



## REVIEW ARTICLE

### CHALLENGES IN THE REGULATION OF TRADITIONAL MEDICINE – A REVIEW OF GLOBAL SCENARIO

SULOCHANA GANAPATI BHAT<sup>1</sup> K.S. DHIMAN<sup>2</sup>

#### ABSTRACT

Traditional medical knowledge and practices are widely prevalent around the world since centuries. With rapidly increasing use of traditional medicine and complementary/alternative medicine (TM/CAM) throughout the world its safety, efficacy and quality became major challenge and has made their regulation an urgent need. The effort to regulate TM is a priority of all governments, which got greater impetus since WHO Declaration of Alma-Ata in 1978. Though there are various guidelines and international consensus, countries face difficulty in the development and implementation of the regulation due to its diversity and complexity. Some literatures are available on global initiatives for regulation of TM and the challenges they are reviewed in this paper with appropriate references. For the compilation and review of information, hand-searching of books, journals, reports on traditional medicine and policy documents were done. Google, Pub Med and Medline online searches were also carried out to access other relevant publications. The key words used to access online materials mainly included traditional medicine, complementary/alternative medicine, folk medicine, traditional healer, herbal medicine, health policy, economic policy, intellectual property rights.

**Key-words:** traditional medicine, alternative medicine, regulation, policy, global scenario, WHO

<sup>1</sup>Research Officer (Ay. Scientist 3), Advanced Centre for Ayurveda (CCRAS), Ministry of AYUSH, National Institute of Mental Health and Neuroscience (NIMHANS), Hosur Road, Lakkasandra, Bengaluru-560029, INDIA

<sup>2</sup>Director General, Central Council for Research in Ayurvedic Sciences, Ministry of AYUSH, Govt. of India, New Delhi

Corresponding author email: [dr.sulochana@gmail.com](mailto:dr.sulochana@gmail.com)

Access this article online: [www.jahm.in](http://www.jahm.in)

Published by Atreya Ayurveda Publications under the license CC-by-NC

## INTRODUCTION

Traditional medicine is the sum total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses<sup>[1]</sup>. Based on this broad definition it may be hard to find a region without some form of traditional medicine and complementary/alternative medicine (TM/CAM) practice often called in various ways such as traditional medicine, alternative medicine, complementary medicine, natural medicine, herbal medicine, phyto-medicine, non-conventional medicine, indigenous medicine, folk medicine, ethno medicine etc. Whereas there is wide diversity at a practical level, the basic philosophy of all such knowledge systems is comprehensive approach to health, keeping in mind physical, mental, social, emotional, spiritual, environmental factors. In many countries TM/CAM services are often used alongside and in addition to conventional medical treatments<sup>[2]</sup>.

Some systems like Ayurveda, Yoga, Homoeopathy or Traditional Chinese medicine were evolved in a historical period with their conceptual, theoretical frameworks and elaborate codified literatures which are part of

the national heritage. The folk knowledge traditions are mostly orally transmitted and ethnic community specific with household level health practices such as home remedies, rituals, specialized techniques both for human and veterinary use. There is also new knowledge generated in the west and other developed countries with a mix of ancient and contemporary scientific knowledge such as Reiki or Shiatsu, Phyto-medicine, Health supplements and Macrobiotics. Often some of these are also a blend of one or more of older medical knowledge systems.

Few publications on the subject were available on global status of TM, however, there was a need to compile all of them for a logical conclusions. In a view to provide an overview on challenges in the regulation of Traditional Medicine the available publications were reviewed. For the compilation of information, hand-searching of books, journals, reports on traditional medicine and policy documents were done. Google, Pub Med and Medline online searches were also carried out to access other publications on the subject. The key words used to access online materials mainly included traditional medicine, complementary/alternative medicine, folk medicine, traditional healer, herbal medicine, health policy, economic policy, intellectual property rights.

### Need for attention

Traditional medicine has been practised for thousands of years. It was the only available method of health care before western modern medicine was introduced. Even after the advent of modern medicine, traditional medicine plays an important role in many countries<sup>[3]</sup>. The global efforts to regulate and mainstream TM/CAM are need based and consumer driven. In some Asian and African countries, 80% of the population depends on traditional medicine for primary health care<sup>[4]</sup>. Between 70% and 95% of citizens in a majority of developing use traditional medicine for the management of health and as primary health care. In some industrialized nations such as Canada, France, Germany and Italy use of traditional medicines is reported between 70% and 90%<sup>[5]</sup>.

