



Biro Pengawalan Farmaseutikal
Kebangsaan, Kemen. Kesihatan Malaysia



WHO Collaborating Centre
For Regulatory Control of
Pharmaceuticals



Member of Pharmaceutical
Inspection Cooperation Scheme



MS ISO 9002 REG. No. /AR 1171
MS ISO 9001:2008 Certified

REGISTRATION OF TRADITIONAL PRODUCTS IN MALAYSIA

17TH NOVEMBER 2013 AT
SCHOOL OF MEDICAL SCIENCES,
KAMPUS KESIHATAN USM,
KUBANG KERIAN, KELANTAN

Presented by :
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PRESENTATION OUTLINE

- **LEGISLATION**
- **REGISTRATION PROCEDURES**
- **REGISTRATION REQUIREMENTS**
- **STATISTICS**
- **CONCLUSION**



National Pharmaceutical Control Bureau MOH Malaysia



LEGISLATION

The enabling powers that allow NPCB to control and regulate the product registration embodied in the following legislations :

- Poisons Act 1952 (revised 1989)
- Sale of Drugs Act 1952 (revised 1989)
- Control of Drugs and Cosmetics Regulations 1984
- Dangerous Drug Act 1952 (revised 1980)
- Medicines (Advertisement and Sale) Act (revised 1983)
- Registration of Pharmacist Act 1951, revised 1989

CONTROL OF DRUG AND COSMETICS ACT 1984 (REVISED 2006)

No person shall manufacture, sell, supply, import,
possess or administer any product

unless:

the product is a registered product,

and

the person holds the appropriate license required
& issued under the CDCR



MALAYSIA



Registration and Licensing Activity
under the *Drug Control Authority (DCA)*



The NPCB acts as the *Secretariat* to the DCA

The **Drug Control Authority (DCA)** is established for the purpose of these Regulations.

(June 1985)

National Pharmaceutical Control Bureau (NPCB)

acts as its secretariat & is responsible for the processing of application for the registration of pharmaceutical, natural products, notification of cosmetics & Licencing of manufactures, importers and wholesalers

(Nov. 1985)



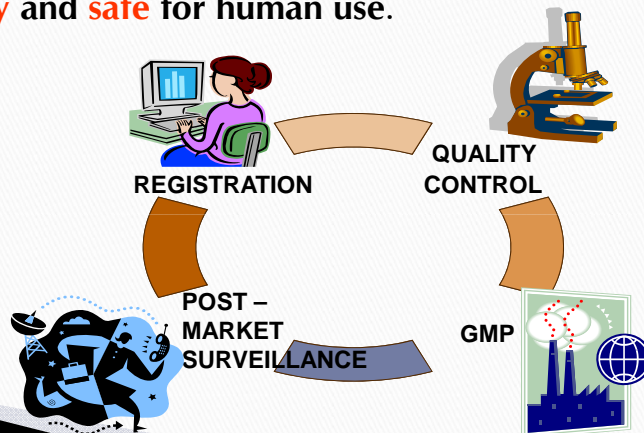
Organization Chart of National Pharmaceutical Control Bureau



The Purpose Of Registration of Traditional Product

- ▶ To ensure that products available on the market are of **quality** and **safe** for human use.

- ▶ Quality
- ▶ Safety



DEFINITION OF TRADITIONAL PRODUCT

Traditional medicine as defined under the Control of Drugs and Cosmetic Regulations 1984

means:



Any product used in the practice of indigenous medicine, in which the drug consist solely of one or more naturally occurring substances of a plant, animal or mineral, of parts there of, in the unextracted or crude extract form, and a homeopathic medicine.

WHAT IS A PRODUCT?

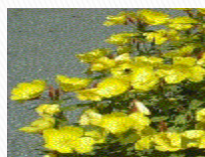
The Control of Drugs and Cosmetics 1984

'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 medical purpose

The Sale of Drugs Act 1952




- ▶ 'drug' includes any substance, product or article intended to be used or capable, or purported or claimed to be capable of being used on humans or any animal, whether internally or externally for a medicinal purposes.



