WHO's policy and activities in the field of traditional medicine

Traditional Medicine
Department for Health System Governance and Service Delivery
World Health Organization
November 2010

- Review the status of traditional medicine globally
- Outline WHO’s own role and activities - current and future - in traditional medicine
- Provide a framework for action for WHO and its partners
  - to enable traditional medicine to play a far greater role in reducing excess mortality and morbidity, especially among impoverished populations.
WHO Traditional Medicine Strategy: 2002-2005

- Four Main Objectives -

- Framing Policy
- Enhancing Safety, Efficacy and Quality
- Ensuring Access
- Promoting Rational Use
WHO Traditional Medicine Strategy: 2002-2005
- Discussion at WHO’s Governing Bodies -
Resolution WHA 56.31; progress report WHA 58 (A58/23)

- Requested WHO to support Member States by:
  ➤ seeking evidence base information on the quality, safety, efficacy and cost-effectiveness of TM to make informed decision in integrating TM into national health system;
  ➤ providing internationally acceptable guidelines and technical standards; and
  ➤ facilitating information sharing
TM/CAM: adequate support provided to countries to promote safety, efficacy, quality and sound use of TM/CAM
- Objectives 2.1, 2.2, 2.3, 2.4 -

2.1 TM/CAM integrated into national health care systems where appropriate

2.2 Safety, efficacy and quality of TM/CAM enhanced

2.3 Availability and affordability of TM/CAM enhanced

2.4 Rational use of TM/CAM by providers and consumers promoted

WHO Global survey on national policy on traditional medicine and on regulation of herbal medicines

- 141 WHO Member States responded
- Statistics on the current situation
- Country profile

Identify country specific needs to enable WHO to provide technical support

Baseline information to assess the impact of WHO traditional medicine strategy
Member States with national policy on traditional medicine (44 countries in 2003)

Number of countries with national policy pending: 51

National policy on traditional medicine and regulation of herbal medicines: report of a WHO global survey (2005)
Six-Points in WHO's Agenda for the Next 5 Years (2006)

1. Health and development
2. Health and security
3. Health systems
4. Information, knowledge
5. Partnerships
6. Performance
Renewing Primary Health Care (PHC) through 4 Areas of Reform (2008)

**UNIVERSAL COVERAGE REFORMS**
to improve health equity

**SERVICE DELIVERY REFORMS**
to make health systems people-centred

**LEADERSHIP REFORMS**
to make health authorities more reliable

**PUBLIC POLICY REFORMS**
to promote and protect the health of communities

Participation
Global strategy and plan of action on public health, innovation and intellectual property (GSPOA)

- Discussion at the Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property

- Resolution on Global strategy and plan of action on public health, innovation and intellectual property (WHA 61.21), adopted at the 61st World Health Assembly, May 2008

- Quick start programme 2: Traditional Medicine
  - Supporting Research and Development and promoting standard setting for traditional medicines in developing countries
WHO Congress on Traditional Medicine
Date: 7 - 9 November 2008
Venue: Jiu Hua Hotel, Beijing, China

- Over 70 Member States attended the WHO Congress
- Satellite symposia were held to discuss related technical topics presented by 4 NGOs - In total, approximately 1500 people present at all the events.
- The "Beijing Declaration" was adopted, promoting the safe and effective use of traditional medicine, and calling WHO Member States and other stakeholders to take steps to integrate TM/CAM into national health systems.
- Member States shared national experiences and information in five areas, which will aid countries in taking further action in the future:
  - National Policy on TM/CAM
  - National Regulation of Traditional and Herbal Medicines
  - TM in Primary Health Care
  - National Regulation of TM/CAM Practice
  - Research on TM/CAM
WHA resolution on traditional medicine adopted at WHA 62 (WHA62.13, 2009)

- Referred to the "Beijing Declaration"
- Requested WHO to strengthen cooperation with WHO CCs, research institutions and NGOs in order to
  - share evidence-based information and
  - support training programmes for national capacity building in the field of traditional medicine
WHA resolution on traditional medicine adopted at WHA 62 (WHA62.13, 2009)

- Requested WHO to continue providing
  - **technical guidance** to support countries in ensuring the safety, efficacy and quality of traditional medicine
  - **policy guidance** to countries on how to integrate traditional medicine into health systems
WHA resolution on traditional medicine adopted at WHA 62 (WHA62.13, 2009)

- Requested WHO to update the WHO traditional medicine strategy, based on
  - countries' progress and
  - current new challenges in the field of traditional medicine
WHO Traditional Medicine Team

- Organizational change, since December 2009

- WHO's work in the field of traditional medicine has been carried out under the Department for Health System Governance and Service Delivery at WHO Headquarters
Traditional Medicine - strategic objectives and priority area -

1. Capitalizing on the potential contribution of Traditional Medicine to self-care and to people-centred primary care

2. Modality for integration of Traditional Medicine into health systems

3. Promoting agreement and consensus on criteria for endorsement, integration, and evaluation of Traditional Medicine as a subsystem of national health systems.

