REGULATION OF OTC MEDICINES IN MALAYSIA

Ministry Of Health Malaysia

QUALITY SYSTEM
SIRIM

MS ISO 9001:2008 Certified

PIC/S

Member of Pharmaceutical Inspection Cooperation Scheme

International OTC Medicine Regulator Forum 2017

Friday 20 October

Novotel Hotel, Sydney

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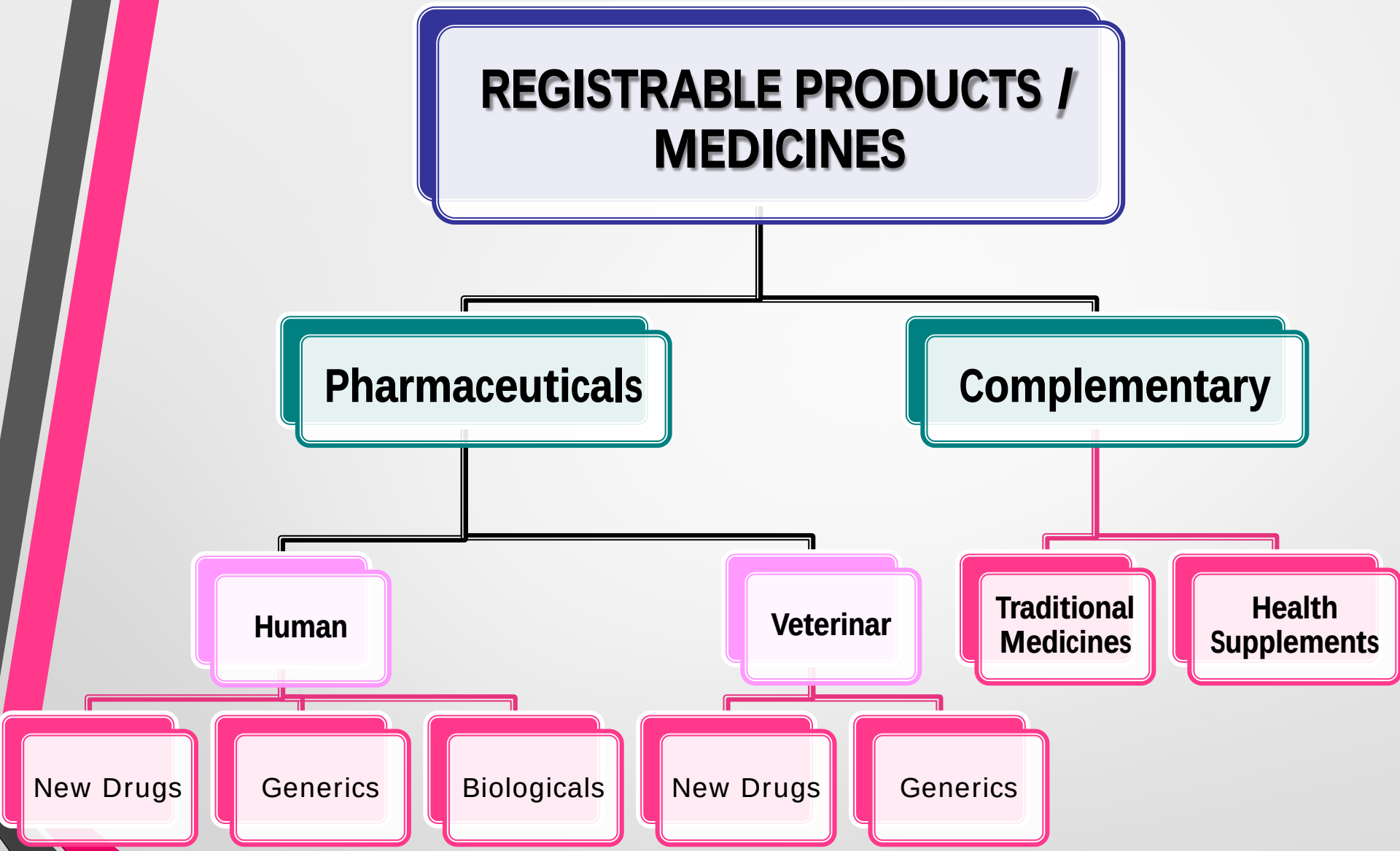
WHO Collaborating Centre
For Regulatory Control of Pharmaceuticals

