

**WORLD HEALTH  
ORGANIZATION**



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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

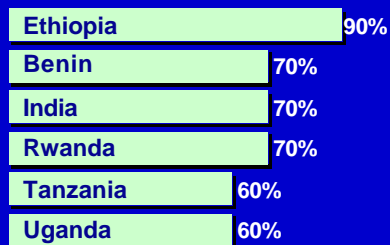


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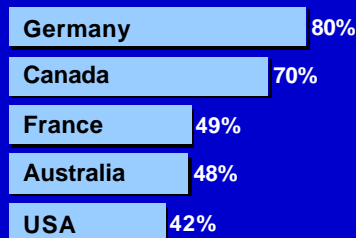


## Populations using TM/CAM worldwide

Populations using traditional medicine for primary health care



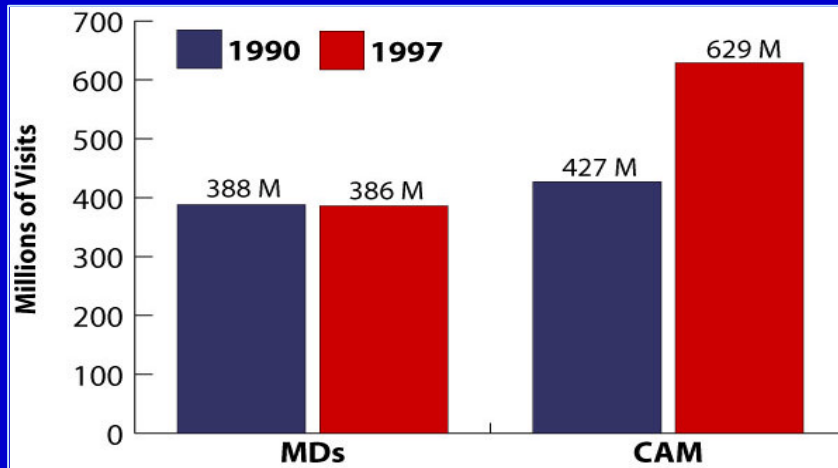
Populations in developed countries who have used complementary and alternative medicine at least once



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



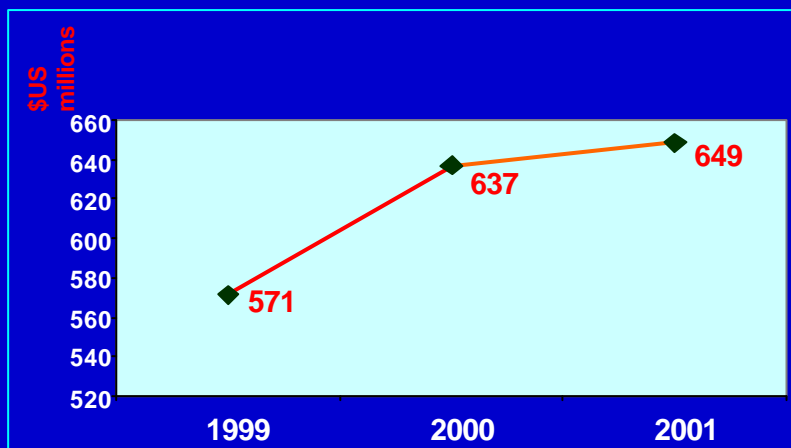
## Growth of CAM Visits in USA



Eisenberg et al. JAMA 1998



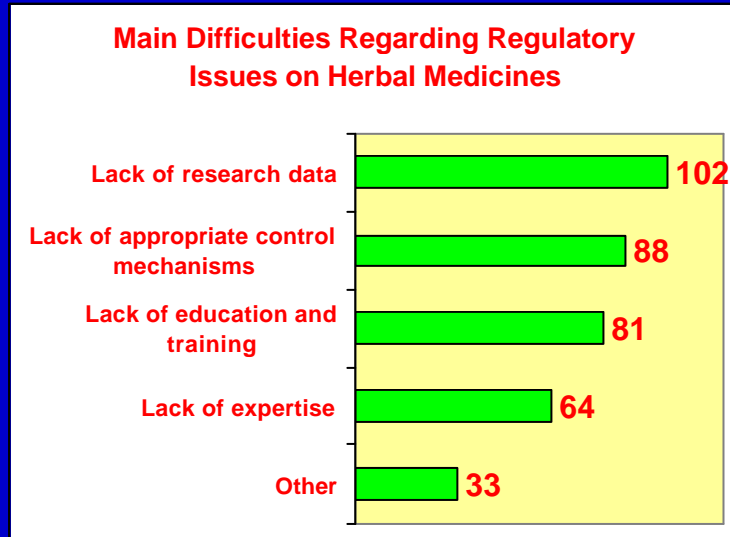
## The Rise in Herbal Medicines Market Sales



