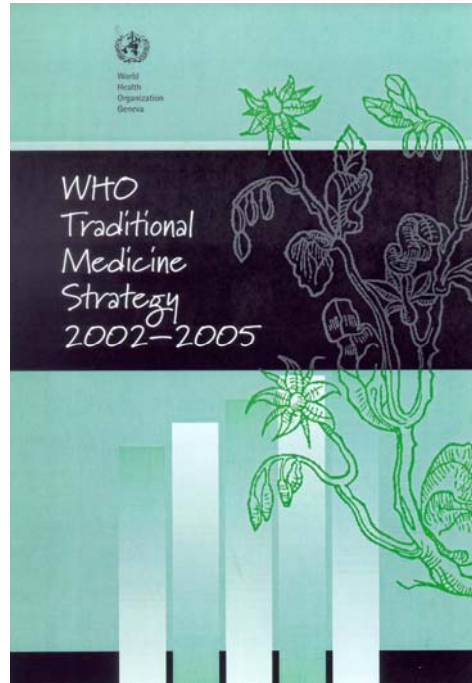


Challenges and Progress for Integration of TM/CAM into National Health Systems



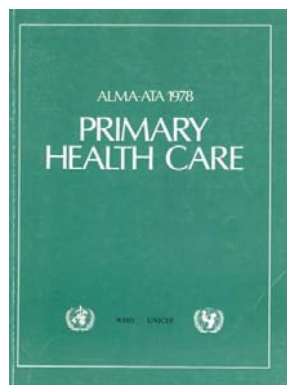
Dr Xiaorui Zhang
Coordinator
Traditional Medicine
World Health Organization



30 Anniversary of Alma-Ata Declaration

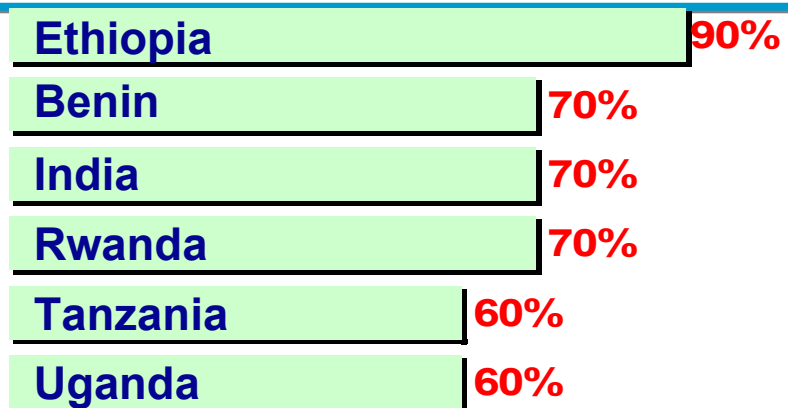


The Alma-Ata Declaration is significant for traditional medicine. It urges countries and governments for the first time to include traditional medicine (TM) in their primary health systems, and to recognize TM practitioners as health workers, particularly for primary health care at community level in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

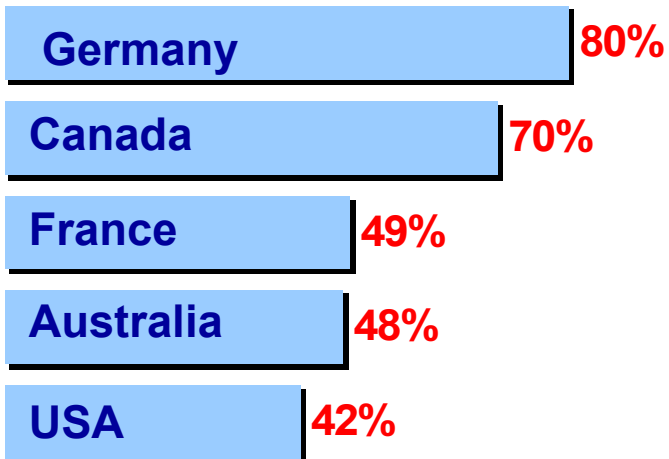


Populations using TM/CAM worldwide

Populations using traditional medicine for primary health care



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

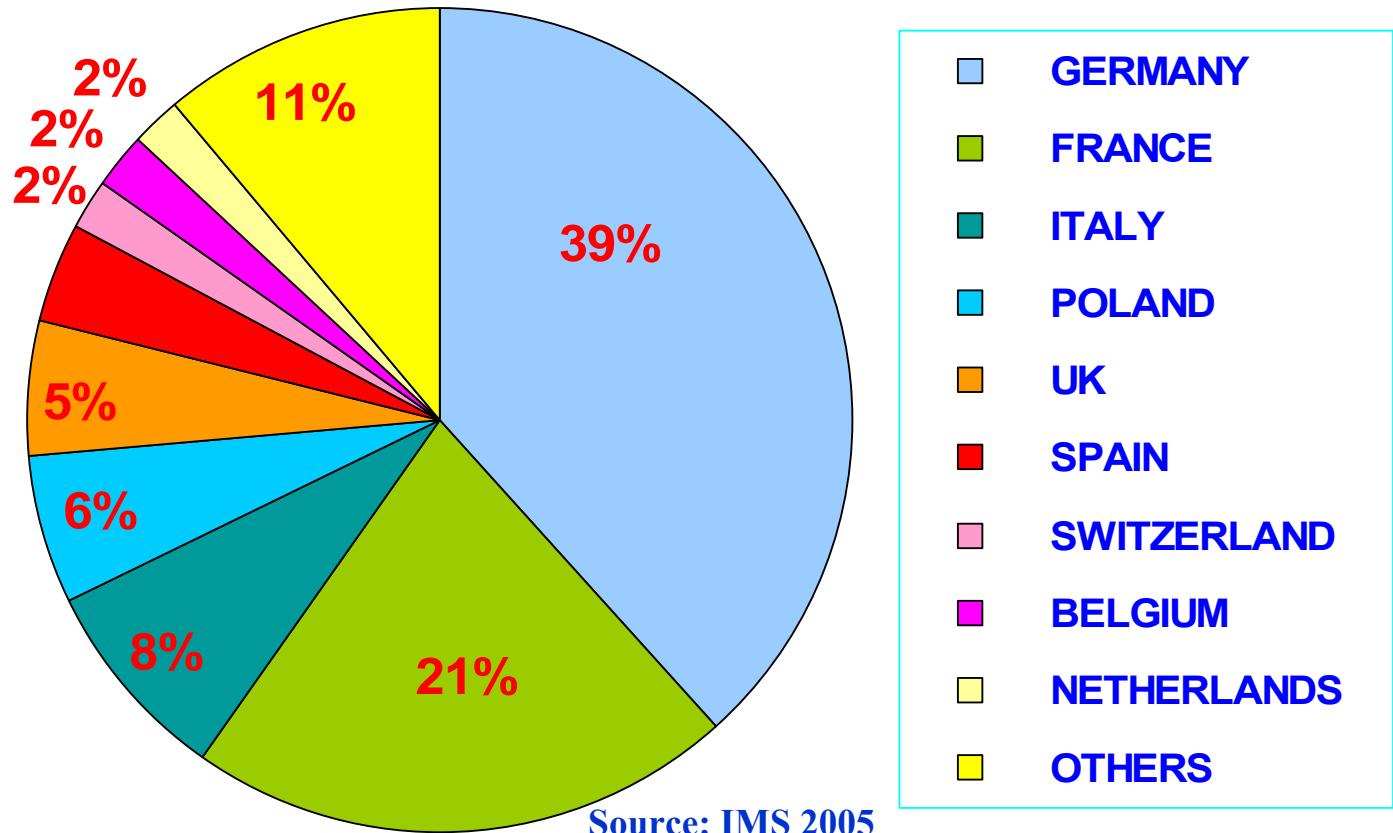


Sources: Eisenberg DM et al. 1998; Fisher P & Ward A, 1994; Health Canada, 2001; World Health Organization, 1998; and government reports submitted to WHO.



