



# **WHO Traditional Medicine Strategy**

# 2014-2023



World Health  
Organization

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## Foreword

Across the world, traditional medicine (TM) is either the mainstay of health care delivery or serves as a complement to it. In some countries, traditional medicine or non-conventional medicine may be termed complementary medicine (CM). The WHA resolution on Traditional Medicine (WHA62.13), adopted in 2009, requested the WHO Director-General to update the *WHO Traditional medicine strategy 2002-2005*, based on countries' progress and current new challenges in the field of traditional medicine. The *WHO Traditional Medicine Strategy 2014-2023* thus reappraises and builds on the *WHO Traditional Medicine Strategy 2002–2005*, and sets out the course for TM and CM (T&CM) in the next decade.

T&CM is an important and often underestimated part of health care. T&CM is found in almost every country in the world and the demand for its services is increasing. TM, of proven quality, safety, and efficacy, contributes to the goal of ensuring that all people have access to care. Many countries now recognize the need to develop a cohesive and integrative approach to health care that allows governments, health care practitioners and, most importantly, those who use health care services, to access T&CM in a safe, respectful, cost-efficient and effective manner. A global strategy to foster its appropriate integration, regulation and supervision will be useful to countries wishing to develop a proactive policy towards this important - and often vibrant and expanding - part of health care.

Much has changed since the previous global strategy was published in 2002. More countries have gradually come to accept the contribution that T&CM can make to the health and well-being of individuals and to the comprehensiveness of their health-care systems. Governments and consumers are interested in more than herbal medicines, and are now beginning to consider aspects of T&CM practices and practitioners and whether they should be integrated into health service delivery. In order to meet this new demand, and in response to Resolution WHA62.13 on TM, WHO recently updated the objectives of the Traditional Medicine Programme.



The *WHO Traditional Medicine Strategy 2014-2023* will help health care leaders to develop solutions that contribute to a broader vision of improved health and patient autonomy. The strategy has two key goals: to support Member States in harnessing the potential contribution of T&CM to health, wellness and people-centred health care and to promote the safe and effective use of T&CM through the regulation of products, practices and practitioners. These goals will be reached by implementing three strategic objectives: 1) building the knowledge base and formulating national policies; 2) strengthening safety, quality and effectiveness through regulation; and, 3) promoting universal health coverage by integrating T&CM services and self-health care into national health systems.

Updating and enhancing the strategy has allowed WHO to acquire a better understanding of how to boost the global integration of T&CM into health systems. My hope is that it will provide Member States with a road map to achieving further success in their T&CM strategic planning.

I am very pleased to introduce the *WHO Traditional Medicine Strategy 2014-2023*. It is my conviction that it will be a valuable tool for governments, system planners and health practitioners and – most crucially – will benefit individuals seeking the right care, from the right practitioner, at the right time.

Dr Margaret Chan  
Director-General

## Acronyms used in this document

AFRO – WHO Regional Office for Africa

AMRO/PAHO – WHO Regional Office for the Americas/Pan American Health Organization

EMRO – WHO Regional Office for the Eastern Mediterranean

EURO – WHO Regional Office for Europe

IRCH – International Regulatory Cooperation for Herbal Medicines

PHC – Primary Health care

SEARO – WHO Regional Office for South-East Asia

UHC – Universal Health Coverage

WHA – World Health Assembly

WHO – World Health Organization

WIPO – World Intellectual Property Organization

WPRO – WHO Regional Office for the Western Pacific

WTO – World Trade Organization



## Executive summary

Traditional medicine (TM) is an important and often underestimated part of health services. In some countries, traditional medicine or non-conventional medicine may be termed complementary medicine (CM). TM has a long history of use in health maintenance and in disease prevention and treatment, particularly for chronic disease.

The *WHO Traditional Medicine (TM) Strategy 2014–2023* was developed in response to the World Health Assembly resolution on traditional medicine (WHA62.13) (1). The goals of the strategy are to support Member States in:

- harnessing the potential contribution of TM to health, wellness and people-centred health care;
- promoting the safe and effective use of TM by regulating, researching and integrating TM products, practitioners and practice into health systems, where appropriate.

The strategy aims to support Member States in developing proactive policies and implementing action plans that will strengthen the role TM plays in keeping populations healthy. It seeks to build upon the *WHO Traditional Medicine Strategy 2002–2005*, which reviewed the status of TM globally and in Member States, and set out four key objectives:

- policy — integrate TM within national health care systems, where feasible, by developing and implementing national TM policies and programmes.
- safety, efficacy and quality — promote the safety, efficacy and quality of TM by expanding the knowledge base, and providing guidance on regulatory and quality assurance standards.
- access — increase the availability and affordability of TM, with an emphasis on access for poor populations.
- rational use — promote therapeutically sound use of appropriate TM by practitioners and consumers.

Despite significant progress made in implementing this strategy around the world, Member States continue to experience challenges related to:

- development and enforcement of policy and regulations;
- integration, in particular identifying and evaluating strategies and criteria for integrating TM into national and primary health care (PHC);
- safety and quality, notably assessment of products and services, qualification of practitioners, methodology and criteria for evaluating efficacy;
- ability to control and regulate TM and CM (T&CM) advertising and claims;
- research and development;
- education and training of T&CM practitioners;
- information and communication, such as sharing information about policies, regulations, service profiles and research data, or obtaining reliable objective information resources for consumers.

This new strategy document aims to address these challenges. It will require Member States to determine their own national situations in relation to T&CM, and then to develop and enforce policies, regulations and guidelines that reflect these realities. Member States can rise to these challenges by organizing their activities in the following three strategic sectors:

1. build the knowledge base that will allow T&CM to be managed actively through appropriate national policies that understand and recognize the role and potential of T&CM.
2. strengthen the quality assurance, safety, proper use and effectiveness of T&CM by regulating products, practices and practitioners through T&CM education and training, skills development, services and therapies.
3. promote universal health coverage by integrating T&CM services into health service delivery and self-health care by capitalizing on their potential contribution to improve health services and health outcomes, and by ensuring users are able to make informed choices about self-health care.

For each objective, the strategy identifies a number of actions to guide Member States, partners and stakeholders, and WHO. The strategy supports Member States in designing and implementing a strategic plan in accordance with their

own national capacities, priorities, relevant legislation and circumstances. Its aim is to assist Member States in determining and prioritizing their needs, to provide for effective delivery of services, to support appropriate regulations and policy development and to ensure that these products and practices are applied safely.

It is anticipated that WHO will initiate a review of the implementation of this strategy approximately halfway through its term. This midterm review will be important in ensuring that the strategy is still relevant and timely as WHO and its stakeholders move into the final five years of the forthcoming mandate.



## 1. Introduction

In many parts of the world, policy-makers, health professionals and the public are wrestling with issues regarding the safety, effectiveness, quality, availability, preservation and regulation of traditional and complementary medicine (T&CM). T&CM continues to be widely used in most countries, and its uptake is increasing rapidly in other countries. At the same time, interest in T&CM is expanding beyond products to focus on practices and practitioners. As a result, WHO carried out a comprehensive analysis of the current status of T&CM around the world and worked with experts to develop the WHO Traditional Medicine Strategy 2014–2023, which will address some of these important issues. To facilitate the understanding of this strategy, box 1 below provides a definition of traditional medicine (TM), complementary medicine (CM) and T&CM.

### Box 1: T&CM Definitions

**Traditional medicine (TM):**

Traditional medicine has a long history. It is the sum total of the knowledge, skill, 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 illness. (<http://www.who.int/medicines/areas/traditional/definitions/en/>).

**Complementary medicine (CM):**

The terms “complementary medicine” or “alternative medicine” refer to a broad set of health care practices that are not part of that country’s own tradition or conventional medicine and are not fully integrated into the dominant health-care system. They are used interchangeably with traditional medicine in some countries.

(<http://www.who.int/medicines/areas/traditional/definitions/en/>).

**Traditional and complementary medicine (T&CM):**

T&CM merges the terms TM and CM, encompassing products, practices and practitioners.



### *T&CM around the world*

T&CM is widely used around the world and valued for a number of reasons. At the International Conference on Traditional Medicine for South-East Asian Countries in February 2013, the WHO Director-General, Dr Margaret Chan, stated that “traditional medicines, of proven quality, safety, and efficacy, contribute to the goal of ensuring that all people have access to care. For many millions of people, herbal medicines, traditional treatments, and traditional practitioners are the main source of health care, and sometimes the only source of care. This is care that is close to homes, accessible and affordable. It is also culturally acceptable and trusted by large numbers of people. The affordability of most traditional medicines makes them all the more attractive at a time of soaring health-care costs and nearly universal austerity. Traditional medicine also stands out as a way of coping with the relentless rise of chronic non-communicable diseases.”<sup>1</sup>. Regardless of reasons for seeking out T&CM, there is little doubt that interest has grown, and will almost certainly continue to grow, around the world.

### *WHO support for T&CM*

WHO’s mission is to help save lives and improve health. In terms of T&CM, WHO promotes these functions by:

- facilitating integration of T&CM into national health systems by helping Member States to develop their own national policies in this sector;
- producing guidelines for T&CM by developing and providing international standards, technical guidelines and methodologies for research into products, practices and practitioners;
- stimulating strategic research into T&CM by providing support for clinical research projects on its safety and effectiveness;
- advocating the rational use of T&CM through the promotion of its evidence-based use;
- and mediating information on T&CM by acting as a clearing-house to facilitate information exchange.

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<sup>1</sup> Speech given by WHO Director-General, Dr Margaret Chan, at the International Conference on Traditional Medicine for South-East Asian Countries. New Delhi, India, 12-14 February 2013.

### *Evolution of the WHO TM Strategy 2014–2023*

This document is intended to provide information, context, guidance and support to policymakers, health service planners, public health specialists, traditional and complementary medicine communities and other interested parties about T&CM, including products, practices and practitioners. It addresses issues in evaluating, regulating and integrating T&CM, as well as in harnessing its potential to benefit the health of individuals.

The *WHO Traditional Medicine Strategy 2014–2023* updates and enhances the framework for action laid out in:

- the *WHO Traditional Medicine Strategy 2002–2005* (2), the first strategy document ever prepared by WHO in this field;
- the traditional medicine sections of the *WHO Medicines Strategy 2004–2007* (3);
- and the traditional medicine components of the *WHO Medicines Strategy 2008–2013* (4).