REGISTRATION PROCEDURES



Registration Phases

NEW PRODUCTS	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5	Phase 6
BIOTECHNOLOGY 	Registration Aug 1985 (Prescription Drugs)	Registration 1988 (OTC)	Registration Jan 1992 (Traditional Medicine)	Registration Feb 2002 (Cosmetics)	Registration Aug 2007 (Veterinary)	Registration beginning with NCE Jan 2012 (API)**
VETERINARY MEDICINE 	Licensing May 1987	Licensing 1992	Licensing Manufacturer Importers Jan 1999	Licensing Jan 2004	Licensing 1 Jan 2012*	No licensing Requirements as registration of API is
ACTIVE PHARMACEUTICAL INGREDIENTS 	Surveillance 1990	Surveillance 1995	Licensing Wholesalers July 2002 Surveillance 2000	Surveillance 2005	Surveillance (to be announced)	Surveillance (to be announced)

National Pharmaceutical Control Bureau MOH Malaysia

What Is ONLINE REGISTRATION ?



Paperless submission using web-based application accessible via internet connectivity

www.bpfk.gov.my

(QUEST 3)

Process includes:

- Filing, editing, completing and submitting registration forms
- Receiving & replying to memos (inclusive of e-mail notification)
 - Change Requisition Processes
 - Approval, Certification and
 - Product Renewal

CRITERIA FOR REGISTRATION

- 1) Applicant must be a **locally incorporated** company,
and be **authorized in writing by the product owner** to be the holder of the registration certificate and be responsible for all matters pertaining to the registration of the product
- 2) Product must satisfy registration criteria with respect **to safety and quality**

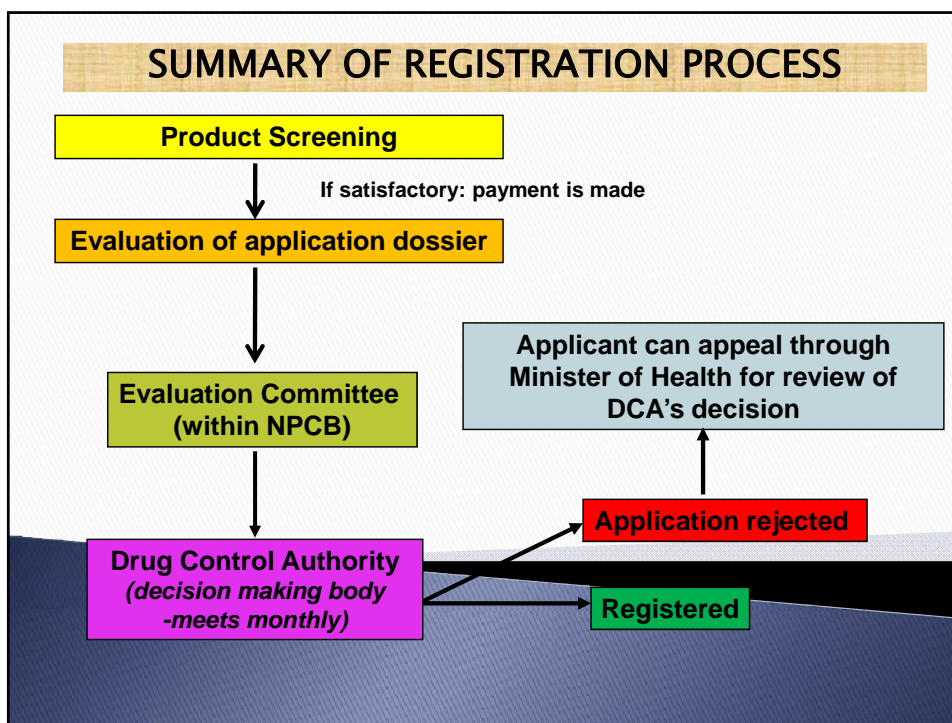



Registration Fees






Bil.	Product category	Processing fees	Laboratory fees
1.	Traditional product	RM 500	RM 700
	<i>Total registration fees for one traditional product (to be sold in Malaysia and export)</i>	 RM 1200	
2.	Traditional product (for export only)	RM 500	-
	<i>Total registration fees for one traditional product (for export only)</i>	 RM 500	