European herbals market

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



Chinese herbs market

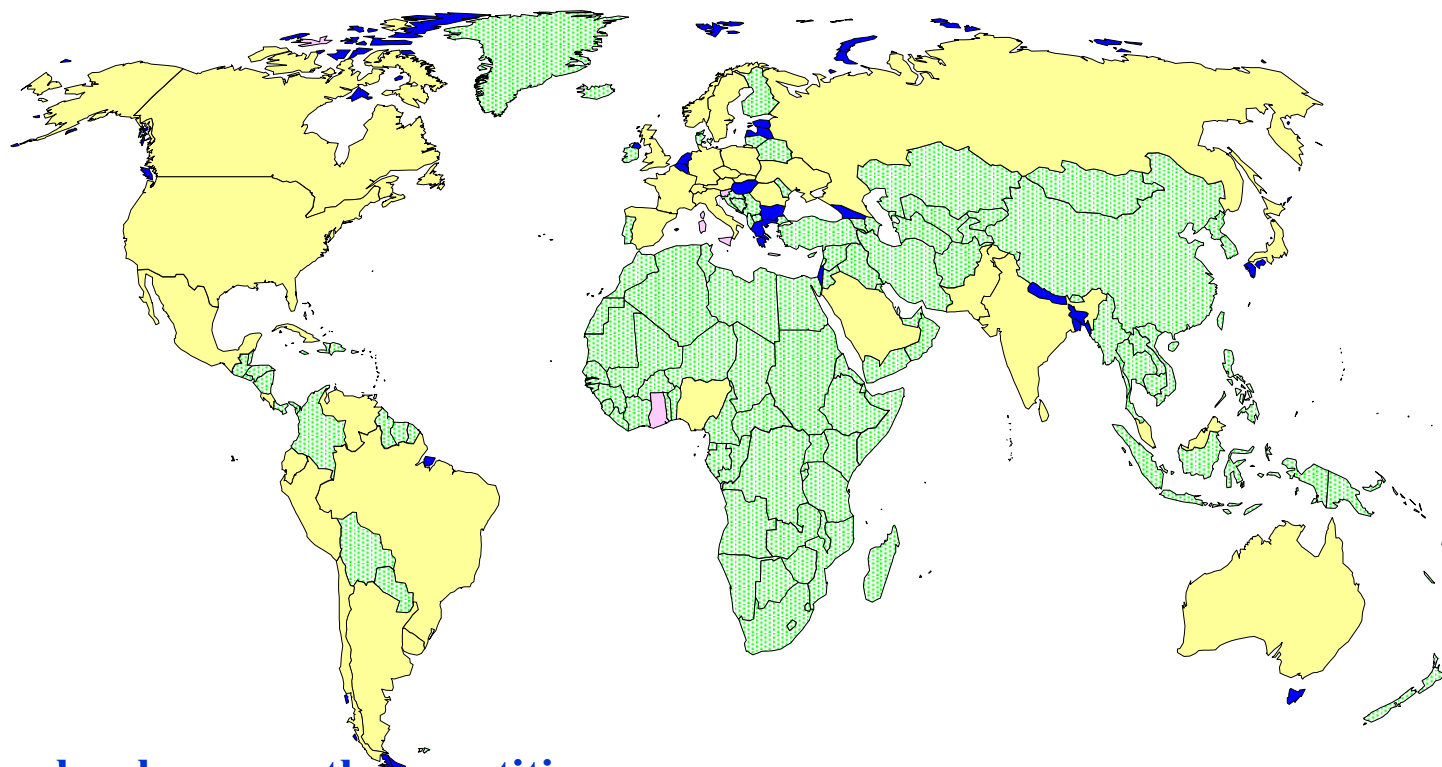


In 2005

- 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 homoeopaths practising in 49 countries



