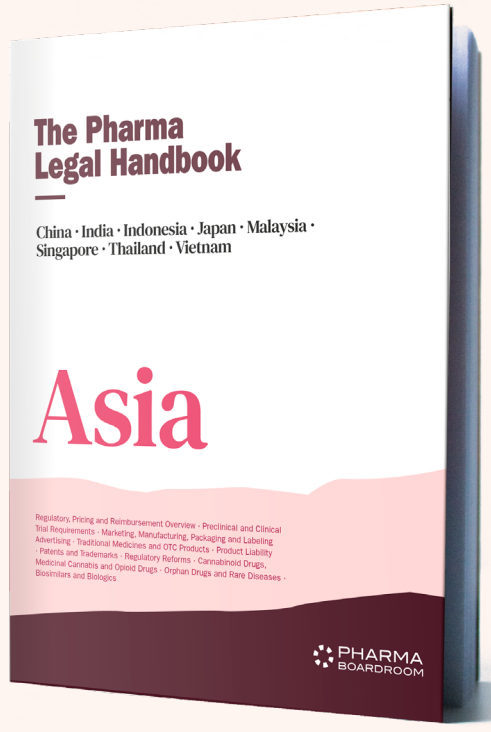
- the name of the person to whom the therapeutic product is to be administered;
- the name, address and any identification number or logo of the licensed healthcare institution or licensed retail pharmacy where the therapeutic product is supplied or dispensed;
- the date that the therapeutic product is dispensed;

- the directions for use of the therapeutic product;
- the name of the therapeutic product, being either the proprietary name or the appropriate non-proprietary name; and
- where the appropriate non-proprietary name is included on the label, the appropriate quantitative particulars of any active ingredient of the therapeutic product.

Under regulation 15 of the Health Products (Medical Devices) Regulations 2010, any person supplying a medical device must ensure that it is accompanied with the following information:

- the trade or brand name of the medical device;
- where the medical device is supplied for use in any investigational testing, the statement "For Clinical Trial Use" or any other statement in English that conveys the same meaning;
- where the medical device is contained in a package and the contents of the package are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the medical device, such as the size, net weight, length, volume or number of units;
- the expiry date of the medical device, if the medical device has one, as determined by the product owner of the medical device on the basis of the component of the medical device that has the shortest projected useful life;
- the product owner's name or trading name, address, telephone number and electronic mail address; and
- an appropriate control number, such as a batch code, lot number or serial number.

The Pharma Legal Handbook



Asia

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Thailand

This chapter about Regulatory, Pricing and Reimbursement in Thailand was published in association with:

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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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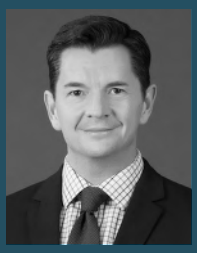

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Alan represents diverse clients, from pioneers in the life sciences to the biggest IP owners in the world, and helps them achieve the dual goals of profit and protection. He has extensive experience in IP acquisitions, strategic structuring, technology 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.

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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.

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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.

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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.

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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?

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 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.

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 Device (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 years and is renewable. The full Common Submission Dossier Template (CSDT) is required.

Examples of Detailed Notification Medical Devices include condoms, contact lenses, surgical gloves, rehabilitation devices, HIV self-test kits, etc.

(iii) Listed (or General) Medical Device (equivalent to Class 1 Medical Device)

Listed Medical Devices are medical devices that pose a low risk to individuals and the general public. Medical devices under this category are subject to the least stringent control by the Thai FDA. Prior to importation and production, the applicant must submit the dossier and obtain an approval certificate for importation or manufacturing of a listed medical device (or product license). The certificate for importation or manufacturing of a Listed Medical Device remains valid for five years and is renewable. The full Common Submission Dossier Template (CSDT) is NOT required.

Examples of Listed Medical Devices include adhesive bandages, examination gloves, specimen receptacles, powered hospital beds, wheelchairs, ophthalmic lenses with optical power, etc.

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

Pharmaceutical Products

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 of the applicable investigation site. Once those first two steps are complete, the company can apply for marketing authorization of the particular drug product.

For imported drug products, importers are also required to submit a GMP clearance application for each drug product in order to ensure that the overseas manufacturing site meets PIC/S GMP standards. The GMP clearance approval granted by the Thai FDA will have the same validity as the GMP certificate issued by the regulatory authority in the country of manufacturing. Thailand is a member of PIC/S GMP.

Medical Devices

There are two steps to obtaining market authorization for medical devices. First, an established company in Thailand must obtain either a medical device manufacturing license or a medical device importation license from the Thai FDA. Once that is complete, the company can then apply for a marketing authorization for the particular medical device.

