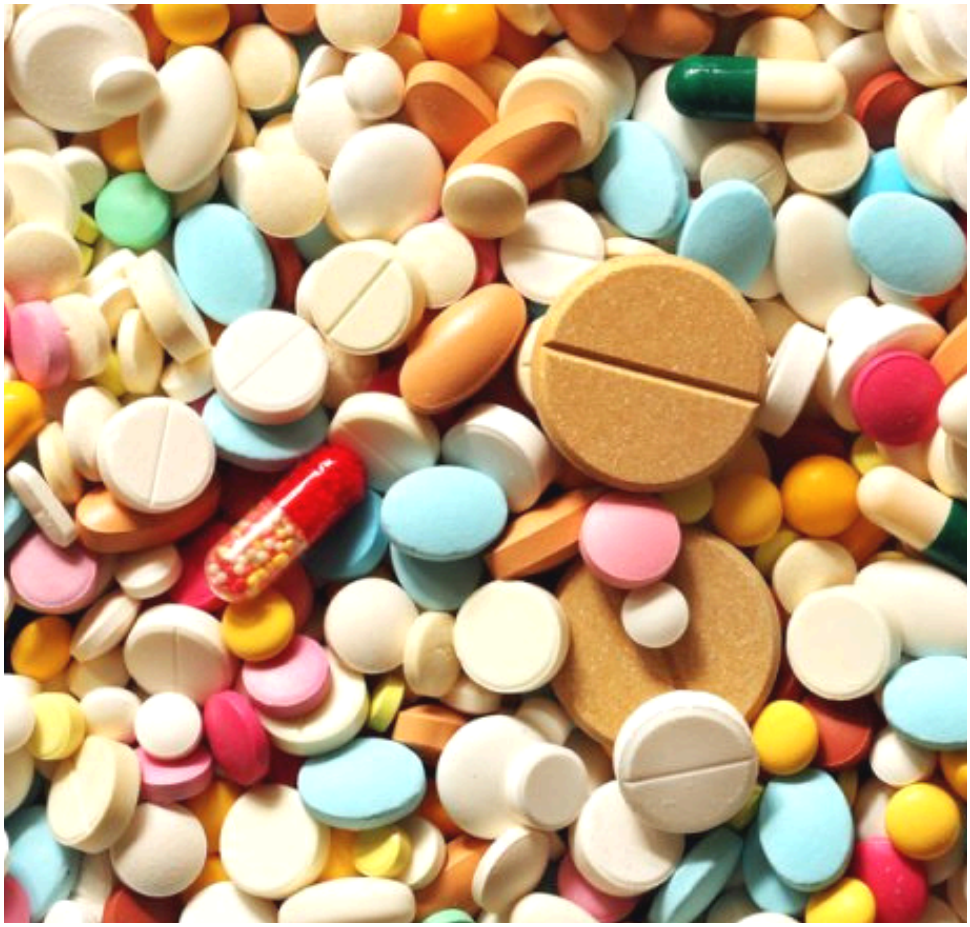
MINISTRY OF HEALTH
MALAYSIA

National Pharmaceutical
Regulatory Agency
(NPRA)



PRODUCT
REGISTRATION

What is “product” ?

Product

also known as medicinal product

The term “**Product**”, under the Control of Drugs and Cosmetics Regulations 1984, Regulation 2 means:

- a drug 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**; or
- a drug to be used as an ingredient of a preparation for a **medicinal purpose**.

“**Drug**”, under the Sale of Drugs Act 1952, “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.

“**Medicinal Purpose**”, under the Sale of Drugs Act 1952, means any of the following purposes:

- alleviating, treating, curing or preventing a disease or a pathological condition or symptoms of a disease;
- diagnosing a disease or ascertaining the existence, degree or extent of a physiological or pathological condition;
- contraception;
- inducing anaesthesia;
- maintaining, modifying, preventing, restoring, or interfering with, the normal operation of a physiological function;
- controlling body weight;
- general maintenance or promotion of health or wellbeing.

How is medicinal product regulated in Malaysia?

Control of Drugs and Cosmetics Regulations 1984, Regulation 7(1) states that:
“Except as otherwise provided in these Regulations, no person shall manufacture, sell, supply, import, possess or administer any product unless:
*a) the product is a **registered product**; and*
*b) the person holds the **appropriate licence** required and issued under these Regulations."*

Registration

Any product that fits the definition of medicinal product requires registration with the Drug Control Authority (DCA).

For confirmation of product category, you may apply for product classification.

Click 

button on NPRA website for more information.

License

The following are licenses that may apply:

- Manufacturing License
- Wholesale License
- Import License
- Clinical Trial Import License (CTIL)

Who can apply for product registration?

Product Registration Holder (PRH)

The applicant for product registration (known as PRH) must be a locally incorporated company, corporate or legal entity, with permanent address and registered with Companies Commission of Malaysia (Suruhanjaya Syarikat Malaysia (SSM)) (with business scope related to the health/pharmaceutical product).