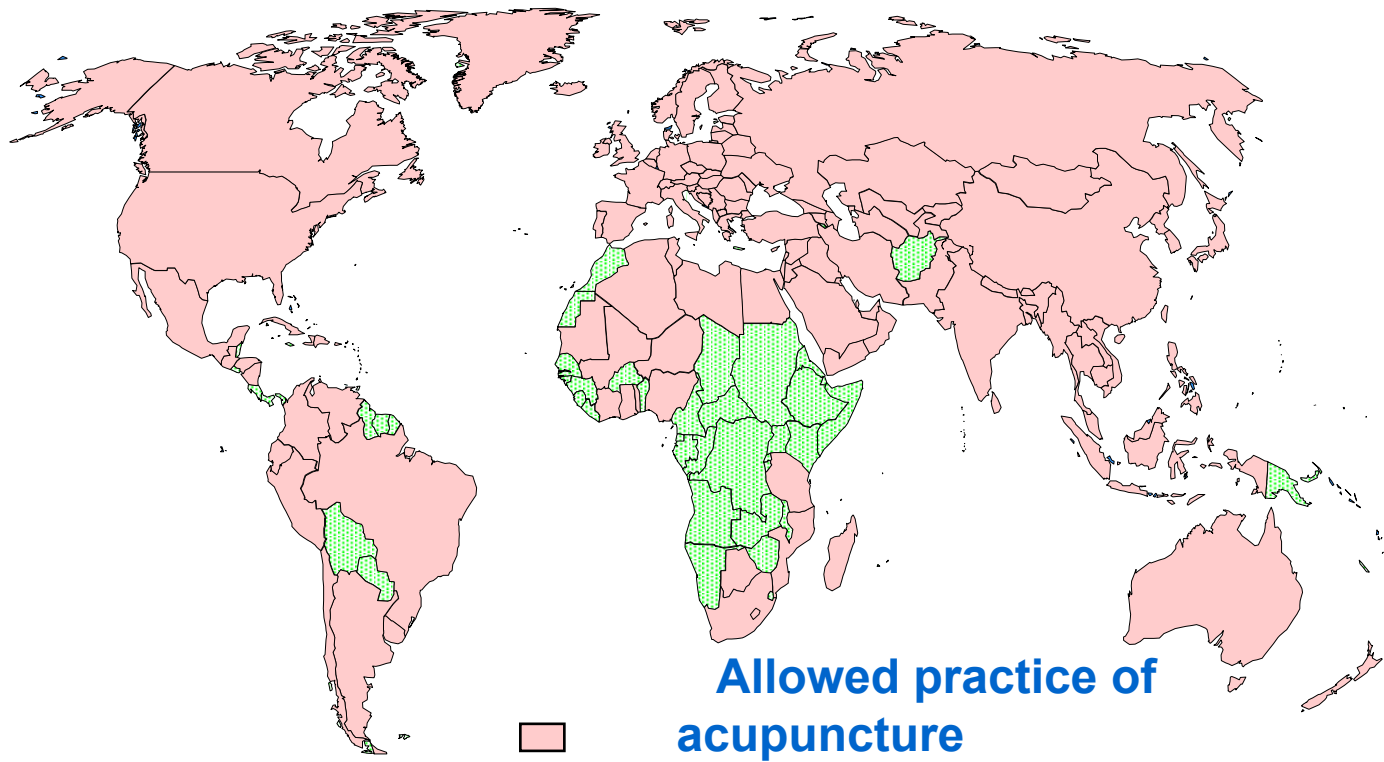
■ country has homeopathy practitioners

Prepared by LIGA Medicorum Homeopathica Internationalis in 2000

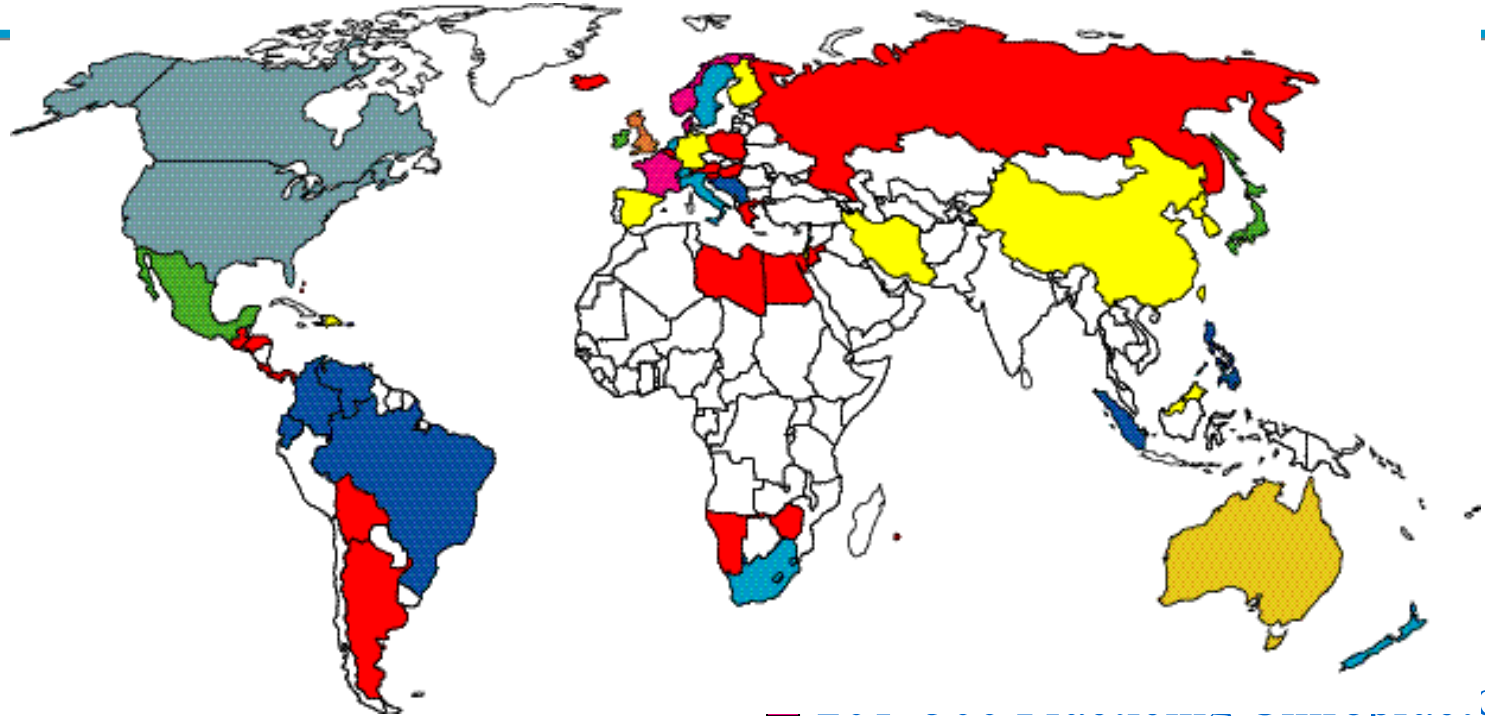


Acupuncture

Countries where the practice of acupuncture is allowed either *only* by medical doctors or *by both* doctors and acupuncturists



Number of Practicing Chiropractors Worldwide



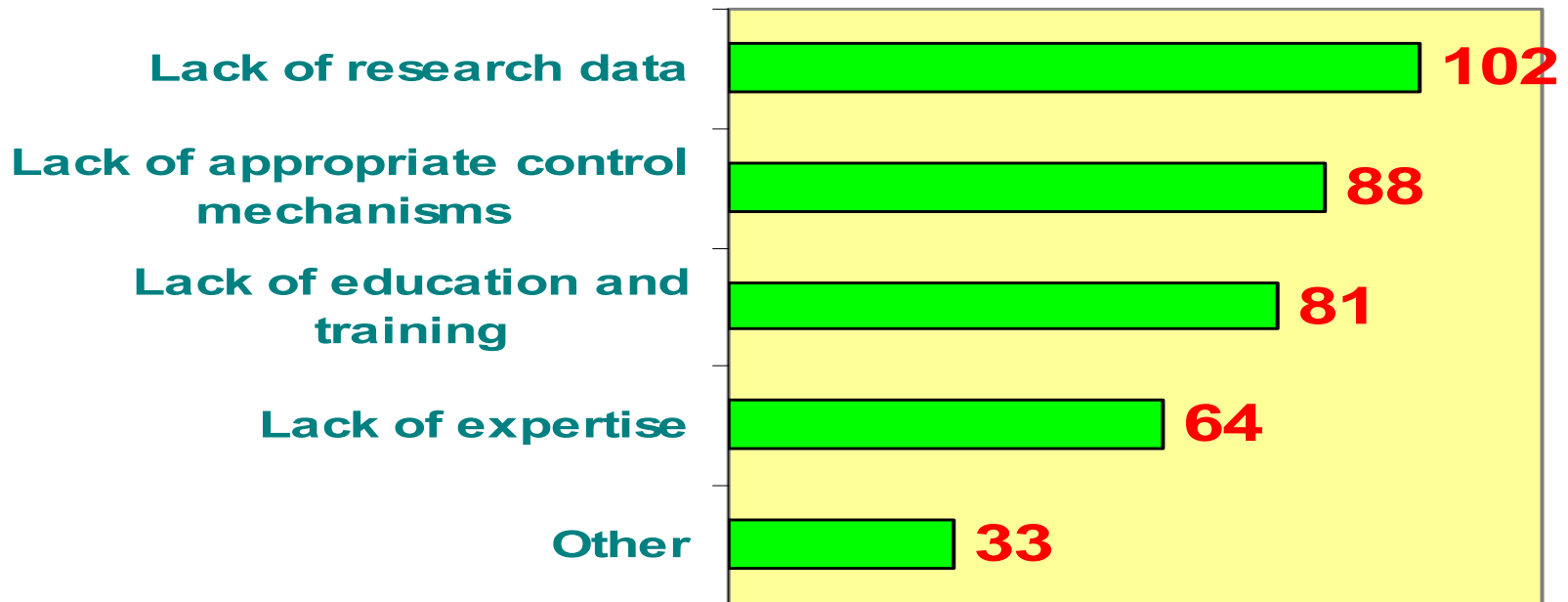
- 1–5 Practicing Chiropractors
- 11–50 Practicing Chiropractors
- 6–10 Practicing Chiropractors
- 101–200 Practicing Chiropractors
- 51–100 Practicing Chiropractors

