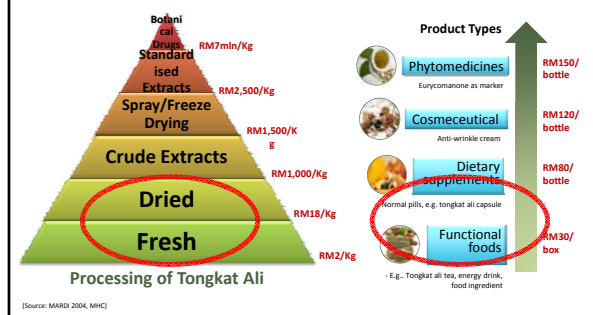


Malaysia: Insignificant Downstream



"SOUTH EAST ASIA occupies

- ~3% of the earth's surface,
- but contain ~ 20% of the global biodiversity,
- ~ 30% of the world's coral reefs,
- and 35% of the world's mangroves,
- with the associated products & services

Association of South East Asian Nations (ASEAN) conserve biodiversity programs

- the ASEAN Heritage Parks Programme,
- the Heart of Borneo (HOB) Initiative,
- the Coral Triangle Initiative,
- and the establishment of the ASEAN Centre for Biodiversity

- > 40% of aborigines & the poor NEED the biodiversity.
- South east asia (SEA) has 1,300 endangered species.
- Balance economic sectors with conservation & development.
- Biodiversity loss : impact health, emergence of diseases & weakened ecosystem services. Food security, water supply & quality, & other resources.
- Biodiversity : source of natural products for new medicines.
- Each unique species, require protection & studies.

The biodiversity target :

- To reduce biodiversity loss.
- Access to benefits by utilization biodiversity resources, & the economics of ecosystem services



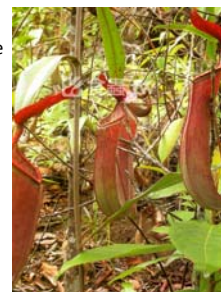
problems identified by the Economic planning Unit & National Central Bank, to strategize what needs done & how.

Approach

- Encourage patent filing through incentives & pressure (as key performance indices KPI) to universities & institutions
- Encourage commercialisation PROVIDE grants to start-up companies -technopreneur (job creation)
- Herbal (biodiversity) development office formed to support the herbal & traditional medicine industry

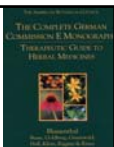
Approach

- Provide directions for focused research.
- All research on indigenous materials involve indigenous researchers & indigenous institutions
- Setting up of gene banks for biodiverse plants.
- Build documentations through monographs & PHARMACOPeIAS
- Control of material taken out from primary forests

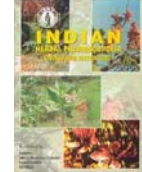
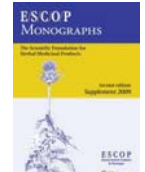
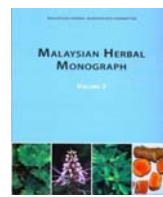
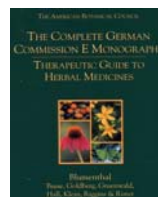


PHARMACOPOEIA

- a book containing directions for the identification of samples and the preparation of compound medicines, published by the authority of a government or a medical or pharmaceutical society.
- the name has also been applied to similar compendiums issued by private individuals.
- Basis from Pharmacognosy disciplines.



HERBAL MONOGRAPHS

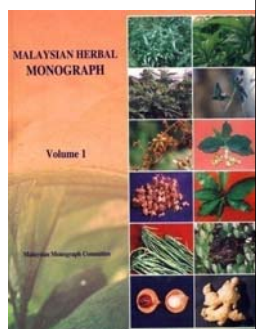


PHARMACOPOEIAL MONOGRAPHS ON PLANT DRUGS AND PREPARATIONS

AIMS

control of product quality in terms of:

- purity/authenticity
- safety
- efficacy
- suitability for use



CRITERIA OF PRIORITIZING MAPs FOR PHARMACOPOEIAL MONOGRAPHS

- Some evidence of beneficial pharmacological action and a history of use in traditional medicine
- Absence of significant safety risks
- Interest of regulatory agency
- Extent of use
- Characterizable to typical pharmacopoeial monograph requirements;
 - a) definable plant species
 - b) known characteristic chemical constituents
 - c) availability of validated chromatographic or spectroscopic methods for quantitative determination of characteristic chemical constituents
 - d) availability of reference standard material for chemical identity and content test