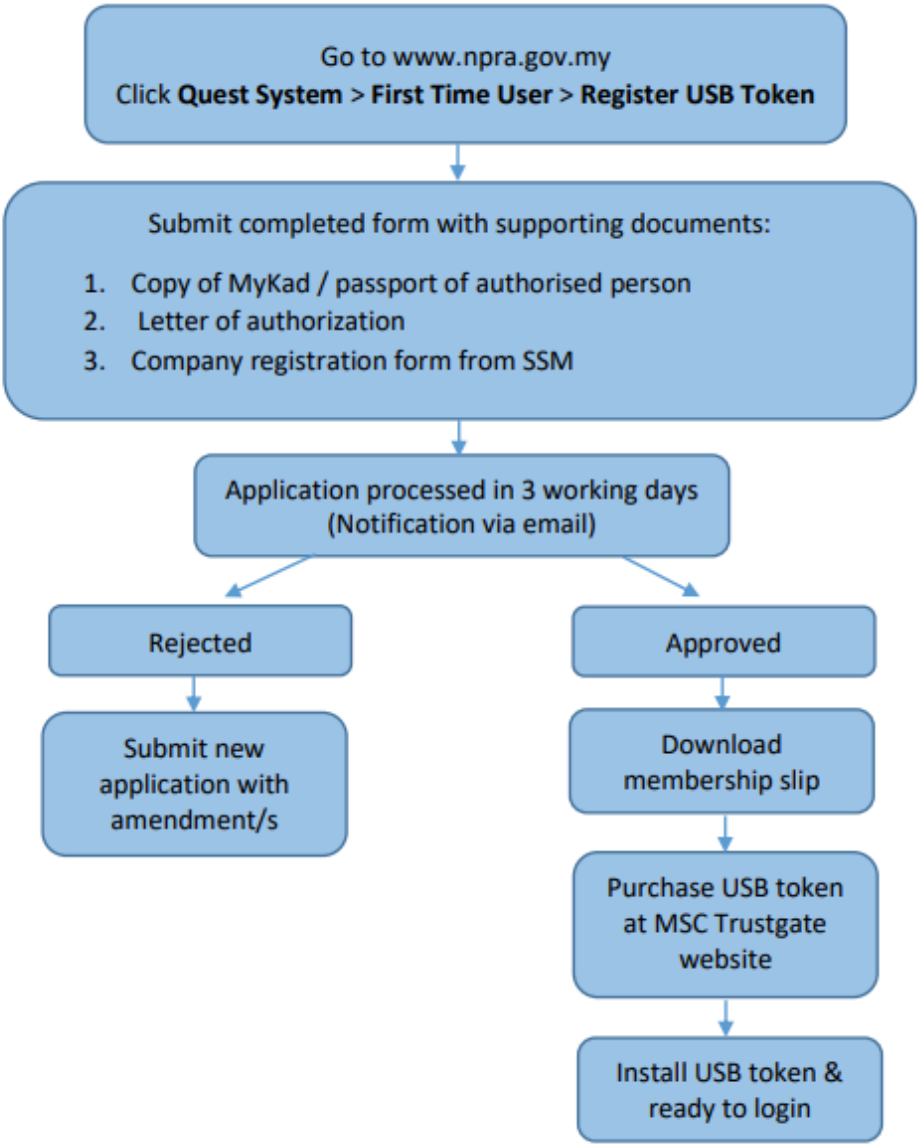
If the applicant is not the product owner,

the product owner shall authorize the PRH in writing to be the holder of the product registration who is responsible for all matters pertaining to the quality, safety and efficacy of the product. This includes the responsibility to update any information relevant to the product / application.

How to submit a product registration application?

01 QUEST Membership

- Register for QUEST membership
- Purchase USB Token



Click FIRST TIME USER button on NPRA website for more information.

