



REFORM OF SELF-CARE WITH NEW MALAYSIA PHARMACY BILL

Muhammad Lukmani Ibrahim
Deputy Director Pharmacy Enforcement
Pharmaceutical Services Division
Ministry of Health Malaysia

OUTLINES



- Introduction to the Divisions under Pharmaceutical Services, Ministry of Health Malaysia
- Current Legislations on Self-Care
- Reform of Self-Care under the new Malaysia Pharmacy Bill
- Conclusion

INTRODUCTION TO EACH DIVISIONS

- Pharmacy Enforcement Division
 - Responsible enforcing the legislations in ensuring that pharmaceuticals, traditional and cosmetics that are available in the market are genuine in terms of registration and notification.

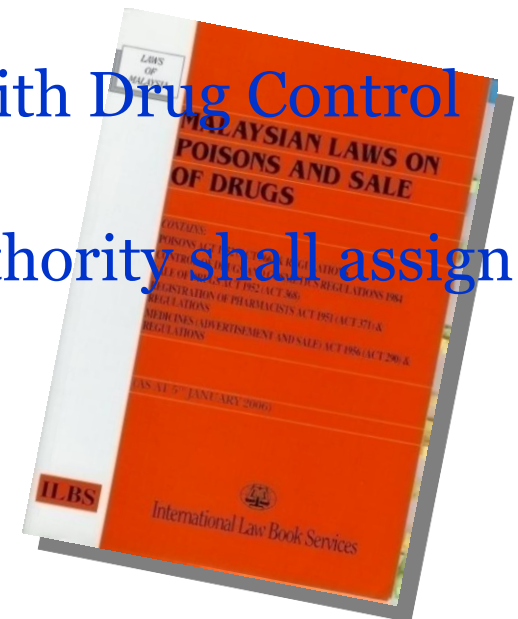
- Pharmacy Practice and Development Division
 - Responsible for ensuring the quality of drug procurement and usage through effective pharmacy practice in order to improve pharmacy services in Malaysia to be on par with other developed countries.

FUNCTIONS OF EACH DIVISIONS

- National Pharmaceutical Control Bureau
 - Responsible in ensuring the quality, efficacy and safety of pharmaceuticals through the registration and licensing scheme.

CURRENT LEGISLATIONS ON SELF-CARE

- The sale, supply, import, possess or administer of medicinal product is subjected to:
 - Control of Drugs and Cosmetics Regulation 1984 (Sale of Drugs Act 1952);
 - Poisons Act 1952.
- All medicinal products must register with Drug Control Authority.
- Upon registration of a product, the Authority shall assign a product registration number.



CURRENT LEGISLATIONS ON SELF-CARE

- The registration number depends on the category of the product.
 - Control Medicine (e.g.: MAL20141234A)
 - Over The Counter Medicine (e.g.: MAL20141234X)
 - Traditional Medicine (e.g.: MAL20141234T)
- All categories of registered medicinal products are available at retail pharmacy.
- The sale, supply, import, possess or administer of un-registered medicinal product is an offence against the Control Drugs and Cosmetics Regulations 1984.

PRODUCT REGISTRATION NUMBER



← MAL20022544A

Control Medicine is labeled with "A" at the end of the Product Registration Number



← MAL20030080X

Over the Counter Medicine is labeled with "X" at the end of the Product Registration Number



← MAL20024420T

Traditional Medicine is labeled with "T" at the end of the Product Registration Number

CURRENT LEGISLATIONS ON SELF-CARE

- No specific provision on the retail sale of different categories of registered medicinal products, except for “Control Medicine” which also subjected to the Poisons Act 1952 and its Regulations.
- “Control Medicine” can be divided into 2 groups; Group B or Group C under the First Schedule, Poisons Act 1952.
 - Group B can only be supplied by a licensed pharmacist upon prescription (e.g.: Antibiotics);
 - Group C can be supplied by a licensed pharmacist without prescription (e.g.: Antihistamines).

