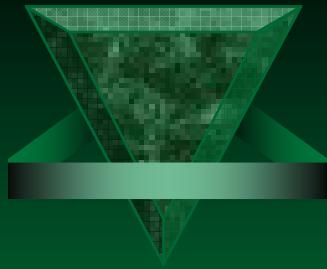




DEVELOPMENT OF TRADITIONAL MEDICINES IN MALAYSIA

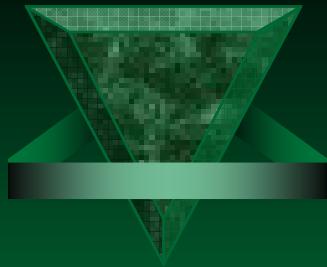
AROGYA 2007
NEW DELHI
26-28 OCT 2007



CONTENTS

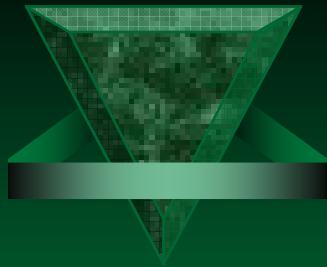


- ✓ *Introduction*
- ✓ *Legislation*
- ✓ *Registration Criteria*
- ✓ *Safety and Quality Criteria*
- ✓ *Post-market Surveillance and Pharmacovigilance*
- ✓ *Current Developments*



Malaysia's Healthcare System

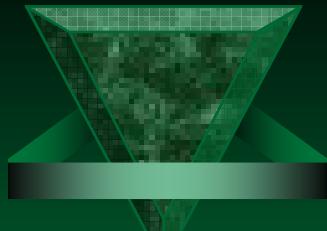
- Based on western medical sciences
- Multi-ethnic, multi-cultural and multi-religious background
- Traditional medicine – significant role in primary healthcare
- Vision and Mission for Health
- National Policy on T/CM – emphasis on practice, education and training, raw materials and products, and research
- Healthcare integration- T/CM into allopathic healthcare system
- Strategies -T/CM Standing Committee, National Committee for R&D on Herbal Medicines, Drug Control Authority



Traditional Medicines

Different T/CM due to different cultural and ethnic origins:

- Chinese
- Indian (Ayurveda, Unani, Siddha)
- Malay /Indonesian
- Aborigines
- Homeopathy

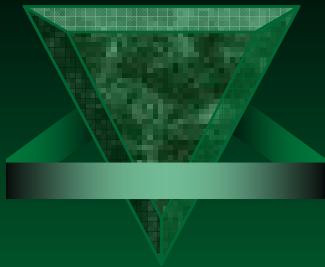


T/CM IN MALAYSIA

- According to WHO, up to 80% of the world's population still depend heavily on TCM for treatment. In Malaysia, WHO estimated that USD500 million is spent annually on this type of health care, compared to about USD300 million on allopathic medicine.

- The local interest in TCM is reflected in the large number of these products submitted for registration with NPCB.

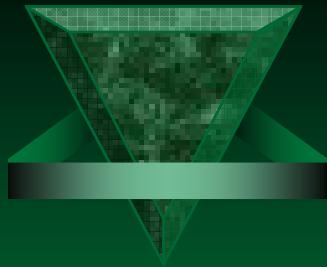
- Traditional medicine in Malaysia is projected to expand with a growth of 15 – 20% annually driven by:
 - Accessibility and affordability.
 - Govt's support and plans to provide a global information hub on traditional medicine.
 - Integrated hospitals



TRADITIONAL MEDICINES

- ✓ Some products are used as health supplements as well as for treatment of benign, self limiting conditions
- ✓ Others are used to self treat serious illnesses
- ✓ Products are widely advertised over the Internet and through the mass media

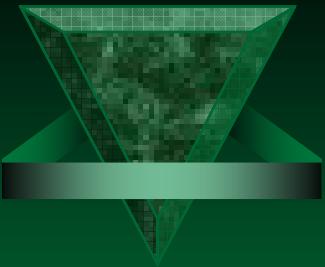




“IT IS NATURAL, THEREFORE IT IS SAFE”

- ✓ Common misnomer
- ✓ Impossible to ensure that all medical interventions including traditional medicines are entirely risk-free
- ✓ Numerous reports of adverse effects associated with the use of TM





KEMENTERIAN KESIHATAN MALAYSIA

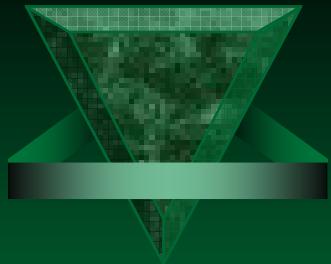


LEGISLATION

**The Control of Drugs and Cosmetic
Regulations 1984 was promulgated under the
Sale of Drugs Act 1952 (Revised 1989)**

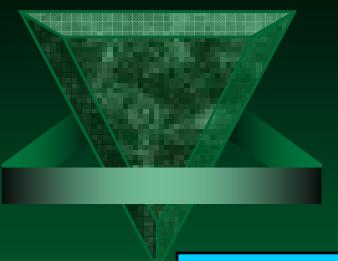
REGULATION 7(1)

