



# MALAYSIA REGULATORY SYSTEM FOR PHARMACEUTICAL PRODUCTS

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**BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN**



*WHO Collaborating Centre  
for Regulatory Control of  
Pharmaceuticals*



*Member of Pharmaceutical  
Inspection Cooperation  
Scheme*



*MS ISO 9001:2008  
Certified*



*Non-OECD Member  
full adherence to the Mutual  
Acceptance Data (MAD)  
System*

# Presentation Outline

1. Introduction
2. Legislations
3. Regulatory Components
4. Objective and Expectation
5. Registration Activities
6. Registration Process of Pharmaceutical Products in Malaysia
7. Product Classifications
8. Maintenance of registration



# INTRODUCTION

# Pharmaceutical Services

**SENIOR DIRECTOR  
Pharmaceutical  
Services**

**DIRECTOR  
(Pharmaceutical  
Practice and  
Development)**

**DIRECTOR  
(Pharmacy  
Enforcement)**

**DIRECTOR OF  
NPCB  
(Pharmacy  
Regulatory)**

**DEPUTY  
DIRECTOR  
(Pharmacy  
Management)**

- **Pharmaceutical Practice and Development Division:**
  - Provides comprehensive pharmaceutical care by ensuring efficient selection, procurement, distribution of pharmaceuticals; ensuring rational; cost-effective and optimal use of medicines through effective up-to-date clinical and professional pharmaceutical services in tandem with the current global development.
- **Pharmacy Management Division:**
  - Consolidates the pharmaceutical sector activities through the implementation of the National Medicines Policy

- The Pharmacy Enforcement Division was formed on January 1, 1976 under the PSD to carry out the enforcement of legislations pertaining to pharmacy and the pharmaceutical trade in the country in a more efficient approach.
- National Pharmaceutical Control Bureau (NPCB):
  - As National Drug Regulatory Authorities in Malaysia
  - Was given the task of ensuring the **quality, efficacy and safety** of pharmaceuticals through the registration and licensing scheme.

# PSD: Program Strategies

- ▶ Ensuring the safety, efficacy and quality of pharmaceuticals including traditional medicines via product registration, licensing of premises, monitoring of adverse drug reactions and market surveillance
- ▶ Improving enforcement of existing Acts and Regulations by strengthening enforcement units, formulating new legislations and intensifying enforcement at entry points
- ▶ Ensuring a continuous and adequate supply of quality pharmaceuticals by expanding and improving storage facilities, modernizing the inventory management system and utilizing ICT
- ▶ Strengthening hospital pharmacy services by improving infrastructure, promoting rational use of drugs and enhancing clinical pharmacy activities through provision of various services
- ▶ Maintaining adequate manpower and increasing competency of personnel through various human resource development programs

# LEGISLATIONS

- ▶ **MALAYSIAN LAWS ON POISONS AND SALE OF DRUGS**
- ▶ CONTAINS:
- ▶ Dangerous Drug Act 1952 (revised 1980)
- ▶ Poisons Act 1952 (Act 366) & regulations
- ▶ Sale of Drugs Act 1952 (Act 368)
  - **Control of Drugs and Cosmetics Regulations 1984**
- ▶ Registration of Pharmacists Act 1951 (Act 371) & regulations
- ▶ Medicines (Advertisement and Sale) Act 1956 (Act 290) & regulations



# LEGISLATIONS

## *Control of Drugs and Cosmetics Regulations (CDCR) 1984*

### Regulation 7(1)

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 **license** required & issued under these Regulations.

# LEGISLATIONS

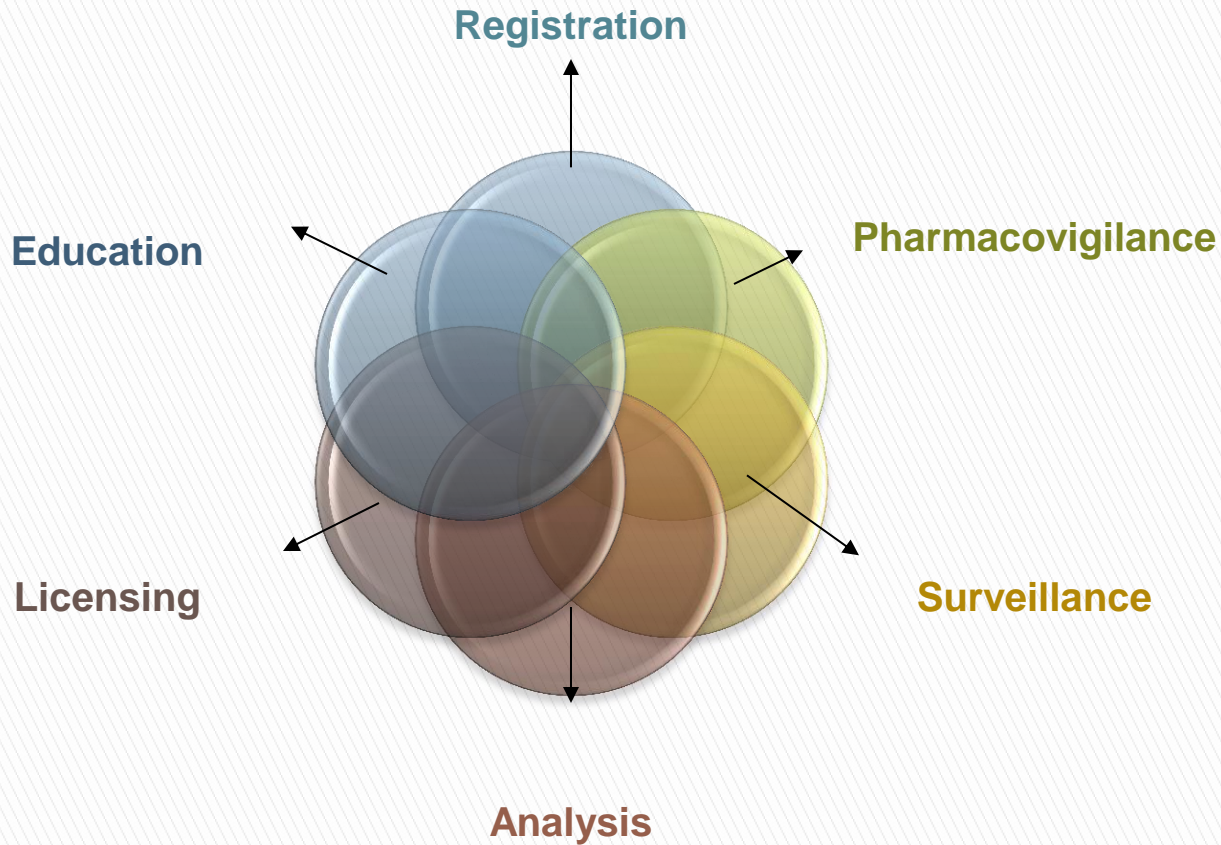
## Regulation 12 of CDCR 1984: Licenses

- ▶ a **manufacturer's licence**, authorising the licensee to manufacture the registered products in the premises specified in the licence and to sell by wholesale or supply the products;
- ▶ a **wholesaler's licence**, authorising the licensee to sell by wholesale or supply the registered products from the address of the business premises specified in the licence;
- ▶ an **import licence**, authorising the licensee to import and sell by wholesale or supply the registered products from the address of the premises specified in the licence. – therefore, imported product can be imported into Malaysia by an importer who holds the import licence for a particular registered product.

