



NPRA
MALAYSIA

Official Portal

NATIONAL PHARMACEUTICAL REGULATORY AGENCY

Formerly known as National Pharmaceutical Control Bureau (BPFK)

BAHAGIAN REGULATORI FARMASI NEGARA | KEMENTERIAN KESIHATAN MALAYSIA



The Registration Process of Natural Products in Malaysia



QUEST MEMBERSHIP

🔒 Bahagian Regulatori Farmasi N... (MY) | <https://www.npra.gov.my/index.php/en/>



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NPRA mission is to safeguard the nation's health through scientific excellence in the regulatory control of medicinal products and cosmetics.

[REGISTER YOUR PRODUCTS NOW](#)



CONSUMERS

ConSERF, AEFI Reporting, RIMUP, Product Cancellation & etc

[ENTER](#)



HEALTH PROFESSIONALS

Safety Alert, Reporting ADR, MADRAC, Product Complaints, Publications

[ENTER](#)



INDUSTRIES

Product Registration, QUEST3+ System, Guideline Central, Application Forms, FAQs.

[ENTER](#)

[Industries Main Page](#)

REPORTING OF SIDE EFFECTS TO MEDICINES OR VACCINES

To report a suspected side effect or adverse drug reaction (ADR) to any medicine or vaccine

[Report ADR as Consumers](#)

[Report ADR as Health Care Professional](#)

PRODUCT STATUS

Check product status including pharmaceutical, natural & cosmetic products

[Product Status](#)

[ANNOUNCEMENTS](#)

[PRESS RELEASE](#)

[CIRCULARS](#)

[SAFETY ALERTS](#)

[PUBLICATIONS](#)

[CALENDAR ACTIVITIES](#)

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JAN

Online Payment Service Notice

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DEC

Pembukaan Data Editing dan Penutupan Data Cleaning

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Bahagian Regulatori Farmasi N... (MY) | <https://www.npra.gov.my/index.php/en/industry>

Directory | Public | QUEST3+ System



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Industry & QUEST3+ System Main Page

Products Registration & Licensing System

First Time User

QUEST3+ System Log In

Helpdesk Support

Drug Registration Guidance E-Book (DRGD)

Data Cleaning Schedule for 2018

Dear QUEST Users,

Please refer to data cleaning schedule for 2018. Data cleaning will close permanently on 31st December 2018

Bulan	Data Cleaning	Tempoh Permohonan	Tempoh Kemaskini
January	Section E13 & Section S	01/01/2018 – 05/01/2018	08/01/2018 – 31/01/2018
February	Product Manually Registered	01/02/2018 – 07/02/2018	08/02/2018 – 28/02/2018
March	Section E13 & Section S	01/03/2018 – 05/03/2018	08/03/2018 – 30/03/2018



More Details

Updated: 19/11/2017 @ 8:00am

Recent Updates

Industry News

New Products Approved

published on 2019-01-14

Garis panduan Pelaksanaan Risalah Maklumat Ubat Untuk Pengguna (RiMUP)

published on 2019-01-09

List of Renewal Approved Veterinary Products

published on 2019-01-09

Additional Indications Approved

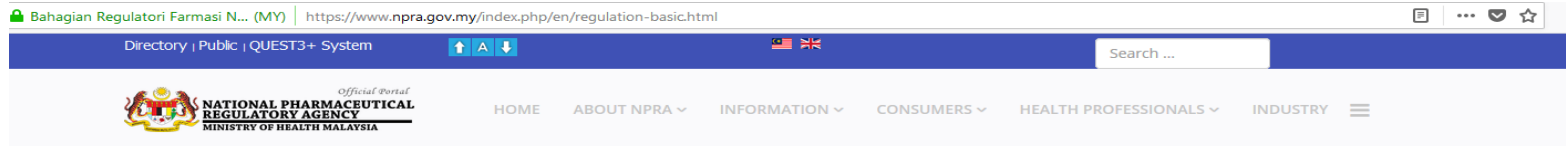
published on 2019-01-09

Internet Browser for QUEST3+ System

published on 2019-01-09

More Recent Updates

QUEST MEMBERSHIP



Regulation Basics

NPRA was given the task of ensuring the quality, efficacy and safety of pharmaceuticals through the registration and licensing scheme. This is achieved through evaluation of scientific data and laboratory tests on all products before they are marketed. A system to monitor products in the market was set-up. Information on drugs to medical profession and consumer was made available through a drug information service.