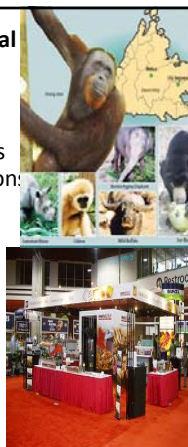
Government agencies e.g the Herbal development office - formed to facilitate in a social & ecologically sustainable way :

- Research collaboration between Universities & institutions, facilitation of private/public sector synergies, & assure the involvement of industries & communities by providing the necessary funds.
- Natural products : cosmetic & healthcare uses for the global markets.
- SMEs obtain ingredients in a social and ecologically sustainable way for the global market.



Government agencies e.g the Herbal development office - formed to facilitate in a social & ecologically sustainable way :

- Small Medium Enterprises access for global markets by participation in international tradeshows
- funds for toxicity studies, clinical trials, discovery researches, standardization of botanical extracts, improving processing technologies & improving agronomic practices.
- anchor companies produce high value & competitive ingredients



Legislations, Regulations & policy - to:

1. Sustainable use of precious herbs,
 - control herbs taken out from the primary rain forests,
 - develop their cultivation,
 - preventing exports of unprocessed raw materials.
2. Distinctive identifications (e.g. trademarks) to promote & protect trade of species of national importance in Malaysia.
3. Identify & select priority species with good market prospects, for focused research for sustainability & benefits.



4. Include Cost benefit Analysis for new product research for commercialization vs current products & market competitors.
5. Bio Trade, domestic & international sales - > US\$ 2.3 billion in 2011, & 14% annual growth.
6. Market potential for biodiversity products & services, - > US\$ 140 billion - create jobs & income, export diversification & rural development, especially for collectors, breeders, hunters, farmers & producers.



1. **Goals & objectives. Sustainable use of the planet's resources, - increase value chains, safe-guarding species & genetic resources - & incentives for their protection.**
2. **Green economy - create positive social, environmental & economic impacts.**
6. **Readjust with global changes & situations, & understanding the realities & limitations.**



7. Identifying obstacles & overcoming them. Hindrance factors e.g non-tariff barriers,
8. credit inaccessibility, & financial & management capacities.
9. Non-tariff barriers : [import bans](#), [general or product-specific quotas](#), [rules of origin](#), various conditions imposed: quality [sanitary & phyto-sanitary](#), [packaging](#), [labeling](#), [product standards](#), [complex regulatory environment](#), eligibility issues, trade documents like [certificate of origin](#), [certificate of authenticity](#) etc, [occupational safety & health regulation](#), [employment law](#), [import licenses](#), state [subsidies](#), procurement, trading, [state ownership](#), [export subsidies](#), minimum import price, [product classification](#), [quota shares](#), [foreign exchange market](#) controls & multiplicity, inadequate [infrastructure](#), "buy national" policy, over-valued currency, [intellectual property](#) laws ([patents](#), copyrights), restrictive licenses, seasonal import regimes, corrupt and/or [lengthy customs procedures](#)



8. Planning : monitor, manage & control resources. Promoting trade & investment in biodiversity for sustainable development: food, cosmetics, handicrafts, health, & ecotourism industries.



