

**WORLD HEALTH
ORGANIZATION**



**REGIONAL OFFICE FOR
SOUTH-EAST ASIA**

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**Global and Regional Perspectives
on Development of Traditional Medicine**

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Global and Regional Perspectives on Development of Traditional Medicine

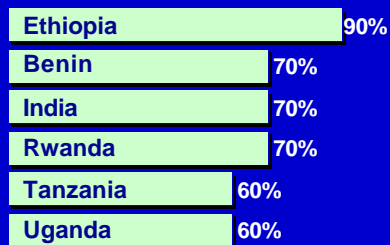


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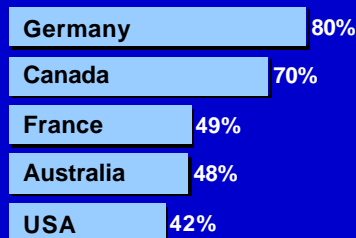


Populations using TM/CAM worldwide

Populations using traditional medicine for primary health care



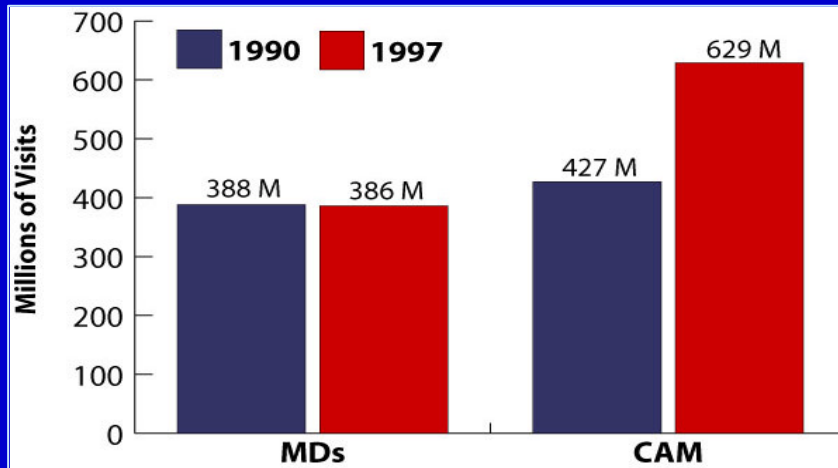
Populations in developed countries who have used complementary and alternative medicine at least once



Sources: Eisenberg DM et al, 1998; Fisher P & Ward A, 1994; Health Canada, 2001; World Health Organization, 1998; and government reports submitted to WHO.