**No person shall manufacture, sell, supply,
import or possess for sale any product unless,
•the product is a registered product ;
•the person holds the appropriate licence issued
under this regulation**



LEGISLATION

- *Control of Drugs and Cosmetics Regulations 1984*
- *Poisons Act 1952 (rev. 1989)*
- *Sales of Drugs Act 1952 (rev. 1989)*
- *Dangerous Drug Act 1952 (rev. 1980)*
- *Medicines (Advertisement and Sale) Act 1956 (rev. 1983)*
- *Others – Wildlife Protection Act 1972 , Patent Act 1983, Trade Description Act 1972, Pesticides Act 1974, Food Act 1983 and Food Regulations 1985*



Registration Phases

Registration and licensing of Drug and Cosmetic Products

Phase I	Phase II	Phase III	Phase IV	Phase V
SCHEDULED POISONS	OTC/ NON POISONS	TRADITIONAL MEDICINES	COSMETICS	VETERINARY
<p>Date of Commencement:</p> <ol style="list-style-type: none">1. Registration 1.11.852. Licensing 1.05.87	<p>Date of Commencement:</p> <ol style="list-style-type: none">1. Registration 1.08.882. Licensing 1.04.92	<p>Date of Commencement:</p> <ol style="list-style-type: none">1. Registration 1.01.922. Licensing Manufacturers & Importers (1.1.99), Wholesalers (1.7.2002)3. Surveillance 2000	<p>Date of Commencement:</p> <ol style="list-style-type: none">1. Hair Dyes : 19912. Tooth Whiteners : 19963. All others : 1.2.20024. Licensing : 1.1.2004	<p>2003-2004: Preparation of Guideline</p> <p>2005: Industry Consultation</p>



TRADITIONAL MEDICINE

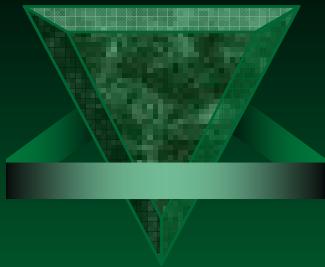
Means any product employed in the practice of indigenous medicine, whereby the drugs used only consist of one or more naturally occurring substances of plant, animal or mineral or part thereof, or extract form or non-extracted form, and any homeopathic medicine.



REGISTRATION PROCESS

- *Classification*
- *Web-based on line application system- Quest2*
- *Evaluation – Criteria*
 - safety and quality
 - CPP, CFS, GMP compliance
 - sample testing
- *Approval – Certification*
- *Rejection – Appeal*





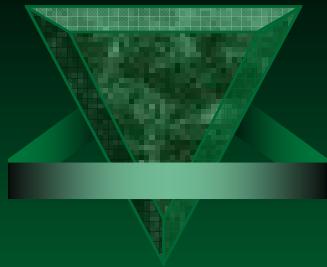
PURPOSE OF REGISTRATION

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

- ✓ Quality
- ✓ Efficacy
- ✓ Safety

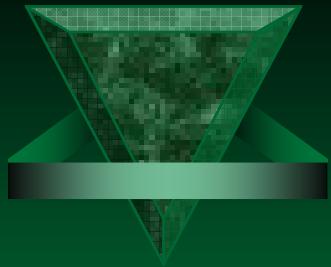


Quest



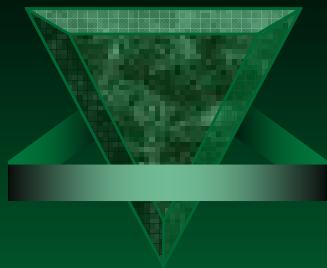
QUALITY CRITERIA

- ✓ Compliance to Good Manufacturing Practice (GMP) / Manufacturing Process
- ✓ Stability studies
- ✓ Limits for disintegration time
- ✓ Uniformity of weight
- ✓ Evidence of marketing authorization

