The Pharma Legal Handbook

Singapore

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

PHARMA BOARDROOM

Singapore

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

Prepared in association with Drew & Napier, one of the largest law firms in Singapore, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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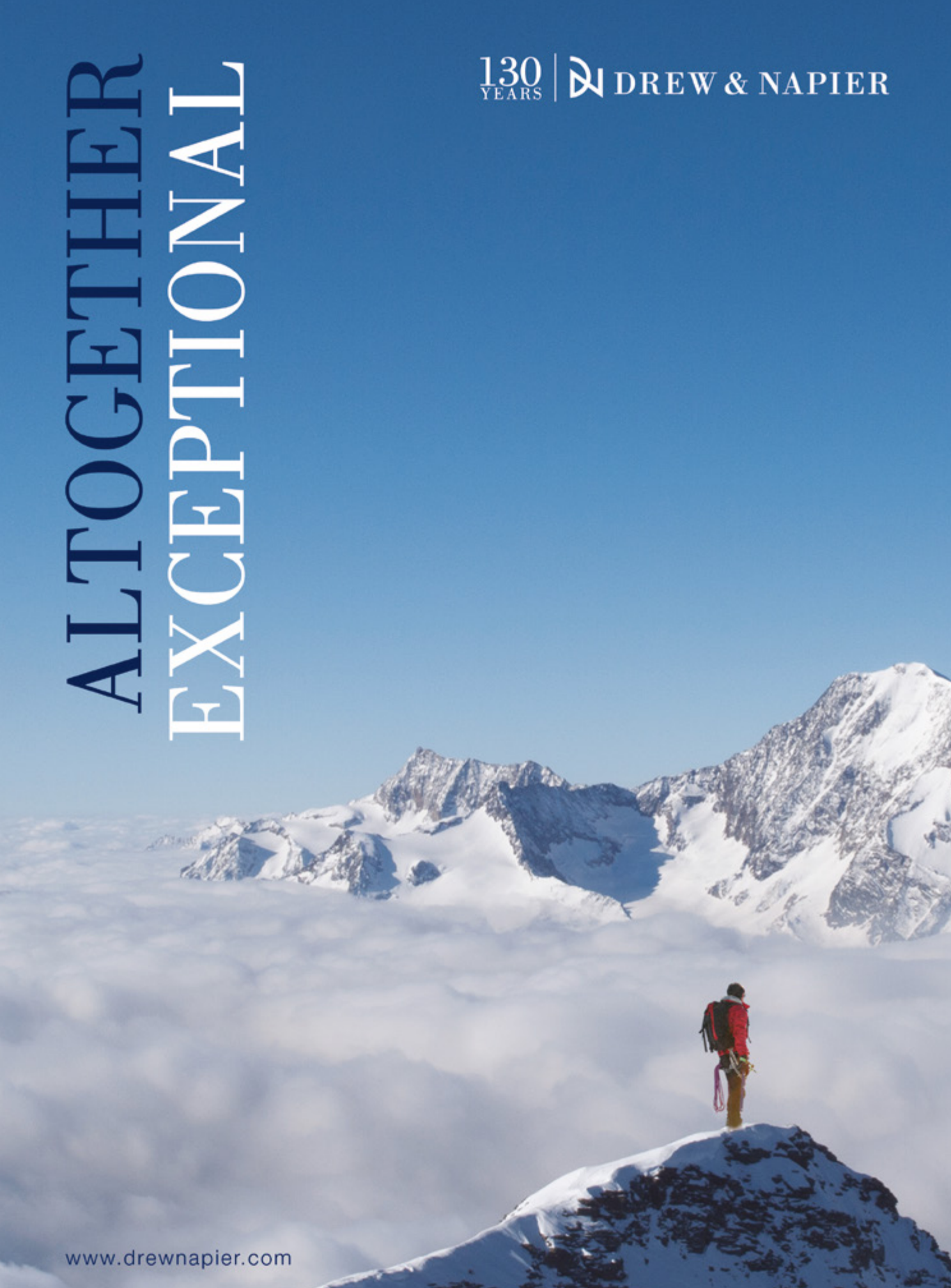
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01

REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

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

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

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

4. What are the approximate fees for each authorization?

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

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

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

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

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

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

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

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

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

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

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

01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

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

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 disea-ses 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 REIMBURSEMENT

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.