Presentation Outline

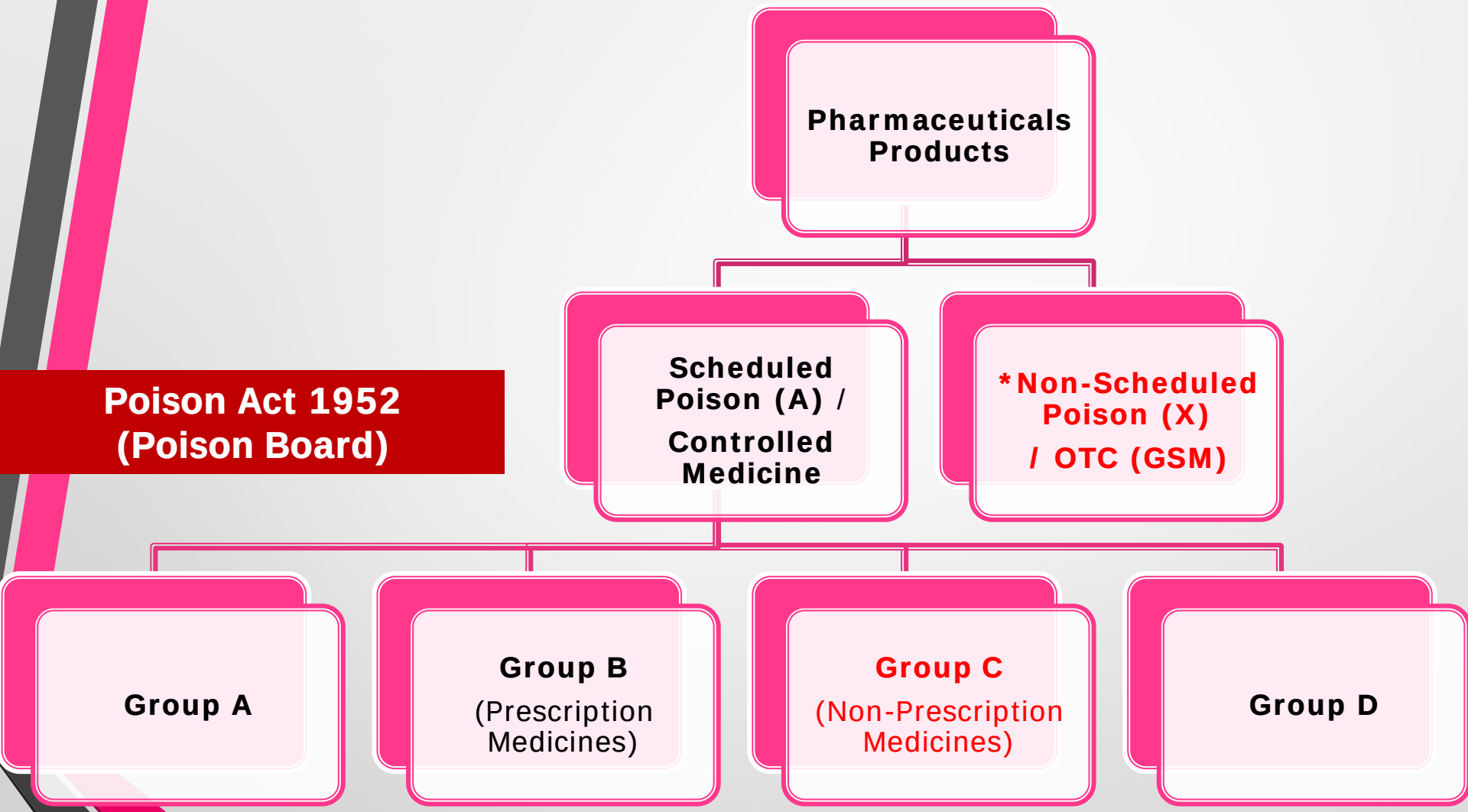
- Introduction
- Registration Process & Timelines
- Challenges

