REGULATION OF OTC MEDICINES IN MALAYSIA

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Presentation Outline

• Introduction
• Registration Process & Timelines
• Challenges
INTRODUCTION
REGISTRABLE PRODUCTS / MEDICINES

Pharmaceuticals
- Human
  - New Drugs
  - Generics
  - Biologicals

Complementary
- Veterinar
  - Traditional Medicines
  - Health Supplements

New Drugs
Generics
CDCR 1984
(DCA, NPRA as secretariat)
Pharmaceuticals Products

Scheduled Poison (A) / Controlled Medicine

*Non-Scheduled Poison (X) / OTC (GSM)

Group A

Group B
(Prescription Medicines)

Group C
(Non-Prescription Medicines)

Group D

OTC : Over-the-Counter Medicine
GSM : General Sale Medicine

Poison Act 1952 (Poison Board)
Poisons Act 1952 (revised 1989)

LAWS OF MALAYSIA

ACT 366
POISONS ACT 1952 (REVISED - 1989)
Incorporating latest amendment - P.U.(A) 52/2009

First enacted: 1952 (Ord. No. 29 of 1952)
Date of coming into operation: West Malaysia-1 September 1952;
East Malaysia-1 June 1978

Revised up to: 1989 (Act 366 w.e.f. 13 April 1989)

ARRANGEMENT OF SECTIONS

Long Title
Section 1. Short title and application.
Section 2. Interpretation.
Section 3. Establishment of Poisons Board.
Section 4. Proceedings of Board.
Section 5. Powers of Boards to regulate proceedings.
Section 6. Power of Minister to amend Poisons List.
Section 8. Control of imports of poisons.
# First Schedule, Poisons List

## Section 2

### Poisons List

<table>
<thead>
<tr>
<th>Names</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
<th>Group D</th>
<th>Part II</th>
<th>Exempt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abacavir; its salts</td>
<td></td>
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<td></td>
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<tr>
<td>Abatacept</td>
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<tr>
<td>Aboi ximab</td>
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<td>Abiraterone</td>
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<tr>
<td>Ambrisentan</td>
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<tr>
<td>Acarbose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>All preparations unless exempted</td>
<td></td>
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<tr>
<td>Acetobutol; its salts</td>
<td></td>
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<tr>
<td>Acetophenone</td>
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<tr>
<td>Acetaminophenylisobutyric acid</td>
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<tr>
<td>Acetazolamide</td>
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<tr>
<td>Acetic anhydride</td>
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<td>All preparations</td>
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<tr>
<td>Acetohexamide</td>
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<tr>
<td>N-acetylglucosamine</td>
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<tr>
<td>Acetyl bromide</td>
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<tr>
<td>Acetyl chloride</td>
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<tr>
<td>Acetylcarromal</td>
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<td></td>
<td></td>
<td></td>
<td>All preparations</td>
<td></td>
</tr>
<tr>
<td>Acetylcholine; its salts</td>
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<tr>
<td>Acetretin</td>
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<tr>
<td>Acyclovir</td>
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<td></td>
<td>All preparations except those in Group C</td>
<td>Preparations containing not more than 5% w/w of Acyclovir for topical use</td>
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</tbody>
</table>

Preparations not for the internal treatment of human ailments
<table>
<thead>
<tr>
<th>Classification</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scheduled Poison (A) / Controlled Medicine</strong></td>
<td>Pharmaceutical products which contain scheduled poison(s) as <strong>listed</strong> in the First Schedule under the Poisons Act 1952. Eg biologicals, new drugs, scheduled-poison generics ie antibiotics, antihypertensives, antidiabetics</td>
</tr>
<tr>
<td><strong>Non-Scheduled Poison (X) / OTC * GSM</strong></td>
<td>Products containing active ingredients which are <strong>not listed</strong> in the First Schedule under Poisons Act 1952; and is <strong>excluding</strong> active ingredient which is categorised under health supplements or natural products or cosmetics. Can be freely obtained from any retailer (general sale). Eg analgesic drugs (paracetamol), topical antiseptics, sore throat prep, laxatives, anti acne</td>
</tr>
<tr>
<td>Classification</td>
<td>Definition</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Group A Poison</strong></td>
<td>High toxicity medicines. Eg alclofenac, amidopyrine, avoparcin</td>
</tr>
<tr>
<td><strong>Group B Poison (POM, Rx Only)</strong></td>
<td>Used in treatment where the doctor’s diagnosis is needed to recognize the symptoms Can be dispensed only against <strong>prescription</strong> Eg Nifedipine, olanzapine, ramipril</td>
</tr>
<tr>
<td><strong>Group C Poison / Non Prescription</strong></td>
<td>Used in treatment where the symptoms are easily recognized Can be dispensed <strong>without prescription</strong> Eg ibuprofen, piroxicam, mefenamic acid</td>
</tr>
<tr>
<td><strong>Group D Poison</strong></td>
<td>Chemicals for laboratory Eg cetyl chloride, ethylidene diacetate, methyl bromide</td>
</tr>
</tbody>
</table>
Regulatory Control of Medicines in Malaysia (NPRA)

- Registration
- Licensing
- Surveillance
- Pharmacovigilance
- Analysis
Registration Process
Registration Road Map