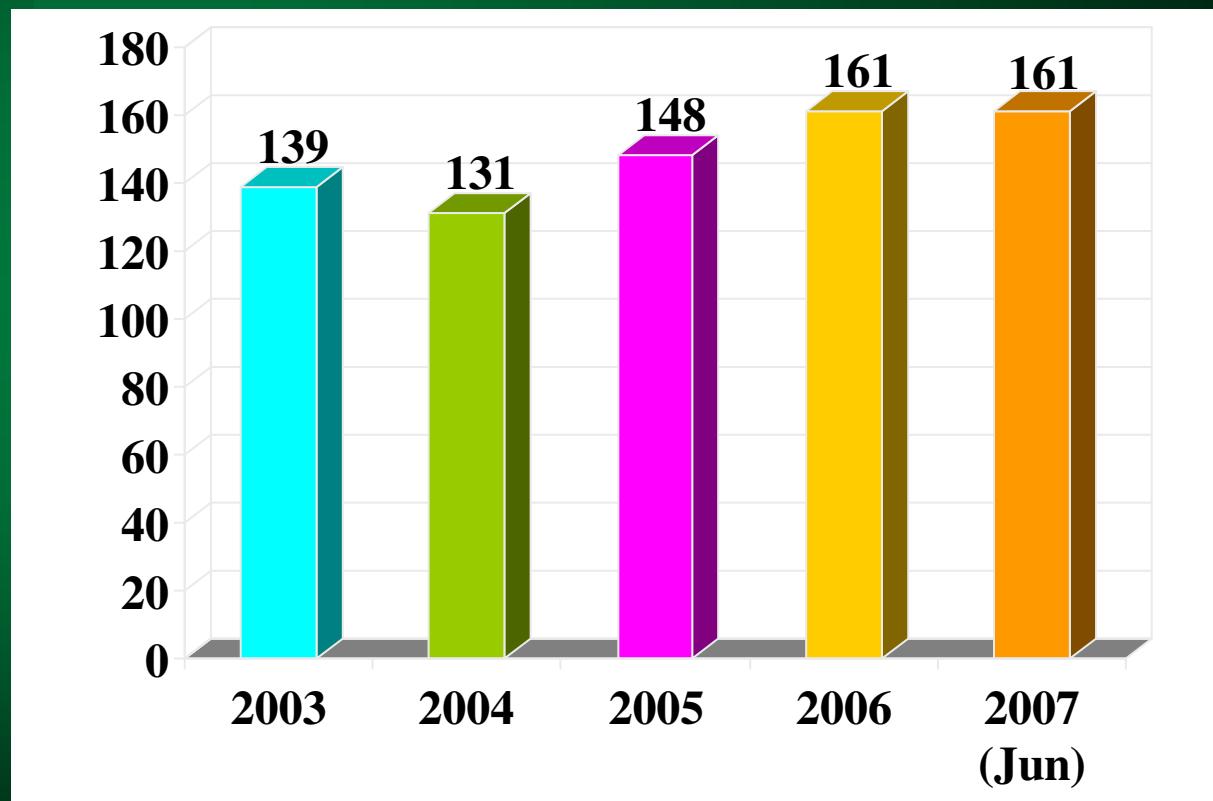


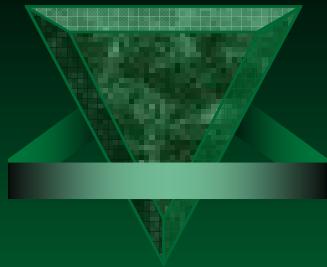
BASIC GMP REQUIREMENT

- 1. Quality Management**
- 2. Personnel**
- 3. Premises and Equipment**
- 4. Documentation**
- 5. Production**
- 6. Quality Control**
- 7. Contract Manufacture and Analysis**
- 8. Complaints and Product Recall**
- 9. Self Inspection**



Number of Traditional Manufacturing License (2003 - Jun 2007)