4. Strengthening research to promote the quality, safety and efficacy of traditional medicines and products
Traditional Medicine
- strategic objectives and priority area -

1. Capitalizing on the potential contribution of Traditional Medicine to self-care and to people-centred primary care

WHO to provide better advice to Member States on:
- the potential of developing and adopting multiple appropriate models and forms in the use of traditional medicine, and its contribution to primary care, based on accessibility, affordability and availability at the community level;
- appropriate self-care using Traditional Medicine, particularly at the community level.
Protection of medicinal plants

Promote sustainable use and cultivation of medicinal plants

- WHO guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants (2003)
- Update of WHO/WWF/IUCN guidelines on conservation of medicinal plants – printed in 1993 – an inter-agency activity
  - WHO consultation on conservation of medicinal plants
  - WHO inter-regional workshop on the use and conservation of medicinal plants in primary health care
Traditional Medicine in Primary Health Care

- WHO interregional workshop on the use of traditional medicine in primary health care (Ulaanbaatar, Mongolia, 23-26 August 2007)
- Benefit from using traditional medicines through self-care to meet primary health care needs
- Some communities have developed different forms of implementation:
  - using a "medikit" in Mongolia
  - "your medicine in your garden" booklets in south Asian countries
  - Haichi model in Japan
  - These experiences are significant in making health services accessible, available and affordable.
- Member States must be cautious about the quality, safety, and efficacy of traditional medicine therapies and products.
- Report available in English, French, Spanish and Russian
Protection and preservation of indigenous traditional medicine knowledge

- Increase recording and preservation of indigenous knowledge of traditional medicine
  - Support for Member States to develop a national inventory of medicinal plants

- As a part of implementation of global strategy and plan of action on public health, innovation, and intellectual property (GSPOA) -
Traditional Medicine
- strategic objectives and priority area -

2. Modality for integration of Traditional Medicine into health systems

WHO to provide better advice to Member States on:

- how to integrate traditional medicine into their health systems, formulating national policies, regulations and standards as part of comprehensive national health plans;
- how to establish regulation and licensing practices for TM/CAM therapies, so as to include TM/CAM services in the health system in accordance with national capacities, priorities, relevant legislation and circumstances;
- how to promote the active participation of health workers through better communication between conventional and traditional medicine providers, including through diversified models and forms of training.
WHO Strategy on Traditional Medicine

Ensuring Access

- Recognition of role of traditional medicine (TM) practitioners in health care

  Advocate recognition of TM practitioners in health care
  
  -> Increased integration of TM/CAM practitioners in health service development
  
  -> National organizations of TM providers
Quality of Practice: Basic training guidelines and benchmarks

- Acupuncture (1999)
- Manual therapies
  - Chiropractic (2005)
  - Osteopathy (2010)
  - Tuina (2010)
  - Nuad Thai (2010)
- Therapies using herbal medicines
  - Traditional Chinese Medicine (2010)
  - Ayurveda (2010)
  - Unani Medicine (2010)
  - Naturopathy (2010)
- National capacity building by organizing a series of training workshops
Major WHO documents on national policy on traditional medicine

Legal status of traditional medicine and complementary/alternative medicine: a worldwide review (2001)

Provides information and data from 123 countries on:

- use of traditional medicine and complementary/alternative medicine
- the regulatory situation of traditional remedies and practitioners
- health insurance coverage
- education and training
Sharing national experience and information on practice of TM/CAM

- Conduct the second WHO global survey on traditional medicine

- Collect, collate, analyse and disseminate national information on:
  - TM/CAM practices
  - Regulation and education of TM/CAM providers, and
  - Health insurance coverage of TM/CAM
The 2nd WHO global survey on national policy and regulation of traditional medicine

- To collect updated and more comprehensive information (e.g. information relating to practices and qualification)
  
  Monitor progress in the Member States

- To identify the new needs of each Member State
  
  WHO’s support for national capacity building

- To update WHO Traditional Medicine Strategy
3. Promoting agreement and consensus on criteria for endorsement, integration, and evaluation of Traditional Medicine as a subsystem of national health systems.