- 1001–2000 Practicing Chiropractors
- 501–1000 Practicing Chiropractors
- 2001–5000 Practicing Chiropractors
- Over 5000 Practicing Chiropractors
- Unknown Status



Common difficulties and challenges in the field of traditional medicine

Main Difficulties Regarding Regulatory Issues on Herbal Medicines



Common difficulties and challenges in the field of traditional medicine

Lack of regulation:

Main quality control problem

- Inconsistent quality
- Incorrect identification of plant species used
- Unclear instructions on leaflets
- Lack of precautions and contraindications in leaflets and/or labelling
- Contamination by heavy metal above legally allowed limit
- Contamination by undisclosed chemical substances and/or substances illegally used

Lack of communication between national drug authorities in sharing regulatory issues



Major Challenges Related to Proper Use of TM/CAM by Consumer

Uninformed / Underinformed Consumers

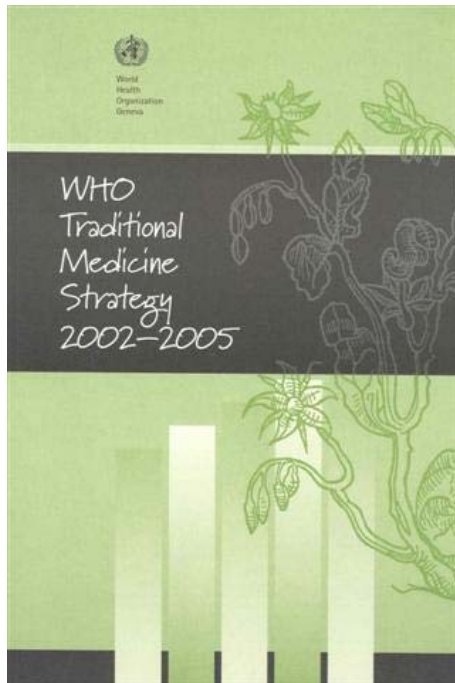
Consumers consider that TM/CAM therapies are natural and that “natural means safe”. They often use TM/CAM for self care.



Unqualified Practice

There is often no licensure and no information available about who is a qualified practitioner.

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

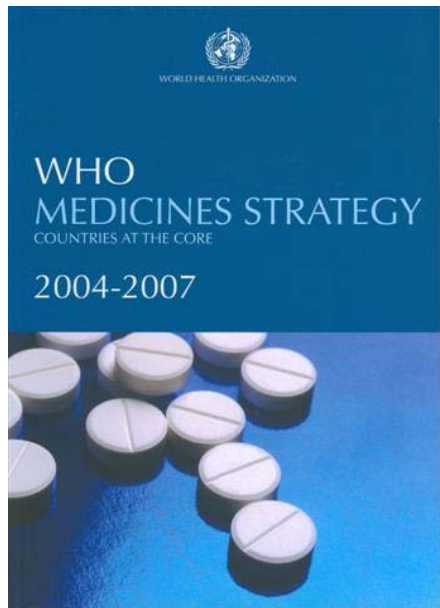
4

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

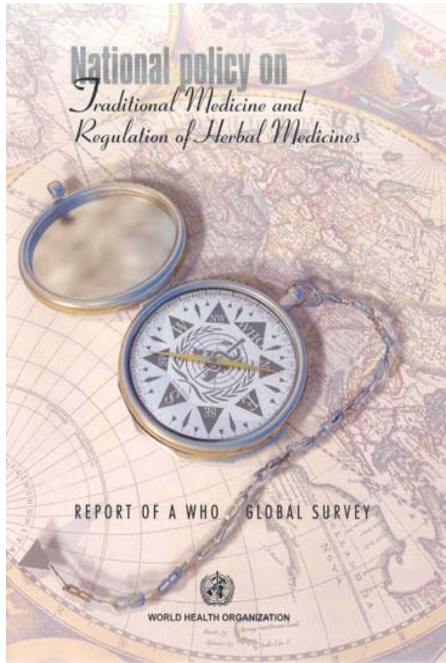


Medicines Strategy 2004-2007

- **TM/CAM integrated into national health care systems by developing and implementing national TM/CAM policies and programmes**
- **Safety, Efficacy and quality of TM/CAM enhancement**
- **Availability and affordability of TM/CAM enhancement**