This new strategy reviews the potential contribution T&CM can make to health, in particular health service delivery, and establishes priority actions for the period to 2023. This strategy is an effective and proactive response to the World Health Assembly Resolution on traditional medicine (1), which encourages Member States to consider T&CM as an important part of the health system and builds on the work introduced in the Beijing Declaration, adopted by the *WHO Congress on Traditional Medicine in 2008*.

This new strategy is an important document for Member States, T&CM stakeholders and WHO in positioning T&CM within countries' health systems. The strategy highlights advances in T&CM research and development and recognizes the experience gained during implementation of the *WHO Traditional Medicine Strategy 2002–2005* and the *WHO medicines strategies mentioned above*.

### *The need for a new strategy*

WHO and its Member States believe it is important to update and enhance the strategy at this time for a number of reasons:

#### **1) *Continued uptake of T&CM***

The public and consumers of health care worldwide continue to include T&CM in their health choices. This obliges Member States to support them in making informed decisions about their options.

#### **2) *T&CM has growing economic importance***

T&CM is growing and expanding, particularly with respect to products bought in person or over the Internet. The T&CM sector now plays a significant role in the economic development of a number of countries. At the same time, with prevailing current global financial constraints, use of T&CM for health promotion, self-health care and disease prevention may actually reduce health-care costs.

#### **3) *The global nature of T&CM***

T&CM products and practices from one region are used throughout the world to complement local health care service delivery, making T&CM a truly global phenomenon. This requires a new level of cooperation among Member States as the sector continues to work on defining and supporting access to safe products and practices.

#### **4) *Levels of education, accreditation and regulation of T&CM practices and practitioners vary considerably***

In an increasingly globalized world, individuals move freely from country to country in order to live and work. Given this trend, a better understanding of T&CM practitioners is needed to ensure professional consistency and safety.

#### **5) *Recent advances in T&CM research and development***

Since the release of the *WHO Traditional Medicine Strategy 2002–2005*, there have been significant advances in what is known about T&CM along with the development of technical standards and guidelines for organized health service delivery.

## **6) Intellectual property**

As T&CM becomes more popular, it is important to balance the need to protect the intellectual property rights of indigenous peoples and local communities and their health care heritage while ensuring access to T&CM and fostering research, development and innovation. Any actions should follow the global strategy and plan of action on public health, innovation and intellectual property (5).

## **7) Integration of T&CM into health systems**

As the uptake of T&CM increases, there is a need for its closer integration into health systems. Policy makers and consumers should consider how T&CM may improve patient experience and population health. Important questions of access as well as population and public health issues must be addressed.

This new strategy document reviews progress made worldwide since the *WHO Traditional Medicine Strategy 2002–2005*, including highlights of successes and emerging challenges, and provides a framework for action into the next decade which will strengthen T&CM globally.



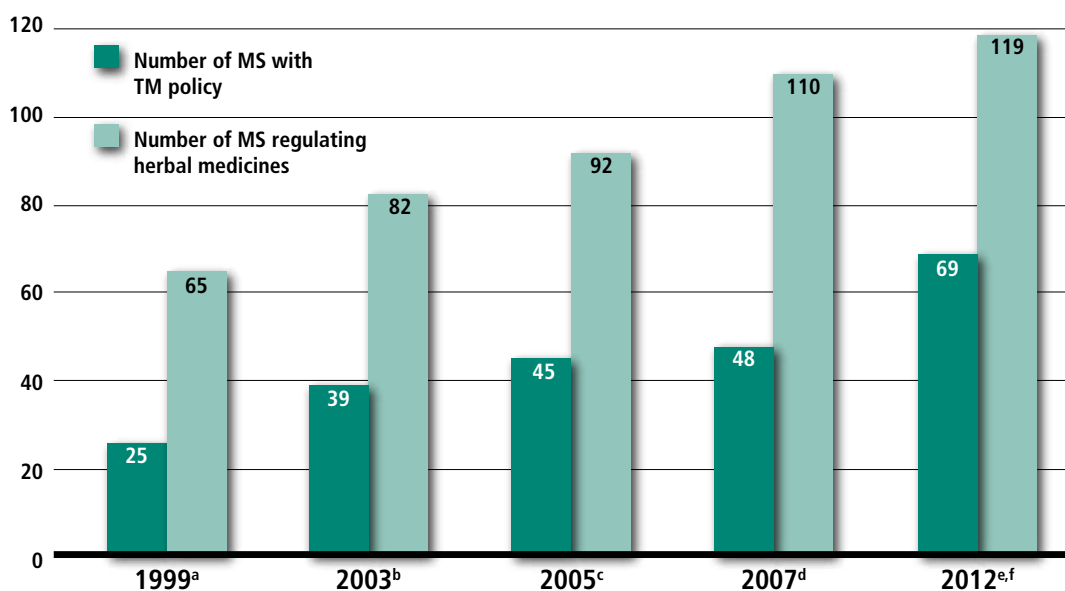
## 2. Global progress

Since the launch of the first the *WHO Traditional Medicine Strategy 2002–2005* (2), there has been significant and steady progress in implementing, regulating and managing T&CM in most regions of the world. Although Member States acted on their own initiative, the original strategy document played an important role in supporting their efforts (Figures 1 and 2). Statistics on global progress have been extrapolated from the recent WHO Global Survey on T&CM and are based on the key indicators outlined in the *WHO Traditional Medicine Strategy 2002–2005* (2).

### 2.1 Policy and regulations

Many Member States have made great efforts to advance T&CM, some of which can be attributed to the implementation of the *WHO Traditional Medicine Strategy 2002–2005*. In recent years, Member States have established or developed national and regional policies and regulations to promote the safe and effective use of T&CM. WHO has developed technical guidelines and

**Figure 1:** Monitoring changes in country progress indicators defined by the WHO Traditional Medicine Strategy



Sources:

a: Reference 2;

b: Reference 3;

c: Reference 6 and 7;

d: Reference 4;

e: **Number of MS with TM policy:** Combined data from: 1) an interim report of the second WHO global survey (mid-2012; with 129 survey and return) and 2) the 1st WHO global survey result (WHO, 2005);

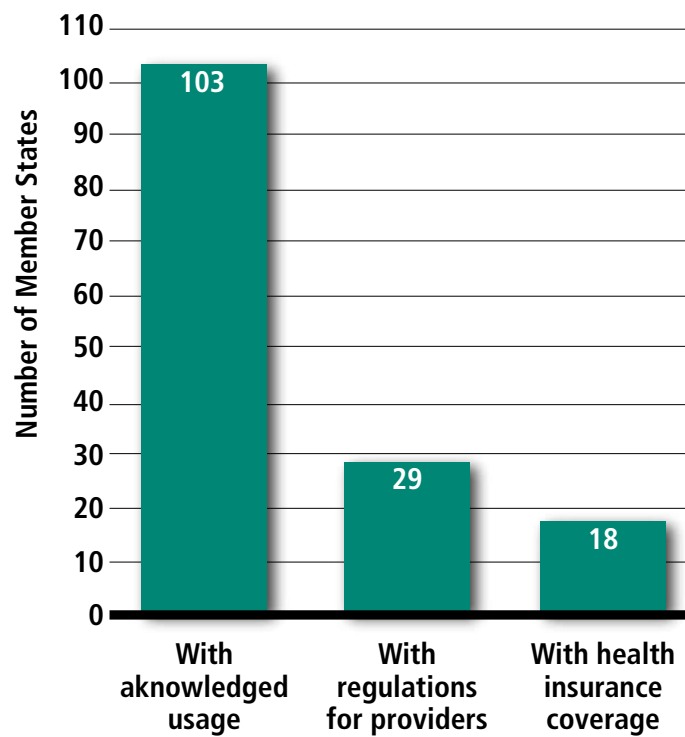
f: **Number of MS regulating herbal medicines:** Combined data from: 1) an interim report of the second WHO global survey (mid-2012; with 129 survey and return) and 2) the 1st WHO global survey result (WHO, 2005), 3) information on IRCH membership and 4) EU membership.

standards and organized trainings/workshops in support of Member States (<http://apps.who.int/medicinedocs/en/cl/CL10/>; see also Annex C). Figure 1 below shows the progress of Member States regarding established national policies on T&CM and national regulations on herbal medicines.

## 2.2 Practices

T&CM practices vary widely from country to country with certain practices (sometimes called modalities) regarded differently depending on the culture, understanding and accessibility of conventional medicine. A practice where significant progress has been made is acupuncture. Although acupuncture was originally a feature of traditional Chinese medicine, it is now used worldwide. According to reports supplied by 129 countries, 80% of them now recognize the use of acupuncture (Figure 2).

**Figure 2:** The Use of Acupuncture by Member States

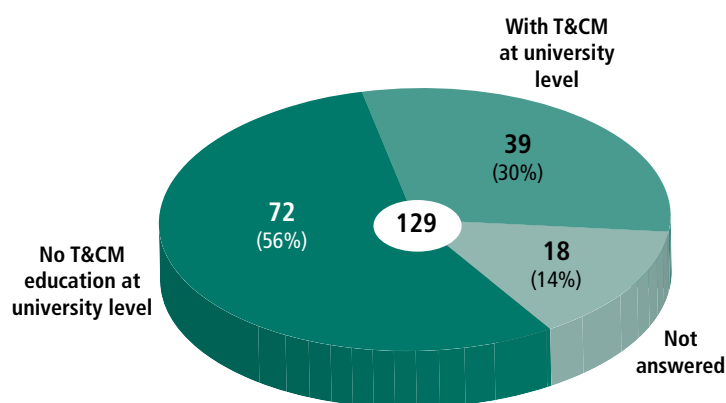


Source: Interim data from 2nd WHO TRM global survey as of 11 June 2012.

## 2.3 Education and research

In order to improve the safe and qualified practice of T&CM, Member States have developed regulations on the quality, quantity, accreditation and education structures for T&CM practitioners, including practitioners of conventional medicine who use T&CM. Significant progress has been made in

**Figure 3:** T&CM education at university level



Source: Interim data from 2nd WHO TRM global survey as of 11 June 2012.

many. For example, the number of Member States providing high-level T&CM education programmes including Bachelor, Master and Doctoral degrees at university level has increased from only a few to 39, representing 30% of the surveyed countries (Figure 3).

