

The Pharma Legal Handbook

Malaysia

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

Malaysia

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

Prepared in association with SKRINE, one of the most awarded legal firms in Malaysia, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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SKRINE

Skrine is one of the largest and leading legal firms in the country, with a sterling global reputation, and a wide range of highly-regarded practice groups. The firm is currently led by 49 partners with over 110 lawyers. Skrine is the exclusive Malaysian member of Lex Mundi, a network of leading independent law firms in over 160 jurisdictions around the world and the Pacific Rim Advisory Council, a network of 30 top tier independent member law firms. The Firm has been named as the Malaysia Law Firm of the Year in 2020 by Chambers Asia-Pacific; Malaysia Firm of the Year 2013 - 2020 by Who's Who Legal; ranked as Leading Firm by Chambers Asia-Pacific 2011- 2021; ranked as Top Tier Firm by Legal 500 Asia-Pacific from 2014 - 2021; recognised as leading international arbitration firm since 2012 by Global Arbitration Review (GAR) 100 and have been named as Malaysian Firm of the Year for 2014 - 2016 by Managing Intellectual Property (Managing IP).

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SKRINE

Skrine is one of the largest and leading legal firms in the country, with a sterling global reputation, a wide range of highly-regarded practice groups to meet the increasingly diverse needs of clients, a commitment to talent development, and alumni who are making a difference in the world.

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CHINA DESK

Skrine's China Desk Group was established to connect and provide services to Chinese clients and corporations. With the ensuing implementation of China's Belt and Road Initiative, Malaysia, with its strategic geographical location along the Maritime Road, rich culture and large Chinese ethnic group, has provided excellent opportunities for Chinese corporations to invest in Malaysia. Skrine's China Desk Group lawyers are fluent in both Mandarin and English, and are selected from different practice groups within the firm to form a synergy to effectively communicate and provide services to Chinese clients.

"Extensive network of connections in the Asia-Pacific region, through which they can reach out for more resources. The lawyers are proactive, providing legal strategies to tackle every issue."

- Chambers Asia-Pacific 2021

"Excellent value for money. Concise and focused advice which demonstrates a real appreciation for business needs."

- Legal 500 Asia-Pacific 2021

Practice Areas

Litigation and Arbitration

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Aviation

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Oil and Gas, and Energy

Projects and Infrastructure

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Technology, Media and Telecommunications

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CONTENTS

01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

Page 6

02 PRECLINICAL AND CLINICAL TRIAL REQUIREMENTS

Page 19

03 MARKETING, MANUFACTURING, PACKAGING AND LABELING ADVERTISING

Page 24

04 TRADITIONAL MEDICINES AND OVER-THE-COUNTER PRODUCTS

Page 37

05 PRODUCT LIABILITY

Page 42

06 PATENTS AND TRADEMARKS

Page 47

07 REGULATORY REFORMS

Page 55

08 CANNABINOID DRUGS, MEDICINAL CANNABIS AND OPIOID DRUGS

Page 58

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 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
 - Erythropoietins 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