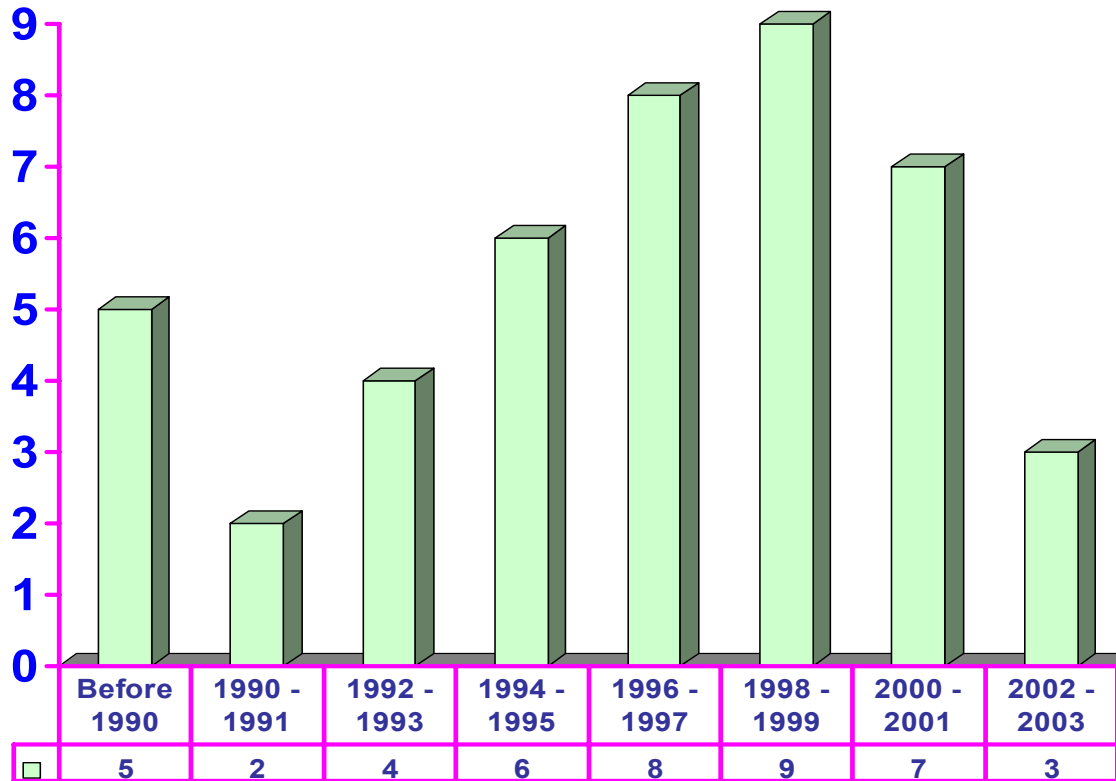


Member States' progress in the field of TM/CAM



- **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



31% of respondents have national policy

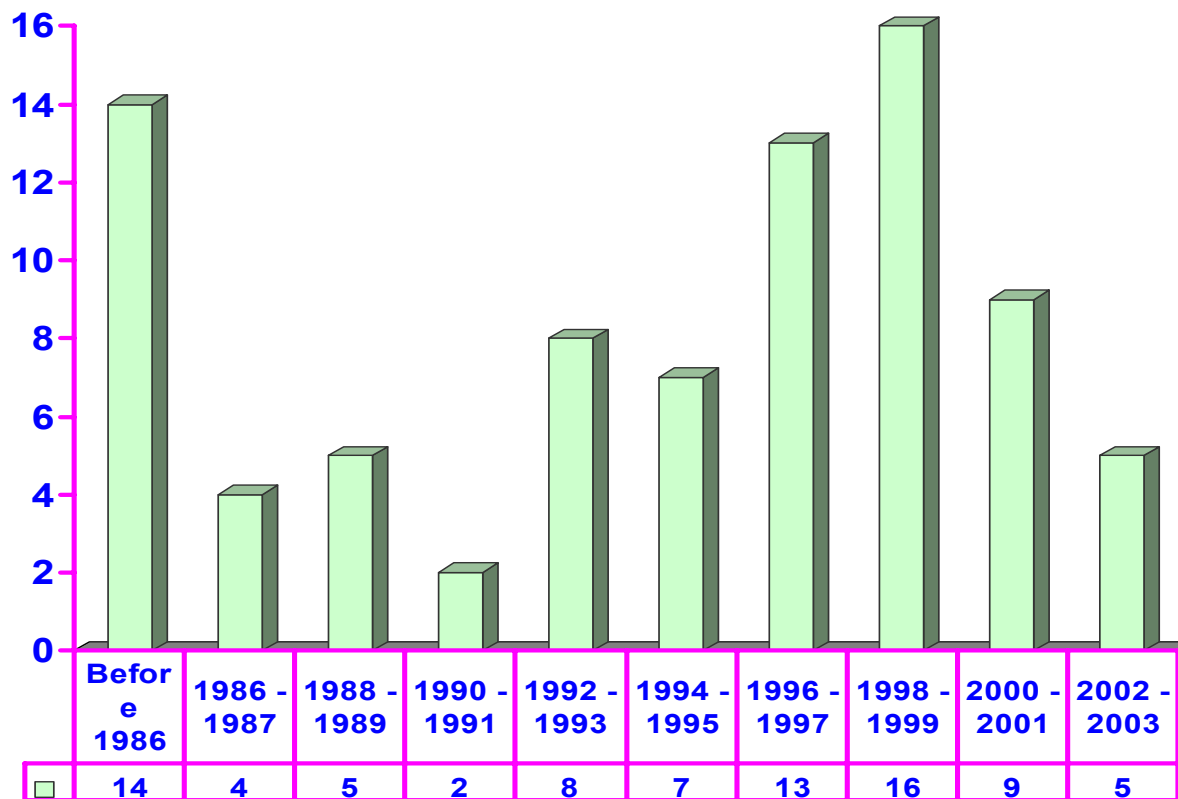
Number of Countries with National Policy Pending: 51

Number of Countries before 1990: 5

Number of Countries Total: 44



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



Achievements in Medicine Strategy 2004-2007

The indicators in TRM Strategy and Medicines Strategy

Objectives	Indicators	1999	2003	2007
		Status	Report	Report
TM/CAM integrated into national health system	Number of MS with TM/CAM policy	25	39	48
Safety, efficacy and quality of TM/CAM enhanced	Number of MS regulating herbal medicines	65	82	110
Rational use of TM/CAM by providers and consumers promoted	Number of MS with national research institute in TM/CAM	19	56	62



WHO's role in the field of traditional medicine

WHO's role in traditional medicine is:

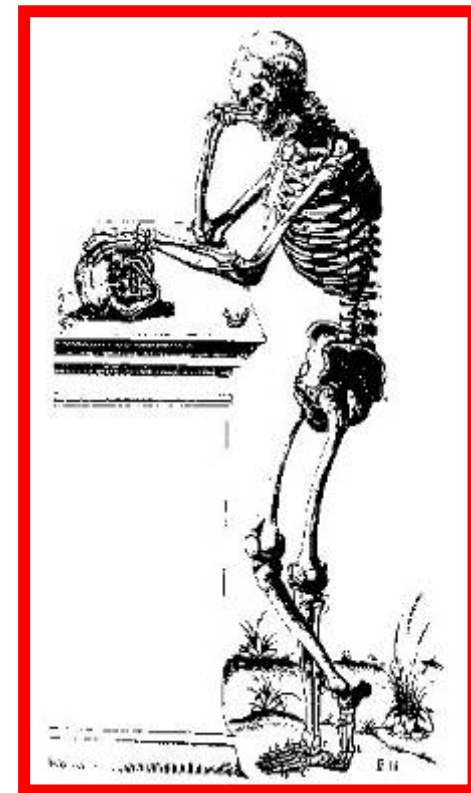
- to expand the recognition of TM/CAM;
- to support its integration into national health systems depending on the circumstance in the use of TM/CAM by countries;
- to provide technical guidance and information which helps people to use TM/CAM effectively and safely; and
- to preserve and protect traditional medicine knowledge and resources of medicinal plants for sustainable use of TM.



Difficult to understand difference between western medicine and TM/CAM

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.

