MALAYSIA REGULATORY SYSTEM FOR PHARMACEUTICAL PRODUCTS

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BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN
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 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.
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
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.
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 license for a particular registered product.
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

Registration

Education

Pharmacovigilance

Licensing

Surveillance

Analysis
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
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
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Steps for searching ‘Guidelines’ at BPFK website

Step 1: Select the ‘News Room’ tab

Step 2: Select ‘Guideline Central’
Listing of Guidelines at BPFK website

Guidelines Central

Guidelines on Regulatory:

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<td>Guidelines for Vaccines Lot Release in Malaysia</td>
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Guidelines on Bioequivalence (BE):

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<td>Bioequivalence Study Reporting Format</td>
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<td>ASEAN Guidelines for &quot;The Conduct of Bioavailability and Bioequivalence Studies&quot; Adapted from the &quot;NOTE FOR GUIDANCE ON THE INVESTIGATION OF BIOAVAILABILITY AND BIOEQUIVALENCE&quot; (The European Agency for the Evaluation of Medical Products, London, 20 July 2001) (EC/MP/MPD/2001/400150) with some adaptation for ASEAN application</td>
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Overview of Product Registration Process

Pre-Submission of Registration Application

Submission of Registration Application and Screening Process

* GMP Inspection

Data Evaluation

** Sample testing

Meeting of the Drug Evaluation Committee (twice monthly)

Meeting of the Authority (monthly)

Approval

Assigning a registration number (MAL no.) & Issuance of notification

Rejection

Post-Registration Process

Surveillance & Pharmacovigilance or Amendments (Variation)

Approval

*** Licensing

Regulation 18, CDCR 1984

* Good Manufacturing Practice (GMP) Certification
** For natural products only
*** Application for Manufacturer, Import and/or Wholesale License
CATEGORIES OF PRODUCTS

Overview of Product Registration
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
1) New Drug Products (NDP)

- defined as any pharmaceutical product that has not been previously registered in accordance with the provisions of the CDCR 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.
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\(^{st}\) July 2014.

• Medicated Feed is controlled by DVS under Feed Act 2009 starting 1\(^{st}\) January 2015.

• Premixes (antibiotics for prevention and growth promotion) will be controlled by DVS under Feed Act 2009 starting 1\(^{st}\) 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)

- **Products Particulars**
  - Product Name
  - Product Description
  - Pack size
  - Type of container

- **Product Formulation**
  - GMP
  - CPP
  - CFS

- **Manufacturer**
  - Compulsory labeling requirement
  - Additional Warning/Precaution

- **Labeling Requirement**
  - Bioequivalence/Bioavailability Studies
  - Banned ingredient Limits
  - Product testing FPQC, Stability

- **Interchangeability**
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

Part I
Table of Contents, Common Administrative Data & Product Information

Part II
Quality
Overall Summary & Reports

Part III
Non-clinical (Safety)
Overview, Summary & Study Reports*

Part IV
Clinical (Efficacy)
Overview, Summary, Assessment Reports, & Study Reports*

Country-specific administrative data. Not part of ACTD

* 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

  - 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
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
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)

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<th>Analysis Fees (RM)</th>
<th>Total Fees (RM)</th>
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<td>1,000.00</td>
<td>Single active ingredient : 3,000.00</td>
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<td></td>
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<td>Two or more active ingredients : 4,000.00</td>
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<td>2</td>
<td>Pharmaceutical (Generics and Health Supplements)</td>
<td>1,000.00</td>
<td>Single active ingredient : 1,200.00</td>
<td>2,200.00</td>
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<tr>
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<td></td>
<td></td>
<td>Two or more active ingredients: 2,000.00</td>
<td>3,000.00</td>
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<tr>
<td>3</td>
<td>Natural Products</td>
<td>500.00</td>
<td>700.00</td>
<td>1,200.00</td>
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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**
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<td><strong>Full Evaluation</strong></td>
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<td>1.</td>
<td>New Drug Products</td>
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<td>2.</td>
<td>Biologics</td>
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<td>3.</td>
<td>Generics (Scheduled Poison)</td>
<td>210 working days</td>
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<td>4.</td>
<td>Generics (Non-Scheduled Poison)</td>
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* Upon receipt of complete application.
## Timeline

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<td>5.</td>
<td>Generics (Non-Scheduled Poison) (Product categories as stated in Table V above)</td>
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<td>80 working days</td>
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</table>
| 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  
   ** Applicable for:  
   i) General or Nutritional Claims; and  
   ii) Functional Claims (Medium Claims)  
   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

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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 Mac 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

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<td>Hosting of 1st Malaysia-Japan Symposium</td>
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<td>Hosting of ACCSQ-TMHS</td>
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<td>Organising the National Regulatory Conference</td>
<td>Aug 2015</td>
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<tr>
<td>3rd Technical Meeting of the OIC - Development &amp; Harmonization of Standards on Pharmaceutical &amp; Vaccines</td>
<td>Nov 2015</td>
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<td>Control of Cellular &amp; Gene Therapy Products (CGTP)</td>
<td>2015</td>
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<tr>
<td>Registration of high/medium claims for herbal products</td>
<td>2015</td>
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</tbody>
</table>
NPCB Website: www.bpfk.gov.my
THANK YOU!

Address: Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor, Malaysia.
Telephone: +603-7883 5400
Fax: +603-7956 2924
Website: www.bpfk.gov.my