

NATURAL PRODUCTS & HALAL AGENDA: A CASE FOR MALAYSIA

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- NATURAL PRODUCT AGENDA
- HALAL PHARMACEUTICAL AGENDA
- CONCLUSION

AGENDA PELAN TINDAKAN

- PENGENALAN
- WHO HERBAL QUALITY CONTROL
- HERBAL STANDARDISATION
- HALALAN TOYYIBAN
- SIAPA & DIMANA
- WAY FORWARD
- KESIMPULAN

KEPUTUSAN BENGKEL HDO & BPFK 21-22 MAC 2012

. Kawalan kualiti tidak dapat dilaksanakan dengan sempurna bagi bahan mentah herba yang di import dalam bentuk kering atau pati yang di ekstrak kerana tiada syarat wajib untuk menyertakan dokumen pengesahan

Jangkamasa Pendek	Jangkamasa Panjang
• Melantik MARDI sebagai pusat sehati untuk tujuan pengesahan ketulenan bahan mentah herba. • Mewujudkan peraturan khusus mengenai spesifikasi herba • Pengeksport disyaratkan mengemukakan Certificated Of Analysis "COA" logam berat dan bacteria analysis bagi bahan mentah kering. • Mewajibkan CoA untuk bahan mentah herba dikemukakan sewaktu pendaftaran produk di BPFK	• Menetapkan keperluan GAP dan GMP bagi bahan mentah yang diimport • Mewujudkan satu 'task force' bagi mengkaji menjadikan standard WHO sebagai rujukan bagi mengenalpasti spesifikasi / parameter yang perlu dikawal bagi bahan mentah herba • Meluaskan skop pengedaran, pembungkusan dan pelabelan (3P) sedia ada • Akta Makanan 1985 yang dilaksanakan oleh Bahagian Keselamatan dan Kualiti Makanan (BKMM), KKM dicadang merangkumi juga bahan mentah kering dan standardized extract • Pengeksport disyaratkan mengemukakan dokumen jaminan kualiti bahan mentah herba. "Certificate of analysis bagi standardized extract" menepati piawaian Malaysian Standard, • Semua produk menggunakan standardized extract sebagai bahan mentah herba bagi produk yang ingin didaftarkan di BPFK

PROBLEM STATEMENT

- HERBA IMPORT MEMPENGARUHI PASARAN & PELUANG HERBA TEMPATAN
- AUTENTIKASI/PENGESAHAN SERTA KETULENAN HERBA IMPORT PERLU PEMBUKTIAN.
- ESTRAK HERBA IMPORT PERLU BUKTI PIAWAI

OBJEKTIF BENGKEL

- MENGENAL PASTI MASALAH HERBA IMPORT
- MENGENAL PASTI CARA MENGATASI MASALAH
- MENGENALPASTI AGENSI/MAKMAL & KAKITANGAN TERLIBAT
- MENYELESAIKAN MASALAH 5M 1I
(MANPOWER, METHODS, MONEY, MACHINERY (EQUIPMENT), MANAGEMENT & INFRASTRUCTURE)
- ISU HALAL

PENGENALAN

- HERBA IMPORT
- HERBA CINA
- HERBA INDIA
- HERBA WESTERN/BARAT
- HERBA INDONESIA/SERANTAU
- HERBA YG OVERLAP DGN SENARAI 10+1

RUJUKAN HERBA IMPORT

JENIS/TEMPAT	RUJUKAN NORMATIF	WHO
SERANTAU/ REGIONAL	MATERIA MEDIKA INDONESIA, FARMAKOPEA HERBAL INDONESIA, THAILAND HERBAL PHARMACOPOEA, ASEAN MONOGRAPHS, MHM 1,2,3	MEDICINAL PLANTS MONOGRAPHS
CINA	CHINESE PHARMACOPOEA	MEDICINAL PLANTS MONOGRAPHS
INDIA	INDIAN HERBAL PHARMACOPOEA	MEDICINAL PLANTS MONOGRAPHS
BARAT/ WESTERN	BRITISH, EUROPEAN, AMERICAN HERBAL PHARMACOPOEA	MEDICINAL PLANTS MONOGRAPHS