Phase 1:
- Registration Aug 1985 (Scheduled Poison)
- Licensing May 1987
- Surveillance 1990

Phase 2:
- Registration 1988 (Non-scheduled Poison)
- Licensing 1992
- Surveillance 1995

Phase 3:
- Registration Jan 1992 (Traditional Medicine)
- Licensing Manufacturer Importers Jan 1999
- Licensing Wholesalers July 2002
- Surveillance 2000

Phase 4:
- Registration Feb 2002 (Cosmetics)
- Licensing Jan 2004
- Surveillance 2005

Phase 5:
- Registration Aug 2007 (Veterinary)
- Licensing 1 July 2012*
- Surveillance (to be announced)

Phase 6:
- Regulation Jan 2012 (API)
- No licensing Requirements as regulation of API is linked to products
- Surveillance (to be announced)

2004: HS removed from OTC
1/1/2008: Registration of cosmetics replaced by notification
1/7/2012: All manufacturer shall certified for GMP
Types of Generic Applications

Generic Pharmaceutical Products

- **Full Evaluation**
  - Scheduled Poison (A) (Part I + Part II)
  - Non Scheduled Poison (X) / OTC (Part I + Part II)

- **Abridged Evaluation**
  - Non Scheduled Poison (X) / OTC (Part I & II, with some exemption)

* Control of API & BABE Report requirement (for other than MR dosage forms) has not been implemented for OTC Full Evaluation products, as compared to Scheduled Poison products.
Non-Scheduled Poison Products (X)

**Full Evaluation**

All products other than the listed categories under Abridged Evaluation

* Generally dosage forms other than external (skin) and locally-acting dosage forms eg. oral, parenteral, rectal, vaginal, ocular, otic etc.

**Abridged Evaluation**

1. Antiseptics/ skin disinfectants
2. Locally-acting lozenges/ pastilles
3. Topical analgesic/ counter-irritants
4. Topical nasal decongestants
5. Emollient/ demulcent/ skin protectants
6. Keratolytics
7. Anti-dandruff
8. Oral care
9. Anti-acne
10. Medicated plasters/ patch/ pad
11. Topical antibacterial

* Generally external (skin) and locally-acting dosage forms eg. creams, ointments, lozenges, pastilles (relatively lower risk compared to OTC Full Evaluation)
<table>
<thead>
<tr>
<th>Product Categories</th>
<th>Fees (RM)</th>
<th>Timeline (working days)</th>
</tr>
</thead>
</table>
| Generics, Scheduled Poison (A), Full Evaluation | 2200 (single API)  
                                          | 3000 (combination API)     | 210                      |
| Generics, Non-Scheduled Poison (X), Full Evaluation | 2200 (single API)  
                                          | 3000 (combination API)     | 210                      |
| Generics, Non-Scheduled Poison (X), Abridged Evaluation | 2200 (single API)  
                                          | 3000 (combination API)     | 116 (single API)  
                                          | 136 (combination API)     |
Flowchart of Registration Process

* Evaluation based on ACTD format
Part I – BMF, CPP (CFS/GMP), labeling, PI,
Part II – CoA, PoA, stability data, BABE, PVR, AVR
* NCE/biologics – sent to panel of experts for comments.
Dossier evaluation by:
1) Centre for Product Registration
2) Centre for Quality Control
3) Centre for Compliance & Licensing

Applicant – submit application

Evaluation of application dossier

Evaluation Committee
(within NPRA, meets bimonthly)

Drug Control Authority
(decision making body – meets monthly)

Registered

Issue Product Registration Number (validity: 5 years)

KIV

More information needed

Rejected

Appeal to Minister of Health
<table>
<thead>
<tr>
<th>Product Categories</th>
<th>Registration Requirement</th>
<th>Exemption</th>
</tr>
</thead>
</table>
| Generics, Scheduled Poison (A), Full Evaluation | Part I ACTD  
Part II ACTD  
DP – inc. BABE Study for IR & MR + lab evaluation  
DS (regulated API)  
Label – ‘Controlled Medicine’ | None                                                |
| Generics, Non-Scheduled Poison (X), Full Evaluation | Part I ACTD  
Part II ACTD  
DP - BABE Study for MR only + lab evaluation  
DS (unregulated API, min requirement) | DP - BABE Report requirement for IR                  |
| Generics, Non-Scheduled Poison (X), Abridged Evaluation | Part I ACTD  
Part II ACTD  
DP - BABE Study for MR only + lab evaluation  
DS (unregulated API, min requirement) | Part I ACTD – PD, PK, P&L  
DP - BABE Report requirement for IR, PV, AMV, PoA |

* OTC Abridged bypass Centre for Quality Control pre-registration documentation evaluation
Challenges

• Switching/reclassification

• Borderline/interphase medicines
  ~ Pharmaceutical/TMHS Interphase
  ~ Medical Device/ Drug Interphase
  ~ Cosmetic/Drug Interphase

• New Drug Products (NDP) containing Non-Scheduled Poisons
  • eg. New form/salt, new dosage form, new route of administration, new combination of active ingredients, new indications/dosage etc.
TERIMA KASIH
THANK YOU