Global review of the challenges in use of traditional medicine and WHO perspective

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# Populations using TM/CAM worldwide

## Populations using traditional medicine for primary health care

<table>
<thead>
<tr>
<th>Country</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethiopia</td>
<td>90%</td>
</tr>
<tr>
<td>Benin</td>
<td>70%</td>
</tr>
<tr>
<td>India</td>
<td>70%</td>
</tr>
<tr>
<td>Rwanda</td>
<td>70%</td>
</tr>
<tr>
<td>Tanzania</td>
<td>60%</td>
</tr>
<tr>
<td>Uganda</td>
<td>60%</td>
</tr>
</tbody>
</table>

## Populations in developed countries who have used complementary and alternative medicine at least once

<table>
<thead>
<tr>
<th>Country</th>
<th>Percentage</th>
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</thead>
<tbody>
<tr>
<td>Germany</td>
<td>80%</td>
</tr>
<tr>
<td>Canada</td>
<td>70%</td>
</tr>
<tr>
<td>France</td>
<td>49%</td>
</tr>
<tr>
<td>Australia</td>
<td>48%</td>
</tr>
<tr>
<td>USA</td>
<td>42%</td>
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</tbody>
</table>

European herbals market

Total Market 09/2003-09/2004: ~ 3.7 billion €

Source: IMS 2005
In 2005

- Sales revenue from traditional Chinese medicines totalled USD 14 billion and increased 23.81% compared to the last year.
- Exports of traditional Chinese medicines totalled USD 830 million and increased 14.55% compared to the same period last year.
- TCM market share: 30% of total sales of medicines
Use of Homeopathy Worldwide
7000 homoeopathists practising in 49 countries

- country has homeopathy practitioners

Prepared by LIGA Medicorum Homeopathica Internationalis in 2000
Difficulties Specific to TM/CAM Research

Characteristics of Western Medicine

The main philosophy of Western Medicine is that if the human body is struck by diseases, the causative agent must be identified and dealt with in order to return patients to a state of good health.
A common feature of most systems of Traditional Medicine is that they take a 'holistic' approach towards the sick individual and treat disturbances on the physical, emotional, mental and living environment levels simultaneously.
Procedure for developing a new chemical drug

Duration: at least 13 years
Cost: at least US$ 100 million
Difficulties in evaluation of safety and efficacy of herbal medicines

The combination of 4 plants creates powerful synergy for maximum anti-tumour effect.

Removing any one of the 4 plants weakens the effectiveness of the formula.
Major Problems in the International Market for Herbal Medicines

- Quality Control
  - Unstable quality
  - Incorrect species of plant(s) used
  - Unclear instructions on leaflets
  - Lack of precautions and contraindications in leaflets and/or labelling
  - Contains heavy metal above legally allowed limit
  - Contains undisclosed chemical substances and/or substances illegally used

- Other Problems
  - Lack of registration information in country of origin
  - Lack of relevant producer information
  - Lack of communication between export and import countries
Major challenges for proper use of TM/CAM by consumer

Misunderstanding by consumer
consumers consider TM/CAM therapies
are nature and “natural means safe” and often
used TM/CAM by self care

Unqualified practice
There is often no licensing practice and
no information on who is qualified
practitioners for consumer
Policy: integrate TM/CAM with national health care systems

Safety, efficacy and quality: provide evaluation, guidance and support for effective regulation

Access: ensure availability and affordability of TM/CAM, including essential herbal medicines

Rational use: promote therapeutically-sound use of TM/CAM by providers and consumers
Background

- WHO Global Survey and Database of National Policy and Regulation of TM/CAM and Herbal Medicines including information from 142 of 192 countries, 2004
- Summary report of the global survey on national policy on traditional medicine and regulation of herbal medicines 2005
Number of Member States with Recently Established National Policy on TM/CAM

Number of Countries before 1990: 5
Number of Countries Total: 44

31% of respondents have national policy

Number of Countries with National Policy Pending: 51
Number of Member States with Recently Established Herbal Medicines Law or Regulation

65% of respondents have established herbal medicines law or regulation.