In the African Region, TM knowledge and practices have been passed on orally among traditional health practitioners for many generations. In recent years, some countries have strengthened training programmes to develop the knowledge of traditional health practitioners. Furthermore, in some countries TM is included in university curricula for health profession students. For instance, various universities in the Economic Community of West African States, Democratic Republic of Congo, South Africa and Tanzania include TM in the curricula for pharmacy and medical students (8).

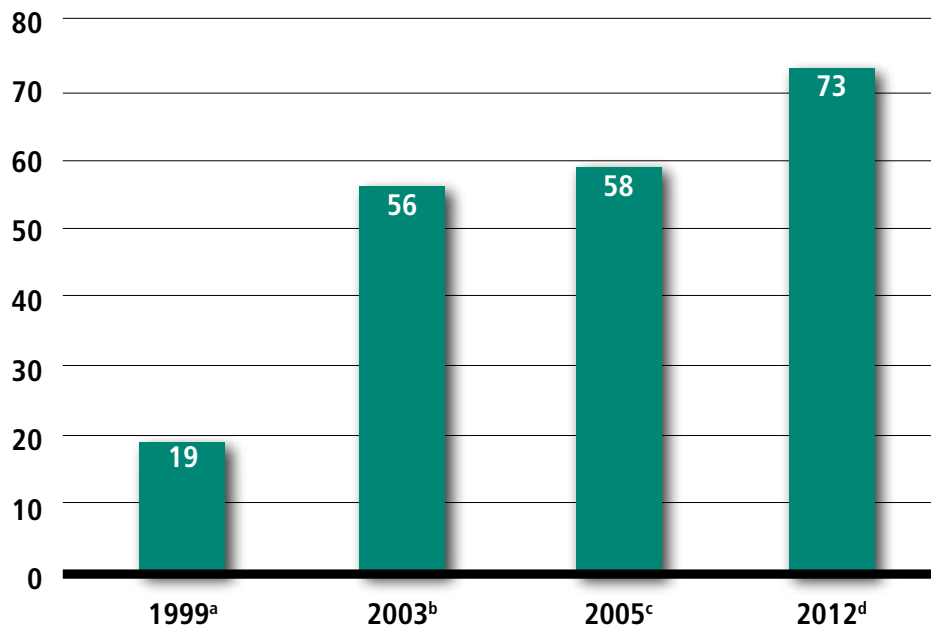
To support Member States in moving towards quality training, WHO has published a series of training guidelines and benchmarks (<http://apps.who.int/medicinedocs/en/c/CL10/>; see also Annex C).

<sup>1</sup> Communication with WHO from the Government of the Republic of Korea, Ministry of Health and Welfare, 2013.



**Figure 4:** Monitoring changes in country progress indicators defined by the WHO Traditional Medicine Strategy:

Number of MS with national research institutes in TM/CM (including those in herbal medicines)



Sources:

**a:** Reference 2;

**b:** Reference 3;

**c:** Reference 6 and 7;

**d:** Combined data from: 1) an interim report of the second WHO global survey (mid-2012; with 129 survey and return) and 2) the 1st WHO global survey result (WHO, 2005) and 3) information on WHO Collaborating Centres for Traditional Medicine.

There has also been progress in setting up national research institutes in the field of T&CM across the world (Figure 4). The number of Member States reporting a national research institute for T&CM has increased significantly.

### 3. Global review of T&CM

The global uptake of T&CM, as outlined in section 2.0, shows that significant momentum has been achieved over the past decade. In order to finalize a strategy for the next ten years, it is important to review and analyse the current status of T&CM worldwide. This will help Member States determine how and when T&CM should be integrated into their national health systems.

To give Member States a better understanding of the current status of T&CM around the world, WHO has gathered a significant amount of data, the scope of which is too extensive for its inclusion in this strategy document. Consequently, this review seeks to contextualise what needs to be done rather than aiming for comprehensiveness. It highlights the ongoing demand for T&CM products, practice and practitioners, describes patterns of use, identifies the need for regulation to protect consumers, describes the importance of integrating T&CM into universal health coverage and identifies some of the difficulties and challenges of integrating T&CM into health systems.

#### 3.1 Continuing demand for T&CM products, practices and practitioners

Many countries have their own traditional or indigenous forms of healing which are firmly rooted in their culture and history. Some forms of TM such as Ayurveda, traditional Chinese medicine and Unani medicine are popular nationally, as well as being used worldwide. At the same time, some forms of CM such as anthroposophic medicine, chiropractic, homeopathy, naturopathy and osteopathy are also in extensive use.

Health systems around the world are experiencing increased levels of chronic illness and escalating health care costs. Patients and health care providers alike are demanding that health care services be revitalized, with a stronger emphasis on individualized, person-centred care (9). This includes expanding access to T&CM products, practices and practitioners. Over 100 million Europeans are currently T&CM users, with one fifth regularly using T&CM and the same number preferring health care which includes T&CM (10). There are many more T&CM users in Africa, Asia, Australia and North America (11).

### **3.1.1 Market for products**

The diversity of regulations and regulatory categories for T&CM products makes it difficult to assess the size of the market for T&CM products across Member States with any degree of accuracy. However, available data suggests that the market is substantial. The output of Chinese materia medica was estimated to amount to US\$83.1 billion in 2012, an increase of more than 20% from the previous year (12). In the Republic of Korea, annual expenditures on TM were US\$4.4 billion in 2004, rising to US\$7.4 billion in 2009 (13). Out-of-pocket spending for natural products in the United States was US\$14.8 billion in 2008 (14).

### **3.1.2 Demand for T&CM practices and practitioners**

There is significant demand for T&CM practices and practitioners worldwide. In Australia, visits to complementary health professionals such as acupuncturists, chiropractors and naturopaths have been growing rapidly with an increase of over 30% between 1995 and 2005, when 750 000 visits were recorded in a two-week period (15). According to a national survey in China, the number of traditional Chinese medicine (TCM) visits was 907 million in 2009, which accounts for 18% of all medical visits to surveyed institutions; the number of TCM inpatients was 13.6 million, or 16% of the total in all hospitals surveyed (16). In the Lao People's Democratic Republic, 80% of the population lives in rural areas made up of a total of 9113 villages: each village has one or two traditional health practitioners. A total of 18 226 traditional health practitioners provide a large part of health care service for 80% of the population's health (17). In Saudi Arabia, a recent study showed that individuals pay US\$560 per annum out-of-pocket for T&CM services (18).

## **3.2 Use of T&CM**

In order to build a knowledge-based T&CM policy, the following information must be obtained and analysed: why are people using it, when are people using it, what are the benefits, who is delivering it and what are their qualifications?

### 3.2.1 Why are people using T&CM?

Patterns of use of T&CM vary among and within Member States depending on a number of factors such as culture, historical significance and regulations. While there is no uniform way to examine patterns of use, it may be helpful to consider how people use T&CM in terms of three general patterns:

- 1) *Use in countries where TM is one of the primary sources of health care.* It is typical of these countries that the availability and/or accessibility of conventional medicine-based health services is, on the whole, limited. The widespread use of TM in Africa and some developing countries can be attributed to its being present on the ground and readily affordable. For instance, the ratio of traditional healers to population in Africa is 1:500 whereas the ratio of medical doctors to population is 1:40 000. For millions of people in rural areas, native healers therefore remain their health providers (19).
- 2) *Use of TM due to cultural and historical influences.* In some countries such as Singapore and the Republic of Korea where the conventional health-care system is quite well established, 76% and 86% of the respective populations still commonly use TM (13).
- 3) *Use of T&CM as complementary therapy.* This is common in developed countries where the health system structure is typically well developed, e.g. North America and many European countries.

Although there are common themes underlying the reasons which motivate people to use T&CM, there are also many differences between individual countries and regions. Some studies have shown that individuals choose T&CM for various reasons, including an increased demand for all health services, a desire for more information leading to an increased awareness of available options, an increasing dissatisfaction with existing health-care services, and a rekindled interest in “whole person care” and disease prevention which are more often associated with T&CM. In addition, T&CM recognizes the need to focus on quality of life when a cure is not possible (20). It has been shown, for instance, that patients attend the Royal London Hospital for Integrated Medicine because other treatments have failed, because that is their personal or cultural preference, or because they have experienced adverse effects with other treatments (21). In Australia, interviews with T&CM users also showed

that the failure of conventional medicine treatments and a desire for a healthy lifestyle were the main motives for using T&CM (22).

In the last decade, across all types of utilization patterns, there has been an increase in self-health care as consumers choose to be more proactive about their own health. Many consumers turn to T&CM products and practices on the assumption that “natural means safe” (23), which is not necessarily true.

### **3.2.2 When are people using T&CM?**

Individual needs often determine when people use T&CM. A number of studies show that patients with specific chronic conditions use T&CM services more often. For example, a study in the United States showed that patients with musculoskeletal complaints who visited osteopathic physicians in family practice settings accounted for 23% of all visits during a one-year period (24). In France, chronic musculoskeletal disorder patients made up a greater proportion of visits to physicians who offered alternatives to conventional medicine (25). An extensive number of patients with multiple sclerosis resort to complementary and alternative medicine (CAM) treatments: prevalence of use ranges from 41% in Spain to 70% in Canada and 82% in Australia (26). In China, based on data from the national monitoring of TCM services, the top five diseases for admission to TCM hospitals in 2008 were: cerebrovascular accident, intervertebral disc displacement, haemorrhoids, ischaemic heart disease and essential hypertension (27). The Republic of Korea reported that the top diseases for admission to Korean medicine hospitals in 2011 were bone, joint and muscle system disorders, dyspepsia, osteoarthritis of the knee and facial nerve disorders<sup>1</sup>.

In many developing countries, TM plays an important role in meeting the primary health care needs of the population, and specific types of TM have been used for a long time (28). Box 2 below shows an example of TM use for primary health care.