Heavy burden of communicable diseases coupled with chronic diseases, maternal and child mortality, rapid demographic changes and urbanization, under utilization of public healthcare, ineffective health support systems for poor population, increasing privatization of health facilities, migration of medical professionals, environmental changes and related epidemics are major public health concerns. High out of pocket spending on health and lack of appropriate health insurance or social security are other concerns. Added to this, increased inaccessibility and unavailability of healthcare

to the economically disadvantaged people is another issue<sup>[6]</sup>.

It is an accepted fact that TM/CAM is playing an important role in care of chronic diseases. Folk healers continue to play a key public health role contributing to availability of human resources in countries where the population to physician ratio is high. In communicable diseases also traditional medicine has proved its significance, e.g. Quinine and Artemisinin are derived from traditional medical knowledge. However unregulated TM/CAM may be a serious patient safety threat.

### **Global Efforts**

Though the United Nations' Millennium Development Goals (MDGs), WHO strategies and United Nations Human Rights office (UNHCHR) call for immediate actions to address access to health care, it vastly continues to remain a challenge at global and national levels. Since the Declaration of Alma-Ata mentioned the role of traditional practitioners in the primary health care in 1978, the traditional medicine got greater impetus among its Member States. WHO Traditional Medicine Strategy was developed with its four primary objectives of framing policy; enhancing safety, efficacy and quality; ensuring access; and promoting rational use<sup>[7]</sup>. Resolution WHA56.31 on traditional medicine was adopted at the 56<sup>th</sup> World Health

Assembly in May 2003. Over the past four decades, WHO has produced several policy documents on TCAM relating to their promotion and development, regulation, guidelines and standards for safety, efficacy, good manufacturing, research, assessment, clinical trials, rational use, training of health practitioners, standardization of terminologies in general and also specific to various disciplines [8], [9], [10], [11], [12], [13], [14], [15], [16], [17], [18], [19], [20], [21], [22], [23], [24], [25], [26], [27], [28], [29], [30]. The WHO also continues to monitor the status of traditional medicines around the world through regular surveys and other data gathering activities.

Apart from this, United Nations Environment Program (UNEP), Food and Agriculture Organization (FAO) initiatives, UN conference on Trade and Development (UNCTAD), UN Industrial Development Organization (UNIDO), World Intellectual Property Organization (WIPO) and other international organizations such as Commonwealth Secretariat, European Union, World Bank and World Trade Organization also have programs on certain aspects of traditional medicine. Similarly nongovernmental bodies such as Cochrane Collaboration, Ford Foundation and World Wide Fund for Nature (WWF) have also been assisting various initiatives in TCAM (WHO 2002). In the United Nations Committee on Economic, Social and Cultural Rights resolution

of 2000, article 34 on the right to the highest attainable standard of health, states' obligations to respect include, "obligation to refrain from prohibiting or impeding traditional preventive care, healing practices and medicines. Besides, there are policies regarding indigenous people, traditional knowledge (TK), bio-diversity etc. The United Nations Declaration on the Rights of Indigenous Peoples of 200712, article 24, is about right to use traditional medicines. The Convention on Biological Diversity (CBD) 199213), Indigenous and Tribal Peoples Convention (ILO) 198914, International Treaty on Plant Genetic Resources (FAO) 200115, UN Declaration on the Rights of Indigenous Peoples (UNPFII) 2006, the Convention for the Safeguarding of Intangible Cultural Heritage (UNESCO) 200316 are some of the major global instruments that address issues related to traditional knowledge [31], [32], [33], [34], [35].

