



Kementerian Kesihatan Malaysia

Trending of Adulteration – ADR in Traditional Medicine & Health Supplement (TMHS) Products

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**WHO Collaborating Centre
For Regulatory Control of Pharmaceuticals**



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Overview

- Introduction
- Adulterant screening in NPCB
- ASEAN Post Marketing Alert System (PMAS)
- Adverse drug reactions associated with adulterated TMHS Products
- Challenges
- Conclusion



MS ISO 9002 REG. No : AP 1171

Introduction

- The use of TMHS products (a.k.a. Natural Health Products in some countries) is growing.
- Widely available in stores and on the internet.
- The World Health Organizations reported that 80 percent of the world's population depends on herbal medicines.
- In Malaysia total of 21807 (TM) and *329 (HS) product being process and registered (cumulative figure)

* 2011 new code for HS



Traditional Medicine and Health Supplement Products (TMHS)

- **Traditional medicine** as defined under the Control of Drugs and Cosmetics 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 thereof, in the un-extracted or crude extract form, and a homeopathic medicine



Traditional Medicine and Health Supplement Products (TMHS)

- **A Health Supplement (HS)** means any product that is used to supplement a diet and to maintain, enhance and improve the health function of human body. It is presented in small unit dosage forms (to be administered) such as capsules, tablets, powder, liquids and shall not include any sterile preparations (i.e. injectables, eyedrops).
- TMHS have been subjected to pre-market approval and licensing for import and sale in Malaysia since 1992.
- Governed by various Acts
 - Poison Act, 1952, Sale of Drugs Act 1952; Dangerous Drugs Act 1952; Medicines (Advertisement & Sale) Act 1956



Traditional Medicine and Health Supplement Products (TMHS)

- Currently, method of evaluation for traditional medicines (TM) and health supplements (HS) – abridge evaluation
- Products with certain claims will be subjected to adulterant screening such as;
 - ✓ Men's health e.g. sildenafil, tadalafil, analogues
 - ✓ Slimming e.g. sibutramine, fenfluramine
 - ✓ Muscle and joint pains e.g. NSAIDs, steroids
 - ✓ Cough and cold e.g. antihistamines
- Heavy metal analysis (routine test for TM)
- Microbial test (routine test for TM)



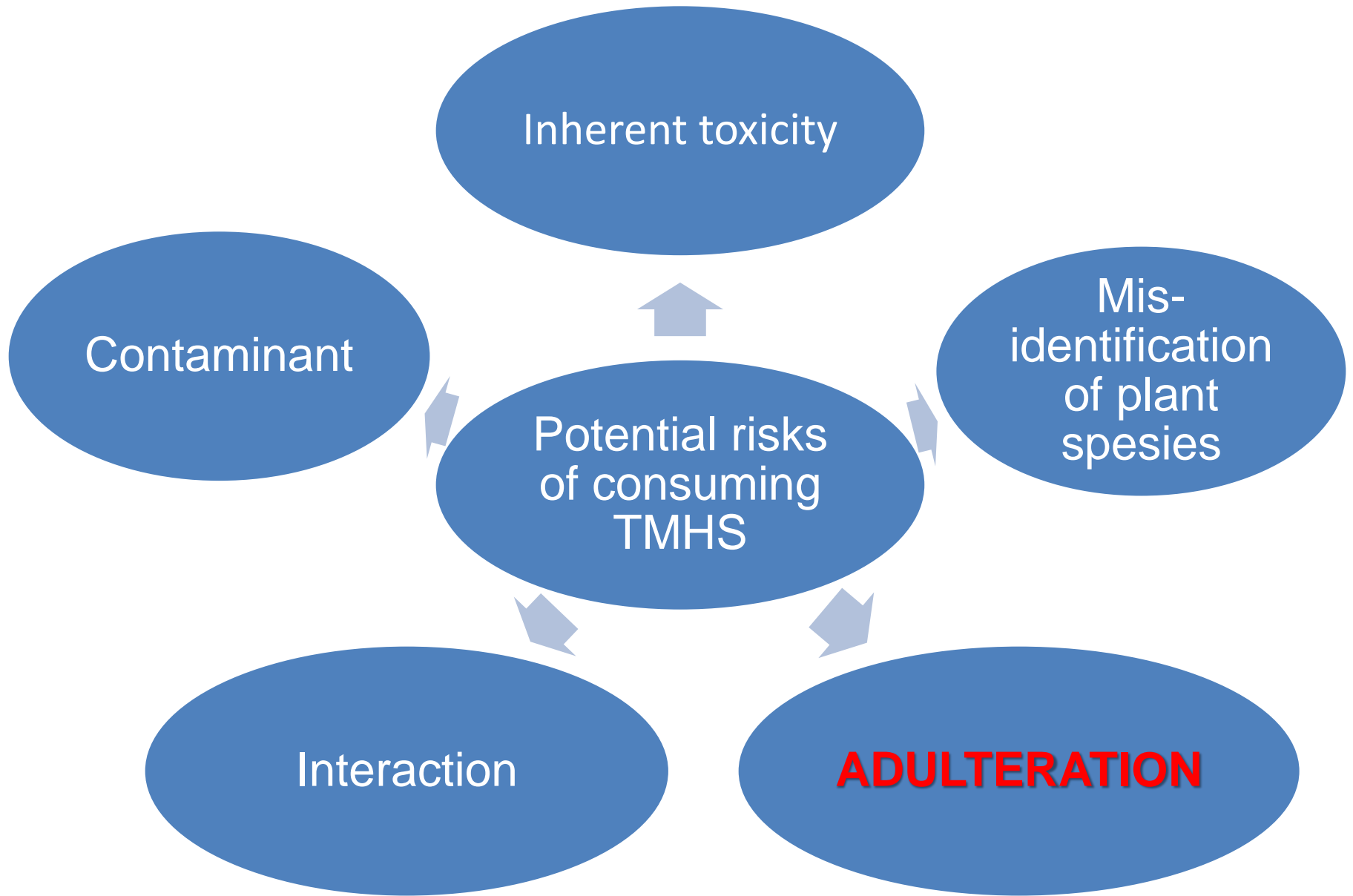
Why TMHS is popular?