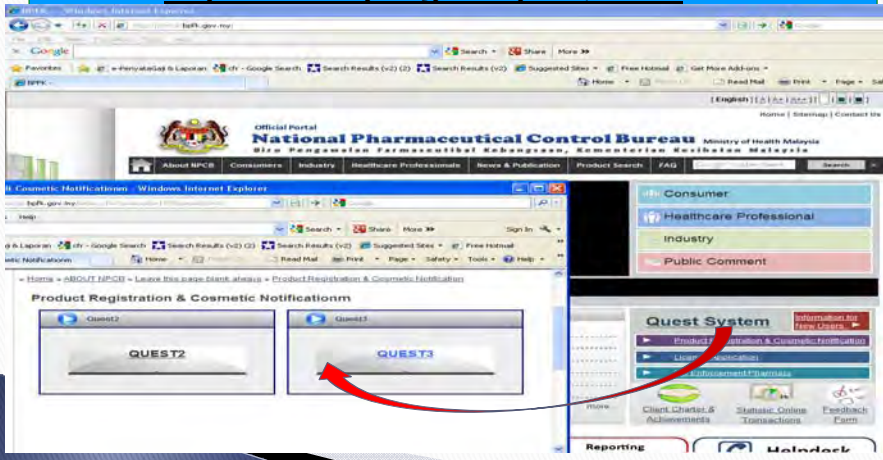




For Online Registration



Biro Pengawasan Farmaseutikal Kebangsaan:
<http://www.bpfk.gov.my> – Quest 3






For Online Registration






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For Drug Registration Guidance Document




1) Biro Pengawasan Farmaseutikal Kebangsaan:
- <http://www.bpfk.gov.my> – Regulatory Information



**2) Drug Registration
Guidance Document**





SECTION A: PRODUCT PARTICULARS	
Fields	Description
A1	Name of Product
A2	Product Description
A3	Dosage Form
A4	Name and Strength of Active and Excipient Substance
A5	Product Indication
A6	Dose / Usage instruction
A7	Contraindication
A8	Warning / Precaution
A9	Drug Interaction
A10	Side Effects / Adverse Reaction
A11	Signs of Overdose
A12	Storage Condition
A13	Shelf Life
A14	Therapeutic Code

Examples of indication allowed Traditionally used.....

GENERAL HEALTH MAINTENANCE / KESIHATAN AM

- for general health maintenance / for general well being
- for health and strengthening the body



BLOOD & BODY FLUID / DARAH & CECAIR BADAN

- for improving blood circulation
- to improve urination
- for improving bowel movement



BONE, MUSCLE AND JOINT / TULANG, OTOT & SENDI

- for strengthening muscle and bone
- for relieving muscular ache .
- for relieving waist ache and backache



SKIN AND EXTERNAL USE

- for symptomatic relief of pain and itch associated with insect bites



Examples of indication allowed Traditionally used.....

PAIN & FEVER / SAKIT AM & DEMAM

- to relieve / alleviate pain
- for relieving headache



COUGH & COLD

- to relief cough and cold
- to relief of nasal congestion



DIGESTIVE SYSTEM




- for relief of stomachache, mild diarrhoea
- for relief of flatulence, stomach ache, mild diarrhoea and loss of appetite



WOMEN'S HEALTH / MEN'S HEALTH



- to relief menstrual pain, headache,
- to relief vaginal discharge
- for energy and men's health/ for vitality



SECTION B - PRODUCT FORMULA	
B 1.1	Batch Manufacturing Formula
B 1.2	Attachment of Batch Manufacturing 
B 2.1	Manufacturing process 
B 2.2	Attachment of manufacturing 
B 3	In Process Quality Control
B 4	Attachment of Finished Product Specification Documentation
B 5	Attachment of Stability Data Documentation

SECTION C – PARTICULAR OF PACKING	
C1	Pack Size eg : 100 capsule 
C2	Container Type/Container Type Description Eg : HDPE Plastic Bottle, Glass Bottle, Aluminium Blister Pack 
C3	Barcode/Serial No.
C4	Recommended Distributor's Price, RM
C5	Recommended Retail Price, RM

SECTION D – LABEL AND PROPOSED PACKAGE INSERT	
D 1	Label (mock up) for immediate container 
D 2	Label (mock up) for outer carton 
D 3	Proposed package insert 