*WHO to provide better advice to Member States on:*  
- the extent to which traditional medicines should be integrated into their lists of essential medicines;  
- the extent to which Traditional Medicine, as a delivery system, should be supported and/or integrated;  
- the extent to which traditional medicine provides an untapped potential for improved service delivery, better outcomes, and better response to expectations.
Extend knowledge base for TM/CAM

- **Technical review on the clinical use of TM/CAM**
  - Acupuncture: Review and analysis of reports on controlled clinical trials (2002)
  - SARS: Clinical trials on treatment using a combination of Traditional Chinese medicine and Western Medicine (2004)
  - Homoeopathy: (in preparation)
  - *Traditional Medicines: Review and analysis of reports on controlled clinical trials* (in preparation)
  - *Safety of herbal medicines with reference to interaction with other medicines* (in preparation)

- **Pilot study on cost-effectiveness relating to the use of TM/CAM**
The significant use of TM worldwide makes it essential to gather information about the provision of TM particularly with respect to use, cost and outcomes.

It in turn requires:
- standardization of the clinical language used by providers of TM and
- the integration of TM into general health information systems

Another need expressed by national pharmacovigilance centres, for an appropriate coding system accommodating adverse events reporting on herbal medicines

Joint project at WHO - Classification and Terminology; Traditional Medicine; and the Quality and Safety of Medicines -

WHO working group meeting on development of traditional medicine modules for inclusion in the International Classification of Disease (IDC-TM) (Hong Kong SAR, China, 11-13 May 2009)
4. Strengthening research to promote the quality, safety and efficacy of traditional medicines and products

**WHO to provide better advice to Member States on:**

- the use of appropriate research methods and approaches for developing traditional and herbal medicines;
- establishing appropriate standards and requirements to ensure and endorse the quality safety and efficacy of traditional medicines and products;
- implementing the Global strategy and plan of action on public health, innovation and intellectual property (GSPOA), particularly the parts related to traditional medicine in the plan of action.
Member States with law or regulation on herbal medicines (92 countries in 2003)

National policy on traditional medicine and regulation of herbal medicines: report of a WHO global survey (2005)
Support National Capacity Building: policy and regulation on TM/CAM

- Regulation of herbal medicines
  - *WHO Regional/national training workshops* on regulation of herbal medicines
    - AFRO: April 2000, February 2003
    - AMRO: February 2003
    - EMRO: December 2002, June 2003
    - EURO: September 2003 (focused for NIS and CCEE)
    - SEARO: June 2003
    - WPRO: September 2004 (China)

  - *Regional minimum requirement* on regulation of herbal medicines

  - *Development of WHO monographs* on selected medicinal plants
commonly used in Newly Independent States (NIS) - EURO
International Regulatory Cooperation on Herbal Medicines (IRCH)

- A network to protect and promote public health and safety through improved regulation for herbal medicines
- Established in 2006
- Membership is open to any national regulatory authority responsible for the regulation of herbal medicines and regional/sub-regional bodies responsible for the regulation of herbal medicines.
- Current members: (23)
  - 20 Member countries;
  - 3 Member Regional/Sub-regional body
- Fourth annual meeting of IRCH
  - Dubai, UAE, 8-10 June 2010
- 7 working groups established to address technical issues identified as top priorities
International Conference on Drug Regulatory Authorities (ICDRA)

- 14th ICDRA – Singapore (Nov/Dec 2010)
- Workshop on herbal medicines: Current regulatory challenges and cooperation

Programme (tentative)
- Current regulatory challenges relating to herbal medicines: Adulteration of herbal medicines
- Current regulatory challenges relating to herbal medicines: Evidence for Health Claim
- Experience with regulatory cooperation - International Regulatory Cooperation for Herbal Medicines (IRCH)

- Moderators: Dr Kustantinah, Indonesia, Mrs Akua Amartey, Ghana
Guidance on research direction and research methodologies

- **Guidelines on research methodology**
  - General guidelines on methodologies for research and evaluation of traditional medicine (2000)
  - *Clinical research in traditional medicine: key technical issues of research methodologies* (in preparation)