INTRODUCTION



CDCR 1984
(DCA, NPRA as secretariat)

Poison Act 1952 (Poison Board)



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

Poisons Act 1952 (revised 1989)

LAWS OF MALAYSIA

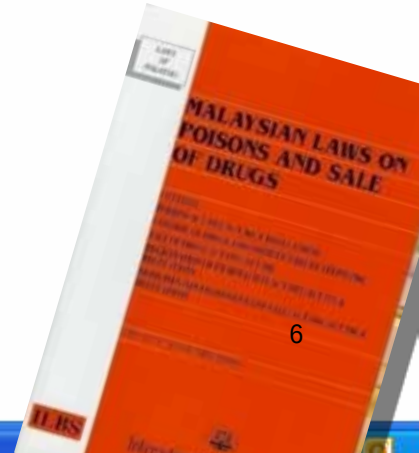
ACT 366
POISONS ACT 1952 (REVISED - 1989)
Incorporating latest amendment - P.U.(A) 52/2009

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 7. Application of the Act.
Section 8. Control of imports of poisons.



First Schedule, Poisons List

"FIRST SCHEDULE

POISONS LIST

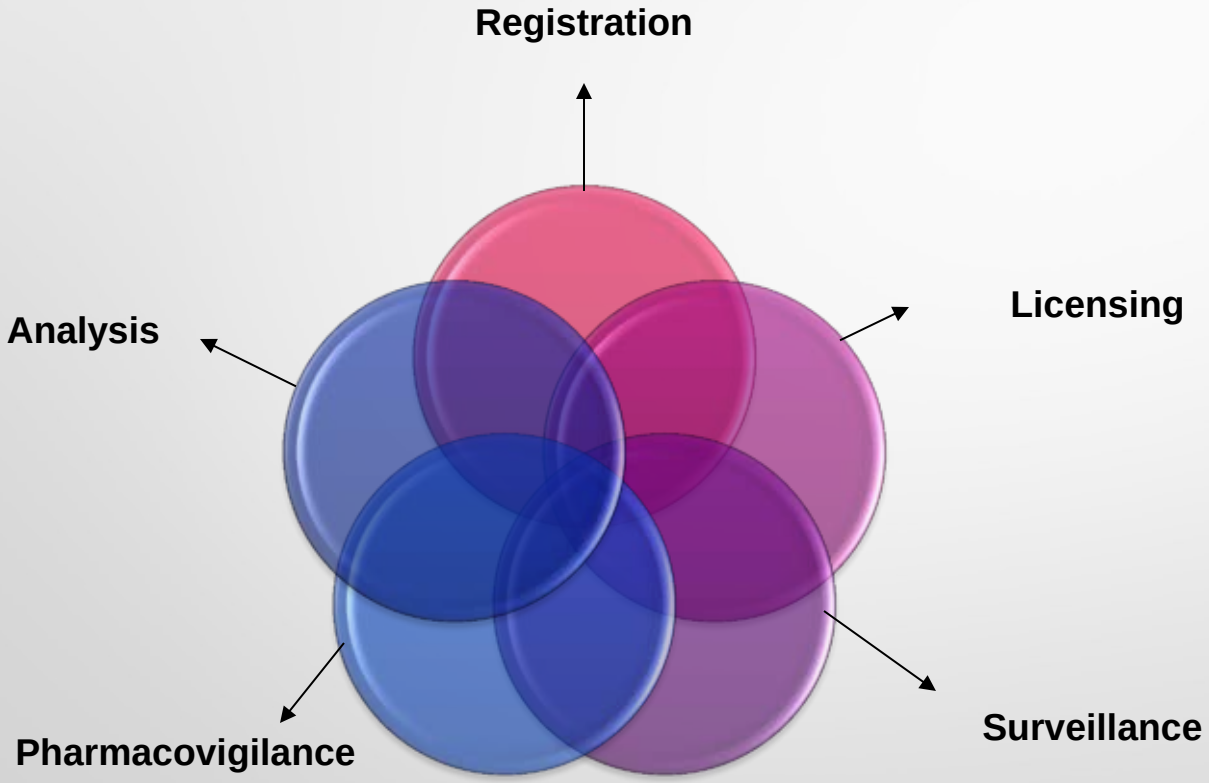
[Section 2]