1.0 Product Classification

It is important to determine the category of a product that falls within the food-drug interphase (FDI) whether the products are regulated as drug (health supplement or natural product under the NPRA's purview) or, as food (under the FSQ's purview) because different regulatory requirements apply. Therefore, the following flowchart serves only as guide to help you determine the category of the product that falls within the FDI

[Product Classification Guideline](#)

[Product Classification Application Manual \(NPRA 300.1\)](#)

[Product Classification Form \(PDF\)](#)

[Product Classification Form \(Ms Word\)](#)

2.0 QUEST3+ System B

The QUEST 3+ system has been implemented from January 2017 for the purpose of registration of medicines and cosmetics and licensing products in Malaysia. As of December 9, 2017, 23,817 drug products and 178,809 cosmetic products have been registered in Malaysia in QUEST 3+.

[Register USB Token](#)

[Token & Java Configuration](#)

[Example of Letter of Authorization for Membership Registration](#)

[Payment Using Personal Account - B2C](#)

[Payment Using Corporate Account - B2B](#)

[Payment Using Credit Card](#)

[User Manual for QUEST Module](#)

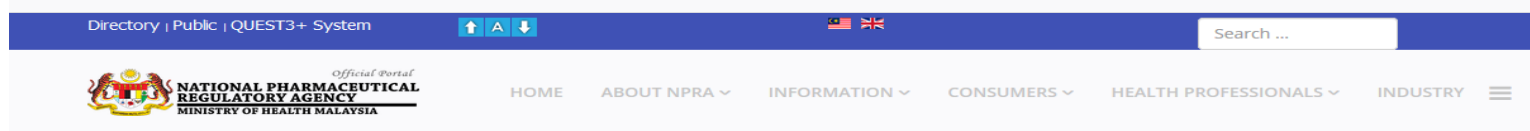
[Internet Browser Configuration](#)

[FAQ - MEMBERSHIP & TOKEN](#)

[FAQ - QUEST ONLINE PAYMENT](#)

QUEST MEMBERSHIP

agian Regulatori Farmasi N... (MY) | <https://www.npra.gov.my/index.php/en/quest3-system-basic/register-usb-token.html>



User Registration Process for QUEST3+ Products Registration & Licensing System

17 JULY 2018 | HITS: 2680

Registration for the QUEST 3+ System is simple, and no regulatory consultant/agent* services should be required. Refer below for the 5 EASY STEPS to register.

5 EASY STEPS to register as a user for the QUEST 3+ System:

1. Go to QUEST3+ System Frontpage [HERE](#)
2. Apply for QUEST 3+ Membership Registration by clicking on [REGISTER HERE](#)
3. Approval email received from Quest 3+ Membership
4. Complete remaining steps at <https://www.msctrustgate.com/mytrustgate/enrollment?q=quest3plus>

BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN (BPFK QUEST3+)

TRUSTGATE
SECURE TRANSACTION. TRUSTED BUSINESS


New Certificate Enrollment Request

Enrollment Request Steps: 1. Instructions, 2. Application Info, 3. Package & Pricing, 4. Disclaimer, 5. Payment, 6. Complete


Please read and understand the Enrollment Instruction below:

Application Info Upload Documents	Fill up your informations required for RA verification. Attach scanned copy of your MyKad/Passport, Company Registration Form and Company Authorization Letter (in JPEG or PDF format, with size below 2MB) to assist verification.
Make Payment	Payment can be made using any of the following: Credit Card / Debit Card (VISA/MASTERCARD) or upload payment receipt if payment made

QUEST 3+ LOGIN

**QUEST 3+** | Online System for
Product Registration, Cosmetic Notification, Licensing & Market Sampling

Login | Register



Username
(alphanumeric, dot, dash and underscore only)

Password

[Forgot your password?](#)

[Register \(NEW USER\)](#)

Welcome to QUEST 3+:

QUEST 3+ Online Submission System enabled Product License Holder, Manufacturer, Importer, Re-packer, Reseller and other related users to conduct secured online transactions for product registration, variation, licensing, market sampling, renewal and other transactions.