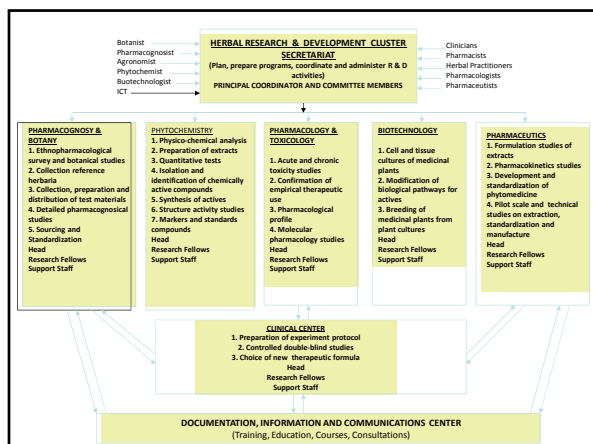


UNIVERSITI
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MALAYSIA

ROAD MAP FOR THE DEVELOPMENT OF NUTRACEUTICALS: OPPORTUNITIES & THREATS

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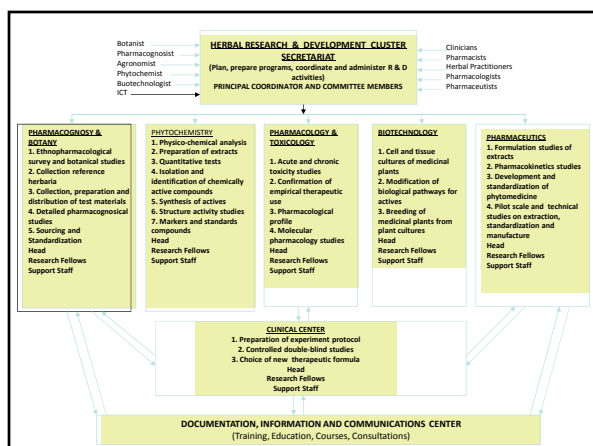


Instruments & measures to manage biodiversity and ABS :protected areas, species conservation, governance, legislation, monetary incentives & disincentives, schemes, payment for ecosystem services & tools for measurement. Access & Benefit Sharing (ABS). Exchange of genetic resources. funds & partnerships in supply chains.



INTRODUCTION

- ETP 2011 Herbal Sector MoA
- Development of high value herbal products
- NKEA strategy via 5 clusters;
 - Drug discovery
 - Agronomy & Crop Production
 - Herbal processing
 - Standardisation & product development
 - Preclinical & Clinical studies
- 5 + 6 selected herbs
- Malaysian Herbal Monographs



DRUG DISCOVERY

- LEAD BY PROF IBRAHIM JANTAN UKM
- NEW USE FOR HERBAL EXTRACT
- Eg T ALI POLYSACCHARIDES AS ERGOGENIC AIDS

AGRONOMY & CROP PRODUCTION

- LEAD BY EN. WAN ZAKI FROM MARDI
- HERBAL SOURCING
- OPTIMISE HERBAL PRODUCTION
- PEST CONTROL

PROCESSING TECHNOLOGY

- LEAD BY PROF RAMLAN FROM UTM
- SCALE UP EXTRACTION
- EXTRACTION OPTIMISATION
- NEW TECHNOLOGIES

INTRODUCTION

- ETP 2011 Herbal Sector MoA
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- 5 + 6 selected herbs
- Malaysian Herbal Monographs

STANDARDISATION & PRODUCT DEVELOPMENT

- LEAD BY PROF ZHARI ISMAIL FROM USM
- OPTIMISE PROFILE & ACTIVITY
- GURANTEED POTENCY EXTRACT

PRECLINICAL & CLINICAL STUDIES

- LEAD BY DR ZAKIAH ISMAIL FROM IMR
- ANIMAL & HUMAN STUDIES

...HERBS are...

consistently inconsistent !!!



STANDARDISATION & PRODUCT DEVELOPMENT CLUSTER

CHECK LIST

1	Quality control and herbal profile involving identified marker compound/s & fingerprints as means for sample reproducibility
2	The use of statistical method for improving sample credibility related to reproducibility of quality, safety and efficacy;
3	Metabolite profile for raw materials and selective bioactive extract involving the use of chromatographic and spectroscopic techniques.
4	Formulation of pharmaceutical dosage forms for standardised extract that fulfils the criteria for stability, storage life pharmacokinetics etc;
5	Formulation of nutraceutical and cosmeceutical based on standardised herbs that fulfils the criteria for stability, shelf life etc;
6	The utilisation of delivery systems for formulation optimisation of pharmaceutical, nutraceutical and cosmeceutical for improving product effectiveness.
7	Producing prototype product that was formulated and standardised to be served to the industry for further preclinical and clinical studies
8	Development of prototype product formulation
9	Optimisation of herbal product processing from lab scale to pilot scale.
10	Concept & activity for process synthesis in the utilisation of pilot processing of herbal product

Nestlé eyes herbal sector with Hong Kong JV; 2013 clinical trials planned

By Shane Starling, 28-Nov-2012

Related topics: Business, Industry growth

Nestlé has amplified its nutrition presence by forming a joint venture to develop Traditional Chinese Medicines (TCM). Orally consumed gastro products will be first off the rank based on an extract from the *Andrographis paniculata* plant grown in India and Sri Lanka. Spokesperson Hilary Green said the extract - HMPL-004 - "is not on the market as yet as phase III trials have not yet been approved by the US Food and Drug Administration (FDA)."

Expansion could occur into metabolic disease and brain health; president and CEO of Nestlé Health Science, Luis Cantarell, said clinical trials would commence in 2013 utilising HMPL-004.