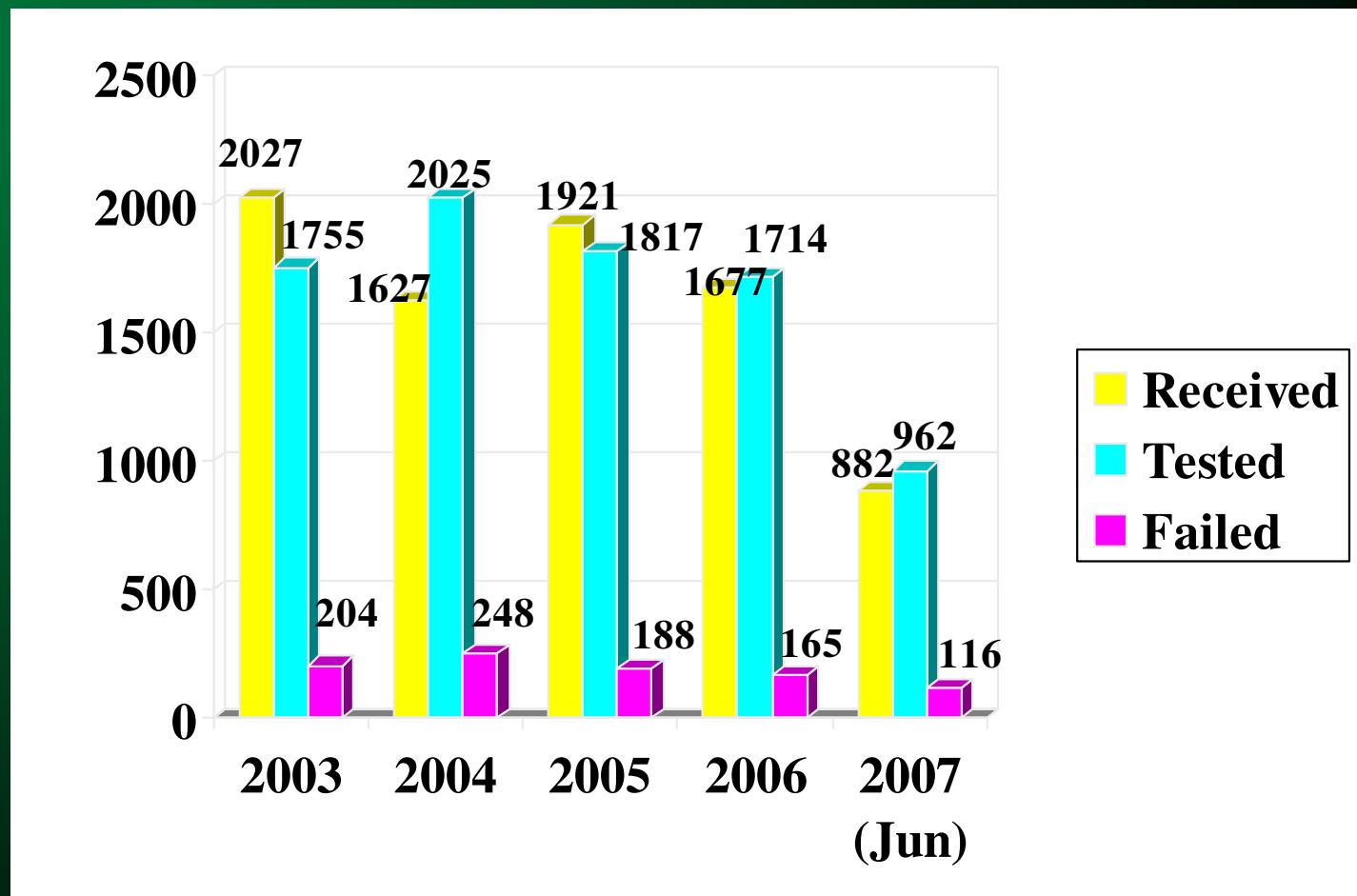




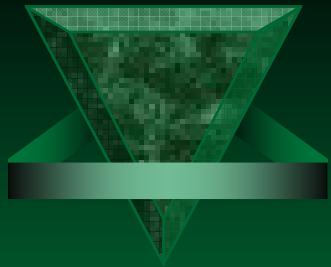
SAFETY CRITERIA

- ✓ Limits for heavy metals
- ✓ Limits for microbial contamination
- ✓ Absence of steroids and other adulterants
- ✓ Indications and claims
- ✓ Prohibition of herbs / ingredients with known adverse effects
- ✓ Labelling

Number of Products Tested 2003 - 2007 (Jun)



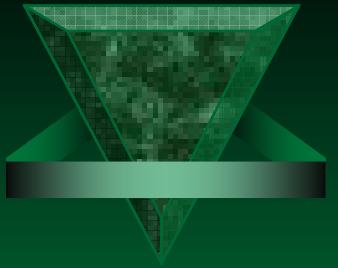
	2003	2004	2005	2006	2007
% Failed	11.6 %	12.2 %	10.3 %	9.6 %	12.1 %



