REGULATORY CONTROL FOR HERBAL/TRADITIONAL MEDICINES AND HEALTH SUPPLEMENT PRODUCTS IN MALAYSIA

11th MARCH 2015
DATIN SHANTINI THEVENDRAN
COMPLEMENTARY SECTION, PPP, NPCB
CONTENTS

- Definition
- Product Registration Process
- Registration Criteria
- Safety, Quality, Efficacy / claimed benefits
- Statistics
Registration Phases

NEW PRODUCTS

Brochures 1985

Registration Aug 1985
(Prescription Drugs)

Licenses May 1987

Registration 1988
(OTC)

Licensing 1992

Registration Jan 1992
(Traditional Medicine)

Licensing Manufacturer
Importers Jan 1999

Registration Feb 2002
(Cosmetics)

Licensing Jan 2004

Registration Aug 2007
(Veterinary)

Licensing 1 Jan 2012

Surveillance 2000

Surveillance 2005

Surveillance (to be
announced)

Surveillance (to be
announced)

** Voluntary registration of API commenced in April 2011. Registration of generic API will be announced at a later date.

1st January 2008 – Registration of Cosmetics replaced by NOTIFICATION
What is a Traditional Medicine?

- **Traditional medicine** is defined as any product used in the practice of indigenous medicine, in which the drug consists solely of one or more naturally occurring substances of a plant, animal or mineral, or parts thereof, in the unextracted or crude extract form.

- **Indigenous medicine** is defined as a system of treatment and prevention of disease established through traditional use of naturally occurring substances.
SUBSTANCE TO BE EXCLUDED

Active Ingredients:
- Toxic constituents/substances exceeding stipulated limits
- Narcotics
- Psycotropics

Others:
- Isolated and chemical characterized substances
- Extemporaneous preparations
- Vaccines
- Human parts derivatives
- Sterile preparations
- Product in food presentations (incl. beverages)
Traditional medicine claims

*traditionally used...*

- Traditional general claims
  - general health
- Traditional medium claims
  - reduction of risk of a disease/disorder
  - relief of symptoms
  - aids/assists in the management of a named symptom/ disease
  - prevents/stops/ slows down the progress of a mild/ self-limiting disease or medical condition
Finished herbal products:
herbal preparations made from one or more herbs. If more than one herb is used, the term mixture herbal product can also be used. Finished herbal products and mixture herbal products may contain excipients in addition to the active ingredients. However, finished products or mixture products to which chemically defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be herbal.

World Health Organization (WHO) Guidelines (4th October 2010)
Herbal product claims

• General health maintenance
• Medium claims
  - reduction of risk of a disease/disorder
  - relief of symptoms
  - aids/assists in the management of a named symptom/disease
• High claims
  - treats/cures/manages any disease/disorder
  - adjunct/to complement any treatment

GUIDELINES : final draft
IMPLEMENTATION : 2015
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, eye drops).

(Malaysian DRGD 2014 July)
Health supplements may contain one or more, or the following combination:

i) Vitamins, minerals, amino acids, fatty acids, enzymes, probiotics, and other bioactive substances;

ii) Substances derived from *natural sources, including animal, mineral and botanical materials in the forms of extracts, isolates, concentrates, metabolite;

iii) Synthetic sources of ingredients mentioned in (i) and (ii) may only be used where the safety of these has been proven.
Claims for Health Supplements

- General or Nutritional Claims
- Functional Claims
- Disease Risk Reduction Claims

Effective 1\textsuperscript{st} March 2013
Maximum Daily Levels of Vitamins and Minerals for Adults allowed in Health Supplements