Supplement products already formulate with *andrographis paniculata* with one claiming it supported, "digestive, cardiovascular and urinary systems" and contained, "andrographolide, deoxyandrographolide and neoandrographolide, 5,7, tetramethoxyflavanone and 5-hydroxy-7, trimethoxyflavone, as well as several other flavonoids and polyphenols."

Nestlé's new partner is Hong Kong-based, Hutchison Whampoa-owned Chi-Med, which has a bank of 50,000 extracts and 1200 plants – a bank that Nestlé will be keen to tap going forward.

"a major acceleration in our quest to expand the boundaries of nutrition"

Cantarell added: "We will bring our unique competencies in nutritional science, diagnostics and commercial capabilities while Chi-Med will provide access to its best-in-class TCM library and discovery platform."

A product could reach shelves by 2014, in the form of an, "oral therapy extracted from a herb used in TCM to address mild to moderate inflammatory bowel disease."

It is not clear if the product will be a supplement or a drug – or which markets it may launch in.

Cantarell added: "We will bring our unique competencies in nutritional science, diagnostics and commercial capabilities while Chi-Med will provide access to its best-in-class TCM library and discovery platform."

Chi-Med CEO Christian Hogg added: "We are joined in this important endeavour by Nestlé Health Science, and are confident that by harnessing the resources of our two groups, we will succeed in bringing a stream of novel botanical medicines and nutritional products to market and in so doing build significant value for patients and for our shareholders."

Expanding nutrition portfolio

The 50/50 joint venture will begin with an undisclosed capital investment from Nestlé.

Since Nestlé Health Science was established in 2011 it has made several acquisitions to aid its quest to explore the food-pharma divide including US gastrointestinal diagnostics company Premetbex, New Zealand-based *Vital Food* and UK-based *Chick Pharma Ltd*.

It also bought UK metabolic disorders specialist Vitafo and US brain health researcher, Accera.

See Cantarell talking about the JV [here](#).

INTRODUCTION

- The market for herbal product is growing rapidly. The global market size for 1996 USD14 billions; expected increase to USD200 billions in 2008 and USD5 trillions by 2050
- Herbal remedies represent complex biological mixture and achieving a reproducible pharmaceutical quality could be a very challenging task.
- Fairbairn (1980) suggested that the aspect of **authentication** and **standardization** should become a priority in producing herbal remedies.
- STANDARDIZATION – **maintaining** the quality of validity from raw material to finished products and **guarantee** herbal products are made from authentic, good quality and correct species with no contaminants.

Ref: Fairbairn 1980, Keller 1998, Werner 2000, Zharl 2003, Zharl et al 1993, Munch et al 2001, Chan 2003.

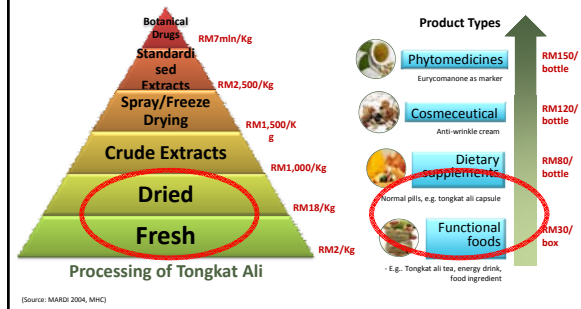
Multiple subsectors



Low to High-End Products available for Herbs



Malaysia: Insignificant Downstream



Potential Local Herbal Products

Herbal Plant	Part used	Ailments	Product	Current Raw material requirement (MT)
Tongkat Ali <i>Eurycoma longifolia</i>	Root	Tonic for men, Aphrodisiac, jaundice, fever, ulcer	Root powder/ Extract	3,329
Misai Kuching <i>Orrhosiphon stamineus</i>	Leaves	Kidney stones, diabetes, gout, cancer	Leaves powder/ Extract	1,285
Pagaga <i>Centella asiatica</i>	Whole plant	Rheumatism, epilepsy, abdominal disorder, asthma	Powder/ Extract	4,062
Hempedu Bumi <i>Andrographis paniculata</i>	Whole plant	High BP dysentery, diabetes Snake bite, fever	Powder/ Extract	1,346
Kacip Fatimah <i>Labisia pumila</i>	Leaves	Tonic for ladies, dysentery, flatulence	Leaves water extract	1,859
Nani/ Mengkudu <i>Morinda citrifolia</i>	Fruit	Liver diseases, cleansing, tonic	Juices	1,224