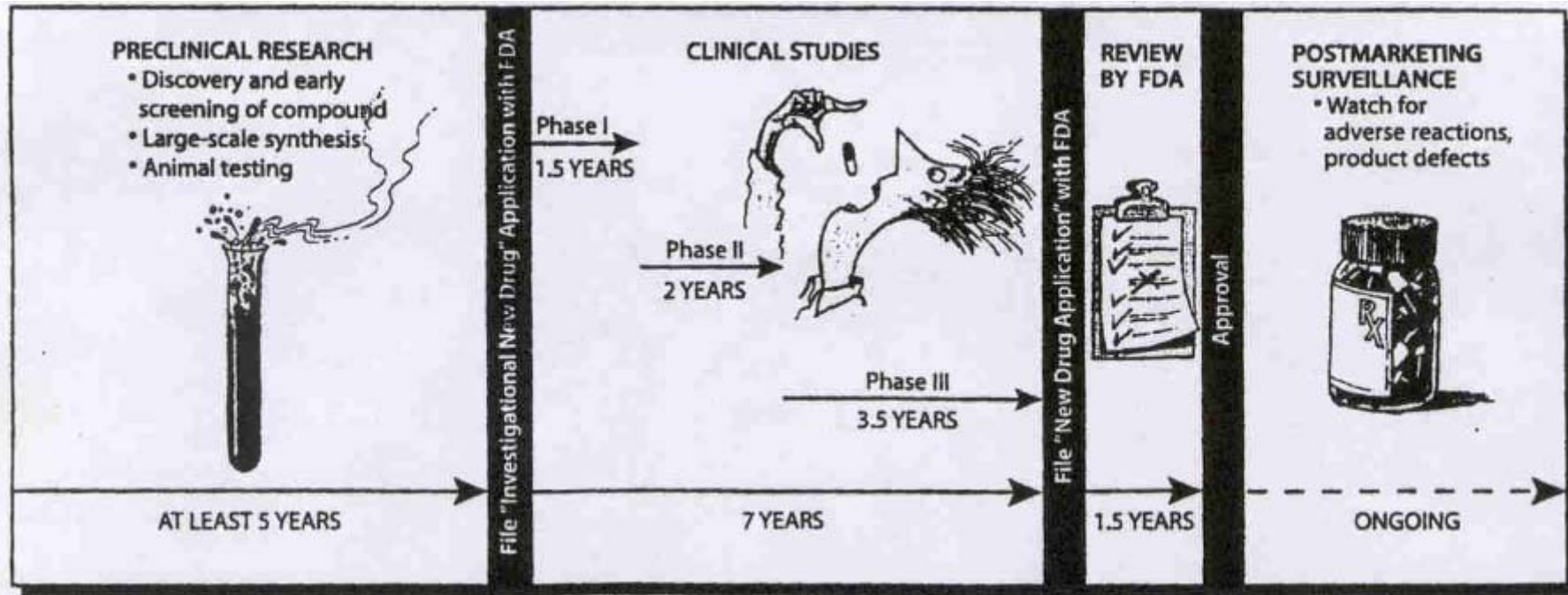


How to understand difference between western medicine and TM/CAM



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.

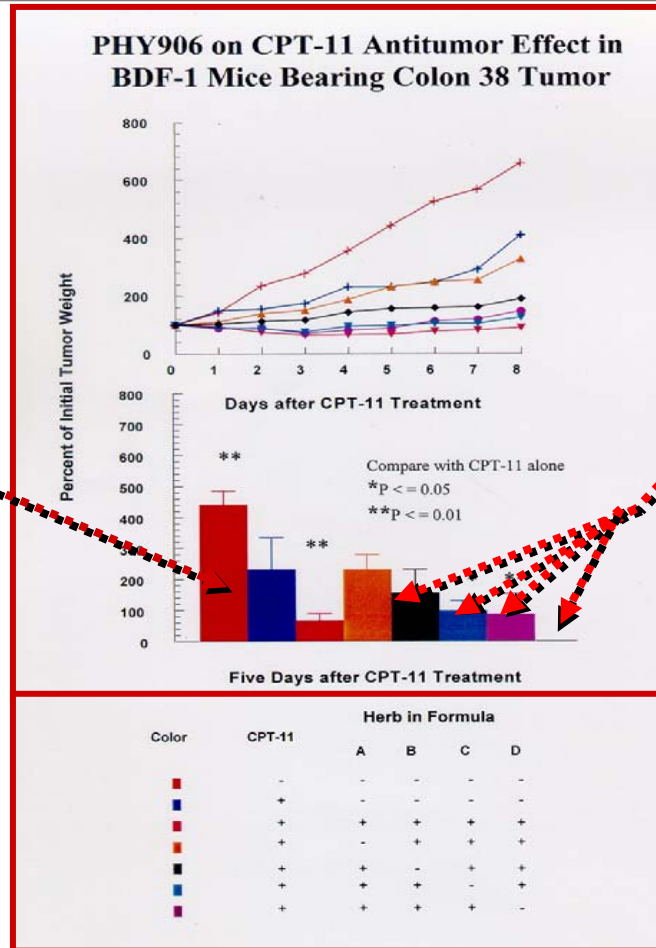
Procedure for developing a new chemical drug



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

Reported by Prof Yeeng-chi Cheng, Yale Medical School 2001



How to integrate TM/CAM into National Health System

" Now, the question, to my mind, should no longer be whether healthcare services should be integrated, but how and how soon it can be done? But you don't just have to take my word for it ...look at all indicators that there are around"

- His Royal Highness the Prince of Wales, 59th WHA



The role of traditional medicine

" I have heard about the importance of primary health care repeatedly during my visits to Latin America, Africa, Europe and Asia. Many countries in Africa face the challenge of rebuilding social support systems. Others in central Asia and Eastern Europe are undergoing transition from planned to market economies. They want WHO support. They want to make sure that equitable and accessible systems built on primary health care are not sacrificed in the process. They reminded me that traditional medicine is an important component that needs to be addressed. I agree."

- Dr Margaret Chan speech on election in WHA 2006



Categories of Situation of TM/CAM in National Health System

Four main kind of systems including TM/CAM

- **Integrative,**
- **Inclusive,**
- **Tolerant**
- **Exclusive.**



Integration of TM/CAM into National Health System

So far, no clear criteria for the integration of TM into national health systems have been established by WHO. It could be explained that the integration of TM and CAM means that the national health system includes two parallel systems, i.e. conventional medicine and TM/CAM.

To be considered as having an integrative system in a country must:

- have comprehensive and coherent national policies and national regulation and legislation including both the practice and products of TM/CAM;
- have remedies and practices at all health care levels, including private and public services;
- have health insurance coverage for TM/CAM (either national or private);
- have fully established official national curricula for TM/CAM at university level and national qualification schemes;
- have TM/CAM research institutions and ensure appropriate research grants to support research institutions and research projects on the same basis as those for conventional medicine.

WHO working group meeting on integration of TM/CAM into national health system 13 May 08 Brazil



Comprehensive approaches of Integration of TM/CAM into national health system

	law	State Office	Regulation for therapies	Service	Registration of practitioners	Regulation for herbal medicines	Health insurance coverage	Education	National research institutions
China	yes	yes	TCM Other minority therapies	2654 TCM hospital with, 1080 TCM pharmacue	340,000 TCM MD 1 million TCM assistants	Yes Pharmarco GMP GAP	Full	27 TCM university	70 TCM research institutions
Korea	yes	yes	Korean medicine	6264 Korean medicines hospital and clinics	9229 K MD 4500 acupun	Yes Pharmarco GMP	Full	11 KM university	2 KM research institutions
Vietnam	yes	yes	TCM	48 TCM hospitals with TCM Department	25,500 TCM MD 20,000 acupun 5,000 Practitioners	Yes Pharmarco GMP GAP	full	3 TCM faculty in University 2 second TCM school	3 TCM institutions

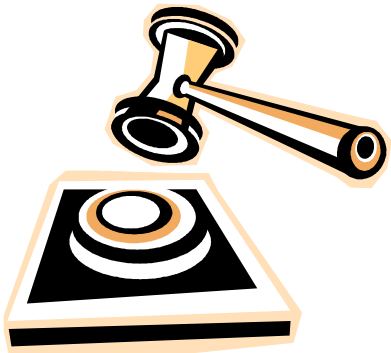


National law and regulation for TM/CAM therapies and practice in Selected European Countries