<table>
<thead>
<tr>
<th>NO.</th>
<th>VITAMINS &amp; MINERALS</th>
<th>UPPER DAILY LIMIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Vitamin A</td>
<td>5000 IU</td>
</tr>
<tr>
<td>2.</td>
<td>Vitamin D</td>
<td>1000 IU</td>
</tr>
<tr>
<td>3.</td>
<td>Vitamin E</td>
<td>800 IU</td>
</tr>
<tr>
<td>4.</td>
<td>Vitamin K (K1 and K2)¹</td>
<td>0.12mg</td>
</tr>
<tr>
<td>5.</td>
<td>Vitamin B1 (Thiamine)</td>
<td>100 mg</td>
</tr>
<tr>
<td>6.</td>
<td>Vitamin B2 (Riboflavin)</td>
<td>40 mg</td>
</tr>
<tr>
<td>7.</td>
<td>Vitamin B5 (Pantothenic Acid)</td>
<td>200 mg</td>
</tr>
<tr>
<td>8.</td>
<td>Vitamin B6 (Pyridoxine)</td>
<td>100 mg</td>
</tr>
<tr>
<td>9.</td>
<td>Vitamin B12 (Cyanocobalamin)</td>
<td>0.6 mg</td>
</tr>
<tr>
<td>10.</td>
<td>Vitamin C (Ascorbic Acid)</td>
<td>1000 mg</td>
</tr>
<tr>
<td>11.</td>
<td>Folic Acid</td>
<td>0.9 mg</td>
</tr>
<tr>
<td>12.</td>
<td>Nicotinic Acid</td>
<td>15 mg</td>
</tr>
<tr>
<td>13.</td>
<td>Niacinamide (Nicotinamide)</td>
<td>450 mg</td>
</tr>
<tr>
<td>14.</td>
<td>Biotin</td>
<td>0.9 mg</td>
</tr>
<tr>
<td>15.</td>
<td>Boron</td>
<td>6.4 mg</td>
</tr>
<tr>
<td>16.</td>
<td>Calcium</td>
<td>1200 mg</td>
</tr>
<tr>
<td>17.</td>
<td>Chromium</td>
<td>0.5 mg</td>
</tr>
<tr>
<td>18.</td>
<td>Copper</td>
<td>2 mg</td>
</tr>
<tr>
<td>19.</td>
<td>Iodine</td>
<td>0.3 mg</td>
</tr>
<tr>
<td>20.</td>
<td>Iron ²</td>
<td>20 mg</td>
</tr>
<tr>
<td>21.</td>
<td>Magnesium</td>
<td>350 mg</td>
</tr>
<tr>
<td>22.</td>
<td>Manganese</td>
<td>3.5 mg</td>
</tr>
<tr>
<td>23.</td>
<td>Molybdenum</td>
<td>0.36 mg</td>
</tr>
<tr>
<td>24.</td>
<td>Phosphorus</td>
<td>800 mg</td>
</tr>
<tr>
<td>25.</td>
<td>Selenium</td>
<td>0.2 mg</td>
</tr>
<tr>
<td>26.</td>
<td>Zinc</td>
<td>15 mg</td>
</tr>
</tbody>
</table>

**Vitamins/ Minerals:**
- Daily levels must not exceed maximum daily levels for adults allowed in health supplement.
- For pre and antenatal use, as part of a multivitamin and mineral preparation, levels higher than the 20mg limit established for adults may be permitted at the discretion of the Authority.

Ref : ASEAN Guidelines for HS
SUMMARY OF CLAIMS

Complementary medicine

TM
- General
- Medium

Herbal
- Medium
- High

HS
- General
  - Functional claim
  - Disease risk reduction
Sources of evidence – TM/Herbal

Scientifically established treatment claims

Human intervention study

Medium claims

Controlled trials / analytical studies/ epidemiological cohort /case-control studies
Evidence from multiple time series
TM formulary

General claims

TM Pharmacopoeia/monographs
Documented history of use
Reference organizations
Sources of evidence - HS

- Disease risk reduction
  - Human intervention study

- Functional claims
  - Human observational studies
  - Animal studies

- General claims
  - Authoritative reference texts
  - International organizations or recognized regulatory authorities
National Pharmaceutical Control Bureau
http://www.bpfk.gov.my – Quest 3

2) Drug Registration Guidance Document

This "DRUG REGISTRATION GUIDANCE DOCUMENT" will serve as the reference guide for both pharmaceutical products for human use and traditional products. It will replace the "Guidelines for Application for Registration of Pharmaceutical Products" Third Edition of October 1990 and "Garis Panduan Permohonan Pendaftaran Keluaran Ubat Tradisional" Second Edition, December 1990. The contents of this version include:

- Updated information relating to administrative requirements and procedures.
- Information on Drug Control Authority (DCA) policies currently applicable.
- Guidelines on the on-line application process and requirements which will incorporate the ASEAN technical requirements and standards for pharmaceuticals (where applicable).