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<sup>1</sup> Communication with WHO from the Government of the Republic of Korea, Ministry of Health and Welfare,

## Box 2: Mongolian TM family medicines kit

In the challenging geography of Mongolia's mountains and deserts, nomadic herdsmen often struggle to reach a district hospital. A family traditional medicine kit project was started in 2004 and covers more than 150 000 people. The survey reported that 74% of respondents said that the kits were convenient to use, and the medicines had been effective when used with a user manual. The medicines used cost approximately US\$8 per family per year (29).

### 3.2.3 Benefits of using T&CM

Potential cost savings are an important reason for individuals to opt for T&CM services. For example, a randomized controlled trial included an economic evaluation of physiotherapy, manual therapy, and general practitioner care for neck pain: results showed that the manual therapy group improved faster than the physiotherapy and general practitioner care group, and that the total costs of manual therapy (€447) were about one third of the costs of physiotherapy (€1297) and general practitioner care (€1379). This suggests that manual therapy is more effective and less costly for treating neck pain than physiotherapy or care provided by a general practitioner (30). Another recent study indicates that patients whose general practitioner has additional complementary and alternative medicine training have lower health care costs and mortality rates than those who do not. Reduced costs were the outcome of fewer hospital stays and fewer prescription drugs (31).

### 3.2.4. Types and qualifications of T&CM practitioners

T&CM practitioners can be TM practitioners, CM practitioners, conventional doctors or other health professionals. Differing approaches to regulation make it difficult to determine the absolute numbers of practitioners worldwide. In many developing countries, particularly in rural areas, TM practitioners are the main or sole providers of health care in their community. In other countries, TM practitioners can be divided into a number of categories based on their training/education, registration status, etc. For example, in India there are two categories of TM practitioners, with 785 185 registered Ayurveda, Yoga

and Naturopathy, Unani, Siddha and Homeopathy (AYUSH) practitioners (32) and an estimated one million village-based, traditional AYUSH community health workers (33). Findings from the CAMbrella project also indicate that T&CM provision in the European Union stems from approximately 160 000 non-medical practitioners and 145 000 medical practitioners (34).

The education/training of T&CM providers differs between countries. Some countries conduct T&CM education and training programmes within the health professional syllabus at university level. Others have well-established education and training that addressed a specific type of T&CM. Box 3 shows an example of the TM education system in India.

### **Box 3: Education system for TM practitioners in India**

In India, all six traditional systems of medicine with official recognition (Ayurveda, Yoga, Naturopathy, Unani Medicine, Siddha and Homeopathy) have institutionalised education systems. India has 508 colleges with an annual admission capacity of 25 586 undergraduate students, 117 of these colleges also admitting 2493 postgraduate students. Colleges can only be established with the permission of central government and the prior approval of their infrastructure, syllabi and course curricula. Annual and surprise inspections ensure that educational and infrastructural standards are met. Central Government has the power to recognize or rescind any qualification and college<sup>1</sup>.

## **3.3 Regulation of T&CM products, practices and practitioners**

As a result of the *WHO Traditional Medicine Strategy 2002–2005*, national and regional policies and regulations have been established to promote the safe use of T&CM products, practices and practitioners (Box 4) in many Member States. It remains a key responsibility of Member States to protect the health of their populations by ensuring the safety of T&CM practice and managing its described risks more effectively (Box 5). Differences between countries are apparent in the type of supervisory structures put in place by governments in order to develop policies and regulate T&CM products, practices and practitioners while being mindful of the need for consumer choice and protection. Since

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<sup>1</sup> Communication with WHO from the Government of India, Ministry of Health and Family Welfare, 2013.

T&CM is diversely perceived and assessed in different countries, it is hardly surprising, given their different national priorities, legislation and resources, that Member States will choose to protect the health of their populations in very different ways.

#### **Box 4: T&CM products, practices and practitioners**

**T&CM products** include herbs, herbal materials, herbal preparations and finished herbal products that contain parts of plants, other plant materials or combinations thereof as active ingredients. In some countries herbal medicines may contain, by tradition, natural organic or inorganic active ingredients that are not of plant origin (e.g. animal and mineral materials). (Ref.: modified questionnaire explanation in the second WHO Global Survey).

**T&CM practices** include medication therapy and procedure-based health care therapies such as herbal medicines, naturopathy, acupuncture and manual therapies such as chiropractic, osteopathy as well as other related techniques including qigong, tai chi, yoga, thermal medicine, and other physical, mental, spiritual and mind-body therapies. (Ref.: modified definition of procedure-based therapies in WHO General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine).

**T&CM practitioners** can be TM practitioners, CM practitioners, conventional medicine professionals and health care workers such as doctors, dentists, nurses, midwives, pharmacists and physical therapists who provide TM/CAM services to their patients (Ref.: modified questionnaire explanation in the second WHO Global Survey).

#### **Box 5: Described risks associated with T&CM products, practitioners and self-care:**

- Use of poor quality, adulterated or counterfeit products;
- Unqualified practitioners;
- Misdiagnosis, delayed diagnosis, or failure to use effective conventional treatments;
- Exposure to misleading or unreliable information;
- Direct adverse events, side effects or unwanted treatment interactions.



### 3.3.1 Products

At present, most Member States regulate herbal products, although they continue to develop, update and implement new regulations as needed. These regulatory approaches are aimed at protecting consumer health by ensuring that medicines are safe and of high quality. In view of the fact that this market is now truly international with products often being made in a country other than that in which they are sold, it may be a challenge to ensure products are safe and of high quality. In order to address this issue, Member States and regulatory agencies are increasingly cooperating and learning from each other's experiences. Some regional bodies have been working on harmonizing regulations on herbal medicines and other herbal products within their region. For example, the goal in the European Union is to adopt a uniform legislation on T&CM products which can be prescribed or recommended by practitioners across the region (35); in the South-East Asian Region, efforts to harmonize the regulation of herbal medicines and other herbal products have been ongoing since 2004 (<http://www.aseansec.org/18215.htm>). An example of a global regulatory network supported by WHO is shown in Box 6.

#### **Box 6: Global Regulatory Cooperation Network for Herbal Medicines (IRCH)**

In recent years, there has been an increased focus on regional and international collaboration on regulating medicinal products. Herbal medicines have been a specific workshop topic at meetings of the International Conference of Drug Regulatory Authorities (ICDRA) since 1986. In the T&CM sector, national regulatory authorities responsible for the regulation of herbal medicines have been meeting annually since 2006 as part of the global regulatory network of the International Regulatory Cooperation on Herbal Medicine (IRCH).

### 3.3.2 T&CM practices

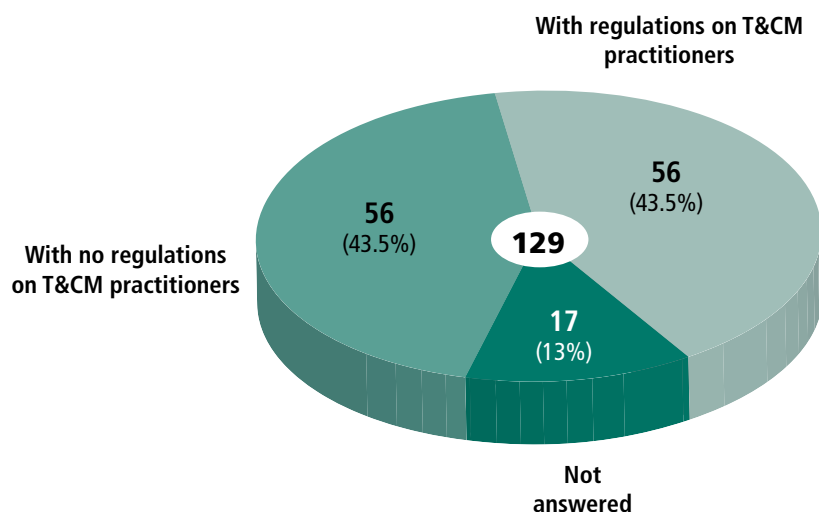
To ensure the safety and quality of T&CM, national health authorities must develop policies and strategies that reflect their specific needs in dealing with the most popular forms of T&CM practised in their country. In addition, in recognition of the fact that T&CM is truly global, they must be prepared to deal with new forms of T&CM being introduced from other countries. This may make it difficult to identify qualified T&CM practices. Accordingly, when Member States formulate and implement national policies and T&CM

regulations, it may be useful to consider the experience and information of other countries. For instance, in Singapore, licensing bodies for acupuncture and TCM recognise certification and qualifications obtained at accredited overseas sites and centres of higher learning (36). A similar situation exists in Thailand, where licences for the practice of T&CM are granted to those with a bachelor's degree in T&CM from universities in Thailand or abroad (37).

### **3.3.3 T&CM practitioners**

The knowledge and qualification of practitioners have a direct bearing on patient safety. The ways in which T&CM practitioners obtain their knowledge and skills vary between countries. In some countries, some T&CM practices have become established and practitioners are required to complete an official education/training programme. For instance, in many European countries and in North America, chiropractic, naturopathic, herbal and osteopathy practitioners must be educated in university-level programmes. Similarly, in China, the Republic of Korea, India and Vietnam, doctors practising specific types of T&CM must graduate from university. In addition to education/training, many Member States have drawn up regulations for T&CM practitioners.

However, in many developing countries, TM knowledge and skills have been transferred from generation to generation orally, making it difficult to identify qualified practitioners. Member States should consider their own situation, and identify their specific needs. These may include upgrading their knowledge base and skills, supporting collaboration between TM practitioners and conventional health care providers and, where necessary, considering regulation or registration of practices. The number of Member States with established regulations on T&CM practitioners can be seen in Figure 5 while an example of T&CM practitioner regulation is given in Box 7.

**Figure 5:** Regulations on T&CM practitioners

Source: Interim data from 2nd WHO TRM global survey as of 11 June 2012.