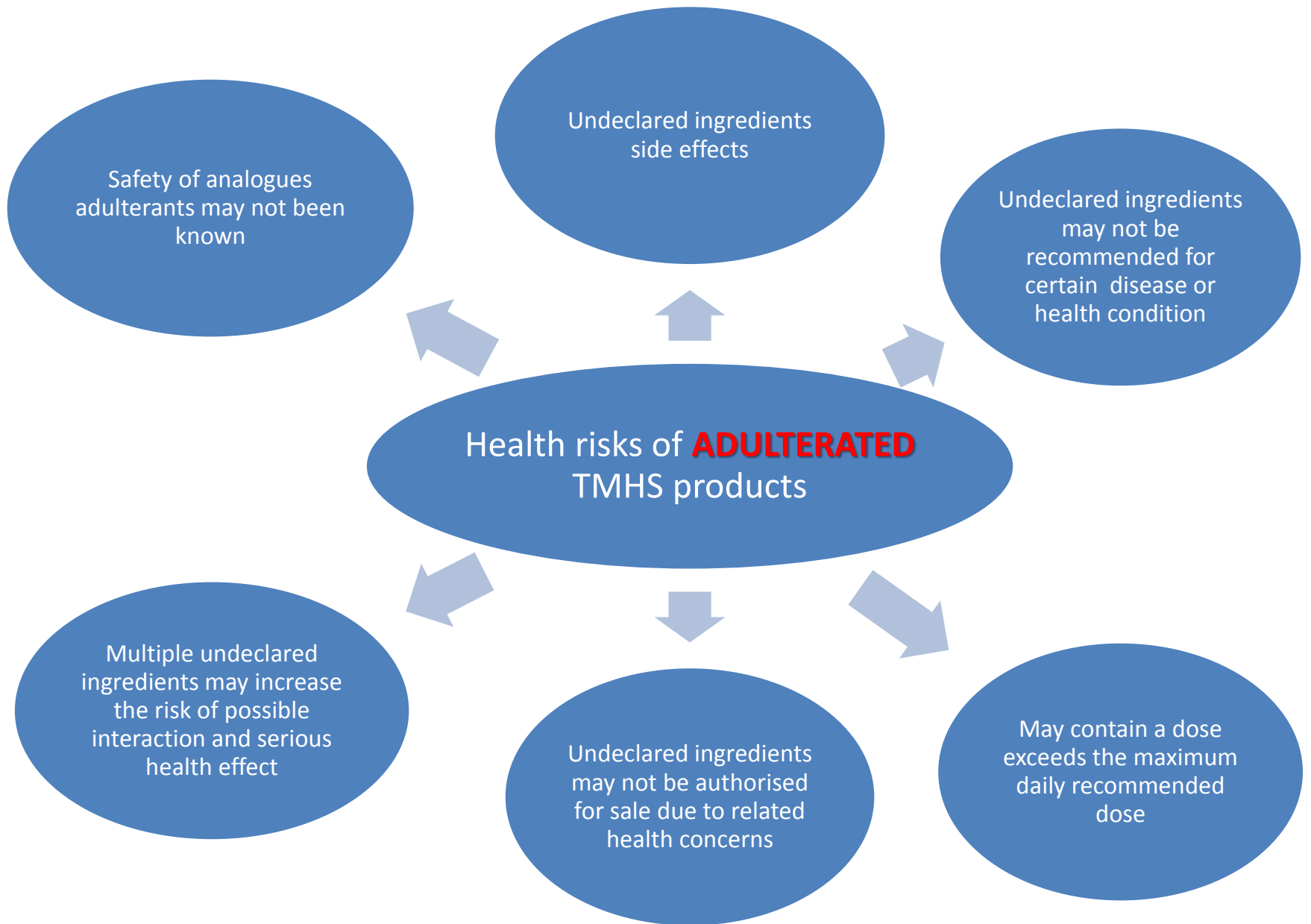
- The perception of “natural means safe”. & “no side effect” (on long tradition of use history)
- Exaggerated claims of the products in the advertisement *via* internet and multi-level marketing implies as ‘cure for all” product.
- Many consumers want to find alternatives to allopathic medicines as result of their potential side effects especially for those with chronic illnesses.