An on-going review of policy matters will continue, taking into account the global regulatory environment, to allow for timely and pertinent changes.

Information relating to DCA policy decisions is current up to its 220th meeting on 01 October 2009. Please visit the National Pharmaceutical Control Bureau (NPCB) website at http://www.bpfk.gov.my for updates in regulatory information.

March 2010 Revision
Product Registration Application
Product Registration Number

MAL2014.... “Code”

A: Scheduled Poisons
X: Non-scheduled Poisons
   (over the counter products)
T: Traditional Medicines
N: Health Supplements
C: Contract Manufacturer
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
## CLIENT’S CHARTER

<table>
<thead>
<tr>
<th>Category</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCE &amp; Biotech</td>
<td>&lt; 245 working days</td>
</tr>
<tr>
<td>Generics &amp; OTC</td>
<td>&lt; 210 working days</td>
</tr>
<tr>
<td>TM &amp; HS (high claims)</td>
<td>&lt; 210-245 working days</td>
</tr>
<tr>
<td>TM &amp; HS (single ing)</td>
<td>&lt; 113 working days</td>
</tr>
<tr>
<td>TM &amp; HS (comb)</td>
<td>&lt; 136 working days</td>
</tr>
</tbody>
</table>

On condition Full Compliance to Requirements
FEES

• PROCESSING FEES
  - Pharmaceuticals    RM 1000
  - Traditional        RM 500
  - Cosmetics          RM 50

• LABORATORY TESTING
  - Pharmaceuticals    RM 1200-2000
  - Traditional        RM 700
REGULATORY REQUIREMENTS

Quality
- Status of manufacturer

Safety
- Maximum daily limits
- Heavy metals
- Microorganisms

Efficacy
- As claimed
<table>
<thead>
<tr>
<th>Fields</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td>Name of Product</td>
</tr>
<tr>
<td>A2</td>
<td>Product Description</td>
</tr>
<tr>
<td>A3</td>
<td>Dosage Form</td>
</tr>
<tr>
<td>A4</td>
<td>Name and Strength of Active and Excipient Substance</td>
</tr>
<tr>
<td>A5</td>
<td>Product Indication</td>
</tr>
<tr>
<td>A6</td>
<td>Dose / Usage instruction</td>
</tr>
<tr>
<td>A7</td>
<td>Contraindication</td>
</tr>
<tr>
<td>A8</td>
<td>Warning / Precaution</td>
</tr>
<tr>
<td>A9</td>
<td>Drug Interaction</td>
</tr>
<tr>
<td>A10</td>
<td>Side Effects / Adverse Reaction</td>
</tr>
<tr>
<td>A11</td>
<td>Signs of Overdose</td>
</tr>
<tr>
<td>A12</td>
<td>Storage Condition</td>
</tr>
<tr>
<td>A13</td>
<td>Shelf Life</td>
</tr>
<tr>
<td>A14</td>
<td>Therapeutic Code</td>
</tr>
</tbody>
</table>
## SECTION B
### PRODUCT FORMULA

<table>
<thead>
<tr>
<th>Fields</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>B 1.1</td>
<td>Batch Manufacturing Formula</td>
</tr>
<tr>
<td>B 1.2</td>
<td>Attachment of Batch Manufacturing</td>
</tr>
<tr>
<td>B 2.1</td>
<td>Manufacturing process</td>
</tr>
<tr>
<td>B 2.2</td>
<td>Attachment of manufacturing</td>
</tr>
<tr>
<td>B 3.0</td>
<td>In Process Quality Control</td>
</tr>
</tbody>
</table>
# SECTION C
## PACKING