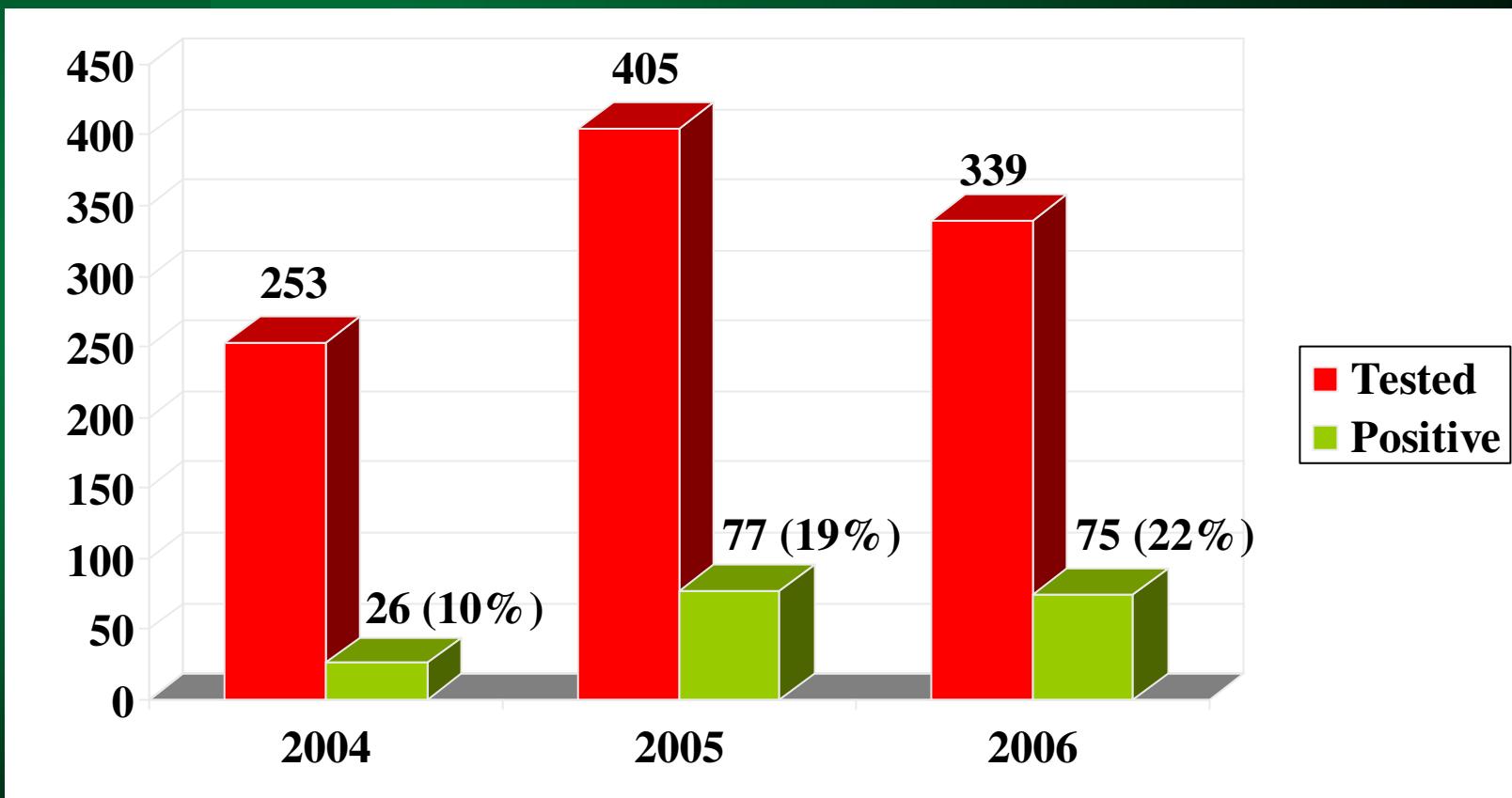
Screening for Adulterants

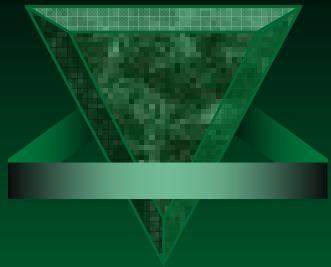
Based on product indications:

- ✓ men's health
- ✓ slimming
- ✓ muscle and joint pains
- ✓ cough and cold



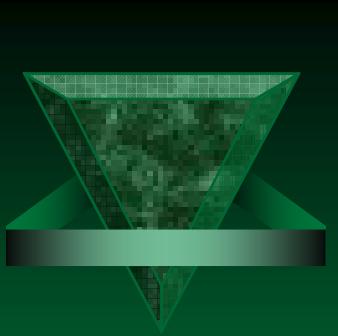
Number of Adulterant Tested 2004 - 2006





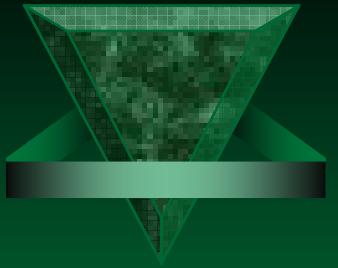
Indications and Claims

- ✓ Low –level claims
(supported by documents on traditional use).
- ✓ 20 (related) diseases in the Medicines (Advertisement and Sale) Act not allowed