Is TMHS really safe?







Adulteration of TMHS products

- Products that are adulterated contains substances that are not declared on the label, including scheduled poison medicines or other potentially dangerous ingredients.
- It is considered as one of causes to the ADR cases.
- Consumer highly demand health products such as for weight loss, sexual enhancement, inflammatory conditions, treatment of diabetes have been considered the high risk products to be adulterated



Adulterant screening in NPCB



Adulteration Screening Unit

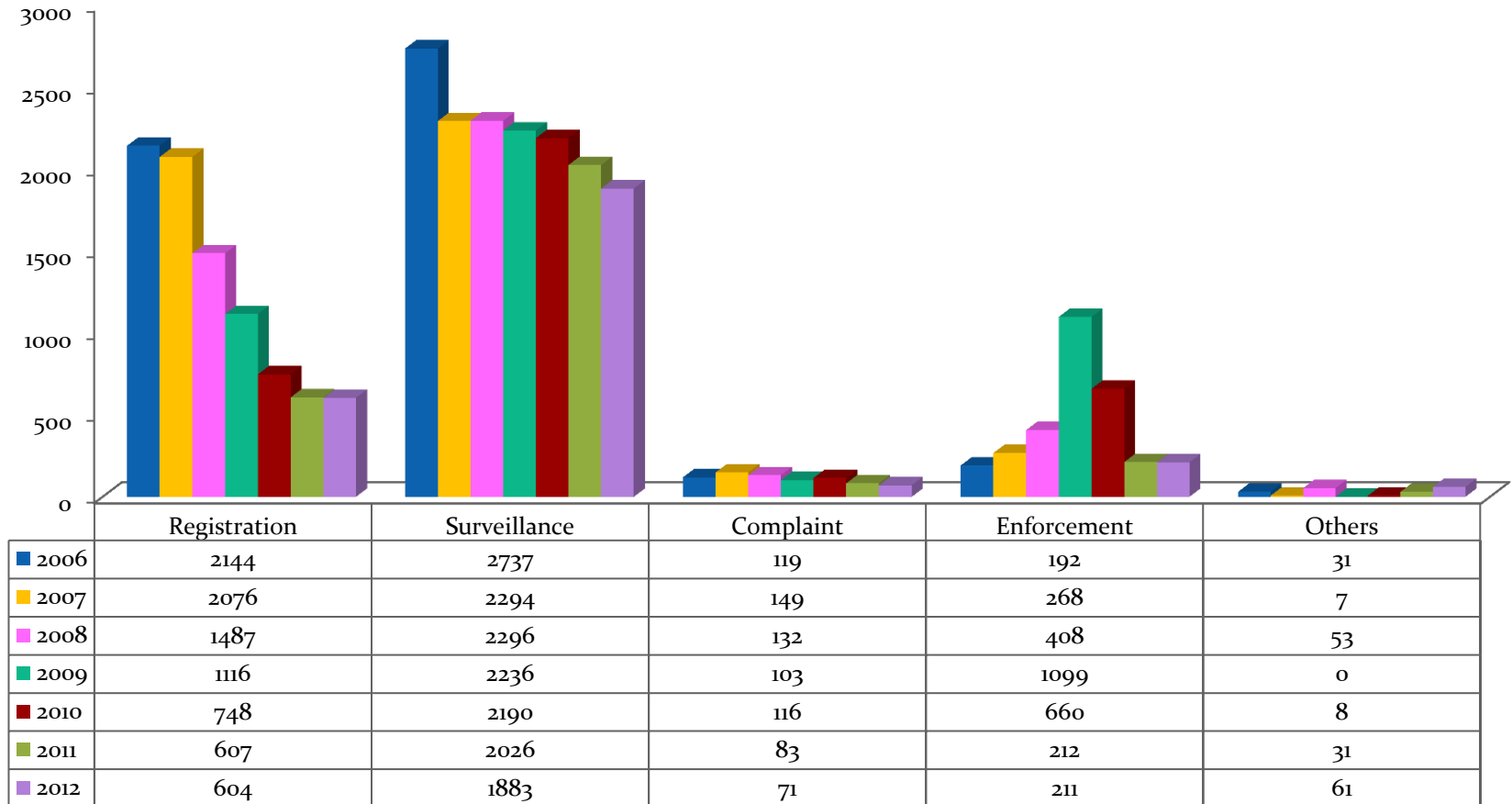
Responsibility

- Screening of adulterant in sample for:-
 - Registration
 - Surveillance
 - Enforcement
 - ADR
 - Complaint