# LEGISLATIONS

- ▶ The Drug Control Authority (DCA) : as the licensing authority (Regulation 3, CDCR 1984).
- ▶ National Pharmaceutical Control Bureau (NPCB) acts as its secretariat & is responsible for:
  - Product registration and cosmetic notification
  - Licensing (manufacture, import, wholesale)
  - Monitoring and surveillance activities.

# Overview of Regulatory Control : Regulatory Components



# ***OBJECTIVE***

**To ensure that therapeutic substances approved for the local market are**

**SAFE, EFFICACIOUS and of QUALITY**

**and also to ensure that cosmetic products approved are safe and of quality.**

# EXPECTATIONS

## Patients

- Expect treatment using new medical innovations
- Timely access to new drugs

## Prescribers

- Expect drugs to be reviewed in approved in a judicious manner
- Expect drugs to be of quality, efficacious, safe

## Industry

- Reduction in bureaucratic procedures
- Harmonisation of standards and technical requirements

# REGISTRATION ACTIVITIES

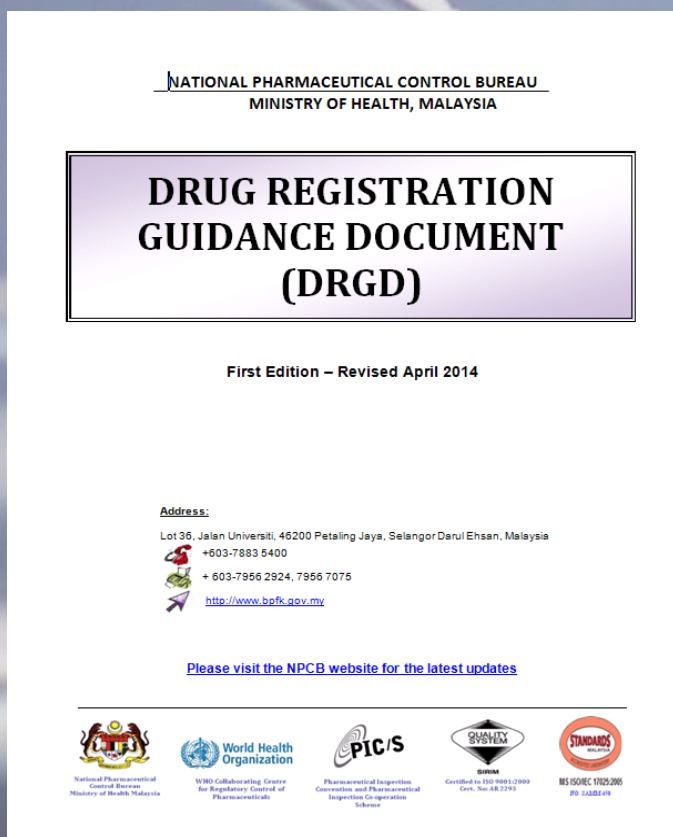


# Registration

- **Product classification**
- **Registration process**
- **Tools – Guidelines, Check-lists, SOPs**
- **Evaluation of Quality, Safety and Efficacy**
- **Marketing Authorization**
- **Additional Indication of New Chemical Entities (NCEs) & Biotech Products**
- **Variations – notification, approval**
- **Certificate of Pharmaceutical Product (CPP) , Certificate of Free Sale (CFS)**
- **Renewals**
- **Appeals**
- **Current Status**
- **Product Classification Guidelines**
- **Product Registration Guidelines**
- **Guidelines for Site Change**
- **Guidelines for Variations**
- **Guidelines for Blood Products**
- **Guidelines for Vaccines**
- **Stability Studies Guidelines**
- **Bioavailability/Bioequivalence Studies**
- **Audit of BA/BE Centers (draft)**
- **Good Clinical Practice**
- **Clinical Trial Import Licence**
- **ASEAN Common Technical Dossier**
- **ASEAN Process Validation**
- **ASEAN Analytical Validation**



# DRUG REGISTRATION GUIDANCE DOCUMENT (DRGD)



DRGD serves as a reference guide for both **pharmaceutical products for human use** and **natural products**.

(Latest revision: January 2015)

A separate guideline is available for registration of **Veterinary products** and **Cosmetics**

# Outline of DRGD

- **Section A:** General Overview
- **Section B:** Product Registration Process
- **Section C:** Quality Control
- **Section D:** Inspection & Licensing
- **Section E:** Post-Registration Process
- **Appendices**

# Appendices

No.	Appendices	Title of Appendix
1.	Appendix 1	Fees
2.	Appendix 2	Requirements For Product Registration
3.	Appendix 3	Guidelines On Registration Of Biologics
4.	Appendix 4	Guideline On Registration Of Health Supplements
5.	Appendix 5	Guideline On Registration Of Natural Products
6.	Appendix 6	Guideline On Regulatory Control Of Active Pharmaceutical Ingredients (API)
7.	Appendix 7	Special Conditions For Registration For A Particular Product Or Group Of Products
8.	Appendix 8	List Of Permitted, Prohibited And Restricted Substances
9.	Appendix 9	Labelling Requirements
10.	Appendix 10	Guideline On Patient Dispensing Pack For Pharmaceutical Products In Malaysia
11.	Appendix 11	Guideline On Filling The Online Application Form For Product Registration Via Quest System
12.	Appendix 12	Conditions And Supporting Documents Required For An Application Of Variation
13.	Appendix 13	Supporting Documents Required For Change Of Manufacturing Site (Cos) Application
14.	Appendix 14	Guidelines On Safety Data Requirements For Complementary Medicine Products

# Steps for searching 'Guidelines' at BPFK website

Step 1: Select the 'News Room'



tab

The screenshot shows the official portal of the National Pharmaceutical Control Bureau (NPCB) under the Ministry of Health Malaysia. The website header includes the logo and name of the bureau. A navigation menu at the top features several tabs, with 'News Room' highlighted in yellow and circled in red. A red arrow points from the 'Step 1' text to this tab. Below the navigation menu, a dropdown menu is visible, listing various categories such as 'Registration Guideline', 'Guidance Document Updates', 'Circulars / Directive', 'Publications', and 'Cancellation of Traditional/Cosmetic Product'. The 'Guidelines Central' option is also circled in red, with a red arrow pointing from the 'Step 2' text to it. Below the dropdown menu, there are several service icons: 'QUEST PRODUCT SEARCH', 'Registration Guideline', 'PRODUCT CANCELLATION', 'Reporting medicinal problem', 'RiMUP', and 'Helpdesk'. The 'Registration Guideline' icon is also circled in red. At the bottom of the page, there are sections for 'SPECIAL ANNOUNCEMENT' (showing 'No new announcement') and 'QUEST SYSTEM' with a list of links: 'Membership Registration Guideline', 'Product Registration & Cosmetic Notification', 'License Application', and 'For Enforcement Pharmacy'. The footer contains a row of buttons for 'ANNOUNCEMENTS', 'PRESS RELEASE', 'CIRCULARS', 'DIRECTIVES', and 'REGISTRATION GUIDELINE'.