42 (49%) declared regulations were in the process of being developed.

Number of Countries before 1986: 14
Number of Countries Total: 83
Number of Member States with Expert Committees by year

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Member States</th>
<th>Increase Since Last Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>1987</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>1991</td>
<td>16</td>
<td>6</td>
</tr>
<tr>
<td>1995</td>
<td>20</td>
<td>4</td>
</tr>
<tr>
<td>1999</td>
<td>32</td>
<td>12</td>
</tr>
<tr>
<td>2003</td>
<td>56</td>
<td>24</td>
</tr>
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Global review challenges on TM for Briefing
9-12 Oct 2007, Geneva
Number of Member States with a national research institute on TM, CAM or herbal medicines

- 15 countries did not provide information as to the year of establishment.
Common difficulties and challenges in the field of traditional medicine

**Main Difficulties Regarding Regulatory Issues on Herbal Medicines**

- Lack of research data: 102
- Lack of appropriate control mechanisms: 88
- Lack of education and training: 81
- Lack of expertise: 64
- Other: 33
Member States need WHO's support

Member States' needs for WHO support

- Information-sharing on regulatory issues
  - Much needed: 83
  - Needed: 44
  - Not needed: 127

- Herbal medicine safety monitoring workshops
  - Much needed: 68
  - Needed: 48
  - Not needed: 116

- General guidelines on research and evaluation of herbal medicines
  - Much needed: 70
  - Needed: 47
  - Not needed: 117

- Provision of databases
  - Much needed: 67
  - Needed: 50
  - Not needed: 117

- Herbal medicine regulation workshops
  - Much needed: 66
  - Needed: 44
  - Not needed: 110

- Global meetings
  - Much needed: 50
  - Needed: 55
  - Not needed: 12

Other: 16

Number of Member States

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Safety, efficacy and quality

- Guidelines for Good Agricultural Practice and Good Collection Practice for medicinal plants (GACP) \textit{in 2003}
- WHO guidelines on assessing safety and quality of herbal medicines with reference to contaminants and residues \textit{(in press)}
- \textit{WHO} model monograph on good agricultural and collection practice (GACP) for \textit{Artemisia annua L. in 2006}
Safety, efficacy and quality

- WHO monographs on selected medicinal plants Volume 1. 1998
  2. 2002 3. 2007, 4 in press
- WHO monographs on commonly used medicinal plants in NIS countries in press
- WHO General guidelines for the methodology of research and evaluation of traditional medicine 2000
Safety, efficacy and quality

- Updated WHO GMP guidelines for herbal products *in 2006*
- WHO guidelines for safety by quality control of homeopathy medicines *(in press)*
- WHO guidelines on safety monitoring and pharmacovigilance of herbal medicines *in 2004*
Rational Use

- WHO guidelines for development of consumer information in properly use of TM/CAM
- Training guidelines for phytotherapies including Traditional Chinese Medicine, Ayurveda, Unani and Naturopathy
  - who can prescribe herbal medicines
  - who can dispense herbal medicines
  - who can distribute herbal medicines
International Regulatory Cooperation for Herbal Medicines (IRCH)

- International Regulatory Cooperation for Herbal Medicines (IRCH) was initiated during a WHO Working group meeting on regulatory cooperation on herbal medicines in Ottawa, Canada 28-30 November 2005 hosted by the Health Products and Food Branch of Health Canada.
- First annual meeting of IRCH took place in Beijing, China on 23-25 October 2006 hosted by the China State Food and Drug Administration.
- Second annual meeting of IRCH took place in Kuala Lumpur, Malaysia, 24-26 July 2007.
Objectives