With the full implementation of the risk classification system, the Thai FDA has implemented the "partial registration scheme" for Detailed Notification

Medical Device and Licensed Medical Device to prevent a shortage of medical devices and to facilitate the registration processes. Under the partial registrations scheme, some of the technical documentation will be waived for three years from the beginning of the risk classification system (i.e., from 15 February 2021 through 15 February 2024). Nonetheless, the complete documentation as required for the normal registration scheme must then be submitted upon the renewal of the product license.

4. What are the approximate fees for each authorization?

According to the Ministerial Notification: Official Fees for Drug Products published on 4 Aug 2017 and Ministerial Notification: Official Fees for Medical Devices published on 4 Aug 2017, the official fees assessed will not exceed the maximum values provided in the table below. This new fee schedule is designed to facilitate the government for levying fees by defining the actual cost for each type of registration.

Pharmaceutical Products

(1) Modern Drug Manufacturing Licenses	THB 8,500	Per license
(2) Modern Drug Selling Licenses (Retail)	THB 2,500	Per license
(3) Modern Drug Selling Licenses (Wholesale)	THB 2,000	Per license
(4) Modern Drug Import License	THB 10,500	Per license
(5) Technical Document Evaluation for New Drug Registration	THB 155,000 – 395,000	Per license
(6) Technical Document Evaluation for Generic Drug Registration	THB 39,000 – THB 59,000	Per product

Remarks:

The fees for Nos. 5-6 do not include (i) application fee, which will be between THB 1,000 – THB 2,500, and (ii) license fee, which will be THB 2,000.

Medical Devices

(1) Medical Device Manufacturing Licenses	THB 33,100	Per license
(2) Medical Device Import License	THB 13,100	Per license
(3) Medical Device Sale License	THB 13,100	Per license
(4) Technical Document Evaluation for Licensed and Detailed Medical Device Registration	THB 38,000 – 88,000	Per product
(5) Technical Document Evaluation for Notified (General) Medical Device Registrationn	THB 1,000 THB 2,000	1-10 products more than 10 products

Remarks:

- Fee No. 4 does not include (i) application fee in the amount of THB 100, and (ii) license fee, which will be between THB 5,000 – THB 20,000.

- Fee No. 5 does not include the; application fee in the amount of THB 100.

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

Pharmaceutical Products

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.

According to Amendment No. 6 of the Drug Act, marketing authorization drug licenses that received approval after October 13, 2019, will have a validity of seven years, and are renewable.

Medical Devices

The medical device manufacturing and medical device importing license are both valid for a period of five calendar years. Each type of license must be renewed before December 31 of the fifth year.

The medical device selling license is valid for a period of one calendar year (from January 1 to December 31) and must be renewed before December 31 each year.

According to the Medical Device Act, as amended, the product licenses of medical devices (Listed Medical Devices, Licensed Medical Devices and Detailed Notification Medical Devices) are valid for a period of five years, and are renewable.

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 registration. Original drugs (or patented drugs) are classified as new drugs, meaning the registration dossier must include both non-clinical and clinical documentation. To register an oral-solid dosage form (i.e., tablet or capsule) generic product which is oral-solid dosage forms i.e., tablet, capsule, 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. Some new generic drugs may be subject to the SMP requirement if the original product has not been yet released from the SMP or the generic drug is considered a highly ethical drug (e.g., anticancer drug).

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 Division and the Medical Device Control Division. However, the final classification decision will be at the Thai FDA's discretion.

For example, drugs available in prefilled syringes are classified as drugs. However, if the main function of the combination acts like a medical device, such combination will be classified as a medical device (i.e., drug eluting stent, condom with spermicide, Heparin-coated catheters, etc.)

Combination products that fall within the scope of medical devices are classified as Licensed Medical Devices – the highest risk (class 4), which must obtain a license prior to import or manufacture the product.

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 Division 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. Information about median pricing can be found on (http://ndi.fda.moph.go.th/drug_value). 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, which requires distributors to report the price of drugs sold to private hospitals. Further the private hospitals must also report the selling price of medicinal products and medical devices they purchase

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 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

Only licensed practitioners such as doctors and dentists are authorized to prescribe drugs in Thailand, after which such drugs will be dispensed by a

those who dispense drugs and devices? What role do they play in providing patient care, information, and safety?

licensed pharmacist. Generally, most drugs are available at the hospital and at pharmacies. Unlike 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.

Vietnam

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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?