Names	Part 1				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				
Ambrisentan	-	All preparations				
Acarbose	-	-	All preparations			
Acebutolol; its salts	-	-				
Acepifylline	-	-	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			

Classification	Definition
Scheduled Poison (A) / Controlled Medicine	Pharmaceutical products which contain scheduled poison(s) as **listed** in the First Schedule under the Poisons Act 1952 Eg biologicals, new drugs, scheduled-poison generics ie antibiotics, antihypertensives, antidiabetics
Non-Scheduled Poison (X) / OTC *** GSM**	Products containing active ingredients which are **not listed** in the First Schedule under Poisons Act 1952; and is **excluding** 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

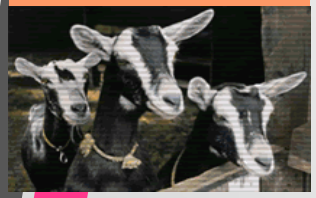
Classification	Definition
Group A Poison	High toxicity medicines. Eg alclofenac, amidopyrine, avoparcin
Group B Poison (POM, Rx Only)	Used in treatment where the doctor's diagnosis is needed to recognize the symptoms Can be dispensed only against **prescription** Eg Nifedipine, olanzapine, ramipril
Group C Poison / Non Prescription	Used in treatment where the symptoms are easily recognized Can be dispensed **without prescription** Eg ibuprofen, piroxicam, mefenamic acid
Group D Poison	Chemicals for laboratory Eg cetyl chloride, ethylidene diacetate, methyl bromide

Regulatory Control of Medicines in Malaysia (NPRA)



