Traditional Medicine: Overview on national policies and regulations of traditional medicine

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Infectious minds presentation
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WHO initiatives

• Major challenges: safety, efficacy, quality control and lack of knowledge

• The WHO global survey (1994): total 141 member countries were surveyed

(National policy on traditional medicine and regulation of herbal medicine, WHO, 2005)
• WHO strategy: Ensuring safety, efficacy and quality of herbal medicines; ensuring proper accessibility of traditional medicine

• WHO resolutions were adopted in 2003: General guidelines, technical standards, policies and regulations

• A global database: National policies and regulation of herbal medicine

• Global database is only open to national drug agencies

• More global surveys on traditional medicine are proposed in future
SOUTH EAST ASIA REGION

Member States in the South-East Region responding positively with the following:

<table>
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<th>Issue</th>
<th>States</th>
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<td>National policy on TM/CAM</td>
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(National policy on traditional medicine and regulation of herbal medicine, WHO, 2005)
INDIA

• National policy, laws and regulations were introduced as early as 1940

• The Central Council of Indian Medicine act (1970): Governs traditional medicine education and traditional medicine practitioners

• The Drugs & Cosmetics act (1940): Regulates the herbal medicines (licensing, inspection and testing)

• Ayurvedic pharmacopoea of India and Unani pharmacopoea of India: Official documents for herbal medicine in India

• There are 4246 registered herbal medicines sold in a special outlets

• Department of Medicine and Homeopathy (1995) under the ministry of health and family welfare was established
Welcome to AYUSH

Department of Indian Systems of Medicine and Homoeopathy (ISM&H) was created in March 1995 and re-named as Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) in November 2003 with a view to providing focused attention to development of Education & Research in Ayurveda, Yoga & Naturopathy, Unani, Siddha and homoeopathy systems. The Department continued to lay emphasis on upgradation of AYUSH educational standards, quality control and standardization of drugs, improving the availability of medicinal plant material, research and development and awareness generation about the efficacy of the systems domestically and internationally.

Visitor No: 185852

http://www.indianmedicine.nic.in/
National policy on traditional medicine (2002)

Traditional medicine accessibility & delivery system

• Central council of family welfare (1999): Integration of traditional medicine practice into national health care program

• Renovation of referral traditional medicine hospitals

• At primary health center and district hospitals, a specialty center for traditional medicine was proposed

• A separate federal funds to procure traditional medicines

• Private hospitals: Speciality center for traditional medicine
Standardization & quality control of herbal medicines

• The enforcement of regulatory laws is lagging behind at state levels

• All pharmacopoeia works were proposed to complete by 2005 and proper enforcement mechanism will be initiated

• Proposed to modernize quality control centers at local level

• A new legislation for nutraceuticals/food supplements is proposed

• Initiatives for traditional medicine industry: priority industry, tax cuts

• Financial support: Clinical trial, pharmacokinetic and toxicological work
The traditional medicine education

- Huge surge in substandard educational institutes
- Proposed model colleges and center for excellence
- A separate common admission test for traditional medicine schools
- Compulsory re-orientation training for physicians and instructors

Minor policy issues

- Conservation of rare medicinal plants was proposed
- Proposed to increase budget allocation towards tradition medicine
- A digital library for ancient medical manuscripts was proposed
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(National policy on traditional medicine and regulation of herbal medicine, WHO, 2005)
Canada

- Canada has no universal national policy, laws or regulations
- No accreditation or validation programs for traditional medicine schools
- Canada food & drug act do not recognize traditional medicine practitioners
- The herbal medicines are called natural health products (NHP)
- About 10,000 registered NHPs in Canada, but no pharmacopoeia
- Under ministry of health, a standing committee was set up in 1997
The key recommendations of the standing committee

• Suggested the Health Canada to define the status of NHPs
• A separate regulatory body for NHPs is recommended
• Separate protocols for GMP, safety, efficacy trials of NHPs
• A Canadian pharmacopoeia and protocols for product licensing
• Urged federal govt agencies to encourage research on NHPs
• Govt of Canada established “Office of Natural Health Products”
(National policy on traditional medicine and regulation of herbal medicine, WHO, 2005)
• No national policy, laws or regulations to govern traditional medicine

• No regulatory authority or expert committees for traditional medicine

• Kenyan Medical Research Institute (KEMRI) - Traditional medicine research

• Safety assessment of herbal medicines are established by KMRI

• The registration of herbal medicines is not in place

• The government of Kenya initiatives - lacks general consensus
Take home message

- WHO initiatives: Global survey, strategic plans and resolutions
- South east asia region (India): Favourable and pro-active
- Region of Americas (Canada): Pro-active, but lacks broader attention
- Region of Africa (Kenya): Striving, but fail to achieve general consensus
References.

• Legal status of traditional medicine and complementary/alternative medicine: a worldwide review, Geneva, WHO, 2001

• National policy on traditional medicine and regulation of herbal medicine, Geneva, WHO, 2005

• National Policy on Indian Systems of Medicine & Homoeopathy-2002, India.

• NATURAL HEALTH PRODUCTS: A New vision, Report of the standing committee on health, November 1998

Thank you