### **Global Status**

Despite many challenges, considerable progress has been made in recent years at the national, regional and international levels to create the institutional frameworks and regulatory environments necessary to support the registration, research and production of traditional medicines. In 2007, it was reported that 110 of the 193 WHO Member States had some type of policy in place regarding regulation and/or registration of traditional

medicines, up from fewer than 15 who were able to make the same claim in 1986. In 2006 the International Regulatory Cooperation for Herbal Medicines (IRCH), coordinated by WHO was created to protect and promote public health and safety through improved regulation of herbal medicines. Currently, the membership of IRCH consists of 22 countries and three regional/sub-regional groups<sup>[36]</sup>.

The global market for traditional medicine products which are marketed as a food or dietary supplement, health food or as a pharmaceutical preparation has expanded significantly over the last decade. Market estimates suggest that the rate of growth in traditional medicine product sales in recent years amounts to somewhere between 5% and 18% per annum<sup>[37], [38]</sup>.

The extent to which TM/CAM is an officially recognized element of health care depends largely on the structure of the health system in individual countries. WHO has identified three types of health system structures in relation to TM/CAM: an integrative health system, an inclusive health system and a tolerant health system. The integrative health system established in China, Republic of Korea and Viet Nam etc. is thought to be best model as TM/CAM is officially recognized, regulated and incorporated into all areas of health care provision. Countries like India and Srilanka also have a good policy frame work for the

recognized traditional medicines in their country<sup>[39], [40]</sup>.

In the recent decades though there have been certain international and national policies for preserving and promoting traditional medicine, the progress of their implementation has been rather slow. Additionally these policies fall short of adequately addressing a number of concerns related to TM/CAM such as safety, efficacy, quality, rational use, availability, preservation and development of such health care, sustainable use of natural resources and assuring equity in transactions at various levels and so on<sup>[41]</sup>. Regulation and capacity building of non-formal practitioners, developing appropriate methodologies for evaluation, resolving conflicts with mainstream medicine are some of the key challenges in the sector. A WHO survey identifies the main difficulties regarding regulatory issues for herbal medicines - lack of research data, lack of appropriate control mechanisms, lack of education and training and lack of expertise<sup>[42]</sup>.

**National policy and regulation:** Key elements of a national policy are definition of TM/CAM, governments' role in its development, provision of safety and quality assurance for therapies and products, legislation relating to providers including capacity building, provision of education and training, promotion of

proper/rational use, provision of coverage by public health insurance and consideration of intellectual property right issues. More than 100 countries have regulations for herbal medicines (WHO 2008). WHO resolutions and guidelines the framing and advocacy of national policies is far from satisfactory in many countries. The general lack of knowledge about herbal medicines within national drug authorities due to lack of documentation and dissemination is also seen as a hurdle in framing policies. Certain regulations like Traditional Herbal Medicinal Products Directive (THMPD) of European Union, USFDA, Medicines and Healthcare products Regulatory Agency (MHRA) of England are viewed as very stringent by the pharmaceutical companies as the requirements of the scheme are either impossible to meet or are prohibitively expensive<sup>[43].[44].[45]</sup>.

**Education:** Main two dimensions in education are to ensure that the knowledge, qualifications and training of practitioners are adequate and there is a good understanding between TM/CAM practitioners. There are various models with respect to education. In some countries TM/CAM courses are integrated into allopathic medical education. Elsewhere TM/CAM courses are taught in the same duration and manner in which allopathic courses are designed. In some regions TM/CAM is taught through short term courses.

In many developing countries informal, experiential learning by apprenticing with physicians continues to be the major trend. While little attention may be paid by allopathic students when it is integrated into their curriculum, a university level formal education for TM/CAM makes it difficult to transfer many of the experience based aspects of tradition in an institutional milieu. Similarly short term courses also fall short of giving sufficient learning for students about certain experiential elements. While experiential learning through apprenticing with a healer used to be the method traditionally, today it does not find its place in an overwhelmingly formalizing system and due to lack of recognition for those trained in family traditions. Following increasing interests and utilization of traditional medicine by the public, the need for qualified practitioners becomes one of the key issues for ensuring the quality of services and safety of consumers. The introduction of licensing of practice of traditional medicine by governments in the Region also requires good education system on traditional medicine<sup>[46]</sup>.