- **National capacity building**

- **Research information sharing**
  - WHO Collaborating Centres for Traditional Medicine (19)
  - WHO Expert Advisory Panel on Traditional Medicine (26)
  - Research communities, academia, NGOs, individual experts
  - National regulatory authorities
  - Industries
  - Scientific journals, publishers
Major WHO documents on medicinal plants

WHO monographs on selected medicinal plants, Volumes 1, 2, 3, 4

- Provides scientific information on the safety, efficacy and quality control of widely-used medicinal plants
- Provides models to assist Member States in developing their own monographs or formularies
- Facilitates information exchange
WHO monographs on selected medicinal plants used in the Newly Independent States (2010)

- includes 30 monographs
  - 17 monographs: adopted from the existing WHO monographs on selected medicinal plants
  - 13 new monographs: developed using the same format employed for the development of WHO monographs on selected medicinal plants.
- available in two languages (English and Russian)
- mutually recognized as an authoritative information source for national regulatory activities among participating countries.

**Participating countries (15):**

Armenia, Azerbaijan, Belarus, Bulgaria, Georgia, Iran, Kazakhstan, Kyrgyzstan, Moldova, Romania, Tajikistan, Turkey, Turkmenistan, Ukraine, Uzbekistan
Safety and Efficacy Assessment

- Guidelines for the assessment of herbal medicines (1991)
- General Guidelines for methodologies on research and evaluation of traditional medicine (2000)
  - Translated into French, Spanish and Russian
Quality Assurance and Control

  - Good Agricultural Practices of medicinal plants
  - Good Field Collection Practices of medicinal plants

Sustainable use of medicinal plants
Major WHO documents on medicinal plants and herbal medicines

Quality assurance and control

- Quality control methods for medicinal plant materials (1998) being updated

- Basic Tests for drugs: pharmaceutical substances, medicinal plant materials, and dosage forms (1998)
Major WHO documents on herbal medicines

Quality Assurance and Control

- WHO guidelines on assessing quality of herbal medicines with reference to contaminants and residues (2007) - being translated into F, S
  - Present general consideration on potentially hazardous contaminants and residues in herbal medicines
  - Include guiding principles of assessing quality of herbal medicines, in terms of major contaminants and residues.
  - Recommends analytical methods for qualitative and quantitative determination of such contaminants and residues.
Major WHO documents on herbal medicines

Quality Assurance and Control

- **WHO guidelines on Good Manufacturing Practices (GMP) for herbal medicines** (2007)

Developed with the view

- **within current pharmacovigilance systems**, monitoring of the safety of medicines should be *enhanced and broadened* in ways that will allow the successful monitoring of herbal medicines.
- It is *not the intention to suggest* that different systems should be instituted for this purpose.
Safety issues in the preparation of homeopathic medicines (2010)

- WHO’s response to requests and recommendations made by relevant World Health Assembly resolutions, by Member States, as well as international conferences of drug regulatory authorities, and is a part of the implementation of the WHO Traditional Medicine Strategy and the WHO Medicines Strategy.

- Provides guidance to Member States on technical aspects of the production and manufacture of homeopathic medicines that potentially have implications for their safety.

- Is of relevance for establishing national quality standards and specifications for homeopathic medicines, as well as for controlling their quality.

- The document, however, does not address issues of efficacy or clinical utilization
Quality and safety of herbal medicines

- Updated edition: Quality control methods for medicinal plant materials (under layout)
- Safety issues in the preparation of homoeopathic medicines (printed in 2010)
- Guidelines for selecting substances for quality control of herbal medicines (in preparation)
- Good processing practices for herbal materials (in preparation)
- Guidelines on safety management of toxic medicinal plants and monograph on selected commonly used toxic medicinal plants (in preparation)
Support National Capacity Building

- Organize a series of inter-regional training workshops on quality assurance and control of herbal medicines (GACP, GMP, Quality control laboratories)
- Organize a series of inter-regional training workshops on regulation of herbal medicines (including safety monitoring)
"The two systems of traditional and Western medicine need not clash. Within the context of primary health care, they can blend together in a beneficial harmony, using the best features of each system, and compensating for certain weaknesses in each. This is not something that will happen all by itself. Deliberate policy decisions have to be made. But it can be done successfully."

Dr Margaret Chan, Director-General, WHO

- opening address at the WHO congress on traditional medicine, Beijing, China, November 2008 -