Step 2: Select 'Guideline Central'

# Listing of Guidelines at BPFK website

Official Portal  
**National Pharmaceutical Control Bureau** Ministry of Health Malaysia  
Biro Pengawalan Farmaseutikal Kebangsaan, Kementerian Kesihatan Malaysia

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NEWS ROOM











- Information
- Registration Guideline Drug
- Registration Guidance
- Document Updates
- Circulars / Directive
- Publications
- Cancellation of Traditional/Cosmetic Product
- Training Seminars
- Guidelines Central**

» Home » **NEWS ROOM** » Guidelines Central

## Guidelines Central









Search Term:

**Guidelines on Regulatory:**

No	Document Name	Type	Size
1.	LIST OF UPDATES ON REGOVP Feb 2015		8.39 KB
2.	LIST OF DRGD UPDATES_JAN 2015		0.11 MB
3.	LIST OF DRGD UPDATES November 2014		0.16 MB
4.	LIST OF DRGD UPDATES September 2014		0.07 MB
5.	LIST OF DRGD UPDATES July 2014		0.02 MB
6.	LIST OF DRGD UPDATES June 2014		0.09 MB
7.	LIST OF DRGD UPDATES May 2014		0.06 MB
8.	List of Updates - GDP 2nd Edition.pdf		0.06 MB
9.	SUPPLEMENTARY NOTES FOR MANAGEMENT OF COLD CHAIN PRODUCTS		0.18 MB
10.	Guidelines for Vaccines Lot Release in Malaysia		0.64 MB

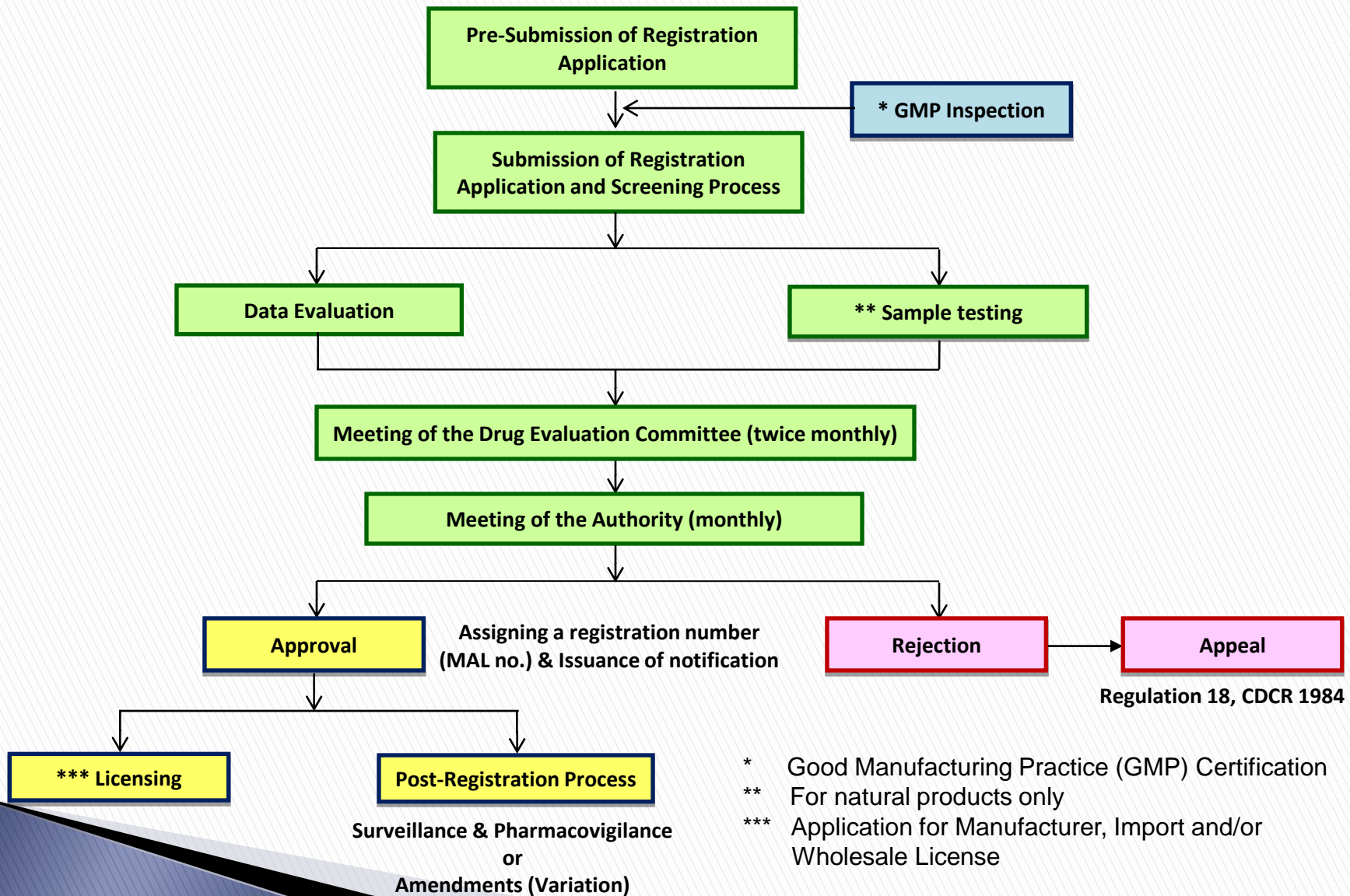
... 1 | 2 | 3 | 4 | Next (1 - 10 of 31 results)

**Guidelines on Bioequivalence (BE):**

No	Document Name	Type	Size
1.	ASEAN_BE_GUIDELINES_-Q_A_VERSION_4.pdf		0.07 MB
2.	ASEAN_BE_Guidelines_-Q_A_Version_3.pdf		0.01 MB
3.	ASEAN BE Guidelines amended according to 1st BABE TWG15th PPWG		0.24 MB
4.	ASEANGUIDELINESBE.pdf		0.08 MB
5.	ASEAN BE Guidelines - Q & A (Version 2)		0.07 MB
6.	ASEAN BE Guidelines - Q & A (Version 1)		0.02 MB
7.	Bioequivalence Study Reporting Format		0.04 MB
8.	ASEAN Guidelines for "The Conduct of Bioavailability and Bioequivalence Studies Adopted from the "NOTE FOR GUIDANCE ON THE INVESTIGATION OF BIOAVAILABILITY AND BIOEQUIVALENCE" (The European Agency for the Evaluation of Medicinal Products, London, 26 July 2001, CPMP/EWP/QWP/1401/98) with some adaptation for ASEAN application.		0.24 MB

'Guideline Central'

# Overview of Product Registration Process





Official Portal

# National Pharmaceutical Control Bureau

Ministry of Health Malaysia

Biro Pengawalan Farmaseutikal Kebangsaan, Kementerian Kesihatan Malaysia

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For enquiries on fee payment, kindly contact:  
 Malaysian Pharmaceutical Society (MPS), Wisma  
 Off Jalan Puchong, 47160 Puchong, Selangor, Malaysia  
 Email: finance.mps@gmail.com

**Terms & Conditions**  
 No refund will be given upon cancellation. The consent of the Government, Registration Fee and

- General Information
- Drug Registration Guidance Document (DRGD)
- Regulatory Information
- Registration and Notification
- Inspection
- Licensing
- New Products/Indication
- Laboratory & Quality Control
- Forms
- Clinical Trial
- Good Laboratory Practice (GLP) Compliance Monitoring Programme
- Quest2 List of Manufacturers / Wholesaler / Importers