- globally promote and facilitate the safe use of herbal medicines, including through regional initiatives, through sharing information and fostering dialogue;
- facilitate and strengthen cooperation between national drug regulatory authorities by sharing experience and information related to the regulation, safety and quality of herbal medicines;
- further discussing existing requirements and standards to promote the regulation, safety and quality of herbal medicines;
- further sharing of research and knowledge on traditional medicines to reduce duplication;
- recommend future activities to WHO related to the safe use of herbal medicines;
- recommend to ICDRA important issues for further discussion related to the safe use herbal medicines.
<table>
<thead>
<tr>
<th>Australia</th>
<th>Japan</th>
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<tbody>
<tr>
<td>Brazil</td>
<td>Malaysia</td>
</tr>
<tr>
<td>Canada</td>
<td>Mexico</td>
</tr>
<tr>
<td>China (including Hong Kong SAR)</td>
<td>Republic of Korea</td>
</tr>
<tr>
<td>Ghana</td>
<td>Singapore</td>
</tr>
<tr>
<td>Hungary</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>Indonesia</td>
<td>United Arabic Emirates</td>
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<tr>
<td>India</td>
<td>United America</td>
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The member sub-regional groups of IRCH

1. ASEAN Experience on Regional Cooperation for Product Working Group on Traditional Medicines and Health Supplements (ASEAN)

2. Western Pacific Regional Forum for the Harmonization of Herbal Medicines (FHH)

3. Pan Latin America Parliament (PARLATINO)

4. European Medicine Evaluation Agency (EMEA)

5. PAN American Drug Regulatory Health (PANDRA)
World Health Organization, 2007–2011

Health
Strengthening health systems
Harnessing science and research

World
Fostering security
Promoting development

Organization
Improving performance
Enhancing partnerships

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Six-points in WHO's agenda for the next 5 years

1. Health and development
2. Health and security
3. Health systems
4. Information, knowledge
5. Partnerships
6. Performance
Health systems

- PHC as inspiration for work on health systems
- Integrated service delivery
- From diaper to grave
- Continuum of prevention, promotion, treatment, care – including self-care
Alma Ata Declaration in 1978

- The goal of the Alma-Ata Declaration was health for all by the year 2000 through promotion and strengthening of primary health care.

- The Alma-Ata Declaration is significant for traditional medicine. It urged countries and governments for the first time to include traditional medicine (TM) in their primary health systems, and to recognize TM practitioners as health workers, particularly for primary health care at community level in 1978.
Traditional medicine development

- WHO traditional programme was established in 1976
- Next year is 30 year anniversary of Alma-Ata Declaration
- During the last 30 years, the use of traditional medicine has increased tremendously, in varying ways, from country to country
WHO Global Survey and database of traditional medicine

- Regulatory review on HM 1994
- Legal status review on TM 2000
- Global Survey on TM 2003

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Preparation for WHO
Four Volumes of Monographs

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9-12 Oct 2007, Geneva

World Health Organization
National law and regulation for TM/CAM therapies and practices

- Belgium 1999
- Germany 1994
- Hungary 1997
- Norway 2003
- Portugal 2003
- Russian Federation 2001
- Ukraine 1998
- United Kingdom pending
- Singapore 2003, 2004
- Brazil 2006
Third PARLATINO Inter-parliamentary Health Conference was held in Sao Paulo in 2005 and attended by 74 parliamentarians from 17 countries. The “Parliamentary Group on Traditional and Complementary Medicine” was created with the purpose of monitoring the question of legislative norms on TCM in Latin America.

Parliamentarians of these countries are working in a framework law that will be adopted during the Parliamentarians Assembly in December 2007 with the 22 countries members.
Use traditional medicine for primary health care

WHO promotes multi-models in use traditional medicine to meet primary health needs. e.g. in Cambodia, Laos, Myanmar, Thailand and Vietnam

"Your medicine in your garden"
in Mongolia: "med-kit" of TM
in China: "med-kits" on horse's back
Integration of TM/CAM into national health system

Which one is the best one or combination for my medical problem

Conventional medicine

Traditional and complementary/alternative medicine