Sample received

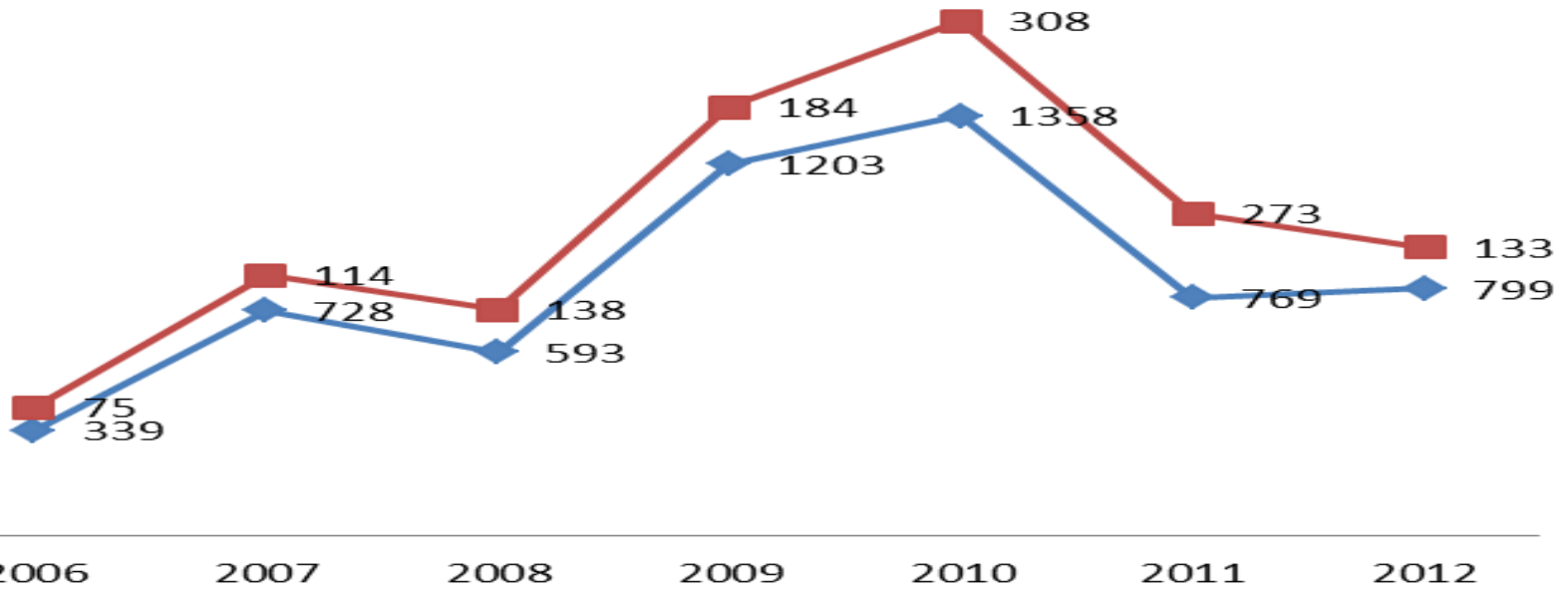
Number of Samples Received by Category (2006 -2012)



Statistic on adulterated samples

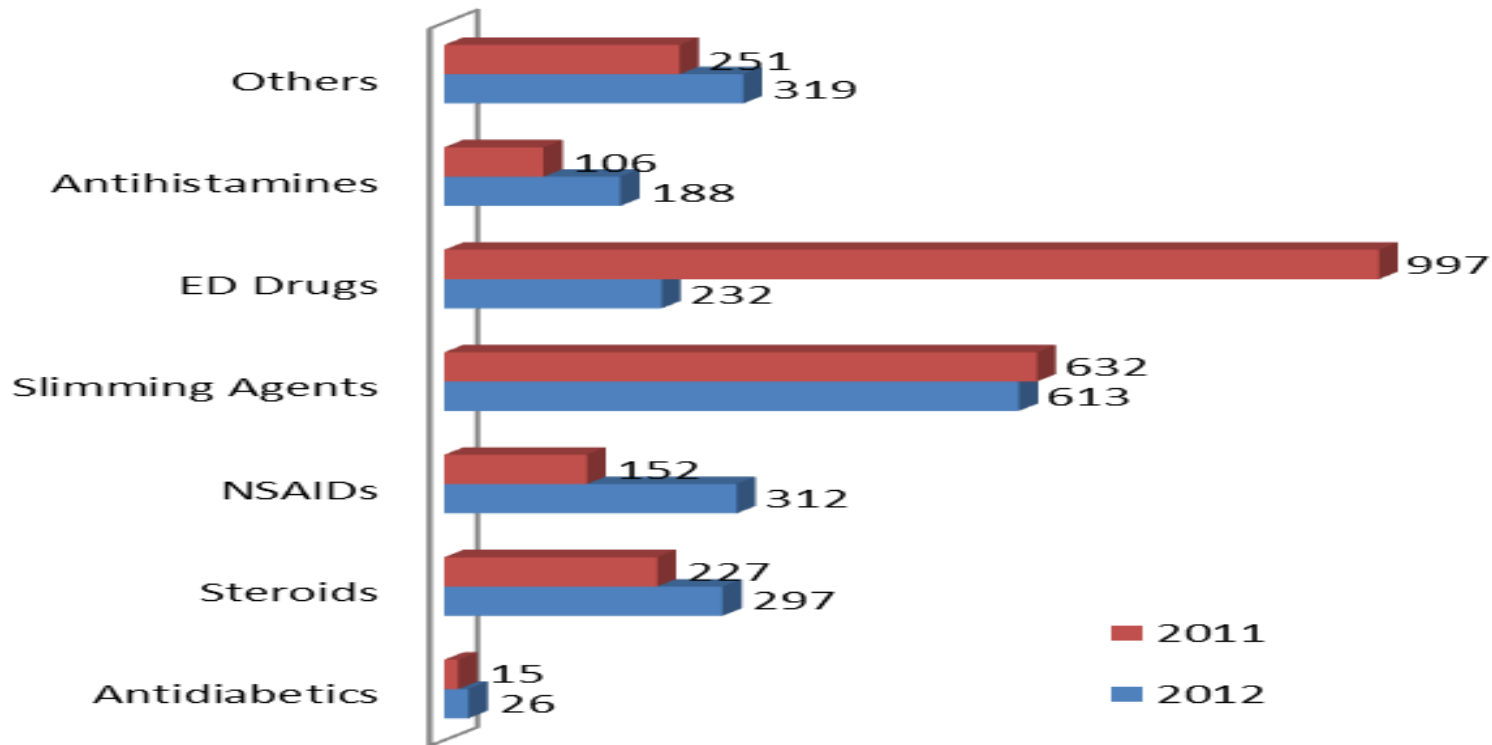
Number of Samples Tested and Adulterated (2006-2012)