[Helpdesk](#)

[Market Sampling](#)
For NON QUEST 3+ member only

[In House Evaluation](#)
For NON QUEST 3+ member only

[Membership Application Status](#)

[NPRA Website](#)

[Login here if you are behind firewall/proxy](#)

SUMMARY OF REGISTRATION PROCESS

Submission of Registration For Screening

If satisfactory: payment and sample testing

Evaluation of application dossier

Meeting of the Drug Evaluation Committee

Applicant can appeal through Minister of Health for review of DCA's decision

Meeting of Drug Control Authority
(decision making body -meets monthly)

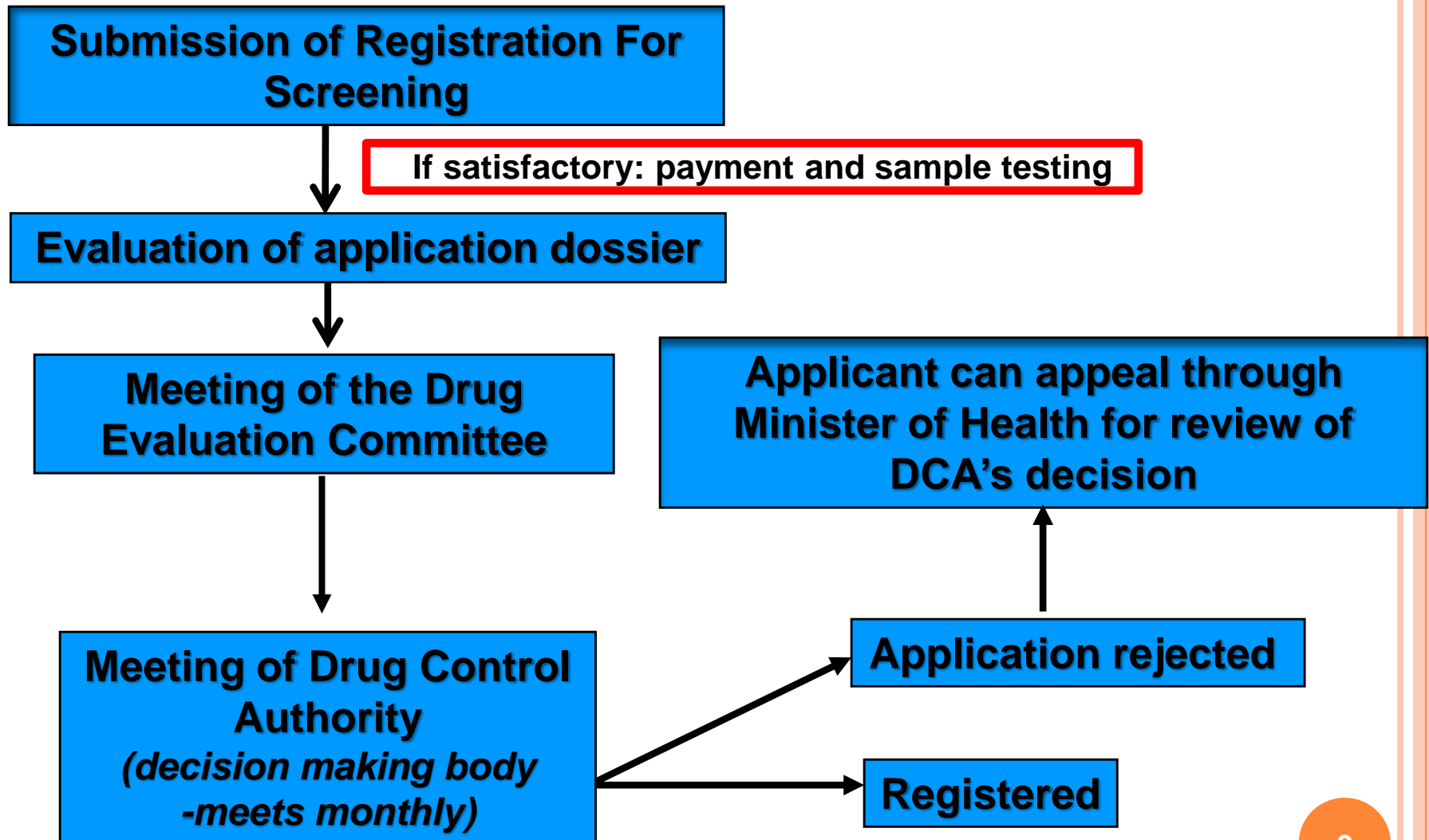
Application rejected

Registered

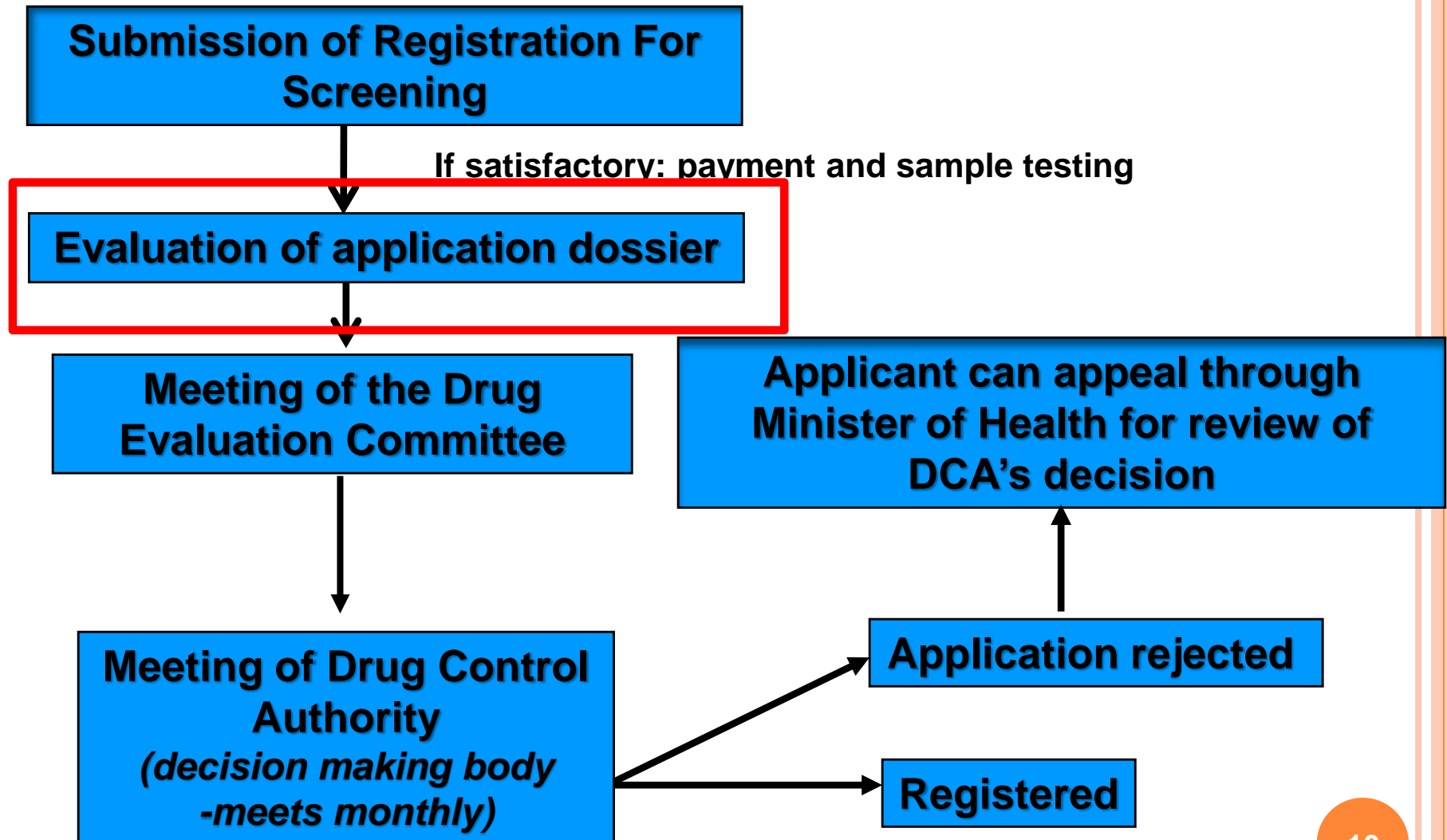
REGISTRATION PROCESS- SCREENING

- Batch Manufacturing Formula
- COA of Raw Material
- COA of Finished Product
- Stability Data
- GMP Certificate
- Certificate of Free Sale