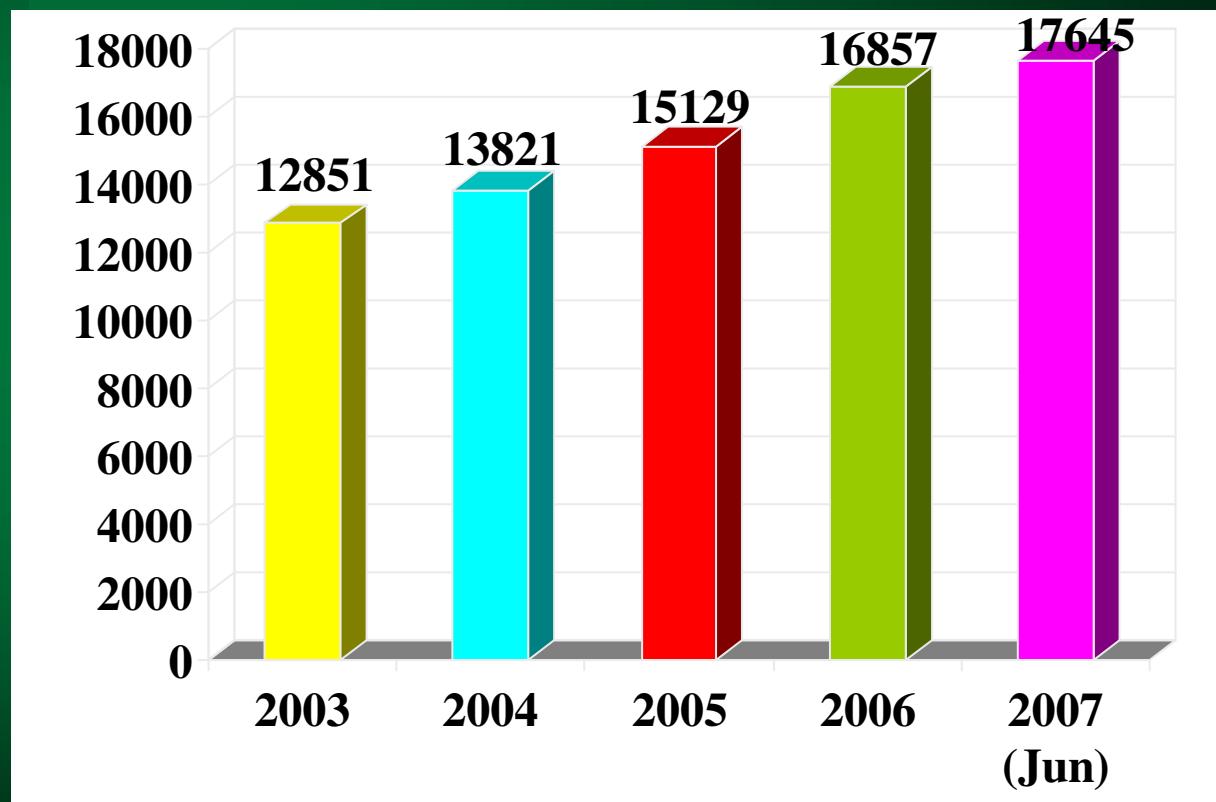


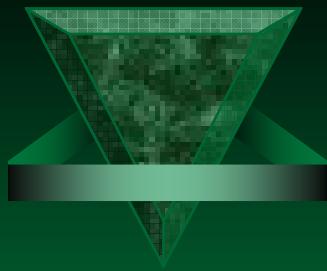
Number of Applications Received 2003 - 2007 (Jun)



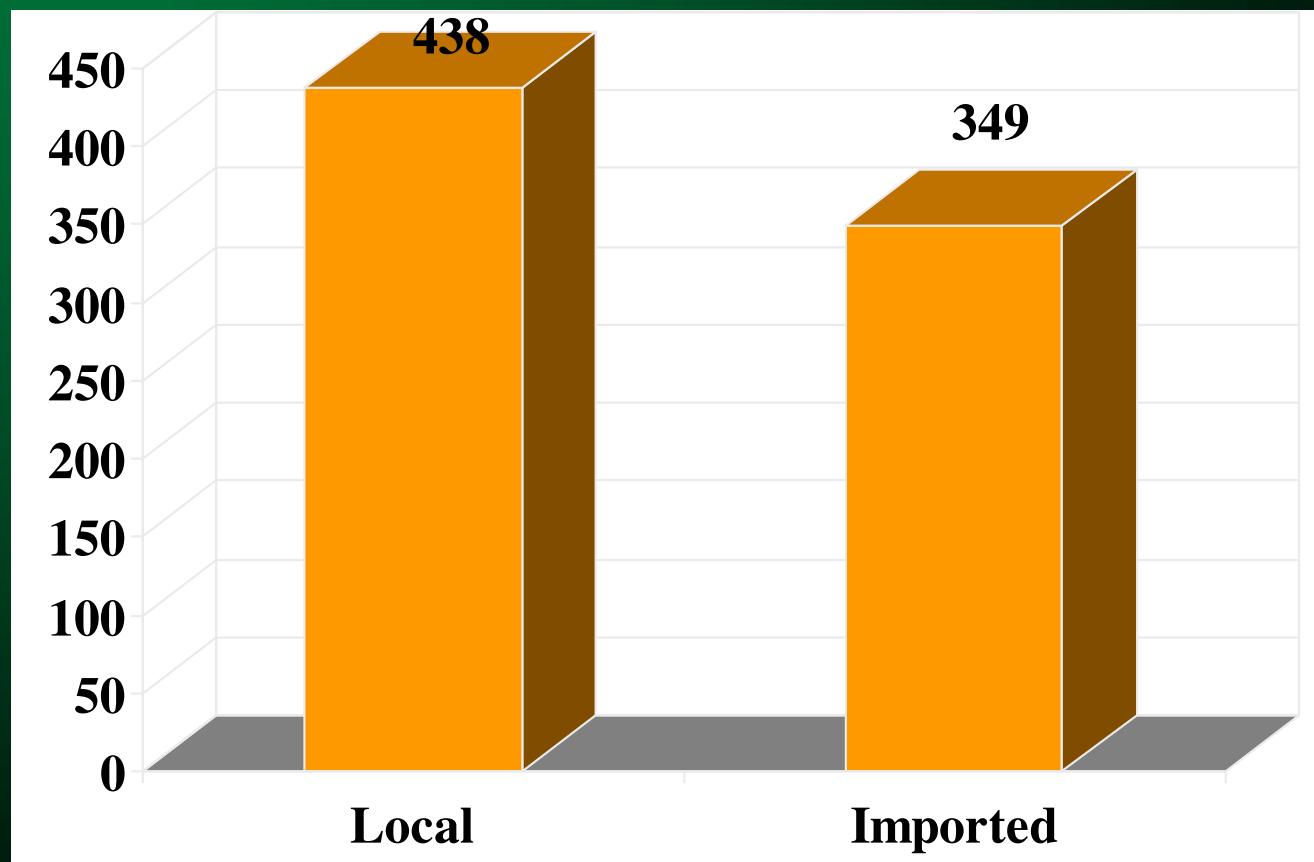


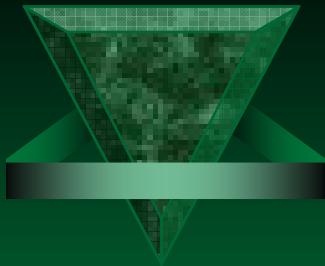
Number of Products Registered 2003 - 2007 (Jun)





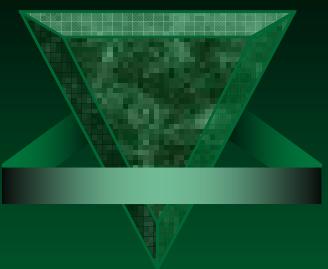
Local vs Imported Products Jan - Jun 2007