—◆— No. of samples tested —■— No. of samples adulterated



Statistic on adulterated samples

No. of Test Done for Different Types of Adulterants (2011-2012)



Categories of adulterant

- Steroid
- Non-steroidal anti-inflammatory drugs (NSAIDS)
- ED drugs
- Slimming agents
- Antihistamine
- Antidiabetic
- Statin



Popular adulterants

Steroid

Dexamethasone

Erectile dysfunction drugs

Sildenafil, tadalafil dan **analog**

Antihistamine

Chlorpheniramine, dextromethorphan, promethazine

NSAIDs

Phenylbutazone

Analgesic

Paracetamol

Slimming Agents

Sibutramine, N-desmethylsibutramine

(**analog sibutramine**)

Antidiabetic

Metformin, Glibenclamide, **Ripaglinide**

Statin

Lovastatin



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Combination of adulterant

- Chlorpheniramine + Dexamethasone
- Dexamethasone + Ibuprofen + Chloramphenicol + Chlorpheniramine
- Chlorpheniramine + Dexamethasone + Betamethasone + Prednisolone
- Paracetamol + Phenylbutazone
- Promethazine + Dextromethorphan + Chlorpheniramine
- Dexamethasone + Chlorpheniramine + Dextromethorphan
- Dexamethasone + Chlorpheniramine + Dextromethorphan + Promethazine



ASEAN Post Marketing Alert System (PMAS)