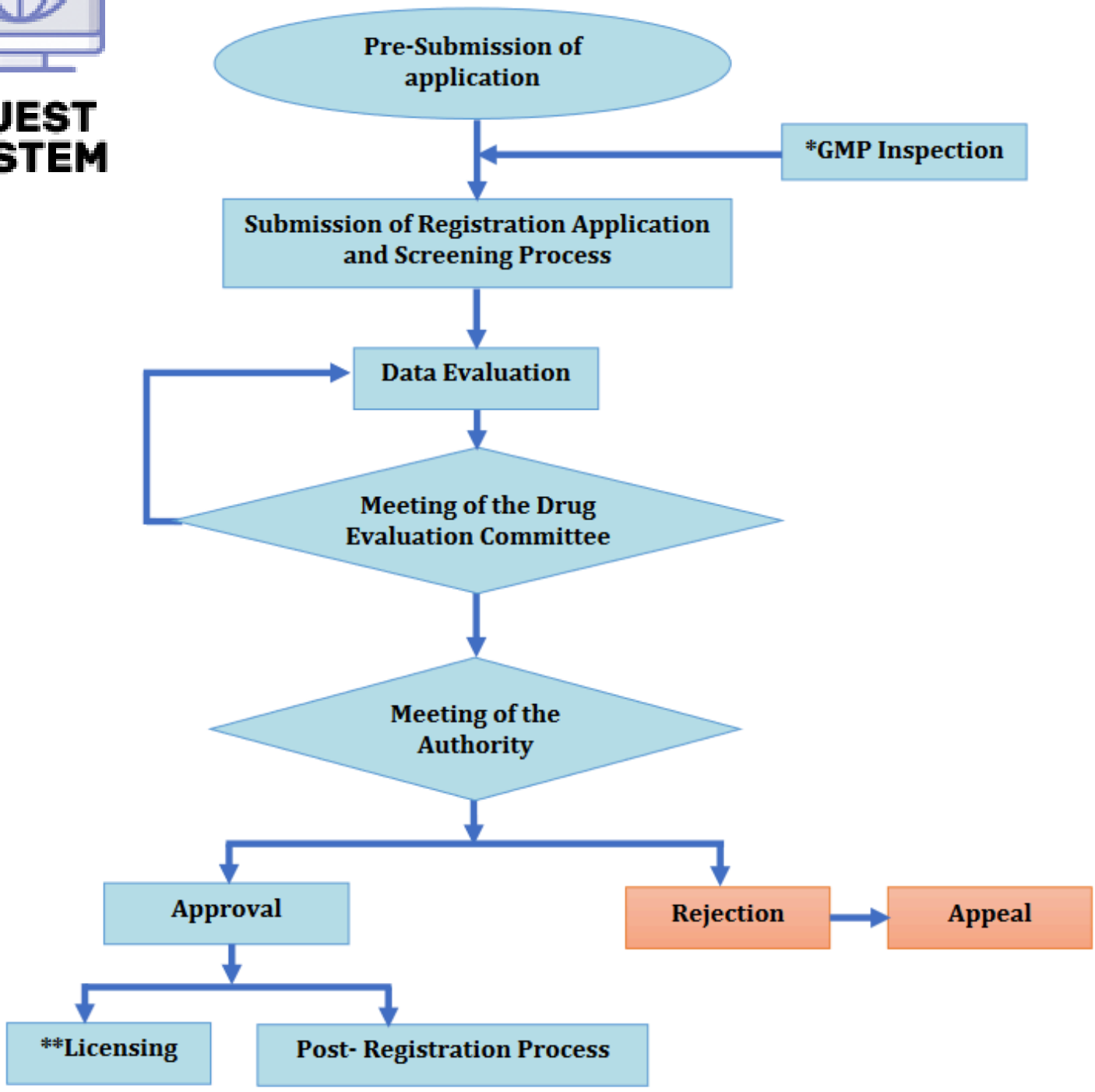
Web-based Online Submission

02

Applicant may refer to USER MANUAL QUEST 3+ System Module: PRODUCT REGISTRATION.

Regulatory requirements are available in the Drug Registration Guidance Document (DRGD)

QUEST SYSTEM



* Good Manufacturing Practice (GMP) Certification

** Application for Manufacturer's, Import and/or Wholesaler's License

Timeline

NO	PRODUCT CATEGORY	EVALUATION TIMELINE
(A)	**FULL EVALUATION**	
1	New Drug Products (NCE)	245 working days
2	Biologics	
3	Health Supplement with Disease Risk Reduction Claim	
4	Natural Products with Therapeutic Claim	
5	New Drug Products (Hybrid)	210 working days
6	Generics (Scheduled Poison)	
7	Generics (Non-Scheduled Poison)	
(B)	**ABRIDGED EVALUATION**	
8	Generics (Non-Scheduled Poison) a) Single active ingredient b) Two (2) or more active ingredients	 a) 116 working days b) 136 working days
9	Natural Product with i) Traditional &Homeopathy a) Single active ingredient b) Two (2) or more active ingredients ii) Modern Claim a) Single active ingredient b) Two (2) or more active ingredients	 a) 100 working days b) 120 working days a) 116 working days b) 136 working days
10	Health Supplements*** a) Single active ingredient b) Two (2) or more active ingredients *** Applicable for: i) General or Nutritional Claims; and ii) Functional Claims (Medium Claims)	 a) 100 working days b) 120 working days

Fees

Fees for USB Token

Type	Validity Period	
	1 year (RM)	2 year (RM)
Main User (Certificate + USB Token)	260	290
Postage	Semenanjung - 10 Sabah/Sarawak - 20	

Product Registration Fees

No.	Category of Product	Total Fees (RM)	
		Single active ingredient	Two or more active ingredients
1	Pharmaceutical (New Drug Products / Biologics)	4000	5000
2	Pharmaceutical (Generic /Health supplement)	2200	3000
3	Natural Products with Traditional Claim	1200	
4	Natural Products with Modern Claim	2200	3000
5	Natural Products with Therapeutic Claim	4000	5000

KEMENTERIAN KESIHATAN
MALAYSIA

National Pharmaceutical Regulatory Agency
(NPRA)

Lot 36, Jalan Profesor Diraja Ungku Aziz,
46200 Petaling Jaya, Selangor, Malaysia

Telephone: +603-7883 5400

Website: www.npra.gov.my

ONE STOP CENTRE, NPRA
2025 EDITION