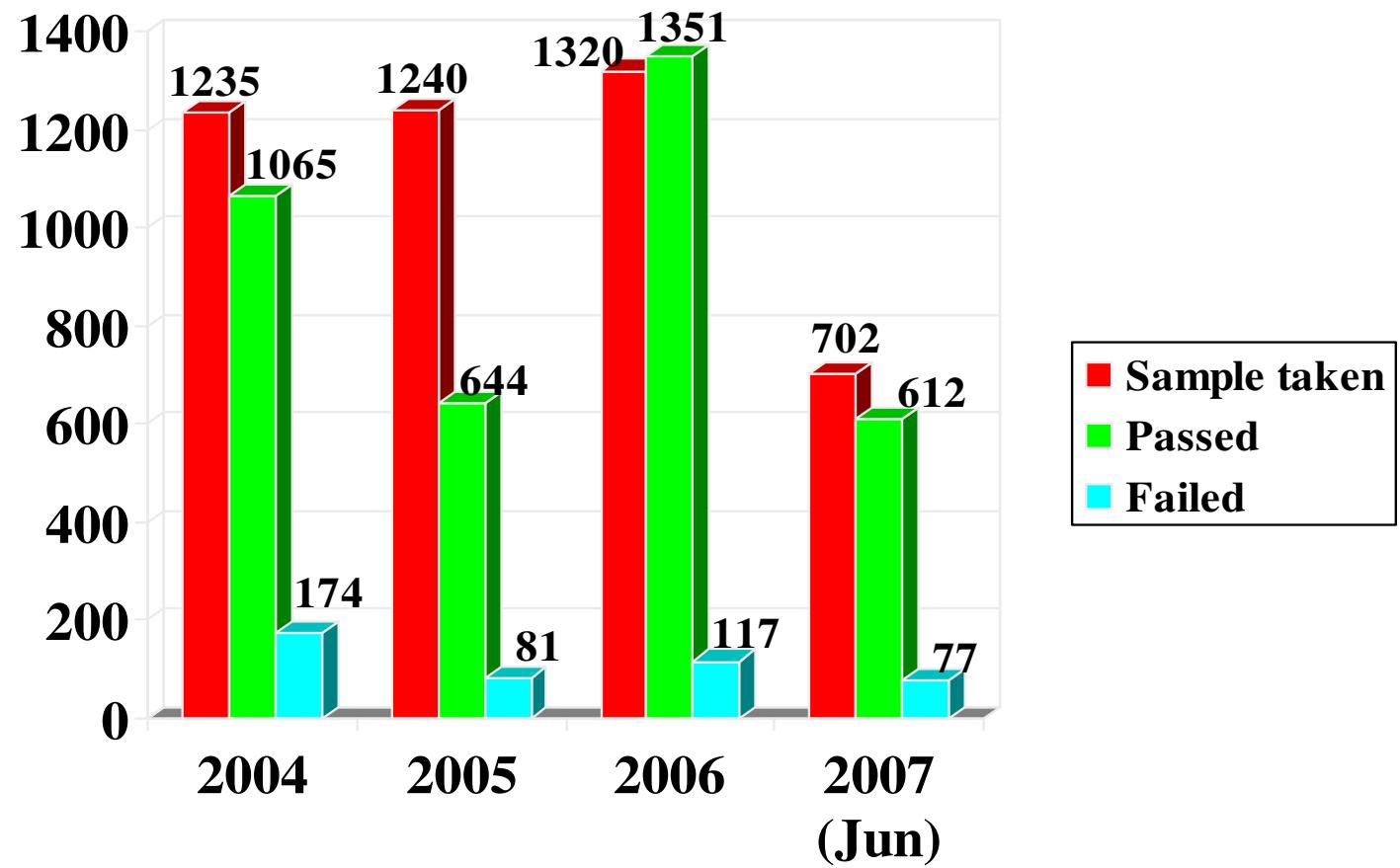


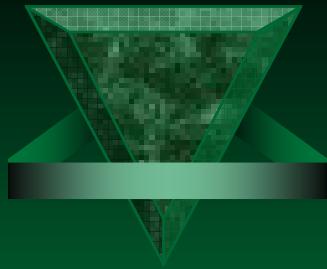
POST-MARKET SURVEILLANCE AND PHARMACOVIGILANCE

- ✓ To monitor all the product that had been registered in Malaysia
- ✓ Complaint investigation
- ✓ To recall stock or batch which is unsatisfied
- ✓ To monitor safety profile of registered product.



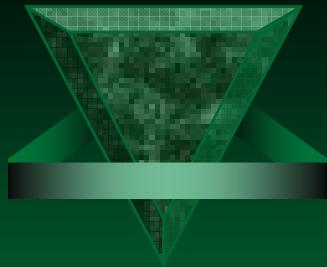
Post Market Activities (2004 – Jun 2007)





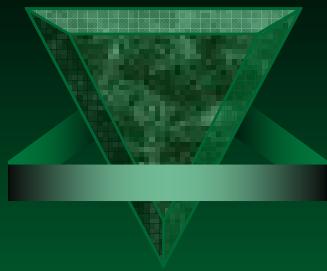
PUNITIVE ACTIONS

- **product recall**
- **warning**
- **cancel / suspend product registration**
- **revoke license**