HERBA 10+1

HERBA	CINA	INDIA	BARAT	SERANTAU	WHO
TONGKAT ALI (<i>Eurycoma longifolia</i>)				/	
KACIP FATIMAH (<i>Labisia pumila</i>)				/	
MISAI KUCING (<i>Orthosiphon stamineus</i>)			/	/	/
HEMPEDU BUMI (<i>Andrographis paniculata</i>)	/	/		/	/
DUKONG ANAK (<i>Phyllanthus niruri</i>)		/		/	
PEGAGA (<i>Centella asiatica</i>)		/	/	/	/
MAS COTEK (<i>Ficus deltoidea</i>)				/	
HALIA (<i>Zingiber officinale</i>)	/	/	/	/	/
MENGKUDU (<i>Morinda citrifolia</i>)			/	/	
ROSEL (<i>Hibiscus sardariffa</i>)				/	
BELALAI GAJAH (<i>Clinanthus nutans</i>)				/	

- **INTRODUCTION**
- why herbal monographs
- whose responsibility
- how is it done
- Malaysian Standards
- conclusion

HERBAL MONOGRAPHS PUSH TRADITIONAL MEDICINES DURING 21ST CENTURY

- USP 1820 -1900s BEYOND
Monographs on botanicals – shift to synthetics. Presently considering inclusion of 15-20 botanical monographs such as Garlic, Ginger, Valerian.
- AHP Founded in 1995; plans 300 botanical monographs; Five developed, six in process (eg. Hypericum).
- ESCOP Developed over 60 monographs.
- GCE German Commission E over 300 monographs.
- CDMA Chinese Drug Monographs & Analysis – in 1996 Bupleurum, Schizandra, Fritillaria, Rehmannia
- WHO Monographs on 28+30 selected Medicinal Plants (1999, 2001).

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.

COUNTRY	TITLE	1. PHARMACOPOEIA COMMISSIONS 2. PUBLISHER/DISTRIBUTOR 3. WEBSITE 4. FREQUENCY OF PUBLICATION	EDITION	YEAR	LANGUAGE
EGYPT	Egyptian Pharmacopoeia	1. Permanent Commission of the Egyptian Pharmacopoeia, Faculty of Pharmacy, Kasr El Ainy, Cairo 2. General Organization for Government Printing Office, Cairo 3. Egyptian Government http://www.egypt.gov.eg/arabic/default.asp	3rd Edition 4th Edition	1984 2005	Arabic English Arabic English
INDONESIA	Farmakope Indonesia	1. Indonesian Pharmacopoeia Commission, Direktorat Jenderal Pengawasan Obat Dan Makanan, Departemen Kesehatan R.I., Jl. Percetakan Negara 23, Jakarta 10560 2. Departemen Kesehatan Republik Indonesia Jl. Percetakan Negara 23 Jakarta 3. National Agency of Drug and Food Control http://www.pom.go.id/	4th Edition	1995	Indonesian
IRAN	Iranian Pharmacopoeia	1. Iranian Pharmacopoeia Drug Administration of Iran, Division of Pharmaceuticals & Narcotic Affairs Fahre- Razi Street Ministry of Health of Iran Building Tehran, SA, Iran			
PAKISTAN	Pakistan Pharmacopoeia	1. Pakistan Pharmacopoeia Commission, Ministry of Health, Special Education & Social Welfare, Islamabad 2. Government of Pakistan, Ministry of Health http://www.pakistan.gov.pk/ministries/index.jsp?MiniID=22&path=251 3. National Agency of Drug and Food Control http://www.dco.gov.pk/			English
TURKEY	Turkish Pharmacopoeia	1. Commission of the Turkish Pharmacopoeia Ministry of Health General Directorate of Pharmaceuticals and Pharmacy Cankiri Cad. No:57 Ulus Ankara, Turkey 3. The Ministry of Health of Turkey Mithrapasa Cad. No:3 39110 Ankara, Turkey http://www.saglik.gov.tr/			Turkish English