**Safety, efficacy and quality:** Towards the end of 19<sup>th</sup> century traditional medicine production shifted from a home level production to cottage industry and subsequently to large industrial mass production making quality control a major

challenge. Currently, the majority of adverse events related to the use of herbal products and herbal medicines that are reported are attributable either to poor product quality or to improper use<sup>[47]</sup>. Counterfeit, poor quality, or adulterated products in international markets are common due to high levels of commercialization. According to WHO, the quantity and quality of safety and efficacy data available including long history of observations on TM are far from sufficient to meet the criteria needed to support its use worldwide. According to National Center for Complementary and Alternative Medicine (NCCAM), set up by the National Institutes of Health (NIH), U.S. Department of Health and Human Services, safety and effectiveness of many CAM therapies are uncertain as rigorous, well-designed clinical trials for many CAM therapies are lacking<sup>[48]</sup>. This is due to variety of reasons such as documentation, publication, policies, research culture in the practitioners and even a suitable research methodology.

**Research and publication:** TM/CAM generally tend to focus on a holistic approach to life, equilibrium between mind and body and the environment and adopt a preventive approach thus making it difficult to develop appropriate methodologies without harming these unique features. Moreover issues such as chemical complexity of multiple plant based

formulations are also challenges for developing a suitable methodology for research. The low level of research has slowed development of national standards and integration efforts. There are also insufficient contributions from social sciences to TM/CAM and most studies consider cultural knowledge as a stumbling block for health sector development. Poor and selective publication is another problem. Out of 5,000 Reviews currently available in the Cochrane Library 556 are related to Complementary & alternative medicine<sup>[49]</sup>. HerbalNet Digital Repository, a wide-ranging collection of digital intellectual materials on herbal and traditional medicine from institutions in the South-East Asia Region is a global effort towards information sharing<sup>[50]</sup>.

**Accessibility and cost effectiveness:** Improving affordability and accessibility to quality medicine through a qualified provider is the ultimate goal of regulation of TM/CAM. In the developing countries TM/CAM continues to be comparatively inexpensive though it is feared that a technology intensive production process would make them unaffordable (Unnikrishnan, 2010). Even though there are certainly instances when the cost of treatment using TM/CAM is much cheaper than the cost of accessing a conventional medical service, several studies have found that they cost the same or more

than conventional treatments for the same conditions<sup>[51]</sup>.

**Rational use:** Information, education and communication are three major pillars of rational use. Availability of essential drugs, access and affordability and rationality of prescription are the issues involved in promoting rational use. Qualification and licensing of providers, proper use of products of assured quality, good communication between TM/CAM providers, allopathic practitioners as well as patients and provision of scientific information and guidance for public are some of the key challenges in assuring rational use. Proper consumer information is most important in facilitating appropriate usage of TM/CAM. Several States have undertaken initiatives like having a National List of Essential Medicines to promote rational use in the government health services.

**Modernization:** Formalization of TM/CAM is resulting in increasing modernization of its practices at par with biomedical system. Fears about safety and efficacy, hierarchical relationship of medical systems, economical and political factors including global dominance of the west, unfamiliarity with TM/CAM approaches among policy makers, are all playing a negative role in this phenomenon (Bodeker et al. 2007). This contributes to erosion of local knowledge

especially relating to non-material or metaphysical aspects, continued marginalization of practitioners, increasing absorption of best drugs and practices into allopathic knowledge and so on. Conflict with formal systems in many countries even those with strong history of TM/CAM, is a major issue as allopathic professionals in most regions have strong reservations and sometimes total disbelief about the benefits of TM/CAM (WHO 2002). It is feared that imposition of Evidence Based Medicine, research on selected aspects of TM/CAM and the absorption of successful practices as evidence based modern medicine would result in medical absorption.

**Sustainable use of natural resources:** TM/CAM is dependent only on biodiversity and there is increasing demand for plants, animal and mineral resources. The expanding herbal product market could drive over-harvesting of plants and threaten biodiversity. Poorly managed collection and cultivation practices could lead to the extinction of endangered plant species and the destruction of natural resources. Efforts to preserve both plant populations and knowledge on how to use them for medicinal purposes is needed to sustain traditional medicine. WHO has prepared guidelines on good agricultural practices but the implementation of this has also been low<sup>[52]</sup>.