Poison



“FIRST SCHEDULE

POISONS LIST

[Section 2]

| Names | Part I | | | | Part II | Exempt |
|--------------------------------|---------|--|---|------------------|------------------|---|
| | Group A | Group B | Group C | Group D | | |
| Abacavir, its salts | - | All preparations | | | | |
| Abatacept | - | All preparations | | | | |
| Abciximab | - | All preparations | | | | |
| Abiraterone | - | All preparations | | | | |
| Abrisentan | - | All preparations | | | | |
| Acarbose | - | - | All preparations | | | |
| Acebutolol; its salts | - | - | | | | |
| Acepylline | - | - | All preparations | | | |
| Acetanilide; alkylacetanilides | - | All preparations unless exempted | - | - | - | Preparations not for the internal treatment of human ailments |
| Acetazolamide | - | All preparations | | | | |
| Acetic anhydride | - | - | - | All preparations | | |
| Acetohexamide | - | - | All preparations | | | |
| N-acetylanthranilic acid | - | - | - | - | All preparations | |
| Acetyl bromide | - | - | - | All preparations | | |
| Acetyl chloride | - | - | - | All preparations | | |
| Acetylcarbromal | - | - | All preparations | | | |
| Acetylcholine; its salts | - | All preparations | | | | |
| Acitretin | - | All preparations | | | | |
| Acyclovir | - | All preparations except those in Group C | Preparations containing not more than 5% w/w of Acyclovir for topical use | | | |

CURRENT LEGISLATIONS ON SELF-CARE

- Only registered medicinal products allow to be imported and sold in Malaysia in order to ensure the quality, safety and efficacy of the product and to safeguard public health.
- Public are urged to get registered medicinal products from local pharmacies and drug stores, instead of night market, online or street peddlers.
- Import of unregistered medicinal product by post or courier is not allowed even for personal use.

REFORM OF SELF-CARE WITH MALAYSIA PHARMACY BILL

- New classification of registered medicinal product;
 - Pharmacist Only Medicinal Product (POMP) (Group C)
 - Prescription Only Medicine (POM) (Group B)
 - General Sale List II (Medicinal product other than “Pharmacist Only Medicinal Product” or “Prescription Only Medicine” including health supplement, homeopathic and traditional medicinal product)

REFORM OF SELF-CARE WITH MALAYSIA PHARMACY BILL

- Possession and Sale by Retail of Pharmacist Only Medicinal Product or Prescription Only Medicine
 - The medicine is lawfully obtained/ supplied for a medicinal purpose.
 - The sale takes place in a registered pharmacy.
 - The medicine is ready for sale in pre-packed state from a licensed manufacturer, wholesaler or importer.

REFORM OF SELF-CARE WITH MALAYSIA PHARMACY BILL

- Sale or supply by retail of General Sale List II
 - The sale takes place in a registered pharmacy or a licensed premises.
 - The medicine is ready for sale in pre-packed state from a licensed manufacture, wholesaler or importer.
- Self-care medications involves “Pharmacist Only Medicinal Product” and General Sale List II only.
- Pharmacist Only Medicinal Product, Prescription Only Medicine and General Sale List II are available at registered pharmacy.

REFORM OF SELF-CARE WITH MALAYSIA PHARMACY BILL

- Prohibition of unregistered and expired medicinal product.
 - Fine < RM100,000 or < 5 year imprisonment.
- Prohibition of adulterated medicinal product.
 - Imprisonment not less than 1 year and not exceeding 10 years and fine < RM500,00.
- Prohibition of counterfeit medicinal product.
 - Imprisonment not less than 4 year and not exceeding 15 years and fine < RM2,000,000.

CONCLUSION

- The new Bill provides better control on the sale by retail of self-care medicinal product.
 - New classification of medicinal product;
 - Requirement of premises registration or license.
 - Legally obtained/ supplied for medicinal purpose.
- The new Bill provides clear prohibition on unregistered, expired, adulterated or counterfeit medicinal product in order to ensure only registered medicinal products are available for sale or use in Malaysia.



TERIMA KASIH