Country	Use	Practice CAM	Law	Insurance
France	75% population	30% GPs practice CAM 50,000 non-MDs provide CAM	MDs legally practice CAM	Social and private cover Homeopathy, Manual Therapy Chiropractic
Germany	80% population	77% pain clinic provide Acupuncture 13,000 traditional practitioners MD need to learn acupuncture	Homeopathy legal Licensed Heilprak- 1994	Partially covered Herbal Homeopathy Acupuncture



National law and regulation for integrating TM/CAM into health system



- Hungary 1997
- Belgium 1999
- Ghana 1999
- Ukraine 1998
- Russian Federation 2001
- Singapore 2001 and 2002
- Norway 2003
- Portugal 2003
- Brazil 2006
- Chile pending
- UK pending
- Bahrain pending
- South African pending

National Policy of Integrative and Complementary Practices in Unified Health System in Brazil (2006)

OBJECTIVES

- To incorporate and to implement the Integrative and Complementary Practices in SUS, in the perspective of injury prevention and the promotion and recovery of health, with emphasis in the basic attention, for the continuous humanized and integral health care.
- To contribute for the increase of the System resolubility and broader access to the Integrative and Complementary Practices, ensuring quality, effectiveness, efficiency and safety in its use.
- To promote the rationalization of health actions, stimulating innovative and socially contributive alternatives to the sustainable development of the communities.
- To stimulate actions regarding the social control/participation, promoting the responsible and continuous involvement of the users, managers and professionals in the different instances of health policies effectiveness.



Selected national law or regulation for TM/CAM practitioners

Portugal legislation in 2003

- The law recognized all practitioners dedicated practice of non-conventional therapies
- The law recognized non-conventional therapeutics are depart from a philosophical base which is different from conventional medicine and use distinct processes of diagnosis and their own therapeutics.
- non-conventional therapeutics included therapeutics of acupuncture, homeopathy, osteopathy, naturopathy, phytotherapy and chiropractic
- The law recognized technical and deontological autonomy in the professional activity of the practice of non-conventional therapeutics



Selected national law or regulation for TM/CAM practitioners

Norwegian regulation for the alternative treatment of disease, illness (2003)

- The regulation reorganized the alternative treatment could be provided by both MD and non-MD within or outside of health services
- Both MD and others who practise alternative treatment need to be registered requested by this regulation

Act No. 64 of 27 June 2003 relating to the alternative treatment of disease, illness, etc.



Selected national law or regulation for TM/CAM practitioners

Norwegian regulation for the alternative treatment of disease, illness (2003)

- The regulation forbidden to use alternative treatment for the communicable diseases
- The regulation not allow non-MD to treat serious diseases and disorders except in consultation with the patients' doctors
- The regulation allow non-MD to use alternative treatment for the alleviate or moderate symptoms or consequence of the disease or side effects of given treatment or strengthen the body's immune system or its ability to heal itself



Selected national law or regulation for TM/CAM practitioners

Germany

- Number of MDs providing: (according to year)

	<u>1994</u>	<u>2000</u>
Herbal medicines	5,700	10,800
Homeopathy	4,500	9,000

- Since 2004, MDs were required to take at least 200 hour training programme to licensing practice acupuncture based on WHO acupuncture training guidelines
- National law of Heilpraktikers was issued 1993
- Non-MDs (around 13,000), including Heilpraktikers and provide: herbal medicines, homeopathy, acupuncture



National law and regulation for TM/CAM therapies and practice



- **Third PARLATINO Inter-parliamentary Health Conference was held in Sao Paulo in 2005 and attended by 74 parliamentarians from 17 countries.**
- **The “Parliamentary Working Group on Traditional and Complementary Medicine” was created with the purpose of developing a framework of legislation on TM/CAM to guide its Member States.**
- **The working group will become a permanent working group within the PARLATINO Committee in the near future.**



National law and regulation for TM/CAM therapies and practice



- A working group composed 10 countries has been set up in 2007
- Based on the experience of the national law on TM/CAM in the countries named Guatemala, Mexico, Cuba And Venezuela, A Framework Law has been drafted.
- Parliamentarians of its Members States reviewed the draft Framework Law and has been adopted in December 2007 during the PARLATINO'S Assembly.
- Then the 22 countries members will propose their own national law referred to the framework law

Legal Status of traditional Chinese medicine in Hong Kong SAR, China

Chinese Medicine Council

Chinese Medicine Practitioners Board

- Registration Committee
- Examination Committee
- Disciplinary Committee
- Committee on Assessment of Chinese Medicine Degree Courses

Chinese Medicines Board

- Chinese Medicines Committee
- Chinese Medicines Traders Committee
- Disciplinary Committee