- Consumer
- Healthcare Professional
- Industry
- Public Comment

## Ensuring the Quality and Safety of Pharmaceutical and Cosmetic Products

**QUEST**  
PRODUCT SEARCH

**Registration Guideline**  
Registration Guideline

**PRODUCT CANCELLATION**  
REGISTERED/NOTIFIED PRODUCTS

**Helpdesk**  
ENQUIRY & COMPLAINTS

### SPECIAL ANNOUNCEMENT

No new announcement

### QUEST SYSTEM

[▶ Membership Registration Guideline](#)



# **CATEGORIES OF PRODUCTS**

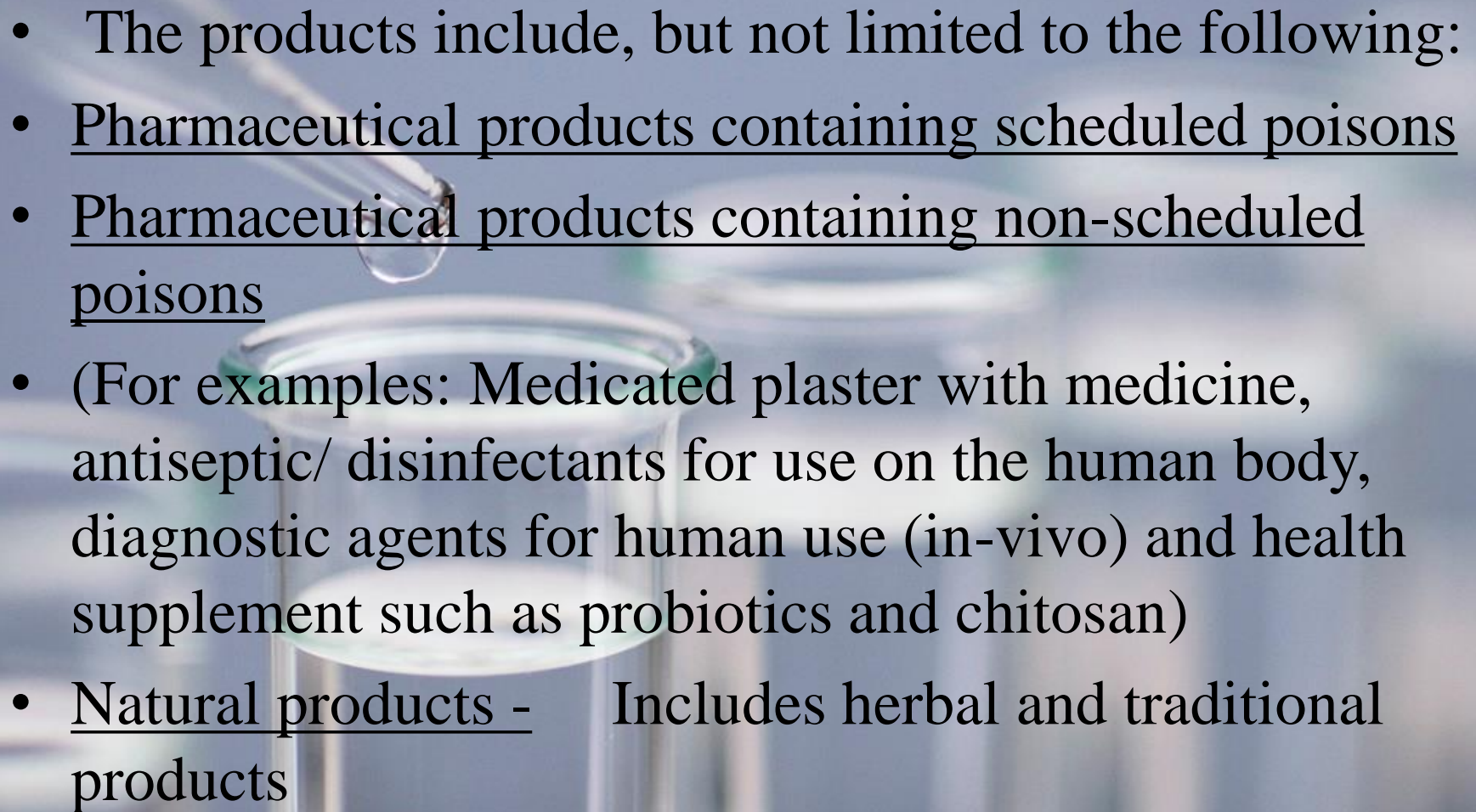


# Product...

*Regulation 2: Interpretation, under the Control of Drugs and Cosmetics Regulations 1984,*

**‘Product’** 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 ingredients of a preparation for a medicinal purpose.

- 
- The products include, but not limited to the following:
  - Pharmaceutical products containing scheduled poisons
  - Pharmaceutical products containing non-scheduled poisons
  - (For examples: Medicated plaster with medicine, antiseptic/ disinfectants for use on the human body, diagnostic agents for human use (in-vivo) and health supplement such as probiotics and chitosan)
  - Natural products - Includes herbal and traditional products

# INNOVATOR PRODUCT

## 1) New Drug Products (NDP)

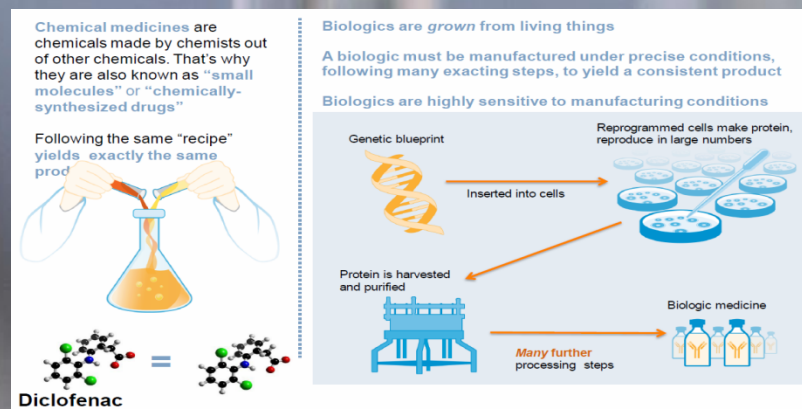
- defined as any pharmaceutical product that has **not been previously registered** in accordance with the provisions of the CDCCR 1984.