### Box 7: Current regulation of Chinese Medicine Practitioners in Hong Kong, SAR, China

The Chinese Medicine Ordinance (CMO) (<http://www.legislation.gov.hk/eng/home.htm>) was enacted in 1999 (Cap 549) to regulate the practice, use, trading and manufacture of Chinese medicine under the aegis of the Chinese Medicine Council of Hong Kong (CMCHK). Under the CMO, any person with a recognised undergraduate degree of training in Chinese medicine who wishes to be registered must pass the licensing examination conducted by the Chinese Medicine Practitioners Board (PB) maintained by the CMCHK. Since Chinese medicine practice has a long history in Hong Kong, the CMO provided for a transitional arrangement for the registration of Chinese medicine practitioners (CMP). Any person practising Chinese medicine in Hong Kong on 3 January 2000 may apply to the PB to be listed as a CMP. A registered CMP must then apply for a certificate of practice which is valid for three years, and must meet continuing education requirements in Chinese medicine before being able to renew their certificate of practice. A limited registration system for CMPs requires Chinese medicine experts to undertake clinical teaching and research in the institutions approved by the PB. In order to regulate their professional conduct and practice, the PB has compiled codes of conduct for CMPs (38).

#### 3.3.4 Intellectual property

Issues related to intellectual property (IP) can have an impact on products, practices and even practitioners. While IP may support innovation and provide

a stimulus to invest in research, it can also be abused to misappropriate T&CM. A joint publication by WHO, WIPO and WTO (39) discusses current policy issues regarding IP, traditional knowledge and genetic resources, of which T&CM is an integral part.

### **3.4 Universal health coverage and integration of T&CM**

At the 65<sup>th</sup> World Health Assembly, the WHO Director-General stated that “universal health coverage is the best way to cement the gains made during the previous decade. It is the ultimate expression of fairness. This is the anchor for the work of WHO as we [WHO] move forward” (40). In addition, achieving universal health coverage (UHC) has been set as one of the overarching goals in WHO’s 12<sup>th</sup> General Programme of Work 2014–2019 (41).

The purpose of UHC is to ensure that all people have access to promotive, preventive, curative and rehabilitative health services, of sufficient quality to be effective, while also ensuring that they do not suffer financial hardship when paying for these services. Universal health coverage is closely connected to achieving the “highest attainable standard of health” outlined in WHO’s Constitution and in the concept of Health For All. Many factors inside and outside the health system contribute to achieving UHC: socioeconomic determinants external to health systems, and health system improvements such as good governance, increased availability and appropriate distribution of appropriate types of health workers, availability and distribution of essential medicines and health facilities, high quality of care, appropriate financing, reliable information, etc.

The path to universal health coverage must overcome existing barriers facing individuals when accessing health-care services such as the fragmentation of health-care services and their lack of patient-centredness. Health services may be too distant (geographical barrier), or poorly staffed with long waiting hours (organizational barrier), or not coherent with people’s cultural and gender preferences (cultural barrier). Moreover, even when the population is able to access services, they may be of poor quality or, in some cases, even harmful. Another paramount problem is the predominance of curative, hospital-based, disease-oriented services, which are often poorly integrated into the broader health system. These top-heavy services are responsible for huge inefficiencies

that could be redirected towards achieving universal coverage. Instead of these existing barriers, qualified T&CM could be a positive contribution to universal health coverage.

In many countries, T&CM has been partially covered by public and private insurance companies since the 1990s. The number of Member States with insurance coverage for acupuncture can be seen in Figure 2. In many European countries, however, T&CM regulation and registration are not well established. An increasing number of medical doctors are interested in T&CM in these European countries, a phenomenon which may increase the likelihood of reimbursement. For example, many French doctors are specialists in acupuncture and homeopathy, both of which are reimbursed by the Social Security when performed or prescribed by a doctor. Since 1997, the Socialist Mutual Insurance of Tournai-Ath in Belgium partially reimburses specific complementary/alternative treatments such as homeopathic remedies. In Finland, when provided by an allopathic physician, acupuncture and other complementary/alternative therapies can be covered by the Social Insurance Institution (SII). In Germany, public and private insurance provides the same kind of coverage for some complementary/alternative treatments (42). An example of insurance reimbursement for TM services in Japan is illustrated in Box 8.

### **Box 8: TM legislation and national health insurance reimbursement in Japan**

In Japan, 84% of Japanese physicians use kampo in daily practice (43). According to the Annual Health, Labour and Welfare Report 2011–2012 (44), the number of registered medical doctors who are sole prescribers of kampo medicines is 295 049. There were 276 517 registered pharmacists who are sole dispensers of kampo medicines. There were also 92 421 acupuncturists, 90 664 moxacauterists, 104 663 massage practitioners and 50 428 judo therapists. As of April 2000, the National Health Insurance Reimbursement List included 147 prescription kampo formulae and 192 herbal materials used in prescription kampo formulae. Acupuncture, moxibustion, Japanese traditional massage, and judo therapy are partially covered by private health insurance (42).

### 3.4.1 Different stages of T&CM integration

Given that T&CM has the potential to improve individual health, its proper integration into national health systems will enable consumers to have a wider choice when they wish to use such services. Though integration may be of the greatest relevance to populations living with chronic disease or in health promotion, in certain circumstances it may contribute to the treatment of acute disease. Appropriate integration has also been addressed by Dr Margaret Chan, Director-General of WHO, who stated that: “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” (45).

In a few countries, certain types of T&CM have been completely integrated into the health care system. In China, for instance, traditional Chinese medicine and conventional medicine are practised alongside each other at every level of the health-care service and public and private insurance cover both traditional Chinese medicine and conventional medicine (Box 9).

#### **Box 9: TM health service integration in China**

In China, there are about 440 700 health-care institutions providing TM services, with 520 600 patient beds, including all levels of TM hospitals and general hospitals, clinics and health stations in urban and rural areas. About 90% of general hospitals include a TM department and provide TM services for both outpatients and inpatients. TM medical institutions are governed by the same national legislation on medical institutions as conventional medical institutions. TM practitioners are allowed to practice in both public and private clinics and hospitals. Government and private insurance fully cover TM including Tibetan, Mongolian, Uygur and Dai traditional medicine. Public or patients are free to choose TM or conventional medicine for health-care services, or their doctors can provide advice on which therapies may be better suited to their health problems (46).

In the Republic of Korea, traditional medicine doctors can provide Korean TM in both public and private hospitals and clinics. A national medical insurance programme has covered Korean TM services since 1987 and currently private

insurance also covers TM services. In Viet Nam, TM practitioners are able to practise in both public and private hospitals and clinics and government insurance fully covers acupuncture, herbal medicines and TM treatment.

In many other countries, T&CM is partially integrated into the national health system. Switzerland became the first country in Europe to integrate T&CM into its health system (Box 10).

### **Box 10: T&CM integration into the Swiss health-care system**

In Switzerland, the average prevalence of T&CM use (persons who have used T&CM) was 49% (47) after 1990. In 1998, the Federal Department of Home Affairs (DHA) decided that, from 1999 to 2005, five complementary therapies – anthroposophical medicine, homeopathy, neural therapy, phytotherapy and TCM (more precisely, traditional Chinese herbal therapy) – would be covered by the compulsory health insurance program (KLV), if the service was provided by a physician certified in CAM. Meanwhile, the Swiss government also set up a comprehensive programme to evaluate CAM (PEK), which was playing an ever-increasing role in the Swiss medical system, in order to determine its role and effectiveness.

According to the PEK evaluation result, CAM practitioners can be distinguished from physicians providing conventional health care in respect of the nature, location and technical resources of their practice. In 2009, more than 67% of national voters opted for a new constitutional article on CAM, with the result that certain complementary therapies have been re-instated into the basic health insurance scheme available to all Swiss citizens (48). The constitutional article on CAM is also likely to speed up compulsory lessons for medical students, standardization of training and certification in complementary therapies for both doctors and non-medical practitioners, and the availability of CAM products in Switzerland (49).

#### **3.4.2 How to integrate T&CM**

When integrating T&CM into the health care system, the process and steps taken will vary from country to country and region to region. The following criteria may help Member States identify the key processes that need to be undertaken in their countries:

- surveying T&CM use including benefits and risks in the context of local history and culture and promoting a keener appreciation of the role and potential of T&CM;
- analysing national health resources such as finance and human resources for health;
- strengthening or establishing all relevant policy and regulations for T&CM products, practices and practitioners;
- promoting equitable access to health and integration of T&CM into the national health system including reimbursement, and potential referral and collaborative pathways.

It is important to consider the importance of each practice in the national context when developing an integration policy. Emphasis should be placed on the importance of documenting and studying T&CM practice in order to categorize T&CM therapies or modalities that will underpin appropriate policies and regulations. In Sweden, a number of lessons and recommendations were learned from the integration of T&CM in primary care and some important issues were highlighted (50): e.g. the availability of specialist training for general practitioners, preferably computer-based documentation reflecting multi-modular management, combination of qualitative and quantitative research methods, interdisciplinary dialogue and collaboration.

A knowledge-based policy is the key to integrate T&CM into national health systems. Research should be prioritized and supported in order to generate knowledge. While there is much to be learned from controlled clinical trials, other evaluation methods are also valuable. These include outcome and effectiveness studies, as well as comparative effectiveness research, patterns of use, and other qualitative methods. There is an opportunity to take advantage of, and sponsor such “real world experiments” where different research designs and methods are important, valuable and applicable. The importance of embracing various kinds of contributory research methods and designs in the effort to build a broad evidence base to inform national policy and decision making has been underlined by the National Institute for Health and Care Excellence (NICE), as well as others (51).