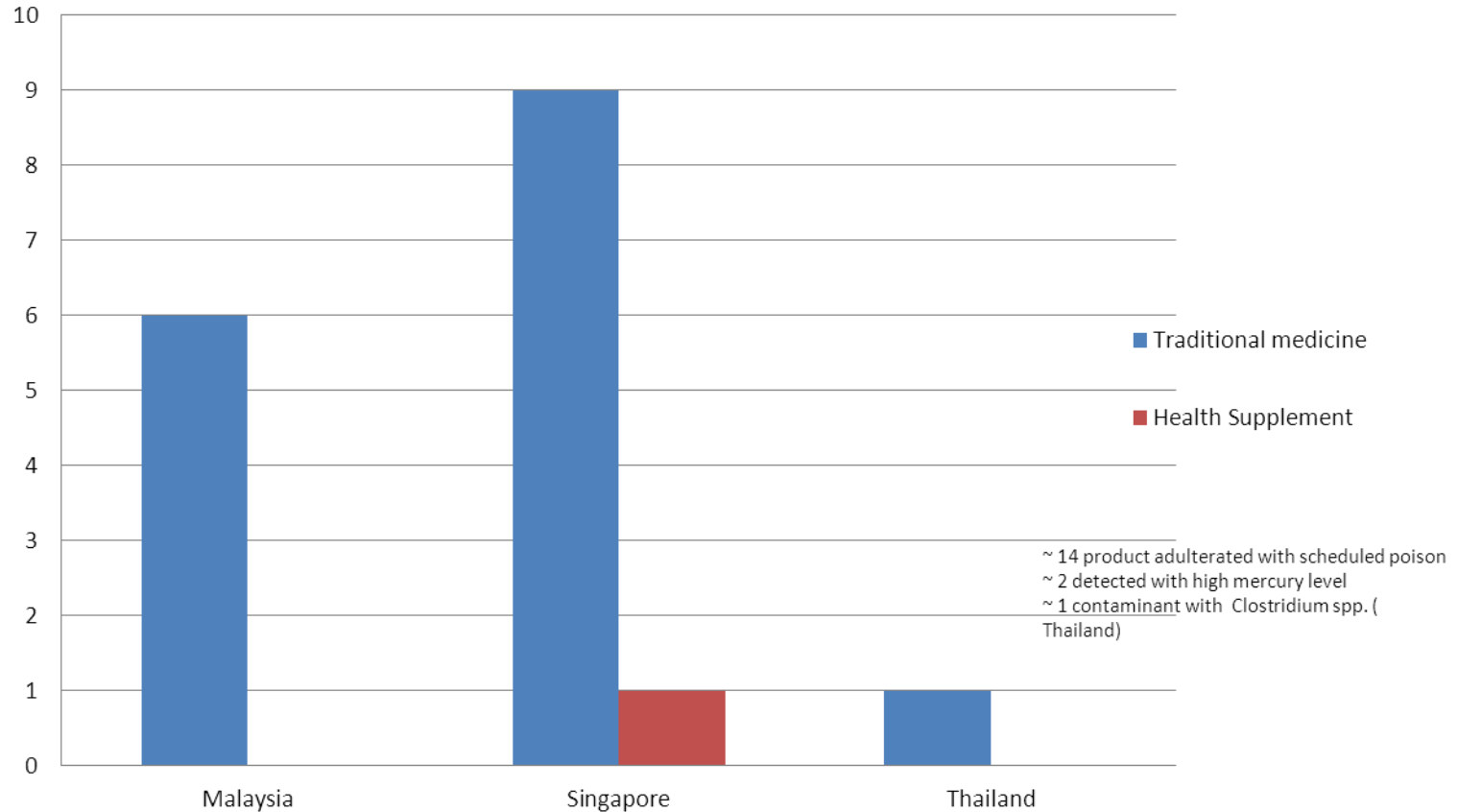
ASEAN PMAS

- Communication tools for ASEAN members in exchanging information with respect to health products especially involving in safety issues
- TMHS products also included in this activities and currently only few TMHS products reported under this tools.



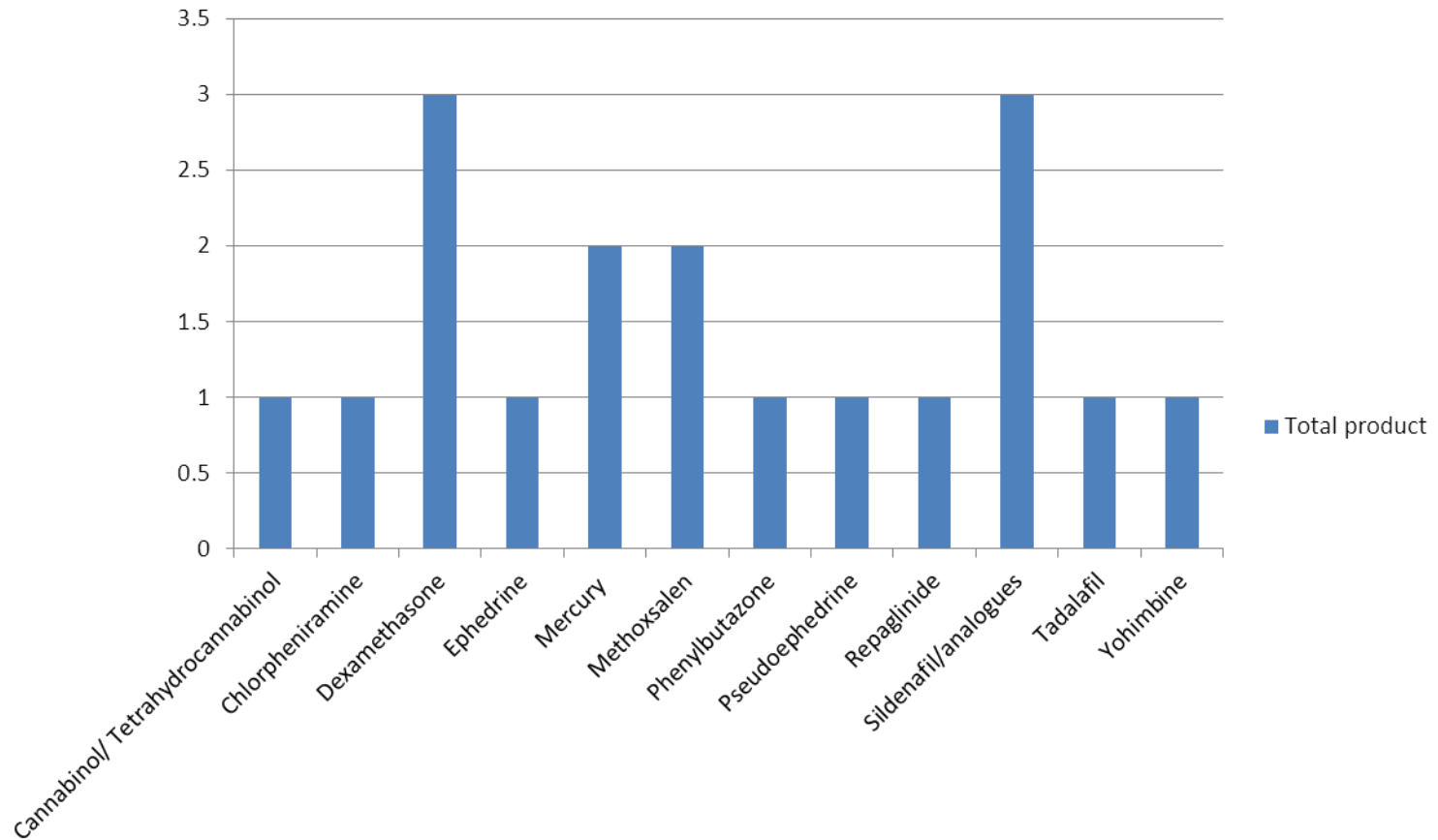
No. of alert under PMAS for TMHS products 2012 (Jan –Dis)