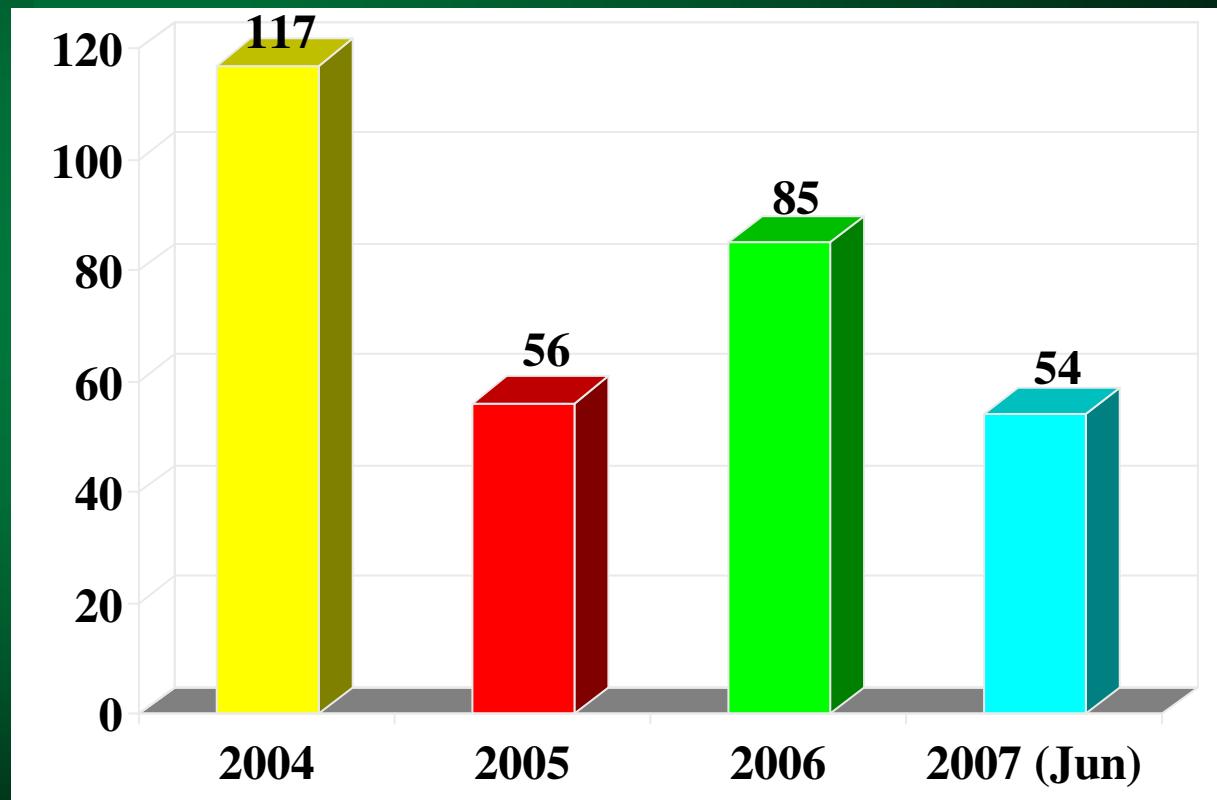
CAUSE / REASON OF RECALL

- ✓ Product tested contains microorganism more than approved limit
- ✓ Adulterated product
- ✓ Failed one of the laboratory test
- ✓ Can cause serious adverse effect
- ✓ Quality of the product not up to expectation

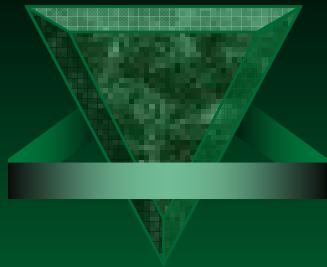


Number of Product Recalls*

(2004 – Jun 2007)

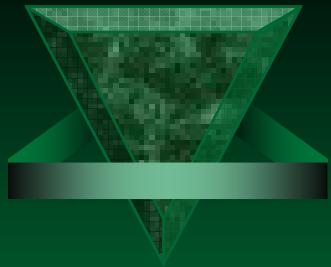


* Recall Level 111



PROBLEMS AND ISSUES

- ✓ Adulterations (Premixes)
- ✓ Illegal manufacturing / Contract Mfg
- ✓ Unregistered / counterfeit products
(Hologram)
- ✓ Misleading advertisements / Exaggerated claims
(Malaysian Advertisement Board)
- ✓ Adverse Drug Reactions (ADRs Reporting)



CURRENT DEVELOPMENTS

- ✓ ASEAN Harmonization initiatives for Traditional Medicines and Health Supplements (ACCSQ TMHS PWG)
- ✓ Safety monitoring - system for consumer reporting of ADRs for over-the counter and traditional medicines products
- ✓ Rapid Alerts
- ✓ QC facilities (Manufacturers)
- ✓ ISO 17025 certified laboratories



WEBSITES

- Pharmaceutical Services Division :
www.pharmacy.gov.my
- National Pharmaceutical Control Bureau
www.bpfk.gov.my
- Malaysian Adverse Drug Advisory Committee (MADRAC) :
www.madrac.gov.my/madrac





THANK YOU

