INTRODUCTION

In 2025, Malaysia's Pharmaceutical Market revenue is expected to reach US$1.74 billion.[1] For any company looking to tap into this lucrative market, understanding the local regulatory landscape is the first and most critical step. This landscape is primarily governed by the Control of Drugs and Cosmetics Regulations 1984 ("**CDCR 1984**"), enforced by the Drug Control Authority ("**DCA**") under the National Pharmaceutical Regulatory Agency ("**NPRA**") of the Ministry of Health.

According to Regulation 2 of the CDCR 1984, "product" is defined as a drug[2] in a dosage unit or otherwise, for use wholly or mainly by being administered to one or more human beings or animals for a medicinal purpose.[3] For instance, biologics, generic drugs, including prescription medicines and Over The Counter (OTC) products, traditional medicines, veterinary products, and health supplements all fall under the purview of the CDCR 1984.

This article aims to present a general overview of the legally mandated processes for product registration, regulatory compliance, and post-registration obligations.

THRESHOLD REQUIREMENT TO ESTABLISH LOCAL PRESENCE

Before a foreign pharmaceutical company can import, market, distribute, and sell products in Malaysia, it must have a recognised presence in Malaysia and register as a Product Registration Holder ("**PRH**"). This is grounded in Regulation 7 of the CDCR 1984,[4] which imposes a blanket prohibition on manufacturing, selling, supplying, importing, processing, or administering a product unless the product has been registered and the person holds the appropriate license to do so.

To qualify as a PRH, a company must be incorporated in Malaysia, have a permanent local address, and be registered with the Companies Commission of Malaysia for a business scope that includes pharmaceutical products.

Although local companies that meet NPRA's requirements may act as their own PRHs, the PRHs do not necessarily have to be the product owner, provided that such PRHs obtain the authorization from the product owners in writing to be the holders of the product registration, who will be responsible for all matters related to the quality, safety, and efficacy of the product.

The PRH takes on significant responsibilities. They are legally accountable for the product's quality, safety, and efficacy. Key duties include:

1. managing and submitting all technical data related to the product's quality, safety and efficacy, and promptly informing the DCA of any changes;
2. providing any documents, samples, or information requested by the DCA regarding the registered product;
3. corresponding with the NPRA directly. The NPRA shall not communicate with any other third party (including product owner and the law firm hired by any of the parties) regarding product registration;
4. ensuring the product consistently meets all quality standards and conditions of its marketing authorization; and
5. notifying the DCA immediately if they cease to act as the PRH.

PRODUCT REGISTRATION

(A) Product Classification

To begin the registration process, the applicant must first correctly classify the product. This is a crucial first step, as the classification, whether it is a new drug, a generic, or a health supplement, will determine the regulatory requirements, fees, and evaluation timeline.

Under the CDCR 1984, the "products" are classified into the following categories:

1. New drug products

- New drug products refer to any pharmaceutical products that have not been previously registered in accordance with the provisions of the CDCR 1984.

2. Biologics

- Biologics/ Biological products refer to any products whose active substance is made by or derived from a living organism (plant, human, animal or microorganism) and may be produced by biotechnology methods and other cutting-edge technologies.
- This product imitates natural biological substances in our bodies such as hormones, enzymes or antibodies.

3. Generics

- Generic products are products that are essentially equivalent to an existing registered product in Malaysia.
- Generic products can be classified into two groups: (i) Scheduled Poison (Controlled Medicine); and (ii) Non-scheduled Poison (Non-Poison or "Over-the-Counter", OTC).

4. Health supplements

- Health supplements refer to any product used to supplement a diet and to maintain, enhance and improve the health function of the human body.
- It can be presented in various forms such as capsules, tablets, powder, liquids and shall not include any sterile preparations (i.e., injectable, eye drops) or products using any other route of administration other than the oral route.

5. Natural products

- Natural products include traditional medicines, herbal products, homeopathic medicines, natural products with modern claims and natural products with therapeutic claims.

6. Veterinary products

- Veterinary products containing Scheduled Poison (as in First Schedule of the Poison Act 1952), Non-Scheduled Poison/OTC, pesticides for internal use, pesticides for external use (control of endoparasite) fall under the jurisdiction of NPRA.

To determine the classification of the products, the following criteria may be taken into account:

1. the primary intended purpose/indication of the product;
2. the primary mode of action/ the principal mechanism of action;
3. the substances and strength of the product; and
4. classification of the products in reference countries.