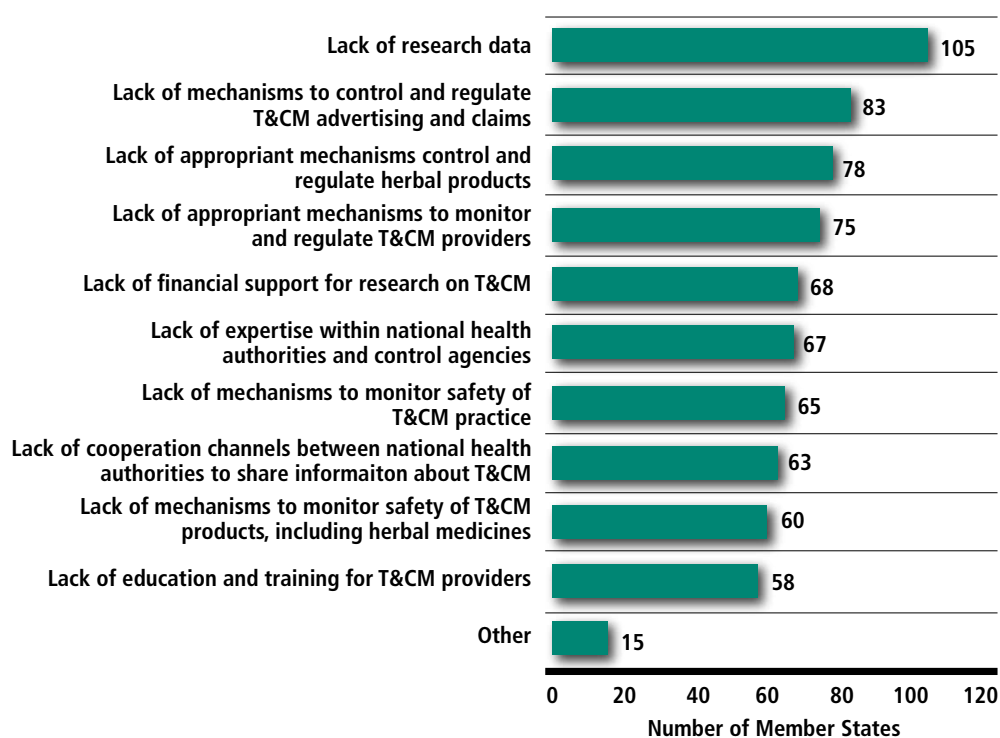


### 3.5 Opportunities and challenges

It is clear from the global review that there are a number of opportunities and challenges in relation to national policies, law and regulation, quality, safety and effectiveness of T&CM, universal health coverage and the integration of T&CM into health systems. Although there are many pressing social and economic issues that serve as an incentive for using T&CM, the predicted increase in the global burden of chronic diseases (WHO Global Status Report on noncommunicable diseases (NCDs), 2011) is the most urgent reason for developing and strengthening collaboration between conventional and T&CM health sectors.

The opportunities and challenges identified in the review are reflected in Member States' reports, surveys and expert meetings (summarized in Figures 6 and 7). Altogether, these findings provide the basis for developing the objectives of this strategy. However, in view of the diversity among Member States about how T&CM is perceived, used, regulated and integrated, the implementation of strategic objectives must be considered in relation to each Member State's specific situation.

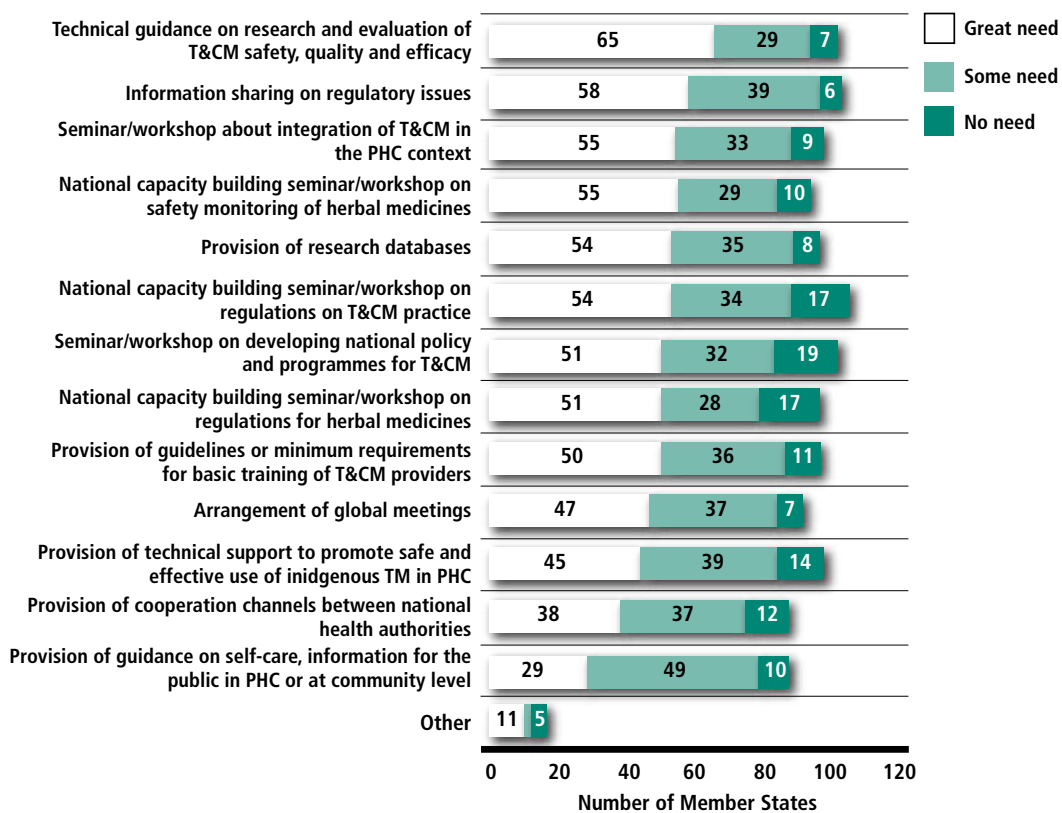
**Figure 6:** Difficulties faced by Member States regarding regulatory issues related to the practices of T&CM



Source: Interim data from 2nd WHO TRM global survey as of 11 June 2012.

The diversity among Member States is illustrated by the findings of a recent study on T&CM in Europe. The 39 nations involved in the study diverge to an extraordinary degree with regard to the regulation of CAM practice. At the same time, the stated policy aim is to adopt a uniform regulation for CAM products that are prescribed or recommended by practitioners within this same geographical area. When patients cross borders in search of CAM treatment, they may encounter substantial differences in the professional background of apparently identical CAM practitioners, who are subject to completely different reimbursement systems. This complicated situation influences rights, access and potential safety, and constitutes a challenge to a harmonized national and European adoption of the new directive on the application of patients' rights in cross-border health care (52). As a consequence, individual states within culturally similar regions should consider harmonizing their complementary and alternative laws and regulations in order to safeguard against over- or underregulating at the national level where there is no reason to do so (35).

**Figure 7:** The type of support for T&CM issues that Member States are interested in receiving from WHO



Source: Interim data from 2nd WHO TRM global survey as of 11 June 2012.

In general, data reported by Member States show that progress in matters related to the regulation of T&CM products, practices and practitioners is not occurring at an equal pace. Progress relating to regulation on herbal medicines and national T&CM policies is moving faster, while regulation on T&CM practitioners and practice creeps forward at a slower rate. As an example, the Figure 2 shows that although majority of reported MS acknowledged the use of acupuncture there are much less MS acknowledged the establishment of regulation on acupuncture. Responding to the needs identified by Member States and building upon the work completed in *the WHO Traditional Medicine Strategy 2002–2005*, this new WHO TM strategy will devote more attention to prioritizing health services and systems than its predecessor.

Analysis of progress since the first WHO global strategy for TM (Section 2), and the Global Review (Section 3) make it clear that there is continuing demand for T&CM around the world. T&CM is used not only to treat diseases, especially chronic diseases; it is also widely used in disease prevention, health promotion and health maintenance, and it has proved to be cost-effective for some governments. In order to meet the demands of the public and Member States, and to help guide countries towards integration of T&CM into health systems, WHO has developed *the Traditional Medicine Strategy 2014–2023*.

## 4. Strategic objectives, strategic directions and strategic actions

In response to the successes and challenges identified during the implementation of the *WHO Traditional Medicine Strategy 2002–2005*, WHO brought together and consulted with experts, Member States and other stakeholders across the six WHO regions to develop the strategic objectives, strategic directions and strategic actions for the new strategy to guide the T&CM sector from 2014–2023. This section provides extensive detail on how T&CM should be further developed and advanced over the next decade.

WHO has recently indicated that significant strategic planning for Member States will focus on the need for better universal health coverage (UHC) around the world. WHO recognizes that good health is essential to sustained economic and social development and poverty reduction. Access to essential health services is crucial for maintaining and improving health. At the same time, people need to be protected from being pushed into poverty because of the cost of health care.

The goals for the *WHO Traditional Medicine Strategy 2014–2023* are to support Member States in:

1. harnessing the potential contribution of T&CM to health, wellness, people-centred health care and UHC;
2. promoting safe and effective use of T&CM through the regulation, research and integration of T&CM products, practices and practitioners into the health system, as appropriate.

The *WHO TM strategy 2014–2023* is designed to help countries determine how best they can both promote health and protect consumers who wish to avail themselves of these products, practices and practitioners. This involves two key steps:

1. Member States should define and better understand T&CM within their own national situation by identifying the forms of T&CM used, defining who uses them, exploring the reasons for their use and determining both

present and future needs. In essence, countries must build their own national profile around T&CM.

2. reflecting on their national profile, Member States should develop policies, regulations and guidelines that address those forms of T&CM which meet the health needs and choices of their people. While common themes and priorities may exist between Member States, national approaches must be developed to address individual countries' needs. Clearly they will be subject to existing legal frameworks, cultural beliefs about T&CM, and structures to supervise individual products, practices and practitioners.

Member States can achieve these two key steps by organizing their activities towards three strategic objectives:

- 1) to build the knowledge base for active management of T&CM through appropriate national policies;
- 2) to strengthen quality assurance, safety, proper use and effectiveness of T&CM by regulating products, practices and practitioners;
- 3) to promote universal health coverage by integrating T&CM services appropriately into health service delivery and self-health care.

#### **4.1 Strategic objective 1: To build the knowledge base for active management of T&CM through appropriate national policies**

There is a great diversity of products, practices and practitioners in T&CM. Some confer health benefits, others are associated with risks or are purely commercially driven. In view of their limited resources, Member States should decide where to focus their attention so as to provide consumers with the best and safest form of health care, while addressing the need to uphold consumer choice. Before an informed decision can be made about how T&CM is to be supervised within their jurisdiction, Member States must understand the specific nature of their national T&CM sector and establish valid and comprehensive baseline data from which to build.

#### **4.1.1 Strategic direction 1: Understand and recognize the role and potential of T&CM**

Member States are encouraged to acknowledge the role T&CM plays in their health-care system. However, there is enormous diversity in the varieties of T&CM that may be considered to be a constituent part of each local health care system. The strategy recommends that Member States acknowledge and appraise, in detail, which types of T&CM are being used by their population and devise their own country profile for T&CM practice. This information will enable them to make informed policy decisions on how to regulate and use T&CM appropriately.