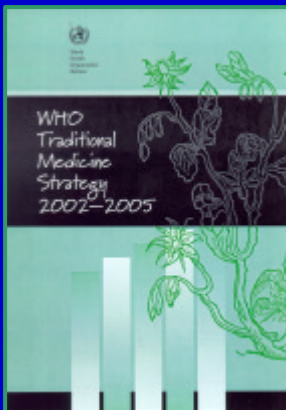
- The 8 member states are : the Kingdom of Bhutan, Canada, the Czech Republic, the Islamic Republic of Iran, the Republic of Madagascar, the Islamic Republic of Pakistan, the Republic of Sudan, the Kingdom of Sweden.



## 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**



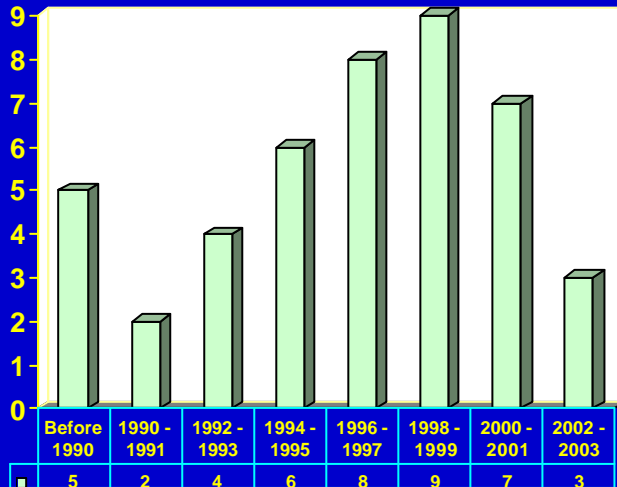
## *Evidence based traditional medicine*