**Traditional/folk healers:** From the local healers point of view lack of successors, erosion of knowledge, conflicts with mainstream knowledge, lack of recognition, restrictive regulations for collection of medicinal materials, lack of adequate intellectual property protection, incompatibility of local ownership values with contemporary laws are some of the key concerns.

**Intellectual property rights and equitable benefit sharing:** Attempts to exploit traditional knowledge for industrial or commercial benefits may lead to prejudicial misappropriation of the same from its rightful holders. Hence it becomes pertinent to develop ways and means of protecting and nurturing traditional knowledge thereby ensuring sustainable development compatible with the interests of the traditional knowledge holders. Discussions on ownership issues of TM/CAM have been centered on two major multilateral bodies; the Convention on Biological Diversity and the World Trade Organizations (WTO) agreement on Trade Related Intellectual Property Rights (TRIPS)<sup>[53]</sup>.

## CONCLUSION

Traditional medical knowledge and practices are widely prevalent around the world since centuries. For the health sector to improve, measures such as improving physical and economic access, preventive strategies,

wellness management, promotion of best and essential practices in both communicable and chronic diseases, increased cooperation between various medical systems, sustainable natural resource use, protection of intellectual property rights, and equitable transactions are vital. It is evident that a single system of medicine will find it difficult to cope with the health care demands in near future. Though there are sufficient guidelines and international consensus, countries face difficulty in the development and implementation of the regulation of TM/CAM due to its diversity and complex challenges. Development of traditional medicines will require national legislation, economic allocation and public support to ensure continued focus on the popularization and development of traditional medicines in the future.

## REFERENCES

1. General guidelines for methodologies on research and evaluation of traditional medicine, World Health Organization, 2000.
2. Unnikrishnan Payyappallimana. Role of Traditional Medicine in Primary Health Care: An Overview of Perspectives and Challenges, Yokohama Journal of Social Sciences, Vol. 14 No. 6, 2010.
3. WHO International Standard terminologies on traditional medicine in the Western Pacific region, World Health Organization, 2007.
4. Traditional medicine Fact sheet N°134, World Health Organization, December 2008.

5. The World Medicines Situation 2011 - Traditional Medicines: Global Situation, Issues and Challenges, 2011.
6. Nambiar et al. Planning health care in developing countries, Anaesthesia, Volume 62, Issue Supplement s1, pages 5–10, December 2007.
7. WHO Traditional Medicines Strategy 2002–2005, World Health Organization 2002.
8. Traditional Medicine and Health Care Coverage, World Health Organization, Reprint 1988.
9. Traditional Practitioners as Primary Health Care Workers. Geneva, World Health Organization, 1995.
10. Guidelines for Training Traditional Health Practitioners in Primary Health Care , WHO/TRM, 1995.
11. Guidelines for the Appropriate Use of Herbal Medicines, WHO Regional publications, Western Pacific Series, No. 23, 1998.
12. Quality Control Methods for Medicinal Plant Materials, World Health Organization, 1998.
13. Regulatory Situation of Herbal Medicine, A Worldwide Review, World Health Organization, 1998.
14. Legal Status of Traditional Medicine and Complementary/Alternative Medicine, A Worldwide Review, World Health Organization, 2001.
15. WHO Monographs on Selected Medicinal Plants, Volume 1,2,3 and 4, World Health Organization, 1999, 2001, 2007 and 2009.
16. Traditional Medicine – Growing Needs and Potential, World Health Organization, Geneva, 2002 .
17. Guidelines on registration of traditional medicines in the WHO African Region, Brazzaville, World Health Organization Regional Office for Africa, 2004.
18. WHO Global Atlas of Traditional, Complementary and Alternative Medicine, WHO Kobe Centre , 2005.
19. Guidelines on minimum requirements for the registration of herbal medicinal products in the Eastern Mediterranean Region, Cairo, World Health Organization Regional Office for the Eastern Mediterranean, 2006.
20. WHO guidelines on good manufacturing practices (GMP) for herbal medicines,. Geneva, World Health Organization, 2007.
21. WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues, World Health Organization, 2007.
22. Report of WHO inter-regional workshop on the use of traditional medicine in primary health care, Ulaanbaatar, Mongolia, 23-26 Aug. 2007.
23. Report of the inter-regional workshop on intellectual property rights in the context of traditional medicine, Bangkok, Thailand, 6-8 Dec. 2008.
24. Benchmarks for training in traditional / complementary and alternative medicine - Benchmarks for Training in Ayurveda, World Health Organization, 2010.
25. Benchmarks for Training in Naturopathy, World Health Organization, 2010.
26. Benchmarks for Training in Naud Thai, World Health Organization, 2010.
27. Benchmarks for Training in Osteopathy, World Health Organization, 2010.
28. Benchmarks for Training in Unani medicine, World Health Organization, 2010.
29. Benchmarks for Training in Traditional Chinese Medicine, World Health Organization, 2010.
30. Quality control methods for herbal materials, World Health Organization, 2011.
31. <http://www.un.org/esa/socdev/unpfii/en/drip.html> . Last accessed on 11<sup>th</sup> March 2013.