As the marketplace for T&CM becomes more global, harmonization and cooperation will increase in value. In this environment, policies and regulation with a national and global perspective ought to be developed. The strategy plan recommends that countries use best-practice approaches in order to develop regulations for different modalities.

##### ***Strategic actions for Member States:***

1. Acknowledge the role and diversity of T&CM within their health-care system.
2. Define the scope of the sector through the use of data identifying the number of people using specific forms of T&CM, their reasons for using it, the most popular (important) forms, whether use follows advice from a health professional, and whether health-care professionals know about patients' use of T&CM.
3. Implement and integrate T&CM policies and programmes as integral components of their national health system, where appropriate.
4. Foster communication and partnership between stakeholders.
5. Prioritize and determine actions to be taken in line with national priorities, capabilities, etc.

##### ***Strategic actions for partners and stakeholders:***

1. Establish best practices in cooperation with accredited bodies of practitioners and researchers which can be shared internationally.
2. Make recommendations concerning research priorities in specific areas for policy formulation.

**Strategic actions for WHO:**

1. Continue to provide support and technical guidance to Member States by developing relevant documents and tools for policy studies.
2. Support Member States in defining and regulating the different disciplines and modalities of T&CM.
3. Coordinate global technical resources to build consensus about the basic definitions of T&CM.
4. Support Member States in promoting information sharing among countries on policy formulation.
5. Collect global data on T&CM utilization; establish and maintain a database to collect information on T&CM policy and regulation by Member States.

**4.1.2 Strategic direction 2: Strengthen the knowledge base, build evidence and sustain resources**

Member States should strengthen their own knowledge generation, collaboration and sustainable use of T&CM resources. It is important that Member States and stakeholders are mindful of biodiversity and international treaties concerning endangered species.

While there is a growing interest in T&CM, there are still many questions about the quality and quantity of evidence which supports its utilization. T&CM research should use methods which are generally accepted in the evaluation of health services, including comparative effectiveness studies and mixed-method designs. There is also a dearth of research and innovation into the various forms of T&CM. In order for T&CM to be considered an integral part of health care, it must be supported by evidence. This can be achieved by greater research and innovation accompanied by a focus on knowledge management, including intellectual property protection rights. This, in turn, is likely to encourage innovation and protect traditional knowledge. Although T&CM is now a popular global phenomenon, there is still a risk that the traditional knowledge for maintaining health and providing health care to people in some countries might be lost. This should be brought to the attention of the appropriate intellectual property agencies.

A key priority is the strategic gathering, analysis and synthesis of data on T&CM use, coupled with an information management strategy to ensure it

remains current and of the highest quality. This may be done by including questions about T&CM uptake in national surveys, adopting existing databases, establishing research centres of excellence or developing national research and multi-stakeholder networks.

Once the basic data has been acquired, Member States need to encourage research into forms of T&CM which may benefit their populations and focus their attention and limited resources on the products, practices and practitioners most likely to be of benefit. At the same time, Member States should be better placed to identify types of T&CM that make exaggerated claims or pose an actual health risk.

Adequate protection of T&CM through conventional intellectual property or sui generis rights can help prevent its unauthorized use. Current intellectual property frameworks may be used to protect innovations based on T&CM and be extended to include appropriate safeguards to prevent the misappropriation of T&CM. Any new sui generis protection system ought not only to ensure prior informed consent and access and benefit sharing, but also to provide for widespread access to T&CM, while encouraging research on T&CM quality, safety and efficacy in order to adapt existing treatments and develop new products. Appropriate strategies can also ensure that third parties do not gain illegitimate or unfounded intellectual property rights over T&CM.

***Strategic actions for Member States:***

1. Based on the greatest potential risks and/or benefits attributable to T&CM used in their country:
  - a. monitor the safety of T&CM;
  - b. identify sources of evidence, whether historical, traditional or scientific, which support or invalidate a particular therapy;
  - c. determine the risk/benefit profile, including cost-effectiveness.
2. Promote research and development, innovation, knowledge management.
3. Encourage knowledge generation, translation and dissemination by establishing a comprehensive and inclusive approach to T&CM research and development including into quality and cost-effectiveness.
4. Develop a national research agenda which acknowledges and includes various types of research models where appropriate.



5. Develop and share appropriate methods and criteria for evaluating the safety, efficacy and quality of T&CM products and for assessing the value of T&CM practice (e.g., develop resources for research, develop appropriate research methodologies, and encourage investment).
6. Prevent the misappropriation of T&CM by implementing the relevant international instruments in line with the WHO global strategy and plan of action on public health, innovation and intellectual property, adopting or amending national intellectual property legislation, and enacting other defensive protection strategies.
7. Protect and conserve T&CM resources, in particular knowledge and natural resources.
8. Identify how T&CM information is communicated through practitioners, product advertising, practices and the media.
9. Foster dialogue and partnership between stakeholders. Where relevant to the national need, seek input from international partners with additional information especially concerning global trends and lessons learned.
10. Publish standard treatment guidelines for use of T&CM, as well as a list of essential herbal medicines.

***Strategic actions for partners and stakeholders:***

1. Support collaboration with Member States and WHO in research projects/ programmes on T&CM.
2. Advise on assessing risks and benefits.
3. Foster a culture of communication, documentation, evaluation and innovation among practitioner communities, both nationally and internationally.
4. Increase the availability and awareness of the literature, database and other knowledge repositories.
5. Develop research methodologies consistent with T&CM theories and practice.
6. Build up the capacity and capability for international research, including such issues as the adequate protection of intellectual property and the prevention of possible misappropriation.
7. Support international research collaboration on T&CM.

**Strategic actions for WHO:**

1. Continue to provide support and technical guidance to Member States by developing relevant documents and tools regarding policy studies, research, resource preservation and sustainable use.
2. Promote international collaboration on T&CM research.
3. Raise awareness of all stakeholders about issues of biodiversity and conservation.
4. Organize training workshops on policy formulation, research methodology, research ethics and resource preservation.
5. Collect and disseminate relevant information.

**4.2 Strategic objective 2: To strengthen quality assurance, safety, proper use and effectiveness of T&CM by regulating T&CM products, practices and practitioners**

Member States should examine the potential of T&CM practices and products in their region and country, and then consider whether they need additional regulations, supervision, systems or institutions to make the quality assurance, safety and effectiveness of T&CM practices and products more credible, while addressing the need for consumer choice.

Once a national agenda and the general policy have been established, regulatory frameworks for both products and practices should be developed to reflect specific regional and national needs. This process ought to include governments, consumers, educators, practitioner groups, manufacturers and researchers, and should seek to define how T&CM is practised and how T&CM products can be safely and effectively used. At the same time, it will enable health system planners to anticipate needs more effectively and to exploit the potential of T&CM methods to meet those health needs.

**4.2.1 Strategic direction 1: Recognize the role and importance of product regulation**

Information from the first WHO Global Survey of T&CM and provisional information from the second WHO Global Survey indicates that Member States are increasingly developing and implementing regulatory frameworks for T&CM products.

Though regulatory frameworks are developed at a national and regional level, countries are encouraged to recognise the global nature of this sector. T&CM is now an international

phenomenon with practices and products often being used in a different part of the world from that in which they were originally developed or manufactured. Global trade in these products, including their Internet-based supply has become an important factor in considering how to ensure that T&CM complies with international treaties on biodiversity and endangered species. This raises a number of challenges: dealing with different legislative frameworks between different countries, ensuring that information on quality and safety is shared and encouraging appropriate use within different cultures.

***Strategic actions for Member States:***

1. Identify existing standards, policies and regulations to ensure product quality and safety. Assess needs and prioritize areas requiring regulation based on risk assessment and while attempting to protect consumer choice.
2. Increase credibility and accessibility by developing and implementing appropriate regulatory frameworks to ensure the safe use of T&CM products.
3. Make provision for a basic regulatory framework that underpins quality, safety and effectiveness. Elements can include registering products, licensing providers and empowering regulators to implement public health measures, e.g. adverse event reporting.
4. Guarantee the regulatory capacity and resources to respond to market needs.
5. Disseminate evidence, guidelines and information which support health claims.
6. Encourage stakeholder awareness of and involvement in regulatory frameworks (including industrial actors, practitioner communities, researchers and consumers).
7. Set or adopt standards for T&CM products.
8. Promote international regulatory cooperation and collaboration including information sharing about T&CM products.

***Strategic actions for partners and stakeholders:***

1. Encourage practitioner communities, industry, researchers and consumers to become involved in devising regulations for products.
2. Cooperate and participate in monitoring and surveillance systems for risk management.

**Strategic actions for WHO:**

1. Develop or update WHO technical documents and tools on promoting safety, quality and effective use of T&CM products as well as applicable norms and standards.
2. Organize training workshops on capacity building for regulators.
3. Promote the international standardization and classification of T&CM.
4. Facilitate information sharing and international regulatory network development.

**4.2.2 Strategic direction 2: Recognize and develop practice and practitioner regulations for T&CM education and training, skills development, services and therapies**

As more countries develop policies and regulatory frameworks on T&CM, there is a need to evaluate their effectiveness and identify ways in which challenges can be addressed by comparison with appropriate reference standards (benchmarking). This can be accomplished both through national audits and reviews as well as by developing and sharing appropriate models at the international level.

Benchmarks are of use in developing approaches and frameworks and evaluating how existing systems might be improved. They can be applied to evaluating individual therapies, developing reimbursement models, creating standards of practice, establishing regulatory frameworks for T&CM providers and practices, providing supervision of practitioners including training, accreditation and remuneration, and determining how a service is delivered within a health-care system.

**Strategic actions for Member States:**

1. Improve access to information and increase the knowledge base on the quality, safety and effectiveness of T&CM.
2. Ensure appropriate supervision of T&CM services (practices and practitioners) by establishing practical regulatory systems that are adapted to the infrastructure of Member States.
3. Set standards and indicators for monitoring performance as part of a comprehensive health system.