<table>
<thead>
<tr>
<th>Fields</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td>Pack Size</td>
</tr>
</tbody>
</table>
| C2     | Container Type /Container Type Description  
         | e.g. : HDPE Plastic Bottle, Glass Bottle, Aluminum Blister Pack |
| C3     | Barcode/Serial Number |
| C4     | Recommended Distributor’s Price, RM |
| C5     | Recommended Retail Price, RM |
### SECTION D
**LABELS & PACKAGE INSERT**

<table>
<thead>
<tr>
<th>Fields</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>D 1</td>
<td>Label (mock up) for immediate container</td>
</tr>
<tr>
<td>D 2</td>
<td>Label (mock up) for outer carton</td>
</tr>
<tr>
<td>D 3</td>
<td>Proposed package insert</td>
</tr>
</tbody>
</table>
### SECTION E
PARTICULARS OF THE MANUFACTURER/IMPORTER/REPACKER/PRODUCT OWNER/STORE ADDRESS

<table>
<thead>
<tr>
<th>Fields</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E 1</td>
<td>Product Owner</td>
</tr>
<tr>
<td>E 2</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>E 3</td>
<td>Repacker</td>
</tr>
<tr>
<td>E 4</td>
<td>Other Manufacturer(s) Involved (If Any)</td>
</tr>
<tr>
<td>E 5</td>
<td>Store Address</td>
</tr>
<tr>
<td>E 6</td>
<td>Importer</td>
</tr>
<tr>
<td>Fields</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------</td>
</tr>
<tr>
<td>F 1.0</td>
<td>Letter of Authorisation from Product Owner</td>
</tr>
<tr>
<td>F 2.1</td>
<td>Letter of Appointment of Contract manufacturer from Product Owner</td>
</tr>
<tr>
<td>F 2.2</td>
<td>Letter of Acceptance from Contract Manufacturer</td>
</tr>
<tr>
<td>F 3.0</td>
<td>Is the Active Substance(s) Patented in Malaysia</td>
</tr>
<tr>
<td>F 4.0</td>
<td>Certificate of Pharmaceutical Product (CPP)</td>
</tr>
<tr>
<td>F 5.0</td>
<td>Certificate of Free Sale (CFS)</td>
</tr>
<tr>
<td>F 6.0</td>
<td>Good Manufacturing Practice (GMP) Certificate</td>
</tr>
<tr>
<td>F 7.0</td>
<td>Summary of Product Characteristics (Product Data Sheet – if any)</td>
</tr>
<tr>
<td>F 8.0</td>
<td>Patient Information Leaflet (PIL)</td>
</tr>
<tr>
<td>F 9.0</td>
<td>Attachment of Protocol Analysis</td>
</tr>
<tr>
<td>F 10</td>
<td>Attachment of Certificate Analysis (Finished Product)</td>
</tr>
<tr>
<td>F 11</td>
<td>Attachment of Certificate of Analysis (Active Ingredient)</td>
</tr>
<tr>
<td>F 12</td>
<td>Other Supporting Document</td>
</tr>
<tr>
<td>SAFETY CRITERIA</td>
<td></td>
</tr>
<tr>
<td>-----------------</td>
<td></td>
</tr>
<tr>
<td>Limits for heavy metals</td>
<td></td>
</tr>
<tr>
<td>Limits for microbial contamination</td>
<td></td>
</tr>
<tr>
<td>Absence of steroids and other adulterants</td>
<td></td>
</tr>
<tr>
<td>Indications and claims</td>
<td></td>
</tr>
<tr>
<td>Prohibition of herbs/ingredients with known adverse effects</td>
<td></td>
</tr>
<tr>
<td>Labeling</td>
<td></td>
</tr>
</tbody>
</table>
SCREENING FOR ADULTERANTS

Based on product indications:

- **Men’s health** - e.g. Sildenafil, Tadalafil and its analogues
- **Slimming** - e.g. Fenfluramine
- **Muscle and joint pains** – e.g. NSAIDs, Steroids
- **Cough and cold** - e.g. Anti-histamines
RED YEAST RICE…

For products containing Red Yeast Rice (*Monascus purpureus*), applicants shall provide certificates of analysis (for both raw material and finished product) showing the Monacolin-K content.