No. of alert under PMAS for TMHS 2012



Type of adulterants under PMAS for TMHS products 2012 (Jan –Dis)

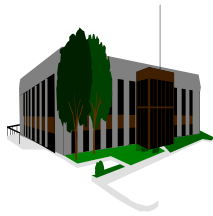
Type of adulterants detected under PMAS 2012



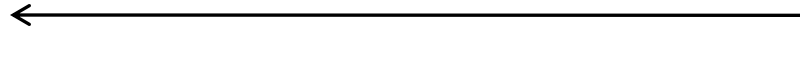
ADR associated with adulterated TMHS Products



ADR MONITORING SYSTEM IN MALAYSIA



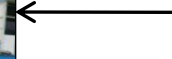
Feedback



ADR Report– Manual form:
faks (03-79567151), emel
(fv@bpfk.gov.my) & online
reporting via www.bpfk.gov.my



Feedback



Reporter:-

- a) Health professionals
- b) Product Registration Holder
- c) Consumer



National ADR
Monitoring Centre

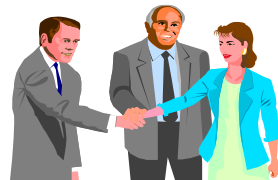
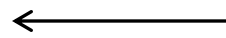


WHO



Malaysian ADR
Advisory Committee
(MADRAC)