SUMMARY OF REGISTRATION PROCESS



SUMMARY OF REGISTRATION PROCESS



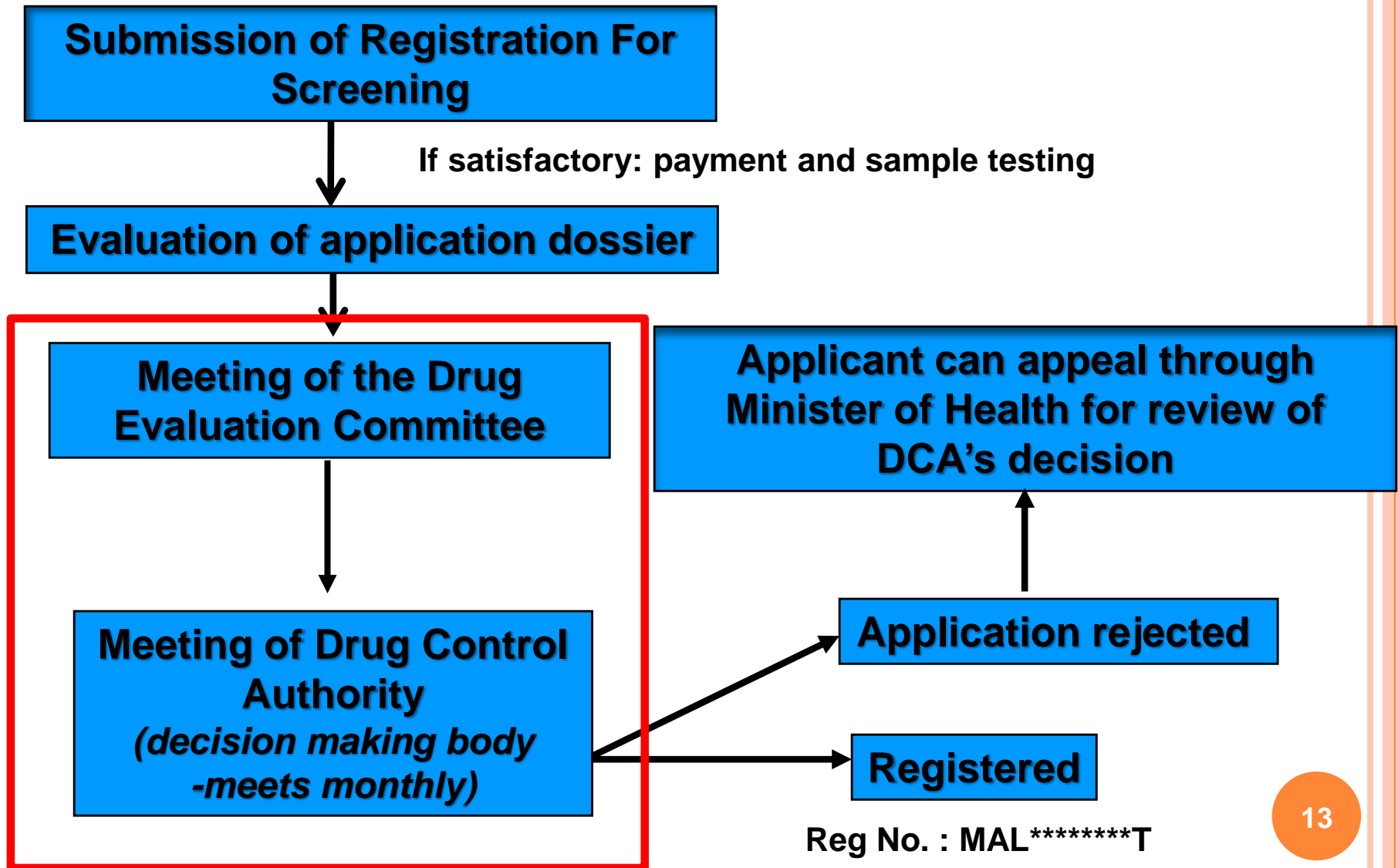
GMP CERTIFICATION

- Standard used by the foreign authority is equivalent with the GMP standard used in Malaysia for Natural products.
- Issued by the governmental authority in the manufacturing country