(B) Application for Quest 3+ Token

All product registrations are managed through Malaysia's online portal, the QUEST 3+ system. To access this, the PRH must first apply for a membership. The Quest 3+ Token also facilitates product registration, licensing applications, post-registration activities, certificate issuance, export support, and regulatory and safety submissions. Upon the NPRA's approval, the applicant must complete the remaining steps via the MSC Trustgate website.

Payment for Quest 3+ Token

Payment for Quest 3+ product registration must be made online through the system's payment portal. The charges for the Quest Membership are as follows:[5]

No.	Description	Validity Period	
		1-Year Fee (RM)	2-Year Fee (RM)
1.	**MAIN USER (Certificate + USB Token)** • New Replacement • Change of Authorized Person	260.00	290.00
2.	**SUPPLEMENTARY USER (Certificate + USB Token)** • New Replacement • Change of Authorized Person	245.00	275.00
3.	**CHANGE AUTHORIZED PERSON (Certificate Only)**	48.00	95.00
4.	**RENEWAL (Digital Certificate Only)**	48.00	95.00

5.	**POSTAGE (Peninsular Malaysia)**	10.00
6.	**POSTAGE (Sabah/Sarawak)**	20.00

(C) Submission for New Product Registration

The processing fees and analysis fees for the online application submission for different product categories via the QUEST system are as follows:[6]

No.	Product Category	*Processing Fee (RM)	Analysis Fee (RM)	Total Fee (RM)
1.	**Pharmaceutical** **a) New Drug Products** **b) Biologics**	1,000.00	Single active ingredient: 3,000.00	4,000.00
			Two or more ingredients: 4,000.00	5,000.00
2.	**Pharmaceutical Generic (Scheduled Poison)** **a) Generic (Non-Scheduled Poison)** **b) Health supplement**	1,000.00	Single active ingredient: 1,200.00	2,200.00
			Two or more active ingredients: 2,000.00	3,000.00
3.	**Natural products with traditional claims**	500.00	700.00	1,200.00
4.	**Natural products with modern claims**	1,000.00	Single active ingredient: 1,200.00	2,200.00
			Two or more active ingredients: 2,000.00	3,000.00
5.	**Natural products with therapeutic claims**	1,000.00	Single active ingredient: 3,000.00	4,000.00
			Two or more ingredients: 4,000.00	5,000.00

Note: *The DCA will charge any applicant such costs as it may incur for the purpose of carrying out laboratory investigations/ testing before the registration of any product.*[7]

(D) Decisions of DCA

A regulatory decision will be made by DCA on whether to approve or reject an application after reviewing the submitted documents. If required, DCA may request product samples. NPRA's evaluation timelines upon final and completion submission may vary depending on the product category and evaluation route, as shown in the table below.[8]

Evaluation Type	Product Category	Timeline (Working Days)
Full Evaluation	Prescription drugs	210
	Non-prescription drugs	210
	New drugs & biologicals	245
Abridged Evaluation	Health supplements and traditional products containing a single active Ingredient	116
	Health supplements and traditional products containing two or more active ingredients	136

Once the NPRA completes its evaluation, the DCA will issue its decision. A successful application marks a major milestone, but it is not the final step.

The decision will be communicated to the PRH via email or an official letter. Under Regulation 11(1) of the CDCR 1984,[9] DCA can reject, cancel or suspend a product registration at any time if there are issues with its safety, quality or effectiveness, or if the registration conditions are not met.

Thereafter, the PRH will be given a product registration number and a certificate of registration to prove that a pharmaceutical product has been approved for sale and use in Malaysia. The product registration number applies to the specific product, which includes its name, identity, composition, characteristics, origin, its manufacturer, PRH, as specified in registration documents.

POST-REGISTRATION PROCESS

(A) Licensing and Certification

Receiving the product registration number and certificate is the green light to begin commercial activity. However, to legally manufacture, import, or sell your product, the PRH must obtain the relevant licenses. The specific licenses required will depend on the PRH's business operations. Under Regulation 12 of the CDCR 1984, the Director of Pharmaceutical Services may issue the following licenses: manufacturer's licence, wholesaler's license, clinical trial import licence and import licence.

The processing fees are as follows:

Type of licence	Fee (RM)	Timeline	Validity
Manufacturer	1,000.00	Less than 1 month	1 year or until 31 December of the same year
Wholesaler	500.00	Less than 1 month	1 year or until 31 December of the same year
Clinical trial import	500.00	30-45 working days	3 years from the date of issuance[10]
Import	500.00	Less than 1 month	1 year or until 31 December of the same year

For certification, issuance of a certification by the Director of Pharmaceutical Services includes a fee of RM50.00.[11]

(B) Maintenance and Renewal of Product Registration

The product registration is valid for five years. To ensure uninterrupted market access, it is crucial to manage the renewal process proactively. An application for re-registration must be submitted within six months before the expiry date. The NPRA typically sends a reminder three months prior, but the ultimate responsibility lies with the PRH.