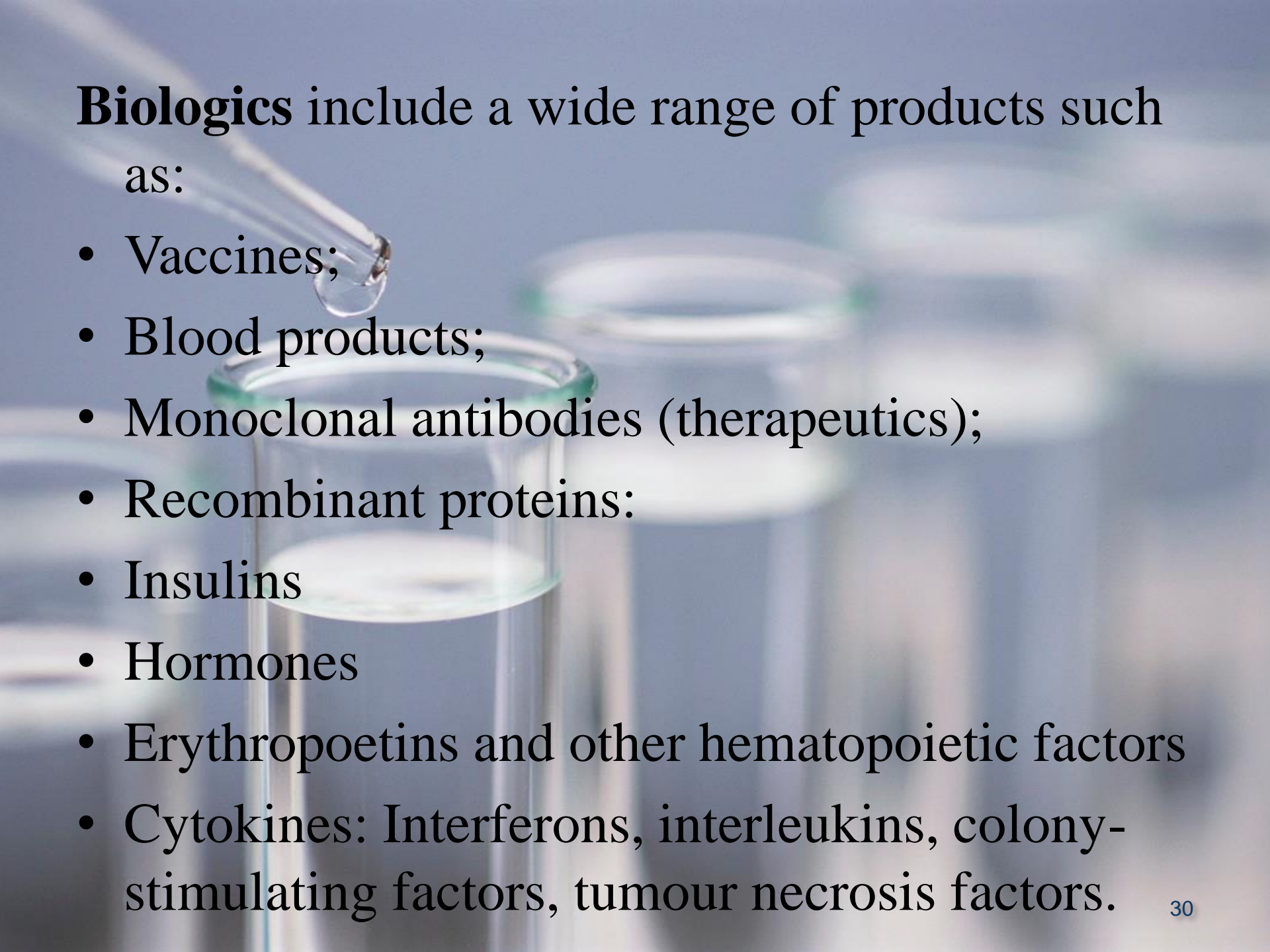
## 1) New Drug Products (NDP)

- An NDP may be classified according to the following categories:
  - a) **New Chemical Entity (NCE)**: An active moiety that has not been registered in any pharmaceutical product.
  - b) **New combination product**: A new pharmaceutical product containing two or more drugs that are physically, chemically or otherwise combined or mixed and produced as a single pharmaceutical product, in a combination that has not been registered in any other pharmaceutical product.
  - c) **Supplemental product**: A new pharmaceutical product containing a drug that has been previously registered as a pharmaceutical product but differing in properties with regards to safety and/or efficacy from the product that has been previously registered.

## 2) Biologics

- Refers to a product 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.



A laboratory setting with a pipette and test tubes. The background is a blurred laboratory environment with various glassware and equipment. A pipette is shown in the foreground, dispensing a small amount of liquid into a test tube. The text is overlaid on the left side of the image.

**Biologics** include a wide range of products such as:

- Vaccines;
- Blood products;
- Monoclonal antibodies (therapeutics);
- Recombinant proteins:
- Insulins
- Hormones
- Erythropoetins and other hematopoietic factors
- Cytokines: Interferons, interleukins, colony-stimulating factors, tumour necrosis factors.

# Moving forward



- Emerging categories of therapeutic products:
  - Cellular and gene therapies
  - Antibody-drug conjugates
  - Therapeutic vaccines

# GENERIC PRODUCT

- A product that is essentially similar to a currently registered product in Malaysia. The term generic is **not applicable** to biologic products.

## 3) Scheduled Poison:

- Known as Controlled Medicine/ Controlled Poison
- Pharmaceutical products which contain scheduled poison(s) as listed in **the First Schedule under the Poisons Act 1952.**



## 4) Non-Scheduled Poison:

- Known as Non-Poison or “Over-the-Counter”, OTC
- Products containing active ingredients which are not listed in the First Schedule under Poisons Act 1952; and is excluding active ingredient which is categorized under health supplements or natural products or cosmetics.

# 5) Health Supplements

- Any product that is used to **supplement a diet and to maintain, enhance and improve the health function of human body**. It is presented in small unit dosage forms (to be administered) such as capsules, tablets, powder, liquids and shall not include any sterile preparations (i.e. injectables, eyedrops). It may contain one or more, or the following combination:
  - ❖ Vitamins, minerals, amino acids, fatty acids, enzymes, probiotics, and other bioactive substances;
  - ❖ Substances derived from natural sources, including animal, mineral and botanical materials in the forms of extracts, isolates, concentrates, metabolite;
  - ❖ Synthetic sources of ingredients mentioned in (i) and (ii) may only be used where the safety of these has been proven.

## 6) TRADITIONAL MEDICINE

- Any product used in the practice of **indigenous medicine**, in which the drug consists solely of one or more naturally occurring substances of a plant, animal or mineral, or parts thereof, in the unextracted or crude extract form and a homeopathic medicine (as defined under the CDCR 1984).
- It shall not include any sterile preparation, vaccines, any substance derived human parts, any isolated and characterized chemical substances.

## 7) Veterinary Products

- Refers to pharmaceutical products for animal use.
- To protect the health of the consumer from food-producing animal as well as to ensure that foods obtained from animals treated with veterinary products **must not contain residues of the drug (Minimum residual limit, MRL)** or its **metabolites** which might constitute a health hazard for the consumer.
- To ensure only **quality** and **safe** products are registered and marketed in Malaysia.

# IMPLEMENTATION DATE



- Implementation date : 1 August 2007
- The implementation of the regulations on veterinary products shall be on all **products** containing **scheduled poisons** and **non – scheduled poisons** intended to be administered to the animals for **medicinal purpose**
- Dietary/health supplements and herbal/natural preparations are controlled by DVS under Feed Act 2009 starting 1<sup>st</sup> July 2014.
- Medicated Feed is controlled by DVS under Feed Act 2009 starting 1<sup>st</sup> January 2015.
- Premixes (antibiotics for prevention and growth promotion) will be controlled by DVS under Feed Act 2009 starting 1<sup>st</sup> July 2015.