The percentage of Monacolin-K shall not exceed 1% and the Monakolin-K consumed shall not exceed 10 mg per day.
Supporting Documents for New Active Ingredients/ New Dose

Reference Countries
- United Kingdom, Sweden, France, United States of America, Australia, Canada, Japan and Switzerland
- Must be provided from competent authorities (e.g. US FDA, TGA, Health Canada)
- Examples: Registration status, established monograph

Clinical Studies / Scientific Evidences / Researches
- Full articles from the published journals
- Examples: Human clinical studies, scientific reviews, animal toxicological studies etc

Established References
- Examples: Martindale, Pharmacopeias, US PDR, The Merck Index etc
QUALITY CRITERIA

HEAVY METAL SPECIFICATION

- Mercury: not more than 0.5 ppm
- Arsenic: not more than 5.0 ppm
- Lead: not more than 10 ppm
- Cadmium: not more than 0.3 ppm
12.6 QUALITY CONTROL TEST SPECIFICATIONS FOR TRADITIONAL MEDICINE PRODUCTS

1. **Limit Test for Heavy Metals**
   Maximum limit for heavy metals:
   - 1.1 Lead : NMT 10.0 mg/kg or 10.0 mg/litre (10.0ppm)
   - 1.2 Arsenic : NMT 5.0 mg/kg or 5.0 mg/litre (5.0ppm)
   - 1.3 Mercury : NMT 0.5 mg/kg or 0.5 mg/litre (0.5ppm)
   - 1.4 Cadmium : NMT 0.3 mg/kg or 0.3 mg/litre (0.3ppm)

2. **Disintegration Test (for tablets, capsules and pills)**
   Disintegration time
   - 2.1 Uncoated tablets : NMT 30 minutes
   - 2.2 Film-coated tablets : NMT 30 minutes
   - 2.3 Sugar-coated tablets : NMT 60 minutes
   - 2.4 Enteric-coated tablets : Does not disintegrate for 120 minutes in acid solution but to disintegrate within 60 minutes in buffer solution
   - 2.5 Capsules : NMT 30 minutes
   - 2.6 Pills : NMT 120 minutes

3. **Test for Uniformity of Weight (tablets and capsules only)**
   Not more than 2 capsules / tablets exceed the limit by ± 10% from the average weight AND no tablet / capsule exceed the limit by ± 20% from the average weight.

