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

PHARMA BOARDROOM

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 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 2017 by Asian Legal Business; Malaysia Law Firm of the Year in 2015 by Chambers Asia Pacific; Malaysian Firm of the Year 2013 - 2019 by Who's Who Legal; ranked as Leading Firm by Chambers Asia Pacific 2011 - 2019; ranked as Top Tier Firm by Legal 500 Asia Pacific from 2014 - 2019; 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).

Address: Level 8, Wisma UOA Damansara, 50 Jalan Dungun, Damansara Heights, 50490 Kuala Lumpur.

Tel: +603 2081 3999
Fax: +603 2094 3211

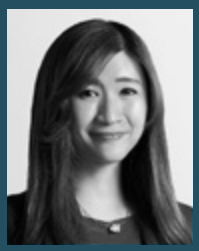
Email: skrine@skrine.com
Website: www.skrine.com

THE AUTHORS

KUEK PEI YEE

Pei Yee is a partner in the Intellectual Property and TMT practice and her work focuses on intellectual property disputes. She advises and represents local and foreign clients across numerous industries concerning a multitude of IP subject matters, including patents, trademarks, industrial designs and copyright. She has acted as lead counsel in litigation matters that cut across all IP subject matters, some of which have served to define milestones in the Malaysian IP landscape.

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.



TAN SHI WEN

Shi Wen is a partner from the corporate division and her portfolio focuses on competition law, maritime and shipping and corporate advisory and transactions.

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 and Boehringer Ingelheim.

She is listed as "Up and Coming" practitioner in Competition/Antitrust practice area by Chambers Asia-Pacific 2019. She is also the finalist for the Young Lawyer and Woman Lawyer of the Year by the Asian Legal Business Malaysia Law Awards 2019.

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- Chambers Asia-Pacific 2019

"... good mix of lawyers with excellent skills, knowledge and acumen"

- Legal 500 Asia-Pacific 2019

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CONTACT US

LEVEL 8, WISMA UOA DAMANSARA
50 JALAN DUNGUN
DAMANSARA HEIGHTS
50490 KUALA LUMPUR
MALAYSIA

T +603 2081 3999
F +603 2094 3211
E skrine@skrine.com

For more information about Skrine, visit **www.skrine.com**.

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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?

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 advices 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

[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

legislations 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 places 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.

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.

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.

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.

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: -