# REGULATION OF VETERINARY PRODUCTS

Products containing:

- 1) **Scheduled Poison** (as in First Schedule of Poison Act 1952)
- 2) **Non Scheduled Poison / OTC**
- 3) **Pesticides for Internal Use**
- 4) **Pesticides for External Use (Control of endoparasite)**

**BPFK**

Products containing:

- 1) **Animal feed**
- 2) **Feed additives**
- 3) **Health/Dietary Supplement**
- 4) **Herbal/Natural**

**Department of Veterinary Services (DVS)**

Products containing:

- 1) **Pesticides as listed under First Schedule of Pesticide Act 1974 for External Use only.**(e.g. **Azadirachtin** which contains in *Azadirachta indica* (**Neem**))

**Pesticide Board**

# PRODUCT REGISTRATION

## CRITERIA FOR :

**COSMETICS :**

**Safety & Quality**

**Product Information**

**TRADITIONAL :**

**Safety & Quality**

**Product Information**

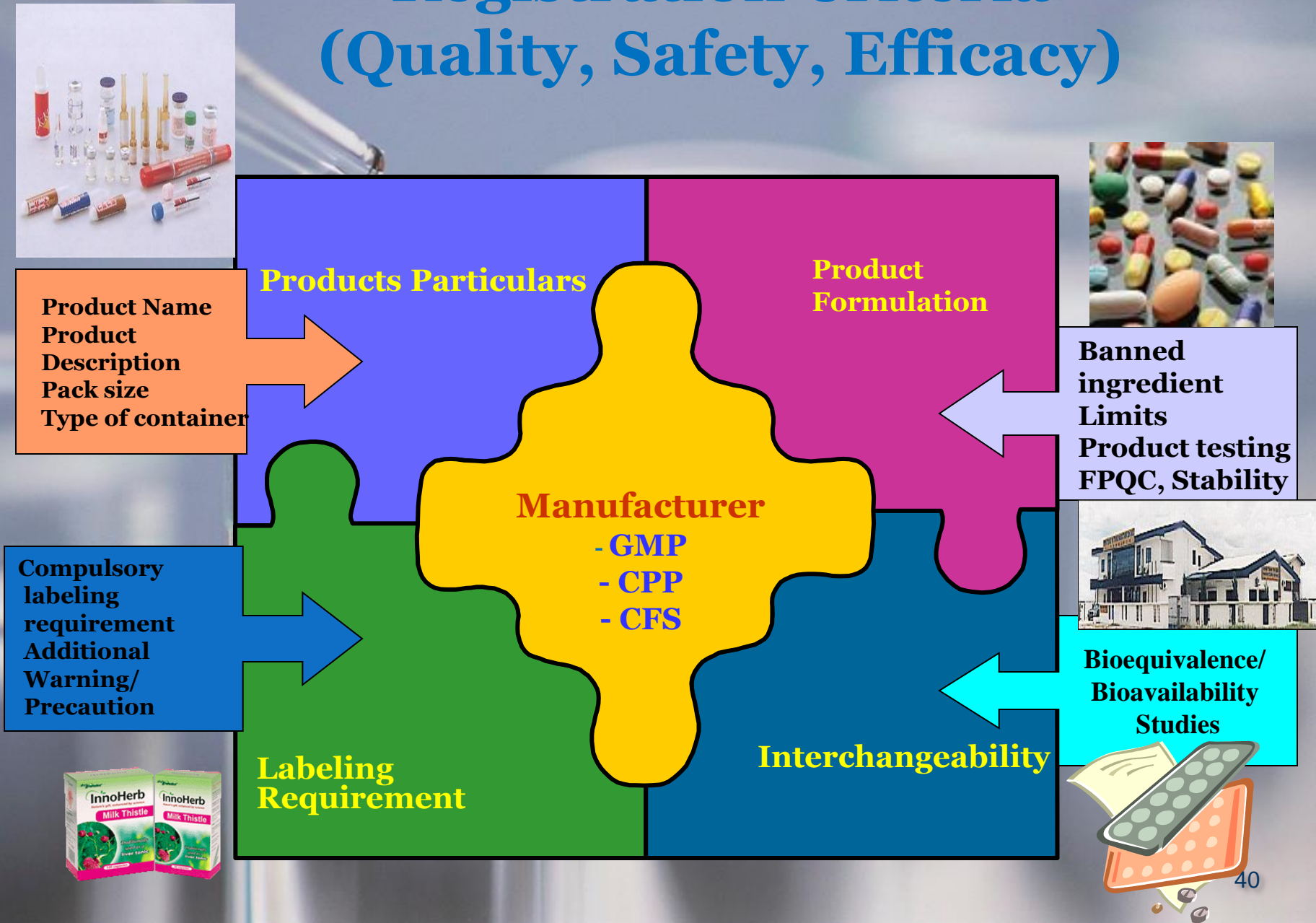
**“Traditionally used”**

**Pharmaceuticals:**

**Safety, Quality & Efficacy**

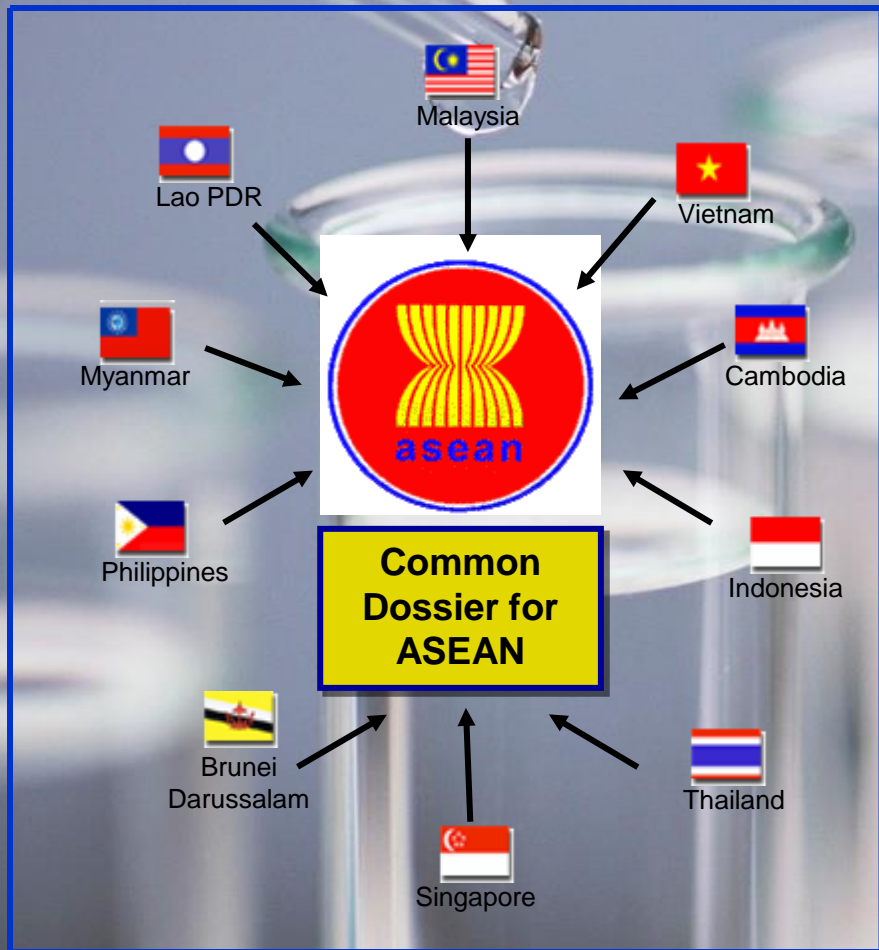
**Product Information**

# Registration Criteria (Quality, Safety, Efficacy)



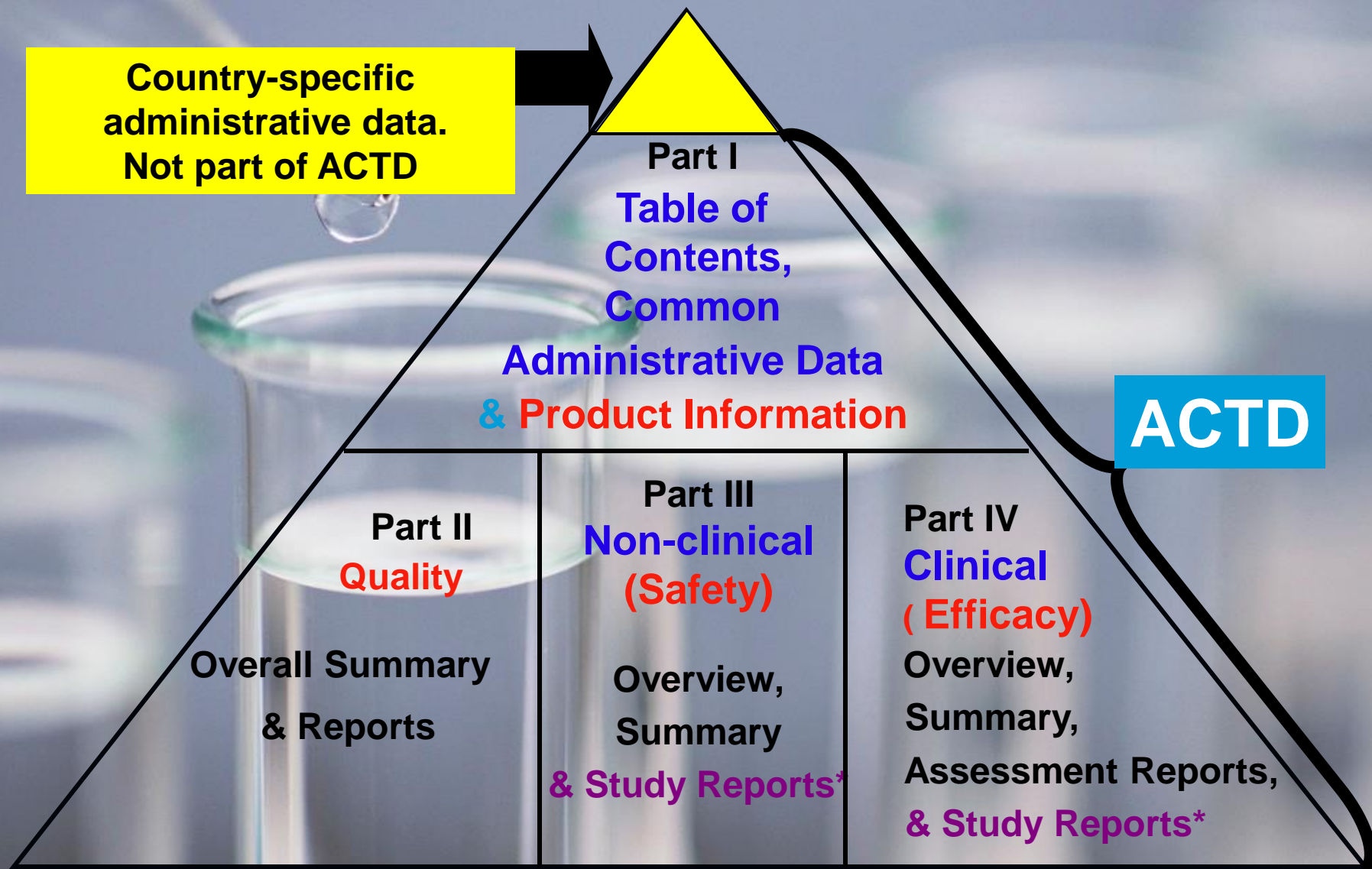


With the advent of globalisation, efforts are currently undertaken towards ASEAN Harmonisation process.



- Pharmaceutical Product Working Group – ASEAN Consultative Committee for Standards and Quality (PPWG-ACCSQ)
- Objective is to develop harmonization schemes of pharmaceutical regulations of the ASEAN member countries to complement and facilitate the objective of AFTA, particularly the elimination of technical barriers to trade posed by regulations, however without compromising product quality, efficacy and safety.
- **ASEAN Common Technical Dossier/Requirements**
- ASEAN Technical Documents – Process Validation, Analytical Validation, Stability, BA/BE

# Organization of Application Dossier



\* Upon Request

# Requirement for Registration

## ASEAN Common Technical Document (ACTD)

Part I – Administrative Data & Product Information

Part II – Quality

Part III – Non-Clinical Data

Part IV – Clinical Data

# PRODUCT REGISTRATION

## *Quality*

- Certificate of Pharmaceutical Product : GMP Certificate & Certificate of Free Sale
  - GMP inspection : Basic GMP Requirement
    - Premise, Location and facilities, Equipment and quality control