Registration Process

Registration Road Map

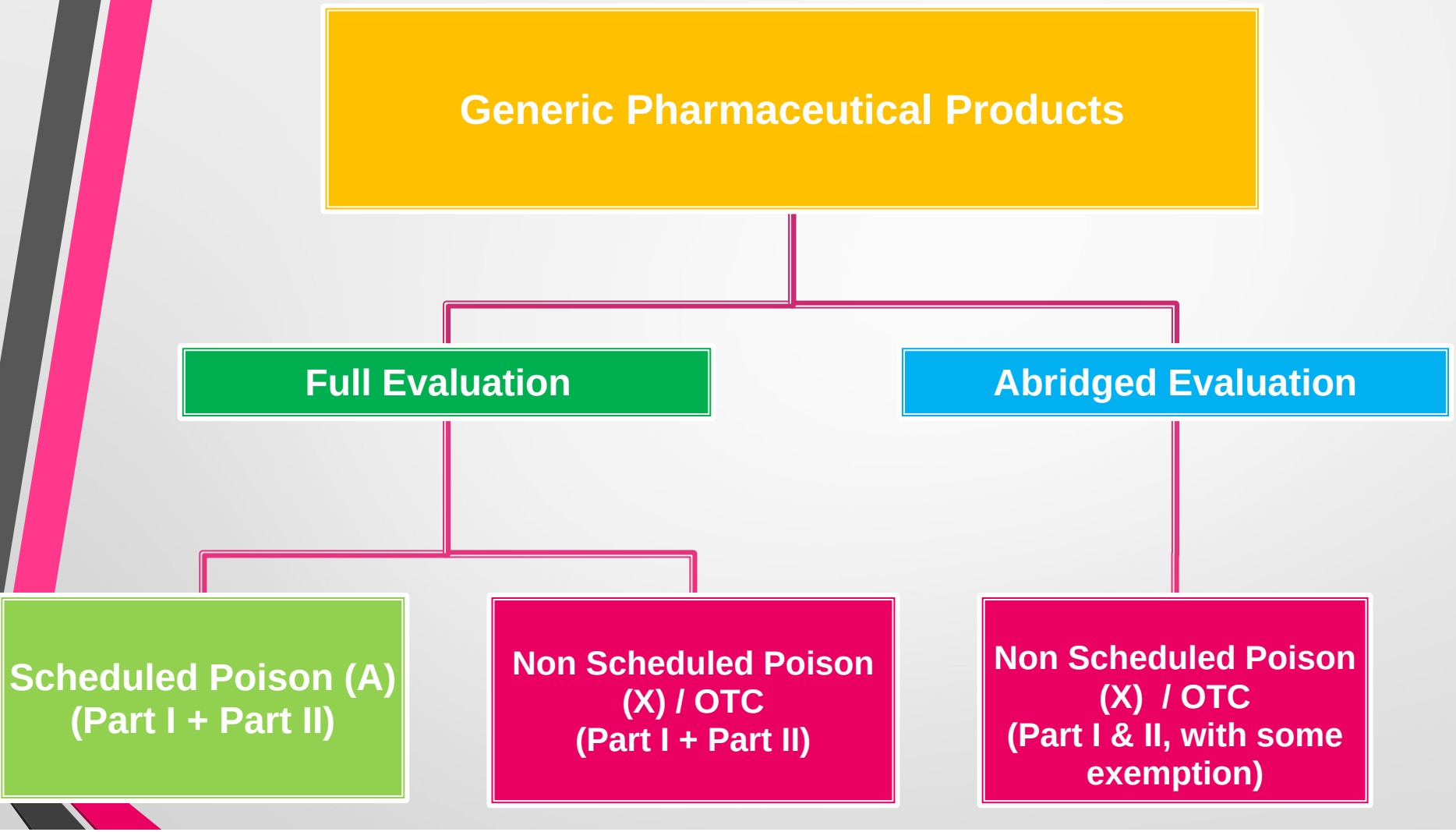
NEW PRODUCTS	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5	Phase 6
BIOTECHNOLOGY 	Registration Aug 1985 (Scheduled Poison)	Registration 1988 (Non-scheduled Poison)	Registration Jan 1992 (Traditional Medicine)	Registration Feb 2002 (Cosmetics)	Registration Aug 2007 (Veterinary)	Regulation Jan 2012 (API)
VETERINARY MEDICINE 	Licensing May 1987	Licensing 1992	Licensing Manufacturer Importers Jan 1999	Licensing Jan 2004	Licensing 1 July 2012*	No licensing Requirements as regulation of API is linked to products
ACTIVE PHARMACEUTICAL INGREDIENTS 	Surveillance 1990	Surveillance 1995	Licensing Wholesalers July 2002 Surveillance 2000	Surveillance 2005	Surveillance (to be announced)	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



* 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)