SECTION E –PARTICULARS OF MANUFACTURER/ IMPORTER / REPACKER / PRODUCT OWNER/STORE ADDRESS	
E1	Product Owner 
E2	Manufacturer
E 3	Other manufacturer(s) involved Eg: Repacker
E 4	Store Address 

- A) Limit test for heavy metals
- B) Tests for microbial contamination
- Prohibition / banned ingredient

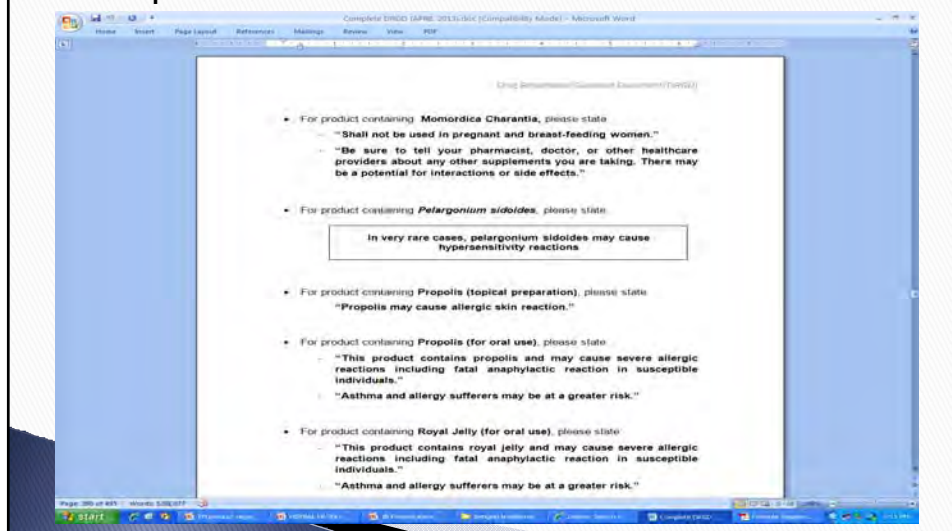
- containing scheduled poisons as listed under the Poisons Act 1952
- reported adverse event

Larrea	insanigera mesemoria	Chaparral		Reported to cause liver toxicity
Hymenocallis	canadensis	Colicweed, Eye Sain, Indian Dye		Reported to cause disturbance of the nervous system
Magnolia	officinalis	Hikoua Magnolia		Reported to cause kidney toxicity
Thalictrum	tetraoida			
Piper methystrinum		Kava kava		
	officinale			
Symphylitum	aspernum x optatumum	Comfrey		Reported to cause liver toxicity

Genus	Species	Common/ Local Name	Part of plant prohibited (whole plant unless otherwise specified)	Constituent(s) of concern
<i>Acetabularia</i>	All species			<i>Acetabularia</i>
<i>Adiantum</i>	<i>quadrifidum</i>	White quadrifid		Ascorbic acid, urolithine
<i>Atriplex</i>	<i>halimifolia</i>	Deadly nightshade		Atropine, hyoscyamine, scopolamine, hyoscyamine
				Scopolamine
<i>Berberis</i>	All species			* Also present in <i>Hydrastis canadensis</i>

C) Labelling (warning and precaution statement)

Example:-



Example of Traditional Product Label



Ini adalah persediaan tradisional

Jika penyakit berlarutan, sila dapatkan nasihat doktor.

Jauhkan daripada kanak-kanak

Keep out of reach of children

Indikasi: Digunakan secara tradisional untuk kesihatan wanita

Tarikh perkilangan:
Trikh luput:
No. Kelompok:

TABLET ABC

500MG

MALXXXXXXX

50 TABLET

Setiap tablet (500mg) mengandungi

Folium Labisia pumila	200 mg
Fructus Quercus infectiona	300mg

Dosej: 2 tablet diambil 2 kali sehari selepas makan.