For withdrawal of the product registration, the PRH shall notify DCA regarding any decision to withdraw a product's registration and if they are no longer authorised to hold

the product's registration. The registration of a product, once withdrawn, shall not be reinstated. A new application for product registration is required if the PRH wishes to have the product registered again at a later date.

For the amendment to the particulars of the product, the applicant must submit an official written request to DCA if there are any amendments to the particulars of the product via variation applications.

(C) Post-Marketing Surveillance

The PRH's responsibilities continue long after a product is registered. They must actively monitor the product's performance in the market and ensure ongoing compliance.

Pharmacovigilance

In accordance with Regulation 28, CDCR 1984, the PRH or any person who possesses any registered product shall immediately inform the Director of Pharmaceutical Services of any adverse reaction arising from the use of the registered product.[12] All PRH must ensure that the company has a pharmacovigilance system in place and takes appropriate action when necessary. PRHs are required to monitor and report any product safety issues that arise locally or internationally to the NPRA and comply with all safety-related directives issued by DCA.

Product Recalls

In certain cases, products may need to be recalled due to reported serious adverse drug reactions. The PRH is responsible for executing any recall directives from the DCA.

CONCLUSION

The path to introducing a pharmaceutical product into the Malaysian market is a structured and multi-layered process designed to uphold the highest standards of public health. As outlined, the entire framework is governed by the CDCR 1984, with the NPRA acting as the central regulatory body.

Nonetheless, gaining market approval is not the end of the journey. The post-registration phase demands strict adherence to licensing, registration renewal, and ongoing pharmacovigilance duties to ensure continued product safety and efficacy.

Ultimately, successfully introducing a pharmaceutical product to the Malaysian market is a journey of meticulous planning and regulatory diligence. While the framework governed by the NPRA is rigorous, it is designed to ensure that only safe and effective products reach the public. For potential entrants, viewing this regulatory process not as a barrier but as a roadmap to building a trusted and sustainable presence is key. Engaging with local experts will be an invaluable asset in navigating this promising and growing pharmaceutical landscape.

1.https://www.statista.com/outlook/hmo/pharmaceuticals/malaysia
2.As per Section 2 of the Sale of Drugs Act 1952, "drug" includes any substance, product or article intended to be used or capable, or purported or claimed to be capable of being used on humans or any animal, whether internally or externally for a medicinal purpose used in humans (and animals).
3.As per Section 2 of the Sale of Drugs Act 1952, "medicinal purpose" means any of the following purposes:
(a) alleviating, treating, curing or preventing a disease or a pathological condition or symptoms of a disease;
(b) diagnosing a disease or ascertaining the existence, degree or extent of a physiological or pathological condition;
(c) contraception;
(d) inducing anaesthesia;
(e) maintaining, modifying, preventing, restoring, or interfering with, the normal operation of a physiological function;
(f) controlling body weight;
(g) general maintenance or promotion of health or well-being;
4.Control of Drugs and Cosmetics Regulations 1984 (PU(A) 223/1984), reg 7.
5.Drug Registration Guidance Document (DRGD) Third Edition, Tenth Revision July 2025, Appendix 9.
6.Drug Registration Guidance Document (DRGD) Third Edition, Tenth Revision July 2025, Appendix 9.
7.Control of Drugs and Cosmetics Regulations 1984 (PU(A) 223/1984),reg 8.
8.https://www.npra.gov.my/index.php/en/component/sppagebuilder/113-faq-product-registration.html#:~:text=After%20a%20product%20is%20registered,manufacturer%2F%20import%2F%20wholesale%20license
9.Control of Drugs and Cosmetics Regulations 1984 (PU(A) 223/1984), reg 11(1).
10.Malaysian Guideline for Application of Clinical Trial Import Licence and Clinical Trial Exemption, page 13-15.
11.Control of Drugs and Cosmetics Regulations 1984 (PU(A) 223/1984), reg 16.
12.Control of Drugs and Cosmetics Regulations 1984 (PU(A) 223/1984), reg 28.

Written by:

Dato' Azmi Mohd Ali
Senior Partner
azmi@azmilaw.com

Khong Ling Qi
Associate
khonglingqi@azmilaw.com

Corporate Communications
Azmi & Associates
22 September 2025