In Vietnam, pharmaceutical products (including drugs and biologicals) and medical devices are under the overall management of the Ministry of Health (www.moh.gov.vn). The Ministry of Health ("**MOH**") is organized into a number of divisions, in which the Drug Administration of Vietnam (https://dav.gov.vn) ("**DAV**") has the overall responsibility for pharmaceutical products and the Department of Medical Equipment and Construction (www.dmec.moh.gov.vn) ("**DMEC**") and provincial Departments of Health monitor the manufacturing, registration and trading of medical devices.

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

The primary legislation for pharmaceuticals in Vietnam is Law No. 105/2016/QH13 on Pharmacy (the "**Law on Pharmacy**"), which was issued on 6 April 2016 and took effect on 1 January 2017, replacing the previous Law on Pharmacy of 2005.

Subordinate legislation includes Decree No. 54/2017/ND-CP guiding the implementation of the Law on Pharmacy, which was issued on 8 May 2017 and took effect on 1 July 2017, as amended by Decree No. 155/2018/ND-CP, which was issued and took effect on 12 November 2018. These decrees focus on drug import/export, pharmaceutical business, pharmacy practice certificates, drug recall, drug advertisement and drug price management.

Further regulations on other matters such as labelling and package inserts, drug quality, clinical trials of drugs and marketing authorization ("MA") are regulated by the MOH in its ministerial circulars. In particular, the marketing authorization of drugs follows Circular No. 32/2018/TT-BYT of the MOH dated 12 November 2018 on MA for drugs and medicinal ingredients ("Circular 32"), as amended by Circular No. 29/2020/TT-BYT dated 31 December 2020 and Circular No. 23/2021/TT-BYT dated 9 December 2021.

The management of medical devices is currently regulated by the following legislation:

(i) Decree No. 98/2021/ND-CP of the government dated 8 November 2021 on medical device management ("Decree 98").

(ii) Circular No. 47/2010/TT-BYT of the MOH dated 29 December 2010 guiding the export and import of medicines and packaging in direct contact with medicines;

(iii) Circular No. 30/2015/TT-BYT of the MOH dated 12 October 2015 regulating the import of medical devices; and

(iv) Circular No. 19/2021/TT/BYT of the MOH dated 16 November 2021 stipulating forms and reports for implementation of Decree 98;

(v) Circular No. 05/2022/TT/BYT of the MOH dated 1 August 2022 detailing some articles of Decree 98.

Medicinal product pricing in Vietnam is based on the policy that medicinal product manufacturers, exporters, importers, MA holders and wholesalers/distributors are free to set their own prices for their products, and compete on price, but are liable by law. Pharmaceutical establishments must declare the prices of their medicinal products to the DAV.

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

Generally, there are three steps to obtaining marketing authorization for a drug. First, a company established in Vietnam must obtain either a drug manufacturing license or a drug trading license from the DAV. After obtaining one of these licenses, the company can submit a request to manufacture or import samples for various purposes (such as clinical trials or research and development). For research purposes, the clinical trial protocol must be approved by the relevant ethics committee, then the company must engage a licensed clinical trial establishment to test the drug. 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 current government fees for authorization applications are as follows:

Authorization type	Fee per application
Drugs (new authorization)	VND 5.5 million (approx. USD 237)
Drugs (renewal authorization)	VND 3 million (approx. USD 130)
Medical devices (Class A)	VND 1 million (approx. USD 43)
Medical devices (Class B)	VND 3 million (approx. USD 130)
Medical devices (Class C and Class D)	VND 5 million (approx. USD 215)

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

Generally, drug MAs have a maximum term of five years. In certain cases, such as the first authorization for a new drug, a new vaccine or where the safety and effectiveness report of the drug is not available or insufficient, the DAV will grant a marketing authorization with a three-year term. Within 12 months before the expiration date of the current marketing authorization, the MA holder may apply for an extension. By law, an extension to the current MA should be issued within three months from the receipt of a complete application dossier.

For medical devices, the registration numbers for all classes are valid indefinitely, except for registration numbers granted under the emergency registration procedure (such as for products for epidemic prevention and control, and overcoming the consequences of natural disasters and catastrophes).