Legal Status of traditional Chinese medicine in Hong Kong SAR, China

Transitional Arrangement

Long-term arrangement

Listed Chinese Medicine Practitioners

Degree in Chinese Medicine

Direct Registration

Registration Assessment

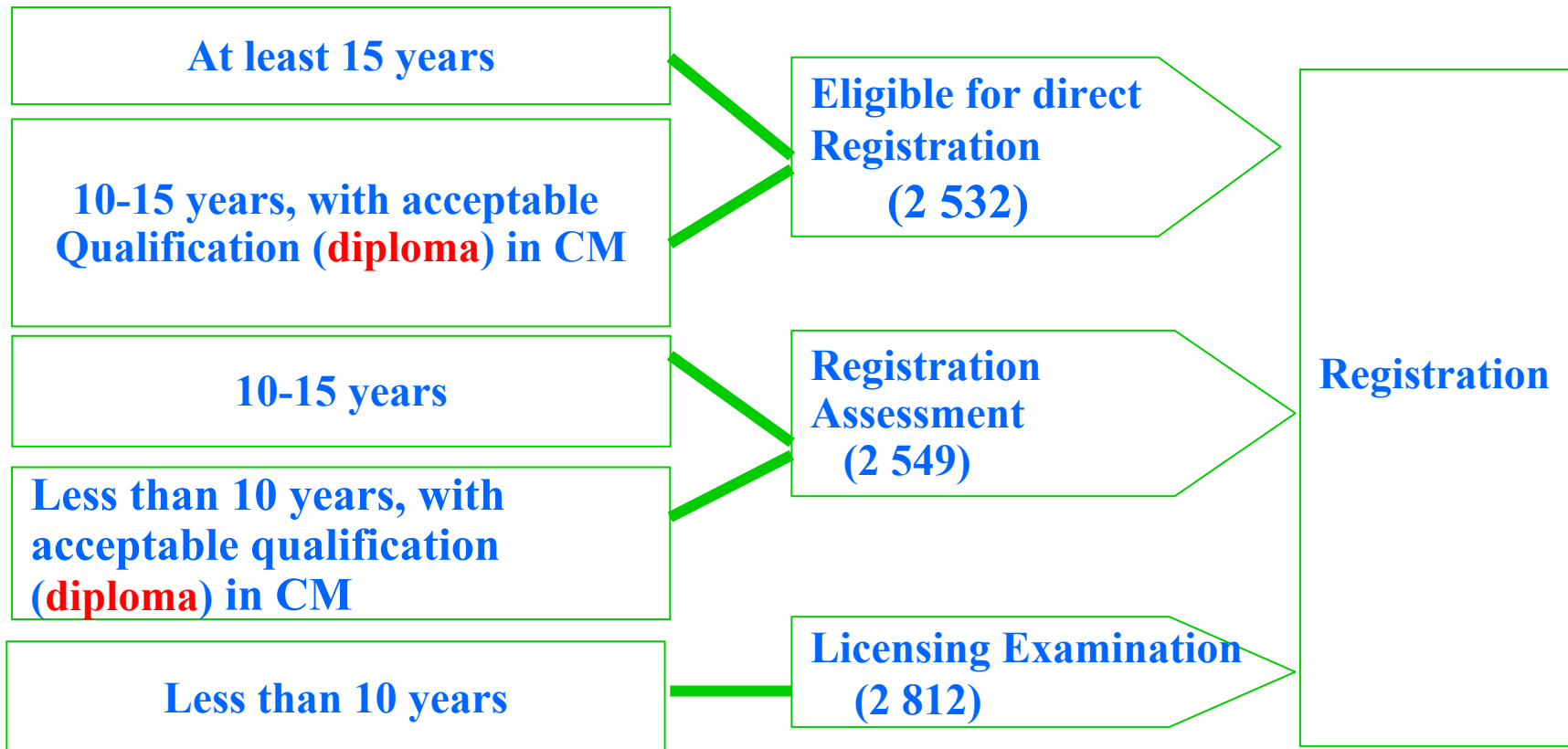
Licensing Examination

Registered Chinese Medicine Practitioners

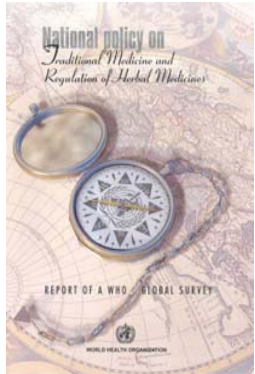


Legal Status of traditional Chinese medicine in Hong Kong SAR, China

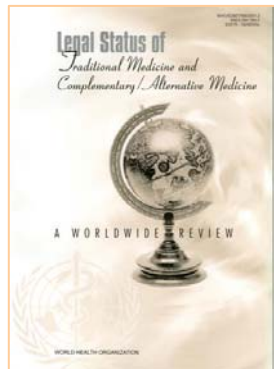
Approach in transit period



WHO provided support to TM/CAM

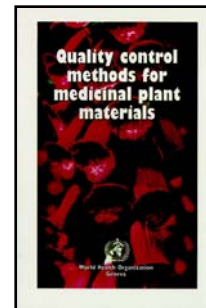
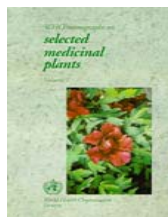
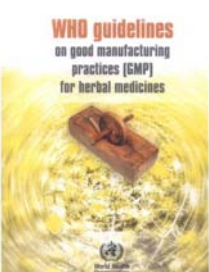
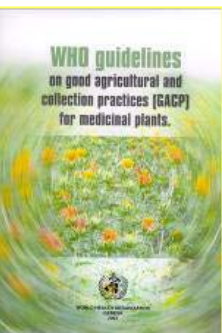


- sharing national policy, regulation and registration of TM/CAM
- sharing national experience on how to step by step to establish relevant policy, regulation and registration for products and practice
- strengthen cooperation in international and regional levels. E, g, coordinated *International Regulatory Cooperation for Herbal Medicines* network (**IRCH**).
- organizing interregional or country training programmes/workshops

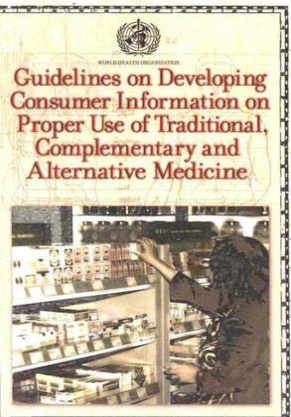


WHO provided support to TM/CAM

- provide technical guidelines to support quality, safety and efficacy of TM/CAM
- promote development and use of TM/CAM based on related available evidence
- strengthen sharing research information including linkage between the 19 Collaborating Centers for traditional medicine through WHO website
- establish relevant mechanisms and requirements to control illegal and inappropriate commercialized TM/CAM

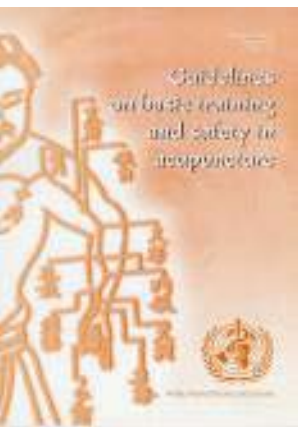
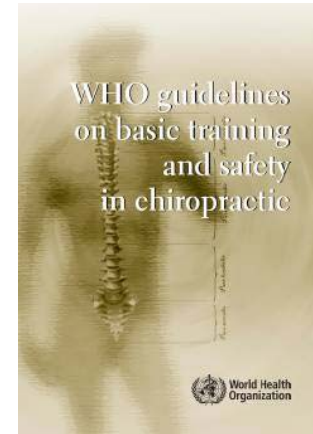


WHO provided support to TM/CAM



Objectives of the training guidelines

- Provide minimum requirements of basic training for different groups
- Provide contraindications
- Respect the different considerations affecting individual CAM professions
- Serve as a reference to national authorities to establish examination systems for the education and licensing to ensure qualified practice.
- provide guides and information for consumers in properly use of TM/CAM



Traditional medicine in the health system strengthening and improving

improving health development and health security means improving health systems and that promoting integrated primary health care to strengthen health systems is simple and it works. Primary health care should be focused on health promotion and disease prevention, with special emphasis on self-care and healthy lifestyles.



陈冯富珍博士
总干事
世界卫生组织

Dr Margaret Chan speech on 119th WHO Executive Board Session 2006



WHO future direction

- **Policy:** to facilitate integration of TM/CAM into health care delivery systems where appropriate through the establishment of national policy and regulation for medicines/products, practice, and providers of TM/CAM
- **Safety, Efficacy, and Quality:** to promote development and use of TM/CAM based on available evidence as it relates to TM/CAM products and practitioners
- **Promotion of Use of TM/CAM in Primary Health Care (PHC):** to increase accessibility of primary health care, along with proper use, protection, and preservation of traditional medicine / complementary and alternative medicine knowledge
- **Human resource:** to promote and upgrade the knowledge and skill of TM/CAM providers to ensure patient safety



Integration of TM/CAM into national health system



WHO Congress on Traditional Medicine,
7-9 November 2008, Beijing, China

Co-sponsored and hosted by
the Ministry of Health and
State Administration of Traditional Chinese Medicine



International Forum on Integration of TM/CAM into Health System



Integration of TM/CAM into national health system

" For the past twenty four years, I have argued that patients should be able to again the benefit of the "best of both worlds"- complementary and orthodox."

- His Royal Highness the Prince of Wales, 59th WHA, 2006



Integration of TM/CAM into national health system

**Conventional
medicine**

**Traditional and
complementary/
alternative
medicine**



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