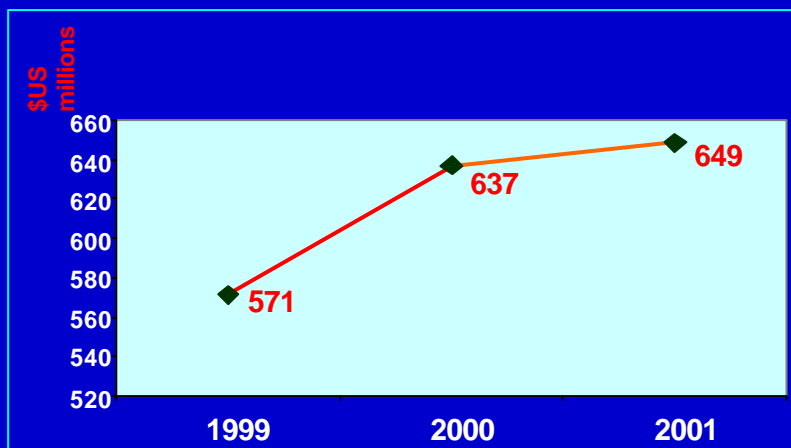
Growth of CAM Visits in USA



Eisenberg et al. JAMA 1998



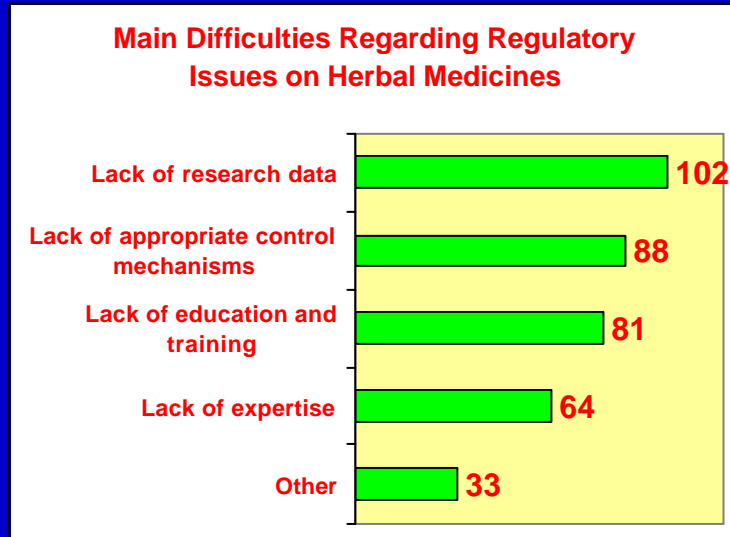
The Rise in Herbal Medicines Market Sales



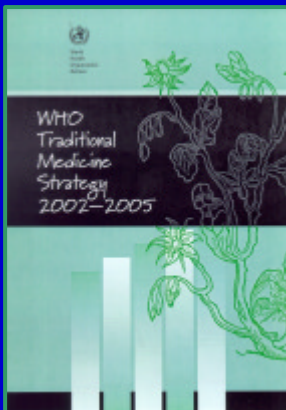
- The 8 member states are : the Kingdom of Bhutan, Canada, the Czech Republic, the Islamic Republic of Iran, the Republic of Madagascar, the Islamic Republic of Pakistan, the Republic of Sudan, the Kingdom of Sweden.



Main Difficulties Regarding Regulation Issues in Herbal Medicines



WHO Traditional Medicine Strategy 2002-2005



- 1 Policy:** integrate TM/CAM with national health care systems
- 2 Safety, efficacy and quality:** provide evaluation, guidance and support for effective regulation
- 3 Access:** ensure availability and affordability of TM/CAM, including essential herbal medicines
- 4 Rational use:** promote therapeutically-sound use of TM/CAM by providers and consumers



Policy



- **Legal Status of Traditional Medicine and Complementary/Alternative Medicine 2001**
- **WHO Global Survey and Database of National Policy and Regulation of TM/CAM and Herbal Medicines including information from 141 countries, 2004**
- **Summary report of the global survey on national policy on traditional medicine and regulation of herbal medicines 2005**
- **Legal status of manual therapies in drafting**



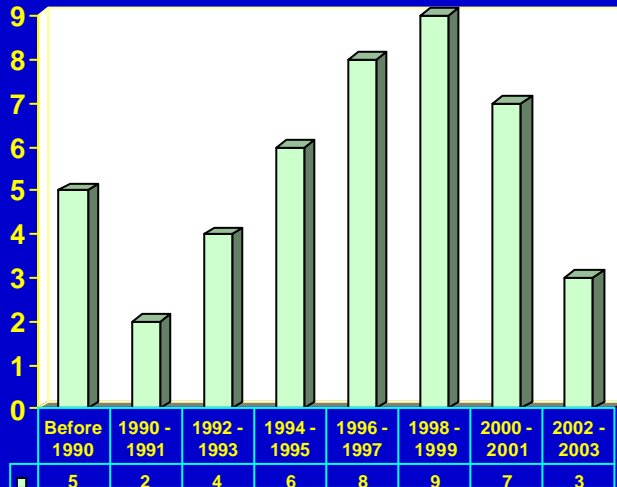
Evidence based traditional medicine



- **WHO traditional medicine resolution request WHO to provide evidence-based information to assist Member States in formulating policy and regulations to control the safety, efficacy and quality aspects. (WHA56)**