Dikilangkan oleh:
Syarikat ABC Sdn Bhd
3, Jalan Universiti
46730 Petaling Jaya

diedarkan oleh:
Syarikat 123 Sdn Bhd
3, Jalan Universiti
46730 Petaling Jaya

D) Screening for adulterants

Based on product indications:

- ▶ Men's health – e.g. sildenafil, tadalafil, analogues
- ▶ Slimming – e.g. fenfluramine
- ▶ Muscle and joint pains – e.g. NSAIDs
- ▶ Cough and cold – e.g. antihistamines
- ▶ Steroids



SUMMARY : QUALITY CRITERIA

- ▶ Compliance to Good Manufacturing Practice (GMP)
- ▶ Stability studies
- ▶ Limits for disintegration time
- ▶ Uniformity of weight



CLIENT'S CHARTER

NCE & Biotech - < 245 working days
 Generics & OTC - < 210 working days

TM & HS (Single ingredient) - < 116 working days
 TM & HS (Combination) - < 136 working days

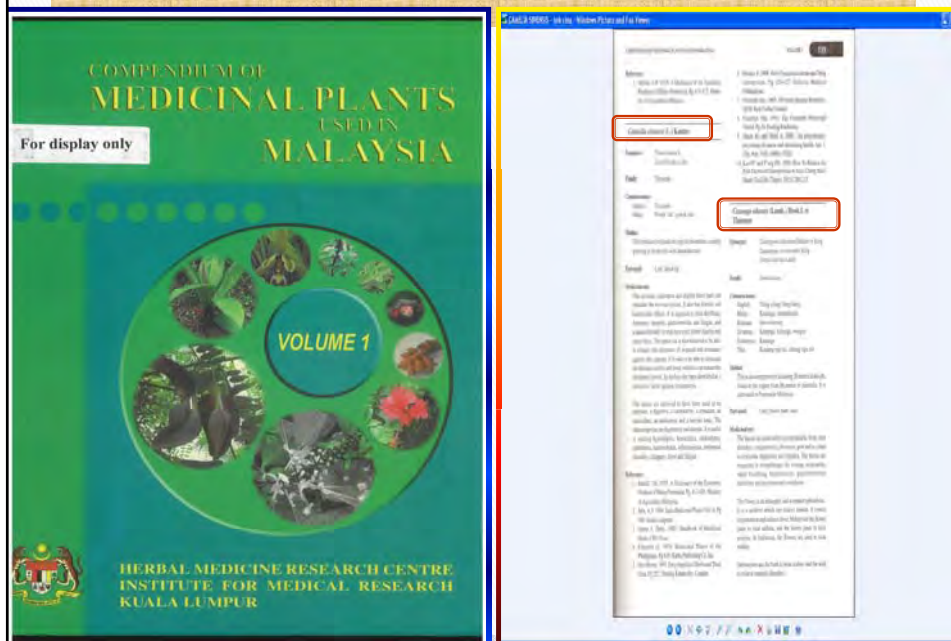
On condition with

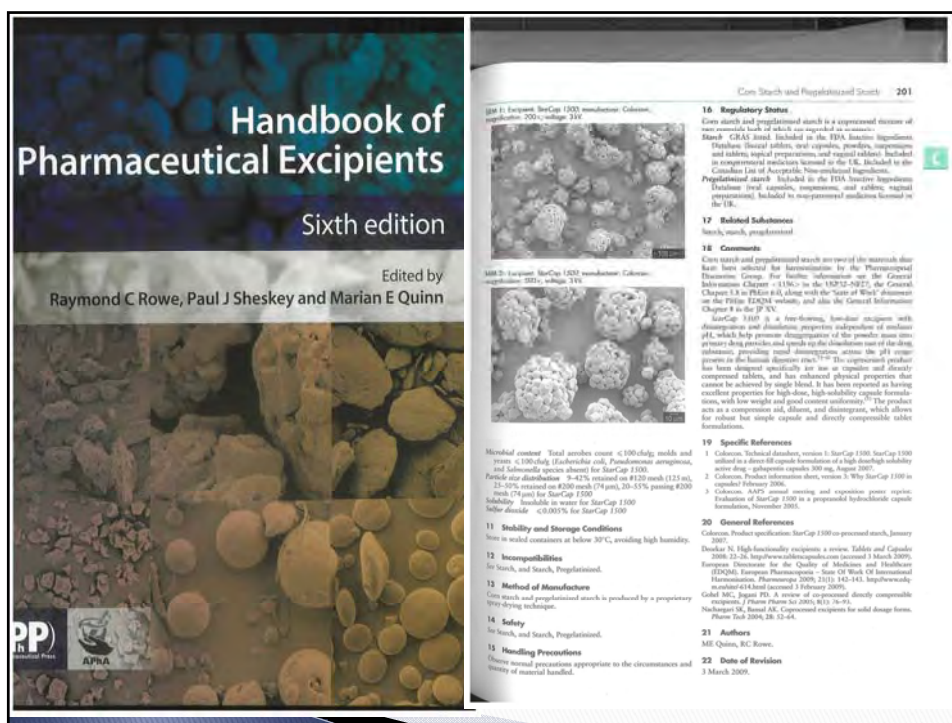
**Full Compliance to
Requirements**

REFERENCES

- *Compendium Medicinal Plants Used In Malaysia (Vol I & II)*
- *Indeks Tumbuhan Ubat Malaysia*
- *Chinese - English manual Of Common- Used In Traditional Chinese Medicine*
- *PDR For Herbal Medicine*
- *Indian Materia Medica (Vol 1 & II)*