Recommendation

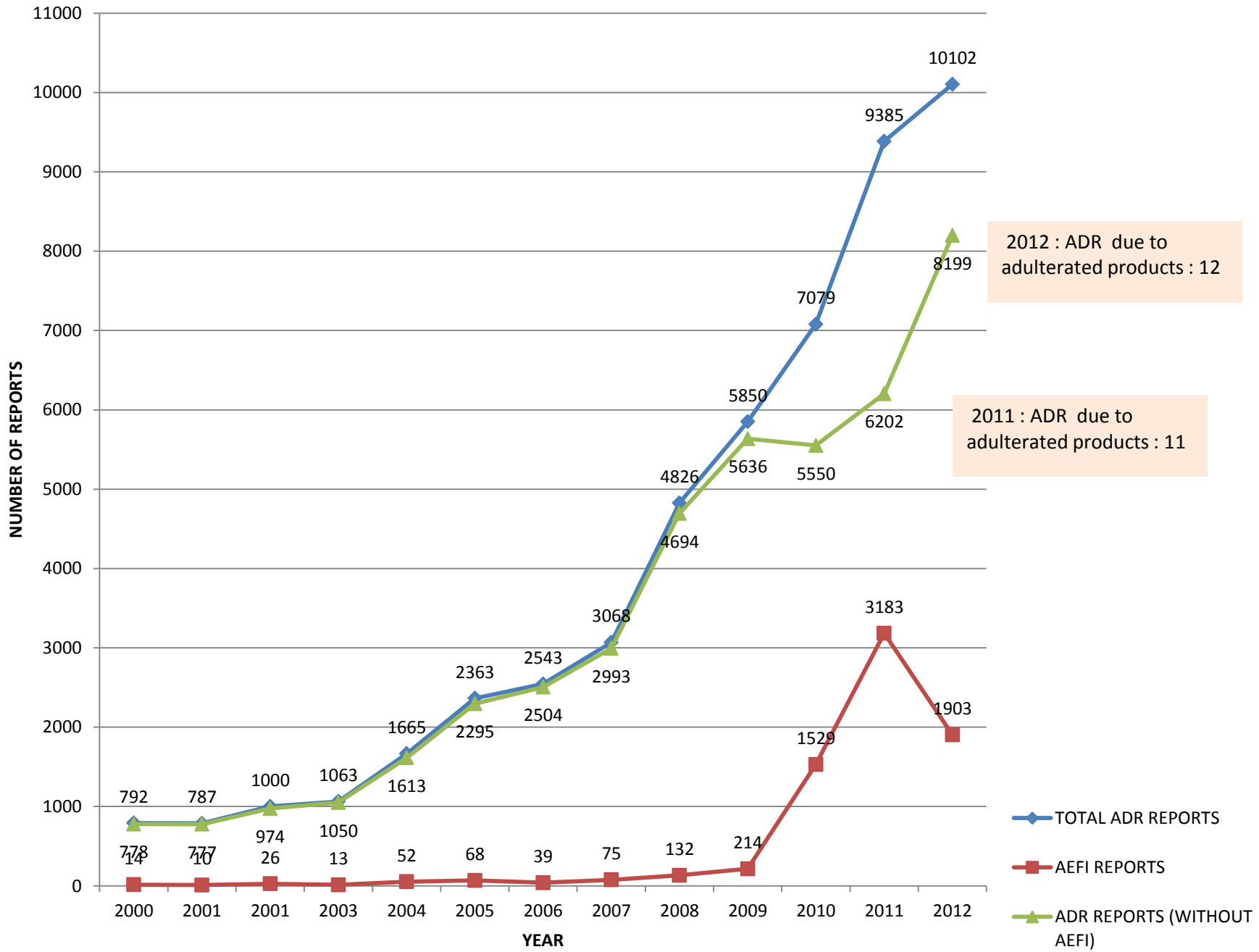


Drug Control
Authority (DCA)

Policy
Implementation



ADR REPORTS RECEIVED (YEAR 2000-2012)



Reported Cases

Famous adulterant detected in Malay Traditional Medicine product known as Makjun/Tonik



Dexamethasone, detected in various product 's name under medicine known as “Makjun” Majun Dua Istimewa, Maajun Burung Unta, Makjun Taufiq Dua Istimewa, Maajun Kuat Khasiat Sakit Pinggang & Maajun Tolak Angin



Reported Cases

No	Suspected Traditional Medicines (Adulterant)	Reported Reaction
1	Madu Adunan Herba (Dexamethasone)	Acute jaundice and hepatitis
2	Jamu Tradisional Asam Urat Jaya Asli (Phenylbutazone)	Epidermal necrolysis, Jaundice, Eosinophilia, Rash maculo-papular, Stevens Johnson's Syndrome, Dress Syndrome
3	Pil Haruan (Chlorpheniramine)	Unexpected Therapeutic Effect (general well being)
4	Air Ikan Haruan (Dexamethasone)	Hypotension, Pneumonia, Cushing's Syndrome
5.	Tonik Warisan Banjar (Dexamethasone)	Weight increase, moon face
6	Pil ibu gamat ratu mahsuri (Dexamethasone & Chlorpheniramine)	Unexpected Therapeutic Effect (Asthma)

Reported Cases

Adulterants detected in Traditional Chinese Medicine (TCM) product



- **Dexamethasone & Chlorpheniramine** detected in product name as Twin Bee Wang Ling
- **Dexamethasone** - Xue Ya Gao Zhong Feng Qing Cao Yao Cao
- **Dexamethasone & Chlorpheniramine** Seven Leave Ginseng



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Reported Cases

Adulterants detected & suspected in Traditional Chinese Medicine (TCM) product



- **Positive Piroxicam & suspected Cortisone** in product Ji Xue Teng

- For joint pain

ADR reported : Breath shortness



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Reported Cases

Adulterants detected in other unregistered products



Maca Tongkat Ali

ADR reported : Myalgia,
Joint Stiffness & Pain in
Limb

Positive : Tadalafil



Vimax Capsule

ADR Reported : Dizziness
& Eye pain

Positive : Sildenafil



PS-

ADR Reported : Blood
glucose decreased

Positive : Repaglinide

ADR due to adulterated food products

- **Adulteration with sex stimulant**

- Mentalk Candy
- Goji Yumberry Powder
- Hotton Vitality Candy
- Kopi Tenaga Tok Lebai Plus
- Kopi Pahlawan



- **Adulteration with anti obesity**

- Lax 9
- NP Trimz



Trending Summary

- An increasing trend over the years especially for the highly demand consumer products
- Implicated products mostly for **sexual enhancement, pain relieving, slimming** and **for increase energy products**
- Common adulterants were found to be therapeutic substances associated with the specific indications of the products such as adulterant for sexual enhancement drugs (sildenafil, tadalafil), pain relieving drugs (dexamethasone, piroxicam) and slimming drugs like sibutramine
- Foods and herbs which have been claimed to be aphrodisiacs also in trending to be adulterated with therapeutic substance.



Challenges

- Emerging of new therapeutic substances have been added as adulterants sometimes without any correlation with the product indication/ substances.
- Drug analogues in sexual enhancement & slimming products is alarmingly high. Such analogues are difficult to detect by ordinary laboratory methods.
- Adulteration in product fall under category of Food-Natural Health Product Interface ?? . Few products still under investigation food based product with added collagen, glutathione , botanical beverages
- Enhance the work systems in terms of work in close collaboration with other health stakeholders and various partners (agencies and community organizations)



CONCLUSION

Industry

Public

QUALITY, SAFETY
& EFFICACY

Health
Professionals

Regulators





Is everybody's responsibility!

Thank you for your attention