- **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

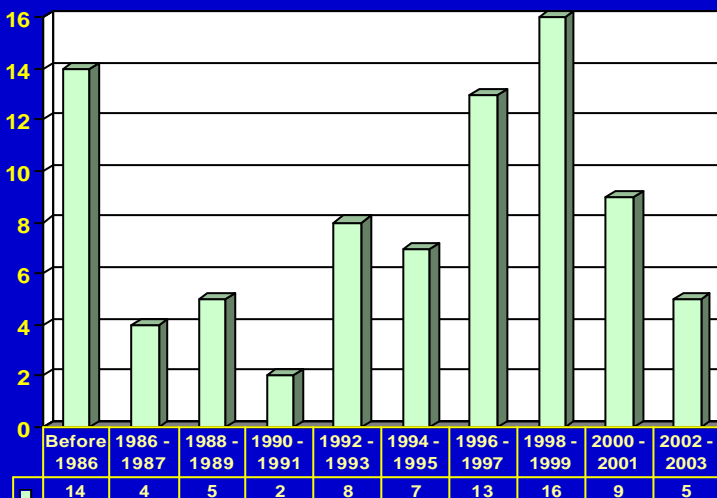
Number of Countries Total: 44

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

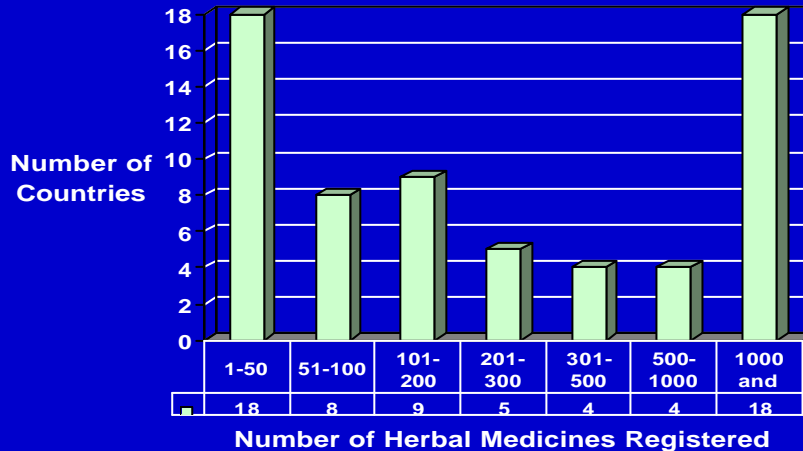
Number of Countries Total: 83

10 Swedish Parliament - Stockholm, 29/30 May 2002

World Health Organization



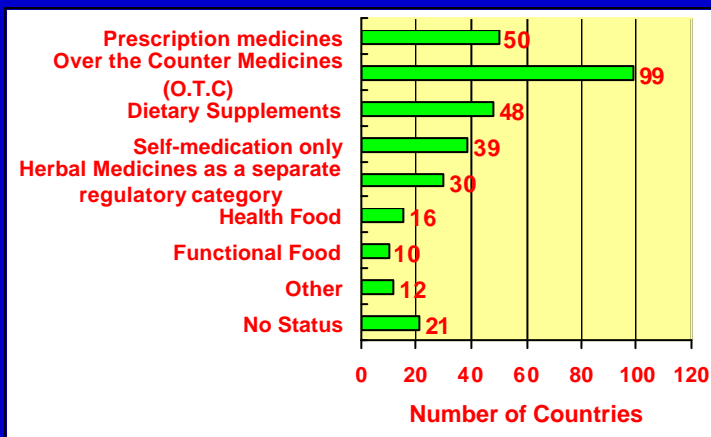
## Number of Registered Herbal Medicines



Number of Countries Total: 66



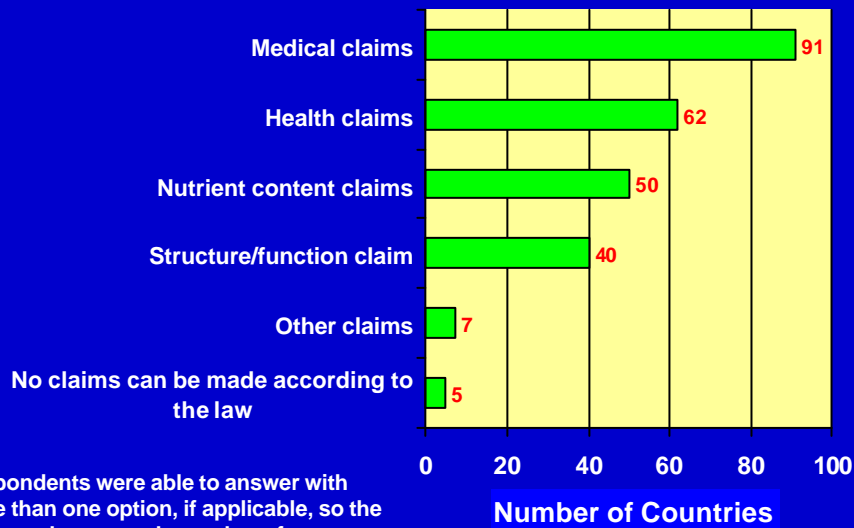
## Regulatory status of herbal medicines



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

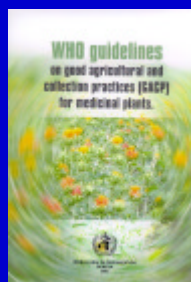


- A series of workshops on regulation herbal medicines

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



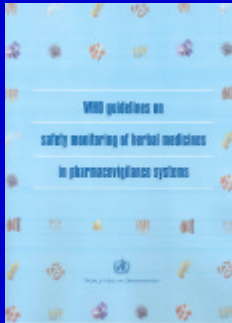
## Safety, efficacy and quality



- 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

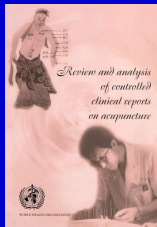


- WHO guidelines on safety monitoring and pharmacovigilance of herbal medicines *in 2004*
- Updated WHO GMP guidelines for herbal products *in drafting*
- Guidelines for mark substance selection for quality control of herbal medicines *in drafting*

*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*

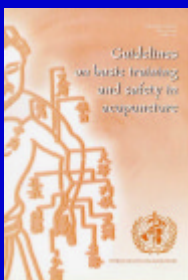
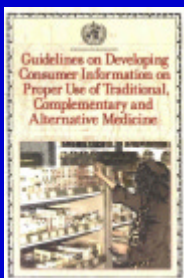
*SARS: clinical trials on treatment using a combination of Traditional Chinese medicine and Western medicine 2004*



*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).



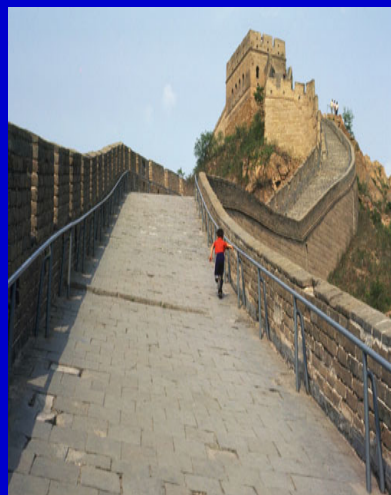
## *International Harmonization for Regulation*

- **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...*