Number of Member States with Recently Established National Policy on TM/CAM



31% of respondents have national policy

Number of Countries with National Policy Pending: 55

Number of Countries before 1990: 5

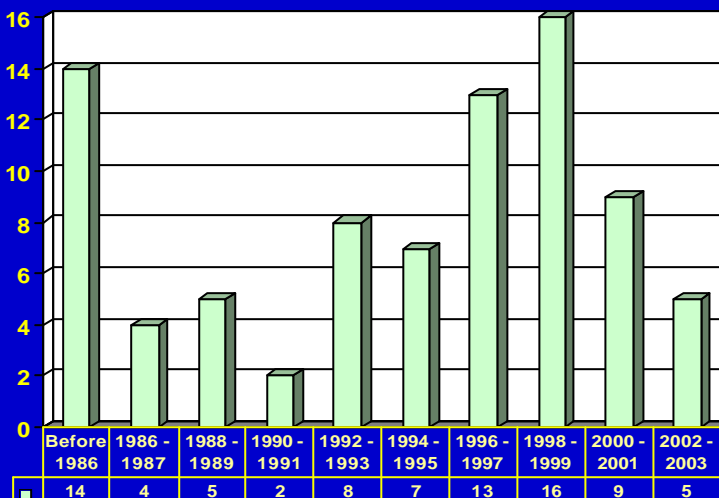
Number of Countries Total: 44

9 Swedish Parliament - Stockholm, 29/30 May 2002

World Health Organization



Number of Member States with Recently Established Herbal Medicines Law or Regulation