CERTIFICATE OF FREE SALE

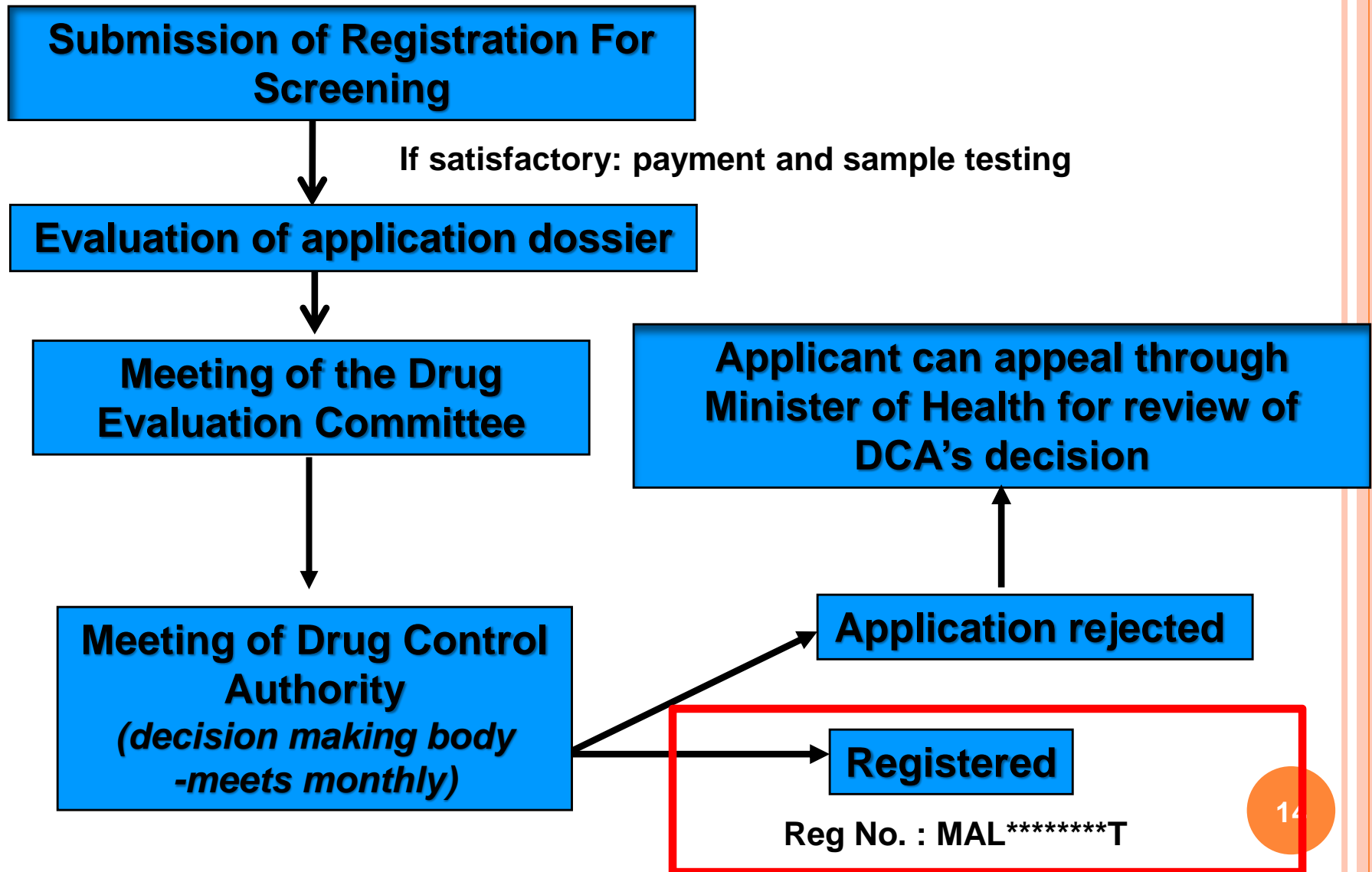
- Issued by the governmental authority in the country of origin