- *Pharmacopoeia Of The People's Republic of China*
- *The Coloured Atlas of Chinese Materia Medica Specified In Chinese Pharmacopoeia*
- *Encyclopedia Of Homeopathic Pharmacopoeia (Vol I. II & III)*

REFERENCES





PRODUCT REGISTRATION NUMBER

▶ Registration number: MAL 1010\$\$\$\$##
Code(##)

A: Scheduled Poisons

X: Non-scheduled Poisons (over the counter products)

T: Traditional Medicines

C: Contract Manufactured

E: Export Only

R: Repacked

S: Second source

▶ Validity period of registration – 5 years

▶ Renewal of product registration should be done not later than 6 month prior to expiry of product registration



STATISTICS ON PRODUCTS REGISTRATION (1991 - JUNE 2013)

STATUS	NATURAL PRODUCTS
Registered	22,044
Rejected	10,745
Cancelled	3,987

NUMBER OF EXISTING PRODUCTS REGISTERED IN MALAYSIA (AS OF SEPT 2012)

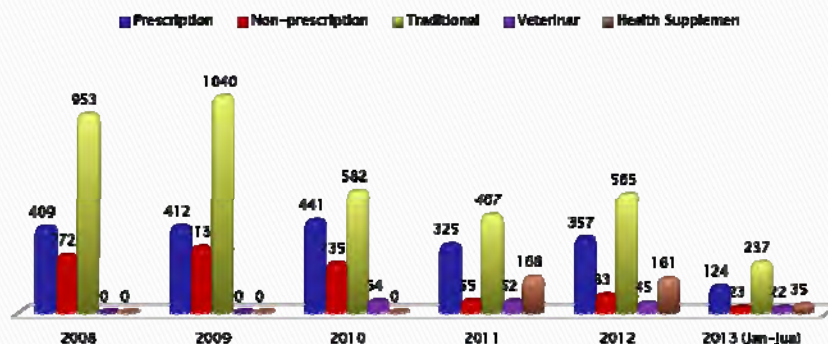
Category	Locally Manufactured	Imported	Total
Traditional	7,731	3,333	11,064

Note: The figures differ from the overall number of products registered due to:-

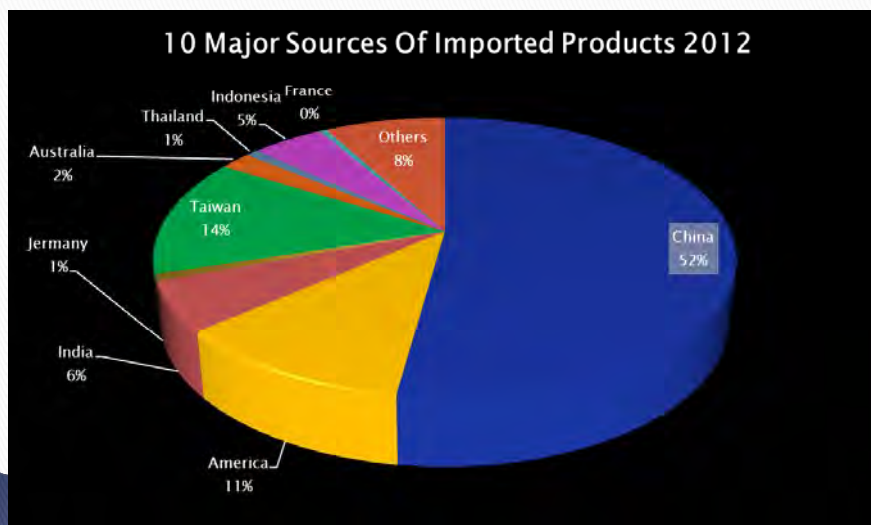
- Products not renewed by holder
- Products withdrawn
- Products cancelled due to regulatory actions