65% of respondents have established herbal medicine law or regulation

Number of Countries before 1986: 14

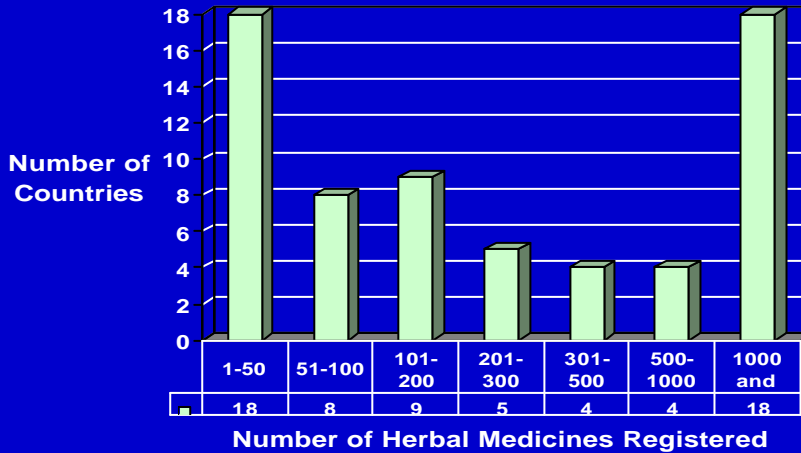
Number of Countries Total: 83

10 Swedish Parliament - Stockholm, 29/30 May 2002

World Health Organization



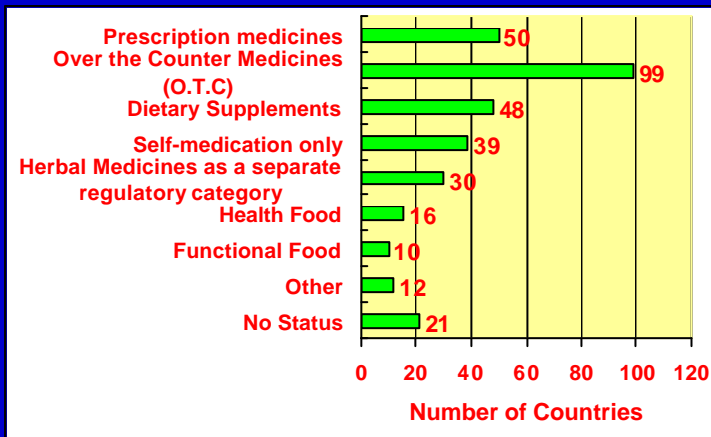
Number of Registered Herbal Medicines



Number of Countries Total: 66



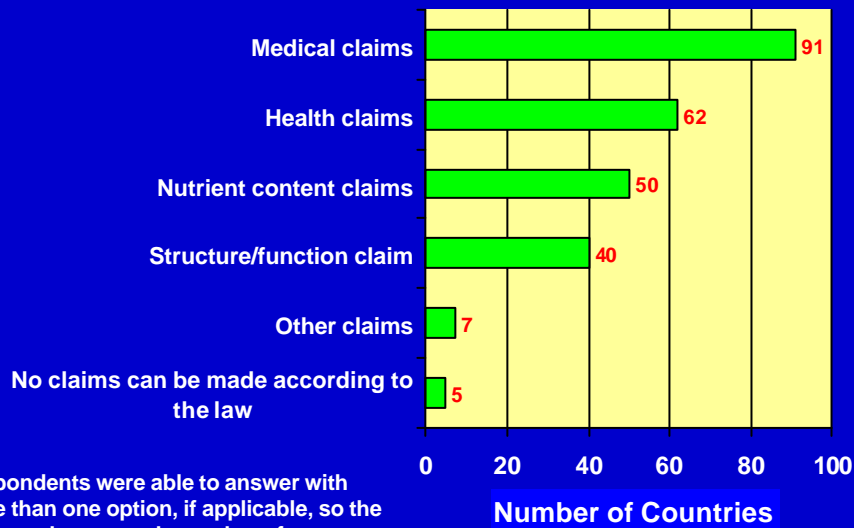
Regulatory status of herbal medicines



Respondents were able to answer with more than one option, if applicable, so the total number exceeds number of respondents



Types of claims allowed for herbal medicines



WHO South-East Asia Region: positive responses

	Member States in the South -East Region responding positively with the following	Regional survey % that responded positively (10)	Global survey % that responded Positively (141)
National policy on TM/CAM	8	80%	32%
Law or regulation on TM/CAM	7	70%	38%
National research institute on TM, CAM or herbal medicines	7	70%	43%
Law or regulation on herbal medicines	7	70%	65%
Registration of herbal medicines	9	90%	61%



Policy

National capacity-building

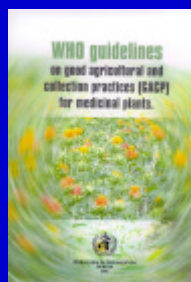


- A series of workshops on regulation herbal medicines

AFRO	1	AMRO	2
EMRO	2	SEARO	1
EURO	1	WPRO	1
- Three Regional guidelines for the minimum requirements for regulation of herbal medicines have been developed. (AFRO, SEARO and EMRO)
- International Meeting on Integration of TM/CAM into National Health System in Nov 2005, Geneva



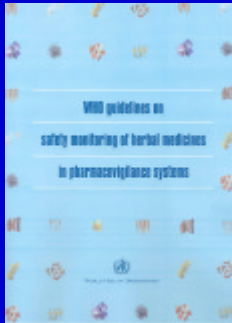
Safety, efficacy and quality



- WHO monographs on selected medicinal plants Volume 1. 1998 2. 2002 3. in press 4. in drafting
WHO consultation will take place on Oct 2005, Italy
- Quality control methods for medicinal plant materials 1998
- Guidelines for Good Agricultural Practice and Good Control Practice for medicinal plants 2003
- WHO guidelines on assessing safety and quality of herbal medicines with reference to contaminants and residues, (in press)



Safety, efficacy and quality

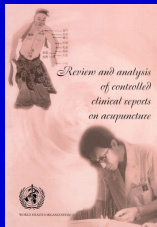


- WHO guidelines on safety monitoring and pharmacovigilance of herbal medicines *in 2004*
- Updated WHO GMP guidelines for herbal products *in drafting*
- Guidelines for mark substance selection for quality control of herbal medicines *in drafting*