NPRA Fees & Timeline

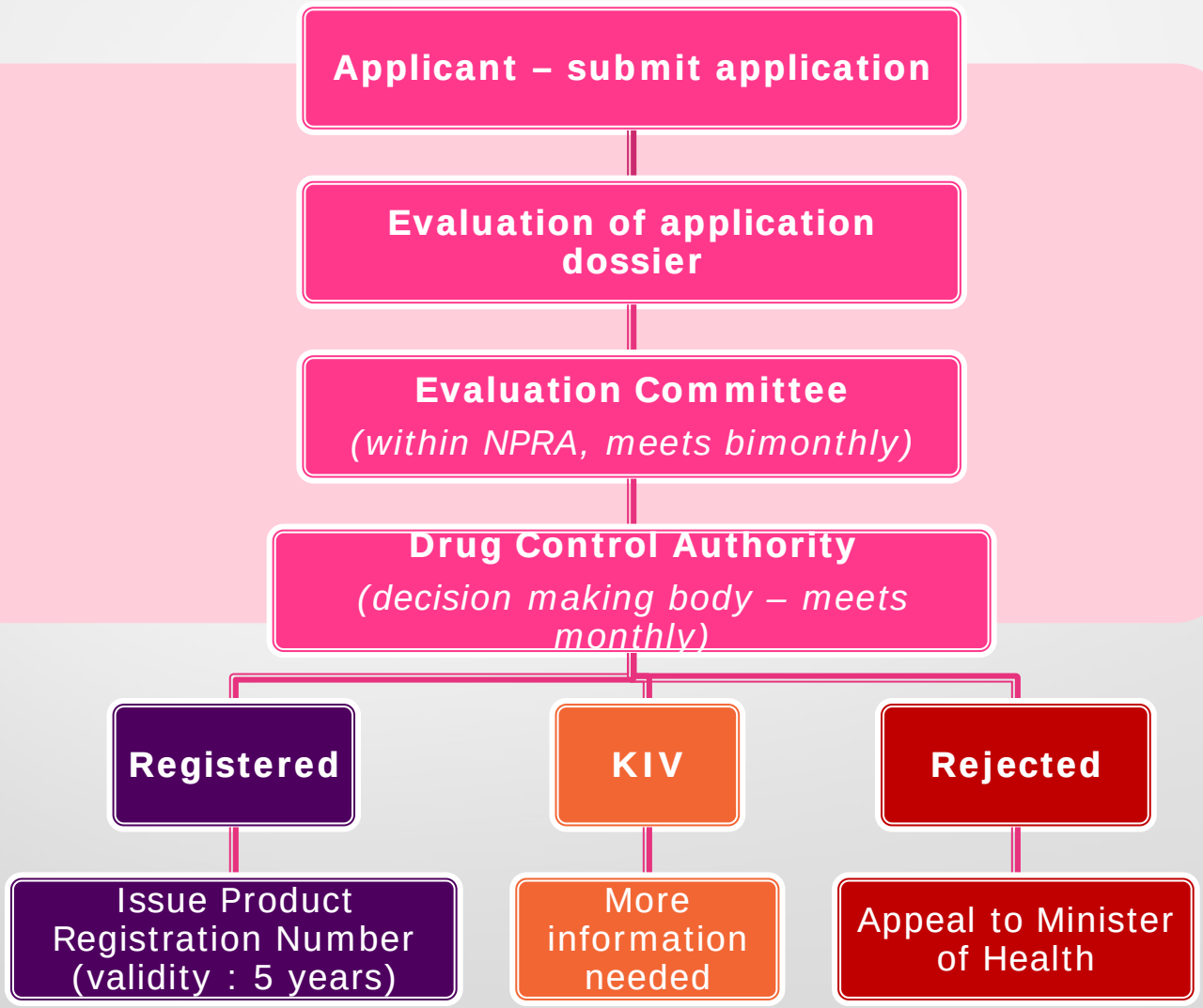
Product Categories	Fees (RM)	Timeline (working days)
Generics, Scheduled Poison (A), Full Evaluation	2200 (single API) 3000 (combination API)	210
Generics, Non-Scheduled Poison (X), Full Evaluation	2200 (single API) 3000 (combination API)	210
Generics, Non-Scheduled Poison (X), Abridged Evaluation	2200 (single API) 3000 (combination API)	116 (single API) 136 (combination API)