4. **Test for Microbial Contamination**

<table>
<thead>
<tr>
<th>Route of Administration</th>
<th>TAMC (CFU/g or CFU/ ml)</th>
<th>TYMC (CFU/g or CFU/ ml)</th>
<th>Test for Specified Microorganisms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rectal Use</td>
<td>NMT $2 \times 10^2$</td>
<td>NMT $2 \times 10^2$</td>
<td></td>
</tr>
<tr>
<td>Oronasal Use</td>
<td>NMT $2 \times 10^2$</td>
<td>NMT $2 \times 10^1$</td>
<td>- Absence of Staphylococcus aureus in 1g or 1ml</td>
</tr>
<tr>
<td>Gingival Use</td>
<td>NMT $2 \times 10^2$</td>
<td>NMT $2 \times 10^1$</td>
<td>- Absence of Pseudomonas aeruginosa in 1g or 1ml</td>
</tr>
<tr>
<td>Cutaneous Use</td>
<td>NMT $2 \times 10^2$</td>
<td>NMT $2 \times 10^1$</td>
<td></td>
</tr>
<tr>
<td>Nasal Use</td>
<td>NMT $2 \times 10^2$</td>
<td>NMT $2 \times 10^1$</td>
<td></td>
</tr>
<tr>
<td>Auricular Use</td>
<td>NMT $2 \times 10^2$</td>
<td>NMT $2 \times 10^1$</td>
<td></td>
</tr>
<tr>
<td>Vaginal Use</td>
<td>NMT $2 \times 10^2$</td>
<td>NMT $2 \times 10^1$</td>
<td>- Absence of Staphylococcus aureus in 1g or 1ml</td>
</tr>
<tr>
<td>SAFETY</td>
<td>QUALITY</td>
<td>INDICATIONS &amp; CLAIMS</td>
<td>LABELLING</td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td>-----------------------------------------------------</td>
<td>-----------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>• Absence of banned/prohibited ingredients</td>
<td>• Compliance with Good Manufacturing Practices</td>
<td>• Low level claims supported by documents/literature on traditional use</td>
<td>• Full ingredient listing</td>
</tr>
<tr>
<td>• Pre registration testing</td>
<td>• Limits for disintegration time</td>
<td>• Prohibition on claims for 20 diseases as stipulated in the Medicines (Advertisement &amp; Sale) Act</td>
<td>• Name of Marketing Authorization Holder</td>
</tr>
<tr>
<td>• Heavy metals – Mercury, Arsenic, Lead, Cadmium</td>
<td>• Uniformity of weight</td>
<td>• Revocation of license if found to be making false / unauthorized claims</td>
<td>• Name of manufacturer (and repacker, if any)</td>
</tr>
<tr>
<td>• Microbial limit test</td>
<td>• Stability data</td>
<td></td>
<td>• Serialized Security label (Hologram )</td>
</tr>
<tr>
<td>• Adulterants</td>
<td>• Evidence of marketing authorization in exporting country</td>
<td></td>
<td>• Warning statements</td>
</tr>
<tr>
<td>• Prohibition on the use of premixes</td>
<td></td>
<td></td>
<td>• Precautions</td>
</tr>
<tr>
<td>• Declaration that product is free from TSE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• ADR reporting</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3 July 2013
Label

- Name and Strength of active substances
- RDA (optional)
- Preservative(s) (where present)
- Alcohol (where present)
- Indication
- Dose / Use Instruction
- Functional Claim (if applicable)
- Warnings (if applicable)
- Storage Condition
- Keep out of reach of children / Jauhi dari kanak-kanak
- Pack Size
- Dosage Form
- Name & address of Product Registration Holder
- Name & address of Manufacturer
- Sources (animal origin)
- Source of capsule shell (if applicable)
- Batch Number
- Manufacturing Date
- Expiry Date

MAL ..........................
HOLOGRAM MEDITAG®

SECURITY FEATURES

- Both overt (visible) and covert (hidden)
Challenges

- TM and HS have differences in their functions, requiring different ‘tools’ for the pre market control and assessment for the risks.
- TM can not only be seen as a trade commodity but also as a comprehensive health care involving traditional practitioner.
- Doses and usage of the same ingredients may be different.
- Selective publication of study results (limited research budget)
- CAM products in most countries are not required to be registered
- Ingredient or product?
Challenges

- New active ingredients
- Products of new combinations of active ingredients
- New claims
- New technology (e.g. bilayer technology)
- New invention (e.g. new dosage form, extended release/slow release)
Challenges

- Adulteration
- Illegal Manufacturing
- Unregistered Products
- Slick marketing campaigns involving unsubstantiated gimmicky products
- Misleading Claims
- Premix
THE WAY FORWARD

✓ Educating the public about current CAM evidence
✓ More quality research
✓ Intellectual property protection
✓ CAM to be used as adjunct to modern medicine (complementary)
✓ CAM to be used in place of conventional therapy (alternative)
✓ Physicians being oriented to CAM modalities and philosophy
THE WAY FORWARD

• Official analytical methods
• Pre-cleared information - Recognized standards monographs
• Herbal reference standards
• Competent expertise
• Laboratories
The Malaysian Herbal Monographs Vol. 1, 2 & 3.