NUMBER OF PRODUCTS REGISTERED IN MALAYSIA (2008-JUNE 2013)

Number Of Products Registered In Malaysia (2008-June 2013)



10 MAJOR SOURCES OF IMPORTED PRODUCTS 2012



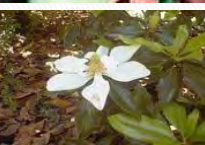
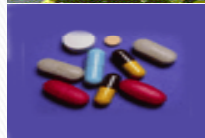
PROBLEMS & ISSUES

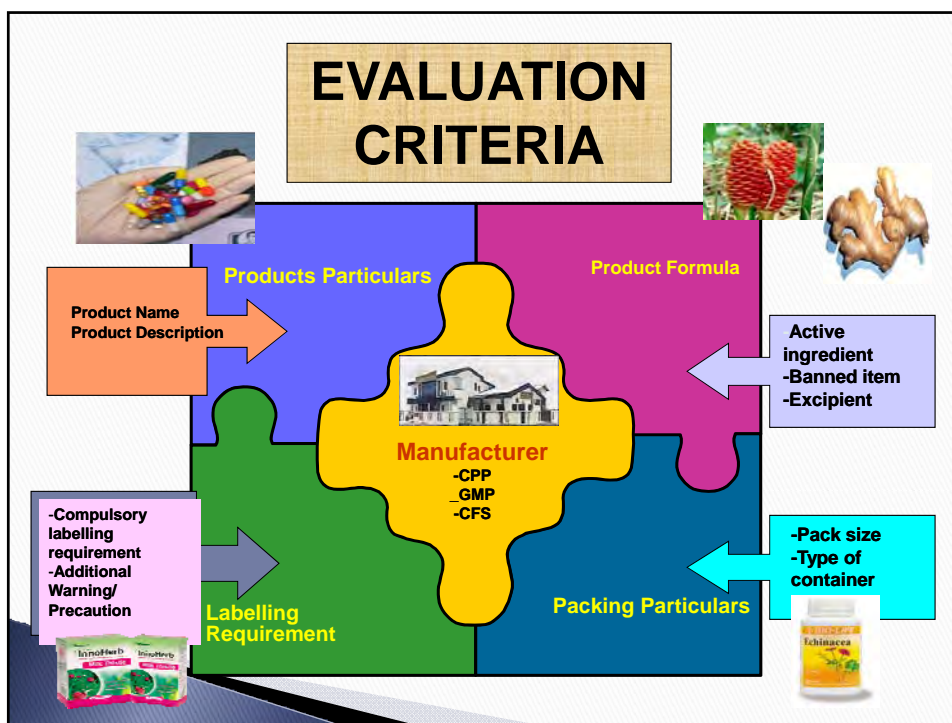
- ▶ ADULTERATION
- ▶ ILLEGAL MANUFACTURING
- ▶ UNREGISTERED PRODUCTS
- ▶ MISLEADING ADVERTISEMENT
 - ▶ MISLEADING CLAIMS
 - ▶ PREMIX
- ▶ CONTRACT MANUFACTURING

REASONS FOR REJECTION

- Incomplete documentation
- Lack of documentation /data
- Contains prohibited ingredients
- Indications not allowed
- No marketing authorization
- GMP non-compliance
- Inappropriate combinations
- Failed laboratory tests

CONCLUSION





Thank You For Your Attention

BAHAGIAN PERKHIDMATAN FARMASI
BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN (BPFK)

www.pharmacy.gov.my www.bpfk.gov.my

KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH
www.moh.gov.my

WHO COLLABORATING CENTRE
IN REGULATORY CONTROL
OF PHARMACEUTICALS

PACIS PHARMACEUTICAL INSPECTION
COOPERATION SCHEME

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