Flowchart of Registration Process

*** Evaluation based on ACTD format**

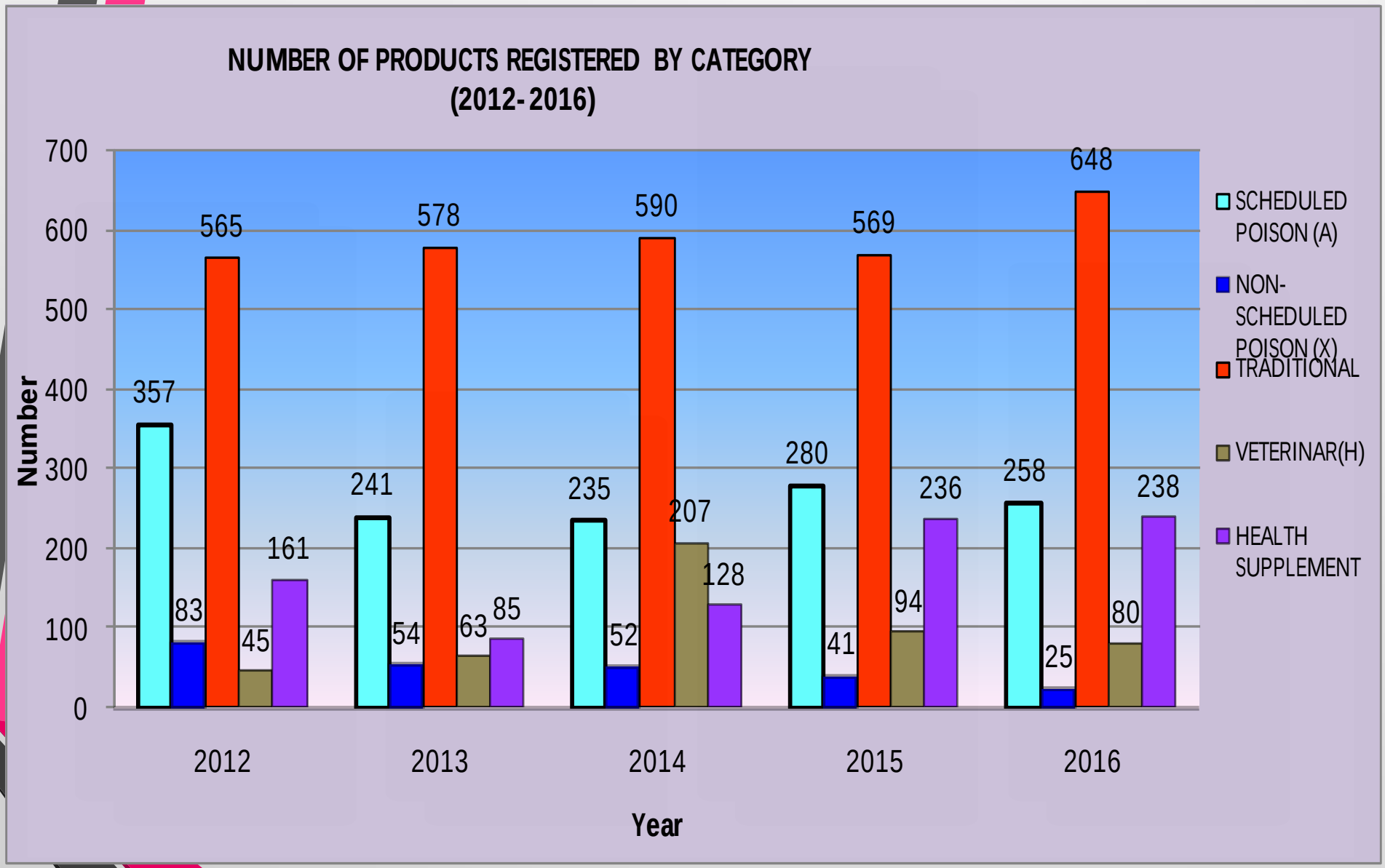
Part I – BMF. CPP (CFS/GMP), labeling, PI, Part II – CoA, PoA, stability data, BABE, PVR, AVR

*** 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



Product Categories	Registration Requirement	Exemption
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**


NUMBER OF PRODUCTS REGISTERED BY CATEGORY
(2012-2016)
Number
Year
700
600
500
400
300
200
100
0
2012
2013
2014
2015
2016
357
83
565
45
161
241
54
578
63
85
235
52
590
207
128
280
41
569
94
236
258
25
648
80
238
SCHEDULED POISON (A)
NON-SCHEDULED POISON (X)
TRADITIONAL
VETERINAR(H)
HEALTH SUPPLEMENT

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