SUMMARY OF REGISTRATION PROCESS

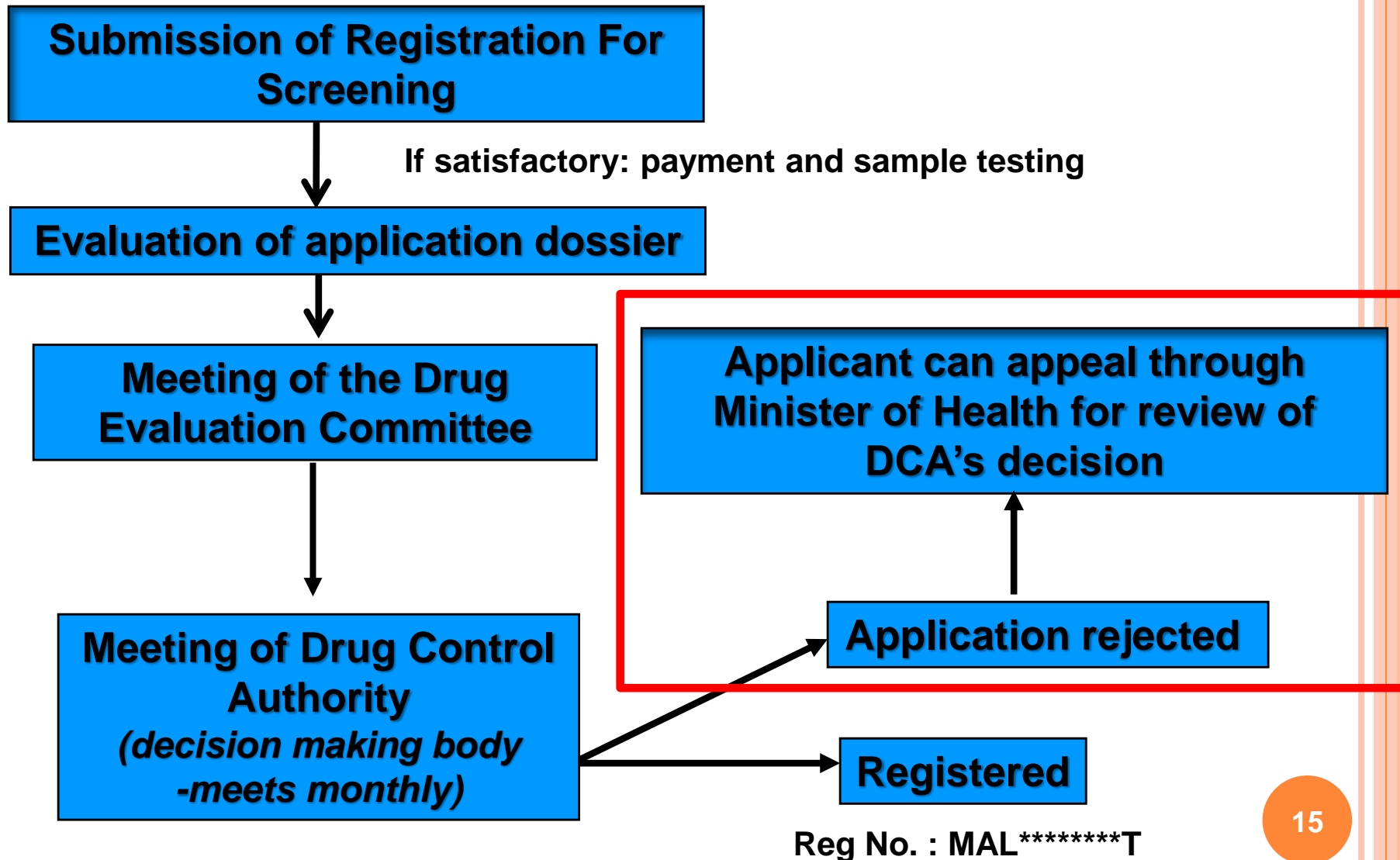


Reg No. : MAL*****T

SUMMARY OF REGISTRATION PROCESS



SUMMARY OF REGISTRATION PROCESS



Reg No. : MAL*****T

CLIENT'S CHARTER

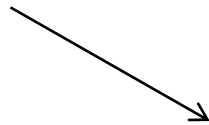
(Single ingredient)

- < 116 working days

(Combination)

- < 136 working days

On condition with



***Full Compliance to
Requirements***

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD)

- Appendix 5: Guideline on Registration of Natural Products

NATIONAL PHARMACEUTICAL REGULATORY DIVISION
MINISTRY OF HEALTH, MALAYSIA

DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD)

Second Edition – September 2016, revised January 2018

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Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor Darul Ehsan, Malaysia

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+ 603-7956 2924, 7956 7075

<http://nppra.moh.gov.my/>

[Please visit the NPRA website for the latest updates](http://nppra.moh.gov.my/)



THANK YOU