32. Convention on Biological Diversity (CBD), article 8J, <http://www.cbd.int/traditional>. Last accessed on 11<sup>th</sup> March 2013.
  33. Indigenous and Tribal Peoples Convention (ILO), article 25, <http://www.ilo.org>. Last accessed on 11<sup>th</sup> March 2013. International Treaty on Plant Genetic Resources (FAO), article 9, <ftp://ftp.fao.org/ag/cgrfa/it/ITPGRRe.pdf>. Last accessed on 11<sup>th</sup> March 2013.
  34. United Nations Educational, Scientific and Cultural Organization (UNESCO), <http://unesdoc.unesco.org/images/0013/001325/132540e.pdf>. Last accessed on 11<sup>th</sup> March 2013.
  35. Guidelines for the regulation of herbal medicines in the South-East Asia Region, World Health Organization, 2004.
  36. <http://www.who.int/medicines/areas/traditional/irch/en/index.html>. Last accessed on 11<sup>th</sup> March 2013.
  37. Calixto JB. Efficacy, safety, quality control, marketing and regulatory guidelines for herbal medicines (phytotherapeutic agents), *Brazilian Journal of Medicine and Biological Research*, 33:179–189, 2000.
  38. <http://indianmedicine.nic.in>. Last accessed on 11<sup>th</sup> March 2013.
  39. <http://www.indigenoumedimini.gov.lk>. Last accessed on 11<sup>th</sup> March 2013.
  40. National Policy on Traditional Medicine and Regulation of Herbal Medicines - Report of a WHO Global Survey, World Health Organization, 2005.
  41. Bodeker G & Burford G. *Traditional, Complementary & Alternative Medicine: Public Health & Policy Perspectives*. Imperial College Press, 2007.
  42. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems, World Health Organization, 2004.
  43. <http://www.thmpd.eu/>. Last accessed on 11<sup>th</sup> March 2013.
  44. <http://www.fda.gov/>. Last accessed on 11<sup>th</sup> March 2013.
  45. <http://www.mhra.gov.uk/>. Last accessed on 11<sup>th</sup> March 2013.
  46. WHO guidelines for quality assurance of traditional medicine education in the Western Pacific Region, World Health Organization, 2005.
  47. Guidelines on developing consumer information on Proper Use of Traditional Complementary and alternative medicine, World Health Organization, 2004.
  48. <http://www.thecochranelibrary.com/view/0/index.html>. Last accessed on 28<sup>th</sup> Feb. 2013.
  49. <http://nccam.nih.gov>. Last accessed on 11<sup>th</sup> March 2013.
  50. <http://herbalnet.healthrepository.org/>. Last accessed on 28<sup>th</sup> Feb. 2013.
  51. Jamison DT et al., *Disease Control Priorities in Developing Countries*, 2nd edition. Washington (DC), World Bank, 2006.
  52. WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants, World Health Organization, Geneva, 2003.
  53. <http://www.wto.org>. Last accessed on 15<sup>th</sup> March 2013
- Cite this article as:** Sulochana Ganapati Bhat, K.S. Dhiman. Challenges in the regulation of Traditional Medicine – a review of global scenario, *J of Ayurveda and Hol Med (JAHM)*. 2015;3(6):110-120  
Source of support: Nil, Conflict of interest: None Declared