    - Testing procedures and Standard Operating Procedures
    - Products security, Manufacturing records and recall procedures
    - Self Inspection
- Product Testing :
  - Product Specifications: Compendial/Non-compendial
  - Heavy metals : Pb, Hg, As
  - Microbial Limit Test

# PRODUCT REGISTRATION

## *Safety*

- Preclinical Data : Animal studies/ Toxicology Studies
- Clinical safety Data : SAE & ADR reporting from Clinical Studies, Periodic Safety Update Report , ADR monitoring
- Non Permitted Ingredients : Eg. phenylpropanolamine(ppa), penicillin for topical use, tartrazine, cyclamate, Magnolia Officinalis,
- Screening of heavy metals in Traditional Products
- Product Information : warning labels/precautions/drug interactions/adverse effects

# PRODUCT REGISTRATION

**EFFICACY : PHARMACEUTICALS**

- **Clinical Efficacy Data : Clinical Trials, Phase 2 and 3**
  - **New Chemical Entity** : New chemical not previously authorized for marketing for any pharmaceutical use in the country .
  - **Biologicals/Biotechnology Products** : Any product of biological origin, prepared with biological processes, derived from human blood and plasma, or manufactured by biotechnology, consisting of substances of higher molecular weight whose purity, potency, and composition cannot readily and reliably be determined by chemical or physicochemical analysis . *(Examples of this group include vaccines, blood products, modified animal tissues, high-molecular-weight hormones, allergens, and the products of genetic engineering or other newer biotechnological techniques*
- **Bioequivalence Studies**
  - **Generics/Multisource/Copy /Me-too Products** : A pharmaceutical product usually intended to be interchangeable with the innovator product, which is usually manufactured without a license from the innovator company and marketed after expiry of the patent or other exclusivity rights

# Application Procedure

- Registration of products shall be done via a web-based QUEST online system at <http://www.bpfk.gov.my>
- Applicant must first register a membership for QUEST system with NPCB and purchase a USB Token that contains a User Digital Certificate from Digicert Sdn. Bhd.
- Submission of data can be done at anytime - 24 hrs a day, 365 days a year, from any part of the world