COUNTRY	TITLE	1. PHARMACOPOEIA COMMISSIONS 2. PUBLISHER/DISTRIBUTOR 3. WEBSITE 4. FREQUENCY OF PUBLICATION	EDITION	YEAR	LANGUAGE
THAILAND	Thai Pharmacopoeia Thai Herbal Pharmacopoeia	1. Thai Pharmacopoeia Committee Department of Medical Sciences Ministry of Public Health Thawane Road, Nonthaburi 11000, Thailand 2. Thai Pharmacopoeia and Reference Substance Section Bureau of Drug and Narcotic Department of Medical Sciences Ministry of Public Health Thawane Road, Nonthaburi 11000, Thailand 3. Ministry of Public Health http://www.moph.go.th/index.php Bureau of Drug and Narcotic http://www.dmsc.moph.go.th/webroot/drug/index.stm	1st Edition Vol. I Part 1 Vol. I Part 2 Vol. II Part 1 Vol. II Part 2 Vol. II Part 3 Supplement Volume I Volume II Supplement	1987 1993 1997 2000 2003 2005 1995 2000 2004	English English English English English Thai English Thai English English
PHILIPPINES	Philippine Pharmacopoeia	1. Bureau of Food and Drugs Civic Drive, Filinvest Corporate City Alabang, Muntinlupa City 1781 Philippines 2. Bureau of Food and Drugs Product Service Division 3. Bureau of Food and Drugs http://www.bfad.gov.ph/	1st Edition	2004	English
AFRICA	African Pharmacopoeia	2. Organization of African Unity STIC Publications Division PMB 2359, Lagos, Nigeria	1 2	1985 1986	English English

COUNTRY	TITLE	1. PHARMACOPOEIA COMMISSIONS 2. PUBLISHER/DISTRIBUTOR 3. WEBSITE 4. FREQUENCY OF PUBLICATION	EDITION	YEAR	LANGUAGE
EUROPE	European Pharmacopoeia 1. & 2. Pharmeuropa 1. & 2.	European Directorate for the Quality of Medicines, Council of Europe, - 226 Avenue de Colmar B.P. 907, F-67029 Strasbourg Cedex 1, France From 3 January 2007 - New Address: 7 allée Kastner, CS 30026 F-67081 Strasbourg Cedex 3. European Directorate for the Quality of Medicines European Pharmacopoeia http://www.ph.eu.org 4. New edition every three years. Supplements three times yearly (March, June, November) 18.4 2006 English/French 18.3 2006 English/French as above 18.2 2006 English/French 3. European Directorate for the Quality of Medicines Pharmeuropa http://www.ph.eu.org/site/page_584.php English 4. Four times yearly	5th edition Supplement 5.1 Supplement 5.2 Supplement 5.3 Supplement 5.4 Supplement 5.5 Supplement 5.6 2007 Supplement 5.7 2007 Supplement 5.8 2007 English/French	2005 2005 2005 2006 2006 2006 2007 2007 2007 English/French	English/French English/French English/French English/French English/French English/French English/French English/French English/French
WHO, GENEVA	The International Pharmacopoeia	1. WHO Expert Committee on Specifications for Pharmaceutical Preparations 2. WHO Press World Health Organization, 1211 Geneva 27, Switzerland FAX (41 22) 791 48 57 e-mail: bookorder@who.int 3. World Health Organization http://www.who.int/medicines/publications/pharmacopoeia/en/index.html	4th Edition, Vol. 1 Vol. 2	2006	English