6. How does the authorization process differ between brand-name products and generic

The authorization process for the registration of brand-name products, i.e., "new modern drugs" as defined in the Law on Pharmacy, must include, among other

products? Are there differences for local manufacturers versus foreign-owned manufacturers?	things, pre-clinical and clinical documentation, while this documentation may not be required for generic products. All drug manufacturers must obtain an Enterprise Registration Certificate, a Certificate of Eligibility for Pharmaceutical Business, and a GMP Certificate in order to manufacture drugs. Foreign-owned manufacturers located in Vietnam, additionally, must obtain an Investment Registration Certificate as a pre-condition for the above-mentioned certificates.
7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?	At the moment, there are no official regulations on combination products in Vietnam. From a practical view, for a drug combination, the classification may be based on the product's intended use; however, the DAV tends to classify them as drugs.
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?	Health inspectorates from provincial Departments of Health ("**DOHs**") and the Health Inspectorate under the MOH are mainly responsible for monitoring compliance for all pharmaceutical-related activities (manufacturing, marketing, authorization, etc.). Their specific practices are not publicized, thus, it is unknown if the local regime is comparable to the expectations and requirements of the FDA or the EMA.
9. What is the potential range of penalties for noncompliance?	Penalties imposed on pharmaceutical business entities for noncompliance are listed out in Decree 117/2020/ND-CP, as amended by Decree No. 124/2021/ND-CP. These penalties include suspension of import licenses, revocation of marketing authorization licenses, fines, and a recall of the violating products.
10. Is there a national healthcare system? If so, how is it administered and funded?	Vietnam has a national healthcare system including central hospitals, provincial and district-level hospitals, and health centers at the district and commune level. The central hospitals are under the management of the MOH, while the other hospitals and health centers are under the management of the provincial DOHs. Under the Law on Health Insurance No. 25/2008/QH12 (as amended in 2014), participation in health insurance is compulsory. The national healthcare system is funded by revenues generated from health insurance. However, only medicines, medical services and health procedures which are specifically indicated by the government are covered. Any others must be funded by the patients themselves.
11. How does the government (or public) healthcare system function with private sector healthcare?	The provincial Social Insurance Authorities publish their respective lists of healthcare establishments that are eligible for registration of initial health examination and treatment, which can be amended from time to time. The lists include most public hospitals and a number of healthcare establishments in the private sector (private hospitals). Patients who undergo health examinations at these establishments are covered for the examination and treatment expenses with the appropriate ratio.

If a patient uses the services of a healthcare establishment that is not in the respective eligibility list, their expenses are not covered by the Health Insurance Fund. They can cover the expenses either by themselves or with private insurance.

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

Drugs

Pharmaceutical establishments must declare their drug prices to the DAV. After an MA has been issued, the importer/manufacturer must declare to the DAV the estimated wholesale price and (optionally) the estimated retail price for the drug before the first lot is circulated in Vietnam. Any change in the declared price must be re-declared to the DAV.

Distributors must not sell drugs at prices higher than the declared prices, and the declared prices should not be higher than the prices of the same drugs in ASEAN countries where such drugs are imported and sold.

Medical Devices

Registration number holders are required to declare the prices of their medical devices on the Portal of Medical Device Management before putting the medical devices on the Vietnam market; the actual prices must not be higher than the declared prices.

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

Government Payers

The government issues lists of drugs and medical devices that are covered by government health insurance. Such lists apply to private and government health establishments that have signed contracts with health insurance institutions. Reimbursement for drugs and devices is only available for those included in the lists and prescribed appropriately by healthcare professionals.

Private Payers

Private health insurance providers are free to decide how they apply the procedure for reimbursement for drugs and devices.

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

Licensed healthcare professionals are permitted to prescribe drugs to patients. Following such prescription, patients can purchase the drugs at licensed drug retailers such as drugstores, including drugstores in hospitals. If the drugs or devices are covered by the Health Insurance Fund, the fund will reimburse the retailers.

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?

Drug retailers must specify a person in charge of pharmacy expertise, who must be present during the working hours of the retail establishment and may only authorize someone with a pharmacy practice certificate (i.e., a licensed pharmacist) to take charge in his/her absence. A pharmacist can only be the person in charge of pharmacy expertise for one drug retail establishment.

Pharmacists must complete a training program and refresher program in pharmacy within three years from the issuance date of their pharmacy practice certificate or the issuance date of the latest certificate of completion of training program

and refresher program in pharmacy. The pharmacist-in-charge of a drugstore may replace drugs in a prescription with other drugs that have the same active ingredients, usage, and dosage upon consent of the customer, and is responsible for such replacement. The pharmacist-in-charge of a drugstore needs to provide drug information to the customer, consult the customer when he/she finds the prescription inappropriate, and monitor the adverse effects of the drugs sold.

There are no specific regulations on dispensers of class-A medical devices. Dispensers of medical devices of classes B, C and D must have at least one person with a college degree (or higher) in a technical, medical or pharmacy discipline. Most drugstores sell both medicines and a number of medical devices.

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