# Fees

(effective January 2007)

No	Product Categories	Processing Fees (RM)	Analysis Fees (RM)	Total Fees (RM)
1	<b>Pharmaceutical (New Drug Products &amp; Biologics)</b>	1,000.00	Single active ingredient : 3,000.00	4,000.00
			Two or more active ingredients : 4,000.00	5,000.00
2	<b>Pharmaceutical (Generics and Health Supplements)</b>	1,000.00	Single active ingredient : 1,200.00	2,200.00
			Two or more active ingredients: 2,000.00	3,000.00
3	<b>Natural Products</b>	500.00	700.00	1,200.00

The processing fee is NOT REFUNDABLE [CDCR Reg. 8(4)]



# FEES FOR VETERINARY PRODUCTS

## Processing fee + analysis fee:

- For Scheduled Poison, Non-Scheduled Poison : **RM1,500**
- For Export Only-Scheduled Poison : **RM 500**
- For Export Only-Notification for Other than Scheduled Poison : **RM 100**

# Timeline

<b>No.</b>	<b>Product Category</b>	<b>* Duration</b>
<b>(A)</b>	<b>Full Evaluation</b>	<b>(Inclusive screening process)</b>
1.	New Drug Products	245 working days
2.	Biologics	245 working days
3.	Generics (Scheduled Poison)	210 working days
4.	Generics (Non-Scheduled Poison)	210 working days

\* Upon receipt of complete application.

# Timeline

No.	Product Category	*Duration (Inclusive screening process)
(B)	Abridged Evaluation	
5.	Generics (Non-Scheduled Poison) (Product categories as stated in Table V above)	80 working days
6.	Natural Products a) Single active ingredient b) Two (2) or more active ingredients	a) 116 working days b) 136 working days
7.	Health Supplements a) ** Single active ingredient b) ** Two (2) or more active ingredients <i>** Applicable for:</i> <i>i) General or Nutritional Claims; and</i> <i>ii) Functional Claims (Medium Claims)</i>  c) Disease Risk Reduction Claims (High Claims)	a) 116 working days b) 136 working days  c) 245 working days

\* Upon receipt of complete application.



**MAINTENANCE OF  
REGISTRATION**

# Maintenance of registration

- Registration number: MAL YYMM\$\$\$\$##

E.g. MAL11070001AR

Code(##):

A= Scheduled Poisons

X= Non-scheduled Poisons

N= Health Supplement

T= Natural Products/ Traditional Medicines

H= Veterinary Product

C= Contract Manufactured

E= For Export Only (FEO)

R= Repacked

S = Second source

Y= Orphan product

Z= Products listed under the National Essential Medicine List (NEML) for zero rated Government Services Tax (GST)

Cosmetic product : NOT \*\*\*\*\*K eg: NOT1234567K

# Maintenance of registration

- Validity period of registration – 5 years
- **Renewal** of product registration shall be done **not later than 6 months prior to expiry of product registration**, e.g. 7 Sept 2011 (expiry) – 7 Mar 2011 onward shall submit renewal application.
- Updating of product information/ amendments/ variations is allowed through proper application (via post-registration centre)
- Any changes that would affect the quality, safety and efficacy of a registered product is not be allowed. E.g. to change formulation. New registration shall be submitted.

# Maintenance of registration

- Post-Market Surveillance (PMS), Adverse Drug Reaction Monitoring and investigation on complaints will be done **from time to time**.
- The DCA wishes that all medical practitioners, health professionals, consumers and the public report any complaints regarding the quality of medicines particularly if they experience adverse reactions or any other problems with these medicines.
- The DCA will not hesitate to suspend, cancel, recall unsafe or substandard products from the market.

# The Way Forward

Hosting of 1<sup>st</sup> Malaysia-Japan  
Symposium

March 2015

Hosting of ACCSQ-TMHS

June 2015

Organising the National Regulatory  
Conference

Aug 2015

3rd Technical Meeting of the OIC -  
Development & Harmonization of  
Standards on Pharmaceutical & Vaccines

Nov 2015

Control of Cellular & Gene Therapy  
Products (CGTP)

2015

Registration of high/medium claims for  
herbal products

2015



# NPCB Website: [www.bpfk.gov.my](http://www.bpfk.gov.my)

The screenshot shows the official portal of the National Pharmaceutical Control Bureau (NPCB) under the Ministry of Health Malaysia. The website features a navigation menu with categories like About NPCB, Consumers, Industry, Healthcare Professionals, News & Publication, Product Search, and FAQ. A search bar is available with a Google Custom Search option. The main content area includes a video player, a sidebar with user categories (Consumer, Healthcare Professional, Industry, Public Comment), and a section for announcements and press releases. A 'Quest System' section provides links for product registration, license application, and pharmacy enforcement. At the bottom, there are four prominent buttons: QUEST (Product Search), PRODUCT CANCELLATION (Registered/Notified Products), Reporting medication problem (ADR Reporting & Product Complaints), and Helpdesk (Enquiry & Complaints). Social media sharing options are also present at the very bottom.

[English] [A] [A+] [A++]

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Official Portal  
**National Pharmaceutical Control Bureau** Ministry of Health Malaysia  
Biro Pengawalan Farmaseutikal Kebangsaan, Kementerian Kesihatan Malaysia

About NPCB Consumers Industry Healthcare Professionals News & Publication Product Search FAQ

Google™ Custom Search Search

Consumer  
Healthcare Professional  
Industry  
Public Comment

**Ensuring the Quality and Safety of Pharmaceutical, Traditional and Cosmetic Products**

ANNOUNCEMENTS PRESS RELEASE CIRCULARS DIRECTIVES DRGD

Press Reviews – QUBAN SHUANG PRODUCTS MERCURY (17 Mar, 2012) **NEW**  
Press statement : Produk Kosmetik Yang Dikesan Mengandungi Merkuri (03 Feb, 2012)  
PRESS STATEMENT PAO NI KANG (20 Jan, 2012)  
TRADITIONAL PRODUCT "TWEE HONG SUAH" RECALLED (29 Dec, 2011)  
Review for a Press statement regarding Johnson's Baby ... (04 Nov, 2011)  
Press statement of cosmetic products which have been found ... (11 Aug, 2011)  
more...

**Quest System** Information for New Users

Product Registration & Cosmetic Notification  
License Application  
For Enforcement Pharmacy

Client Charter & Achievements  
Statistic Online Transactions  
Feedback Form

**QUEST**  
PRODUCT SEARCH

**PRODUCT CANCELLATION**  
REGISTERED/NOTIFIED PRODUCTS

**Reporting medication problem**  
ADR Reporting & Product Complaints

**Helpdesk**  
ENQUIRY & COMPLAINTS

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MINISTRY OF HEALTH  
www.moh.gov.my



WHO COLLABORATING CENTRE  
IN REGULATORY CONTROL  
OF PHARMACEUTICALS



PHARMACEUTICAL INSPECTION  
COOPERATION SCHEME



QUALITY  
SYSTEM  
SIRIM

BAHAGIAN PERKHIDMATAN FARMASI [www.pharmacy.gov.my](http://www.pharmacy.gov.my)  
BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN (BPFK) [www.bpfk.gov.my](http://www.bpfk.gov.my)

*THANK  
YOU!*

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