WHO consultation will take place in June 2005, UAE



WHO documents on clinical reports



Acupuncture: Review and analysis of reports on controlled clinical trials 2002

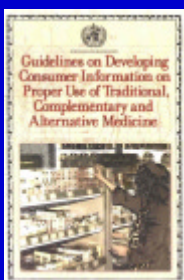
SARS: clinical trials on treatment using a combination of Traditional Chinese medicine and Western medicine 2004



Homeopathy: review and analysis of reports on controlled clinical trials in press



Rational Use



- WHO guidelines for developing consumer information on the proper use of TM/CAM **2004**
- WHO guidelines for basic training and safety of acupuncture *in 1999*
- Training guidelines for phytotherapies, *in drafting*
 - who describing
 - who can prescribe herbs,
 - who can sell herbs
- Training guidelines for manual therapies *in drafting*
 - Chiropractic
 - Osteopathy
 - Chinese Tuina
 - Thai massage etc



Activities in Interregional and Regional Level related to safety, efficacy and quality control

- National Capacity Building
WHO regional or interregional Training workshop for regulation and quality control:
 - One in AFRO
 - One Interregional Training workshop on GACP and GMP for quality control (take place in Sep China)
- WHO monograph for GACP of *Artemisia annua L*
WHO consultation in Nan Ning, China 5-7 of July 2005



International Harmonization

11th ICDRA recommended (2004, Spain)

- Regulatory agencies should work together to make the best use of scientific resources related to herbal medicines.
- Sharing national experience and information is crucial. WHO should facilitate these activities e.g. by providing updated monographs on medicinal plants and technical/regulatory guidance.



International Harmonization At Regional Level

FHH/WPRO

"Western Pacific Regional Forum for Harmonization of Herbal Medicine" (FHH) under support by WHO/WPRO

- The Forum has seven founding member parties:
Australia, China,
Japan, the Republic of Korea,
Singapore, Vietnam.
Plus Hong Kong (SAR China)



International Harmonization At Regional Level

The expected outcome of harmonization of FHH would be the development and commitment to common technical guidelines accepted by participating parties and based on discussions and consensus.

The specific purposes of harmonization include:

- To provide a scientific basis for improvement or development of standards in safety, quality and efficacy of herbal medicines;
- To reduce duplication of efforts;
- To create economic use of valuable resources;
- To address lack of standards in areas of public health importance to regulatory agencies.



International Harmonization At Regional Level

NIS monographs /EURO:

- NIS want monographs
- NIS countries decided list:
 - 16 from WHO existed monographs
 - 14 new ones need to be developed

SEARO

- monographs for commonly used herbal medicine for primary health care (take place in June, DPR Korea).



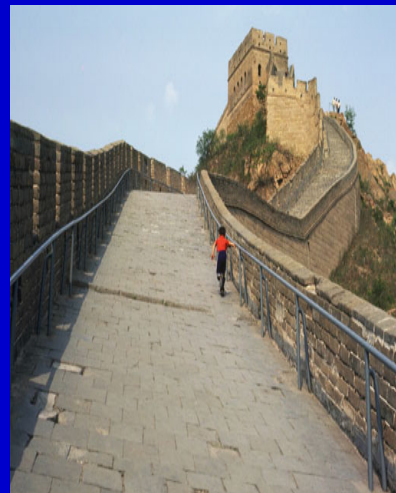
International Harmonization for Regulation

- **Initiation of international harmonization in the field of regulation particularly for safety and quality control of herbal medicine products**
- **A International Conference on harmonization in the field of regulation of herbal medicines will take place in mid of Nov, Canada**
 - **Why need international harmonization**
 - **What kind of information and data need to share**
 - **How to establish the mechanism of international harmonization**



Conclusion

- **Traditional Medicine will contribute to human health care in the 21st century.**
- **There are many challenges to the safety and effective use of traditional medicine.**
- **The WHO Strategy will meet the gaps and challenges, but...**



it is a long way to go...