1. Andrographis paniculata Nees
2. Centella asiatica (L.) Urban
3. Eurycoma longifolia Jack
4. Ficus deltoidea Jack
5. Hibiscus sabdariffa Linn
6. Labisia pumila
7. Morinda citrifolia Linn.
8. Orthosiphon stamineus Benth
9. Phyllanthus amarus Schum
10. Zingiber officinale Rosc
On-going research projects

- Gamma Aminobutyric Acid (GABA) active ingredient
  - GABA will be prohibited until data of it’s safety and recommended dosage can be provided.

- Active ingredients containing naturally occurring Theophylline and Caffeine.
  - Assessment of the level of Theophylline and Caffeine in registered products will be done starting with the list of registered products in QUEST 2.
  - Maximum level of Theophylline/ Caffeine will be set based on safety assessment for traditional products.
Quantification of α & β-asarone in finished traditional products
- α and β-asarone were reported to cause toxicity and carcinogenicity in mammalians
- EMEA has set the safety level as not more than 115 µg/ day or 2 µg/ kg bw/ day
- On-going assessment of the levels of α and β-asarone on registered finished products on the market
NEW INDICATIONS FOR Traditionally used........

- To conduct a pilot study starting with the CHINESE PHILOSOPHY OF USE first, followed by the other traditional practices later.

- A working group will be formed to address the issues and prepare a guideline for the convenience of the industry.

- The committee may wish to list our the acceptable references.
### NEW INDICATIONS FOR *Traditionally used* ........

#### BASED ON PHILOSOPHY OF USE – EXAMPLES

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>INDICATION REGISTERED</th>
<th>INDICATION BASED ON THE PHILOSOPHY</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC Tablet</td>
<td>Traditionally used for general health</td>
<td>Deficient and insecure exterior pattern manifested as spontaneous sweating, aversion to wind, bright pale complexion or people with weak constitution who are susceptible to wind</td>
</tr>
<tr>
<td>Dang Gui Bu Wie Tang Extract XYZ</td>
<td>Traditionally used for improving blood circulation</td>
<td>To tonify Qi and nourish blood</td>
</tr>
<tr>
<td>DEF</td>
<td>Traditionally used for reducing toothache</td>
<td>Stomach heat with yin deficiency, marked by fever, thirst, headache, toothache, nosebleed, hemoptyisis, red tongue with white or dry yellow coating and rapid pulse</td>
</tr>
</tbody>
</table>
**REPORT ON SUSPECTED ADVERSE DRUG REACTIONS**

NATIONAL CENTRE FOR ADVERSE DRUG REACTIONS MONITORING

www.madrac.gov.my/madrac

(Please report all suspected drug reactions including those for vaccines and traditional medicines. Do not hesitate to report if some details are not known. Identities of Reporter, Patient and Institution will remain Confidential.)

A. PATIENT INFORMATION

<table>
<thead>
<tr>
<th>Initials or R/N only</th>
<th>Sex</th>
<th>WH(kg)</th>
<th>Ethnic Group</th>
<th>Hospital/Clinic</th>
</tr>
</thead>
<tbody>
<tr>
<td>G498</td>
<td>M</td>
<td></td>
<td>Chinese</td>
<td></td>
</tr>
</tbody>
</table>

B. ADVERSE REACTION DESCRIPTION

- **Suspected Drug**: Traditional Medicine
- **Dosage Given**: Traditional Medicine
- **Manufacturer Reg. No. & Batch No.**: Traditional Medicine
- **Therapy Dates Start**: Month
- **Therapy Dates Stop**: Month
- **Indication**: Joint pain, increase strength of the body

Suspected Drug: Traditional Medicine
Local Report : Whitening Cream

• Information on product used and where it was purchased was provided
• Sample taken for testing and was found to contain 25% hydroquinone
• Actions taken:
  – GMP audit done of manufacturing premise
  – Found gross violation of GMP principles
  – Manufacturer instructed to shut down
  – Total product recall
  – Decision made not to allow use of hydroquinone in Over-The-Counter products
Number of applications (payment made) (2010-2014)
TAMAN HERBA
Malaysia
 Truly Asia