4. Support the development of a code of conduct to bolster ethical practice, in partnership with all relevant stakeholders.
5. Support the development and implementation of practice guidelines for ensuring the safety, quality and effectiveness of T&CM services.
6. Establish provisions for the education, qualification, and accreditation or licensing of T&CM practices and practitioners based on needs and risk assessment.
7. Initiate the development of benchmarks, standards and regulations for education, training, accreditation and reimbursement for different forms of T&CM.
8. Establish formal channels of communication to facilitate education including continuing education and accreditation, licensing and registration of T&CM practitioners.

***Strategic actions for partners and stakeholders:***

1. Encourage consumers, practitioner communities and researchers to become actively involved in setting standards for and regulating training, services and therapies.
2. Support the development of guidelines and a code of conduct for the ethical sponsorship of education, training and practice of TM practitioners.
3. Encourage communication and knowledge sharing between practitioners in order to document and evaluate their practice.
4. Foster cohesiveness among traditional health practitioners and empower them to organize into associations or groups.
5. Encourage and promote accreditation of education and training institutes.
6. Promote mutual understanding and respect between T&CM practitioners and other health practitioners.
7. Encourage conventional health care professionals to know more about the use of T&CM.

***Strategic actions for WHO:***

1. Develop or update WHO technical documents and tools on promoting the safety, quality and effectiveness of T&CM practice and practitioners, including benchmarks for training and practice.

2. Organize training workshops on capacity building for regulators.
3. Facilitate information sharing and the development of an international network of regulators.

### **4.3 Strategic objective 3: To promote universal health coverage by integrating T&CM services into health care service delivery and self-health care**

It is increasingly recognised that safe and effective T&CM could contribute to the health of our populations. One of the most significant questions raised about T&CM in recent years is how it might contribute to universal health coverage by improving service delivery in the health system, particularly PHC: patient accessibility to health services, and greater awareness of health promotion and disease prevention are key issues here. Insurance coverage of T&CM products, practices and practitioners varies widely from full inclusion within insurance plans to total exclusion, with consumers having to pay for all T&CM out of pocket. Simultaneously, there is emerging evidence that T&CM, when included in UHC plans, may reduce pressure on the system and diminish costs. This shows why it is important for Member States to consider how to integrate T&CM into their health systems and UHC plans more comprehensively.

In order for T&CM to achieve its potential, individuals must be informed about the likely benefits and risks of supplementing their access to conventional medicine with T&CM. The T&CM community must become better at giving consumers more information about its products, practices and practitioners so they can make an informed choice.

Member States should encourage cooperation and information sharing between conventional health care professionals and T&CM practitioners. Information which is easy to understand is the key to the safe and appropriate use of T&CM self-health care. This includes encouraging patients to inform their usual health care professionals about their use of T&CM products.

### **4.3.1 Strategic direction 1: Capitalize on the potential contribution of T&CM to improve health services and health outcomes**

Mindful of the traditions and customs of peoples and communities, Member States should consider how T&CM, including self-health care, might support disease prevention or treatment, health maintenance and health promotion consistent with evidence on quality, safety and effectiveness, in line with patient choice and expectations.

Based on each country's realities, models for integrating T&CM into national health systems should be explored. This includes deciding which forms of T&CM ought to be integrated, and how. If integration is not feasible, alternatives can be identified.

Many initiatives are under way across the world: their goal is to develop models of best health care delivery which are sustainable, feasible and likely to improve health outcomes. Depending on the circumstances of the individual country, care may take the form of a single discipline, multiple disciplines, a self-health care model or adopt a more integrative approach. Often the best models are developed by partnerships and collaborations and will be people-centred, relying on approaches that are safe, appropriate and cost-effective.

#### ***Strategic actions for Member States:***

1. Recognize TM as a resource that could contribute to the improvement of health care services, particularly PHC, and that TM is relevant to improved health outcomes.
2. Explore how T&CM might be integrated into the national health service delivery system based on national capacities, priorities, relevant legislation and circumstances, and on evidence of safety, quality and effectiveness.
3. Encourage the development of appropriate health facilities for T&CM public health services by ensuring key health system elements are in place for integration.
4. Ensure equitable consideration for safe and effective T&CM in existing insurance coverage and in national health reimbursement models.

#### ***Strategic actions for partners and stakeholders:***

1. Promote mutual respect, collaboration and understanding between conventional and T&CM practitioners.
2. Promote international communication among practitioner communities regarding integrative models.

3. Promote research on the cost-effectiveness of integrating T&CM approaches.
4. Promote continuing education, evaluation, evidence and research into T&CM practices.
5. Involve nongovernmental organizations and the for-profit sector, including health reimbursement systems where appropriate, in the above objectives.

***Strategic actions for WHO:***

1. Develop or update WHO technical documents and tools on integrating T&CM into national health systems. This includes access to safe and qualified T&CM services, T&CM terminology and the inclusion of T&CM in the International Classification of Diseases. Support Member States in identifying models and approaches for integration of T&CM into health systems.
2. Organize education and training workshops for policy makers and T&CM practitioners.
3. Collect and disseminate information on integrating T&CM into national health systems.
4. Bring together T&CM professional associations and conventional medicine groups to promote the safe and effective use of the former.

**4.3.2 Strategic direction 2: Ensure consumers of T&CM can make informed choices about self-health care**

Informed choice is one of the cornerstones of good health care practice. Shared decision-making promotes people-centred care. Ethical and legal aspects should support and shape the key aspects and considerations of informed choice. Education should also play an important role in informed choice. In many Member States, self-selection of T&CM products account for a large part of the T&CM sector.

It is important to note that consumers' desire for accessibility and availability may conflict with a government's mandate to protect its population by adopting the precautionary principle when risk is unclear. The way in which these two factors are kept in balance varies from country to country and may impinge on a self-health care model.



***Strategic actions for Member States:***

1. Develop mechanisms/guidelines for consumer education and protection, complaint channels and the proper use of T&CM products, practitioners and services, including their promotion and advertising.
2. Strengthen interdisciplinary education and collaborative practice between conventional medicine practitioners and T&CM practitioners with a people-centred emphasis.
3. Foster partnership and dialogue about self-health care among all stakeholders.
4. Encourage Member States to take steps to ensure consumers can make informed choices.

***Strategic actions for partners and stakeholders:***

1. Provide information and advice to consumers on T&CM including the potential risk of practices and products, including those obtained outside national regulatory controls (Internet-based purchase, etc.).
2. Promote health care practitioner education about T&CM, and encourage patients to declare their use of T&CM with conventional medicine practitioners.
3. Advocate responsible and accurate advertising and promotion.

***Strategic actions for WHO:***

1. Develop or update WHO documents and tools on consumer education and self-health care.
2. Organize education and training workshops for policy-makers and T&CM practitioners
3. Collect and disseminate information about self-health care.

## 5. Implementing the Strategy

The goals for the *WHO Traditional Medicine Strategy 2014-2023* are to support Member States in:

1. harnessing the potential contribution of T&CM to health, wellness and people-centred health care;
2. promoting safe and effective use of T&CM through the regulation, evaluation and integration of T&CM products, practices and practitioners into health systems, as appropriate.

The strategy has been developed to aid Member States in determining and prioritizing their needs, providing for effective delivery of services, and developing appropriate regulations and policy to ensure the safe use of T&CM products and practices. It is important to remember that this strategy is merely a guide to assist countries in developing T&CM strategic goals in accordance with their own national capacities, priorities, relevant legislation and circumstances. To this end, WHO is committed to monitoring the implementation of the strategy and will disseminate it as broadly as possible.

### ***Keeping it current***

Over the next decade, this strategy will need to be reviewed and reconsidered in order to ensure it remains relevant. It is anticipated that the strategy will be reviewed after five years to determine whether its objectives, directions and goals are still applicable and current. To determine the full impact of the strategy, a more thorough review will be completed at the end of its 10-year lifespan.

### ***Measuring success***

For the strategy to be effective, its outcomes must be measurable in a consistent and objective way. Though there are common elements in the way T&CM is used, differences exist between Member States. Performance indicators based on the three strategic objectives will have to be developed at the national level by each Member State individually. It is hoped that the general examples offered in this strategy document will aid Member States to develop indicators relevant to their specific needs. For the time being, WHO has developed a short list of key performance indicators bearing on each of the strategic objectives that will help to measure the success of the TM strategy and its advancement in Member States (see Table 1).

**Table 1: Key performance indicators**

Strategic objective		Strategic direction		Expected outcomes	Critical indicator
4.1	To build the knowledge base for active management of T&CM through appropriate national policies	4.1.1	Understand and recognize the role and potential of T&CM	<ul style="list-style-type: none"> <li>■ T&amp;CM practices and practitioners identified and analysed by Member State and country profile devised for T&amp;CM.</li> <li>■ T&amp;CM policies and programmes established by government.</li> </ul>	<ul style="list-style-type: none"> <li>■ Number of Member States reporting a national/provincial/state T&amp;CM policy.</li> <li>■ Number of Member States reporting increased governmental/public research funding for T&amp;CM;</li> </ul>
		4.1.2	Strengthen the knowledge base, build evidence and sustain resources	<ul style="list-style-type: none"> <li>■ Strengthened knowledge generation, collaboration and sustainable use of TM resources.</li> </ul>	
4.2	To strengthen quality assurance, safety, proper use and effectiveness of T&CM by regulating products, practices and practitioners.	4.2.1	Recognize the role and importance of product regulation	<ul style="list-style-type: none"> <li>■ Established and implemented national regulation for T&amp;CM products including registration.</li> <li>■ Strengthened safety monitoring of T&amp;CM products and other T&amp;CM therapies.</li> <li>■ Technical guidelines and methodology developed for evaluating safety, efficacy and quality of T&amp;CM.</li> </ul>	<ul style="list-style-type: none"> <li>■ Number of Member States reporting national regulation for T&amp;CM products</li> <li>■ Number of Member States reporting national/provincial/state regulation for T&amp;CM practice</li> <li>■ Number of Member States reporting national/provincial/state regulation/registration for T&amp;CM practitioners</li> </ul>
		4.2.2	Recognize and develop practice and practitioner regulation for T&CM education and training, skills development, services and therapies	<ul style="list-style-type: none"> <li>■ Standards for T&amp;CM products, practices and practitioners developed by government.</li> <li>■ Established education/training programme, benchmarks and implementation capacities for T&amp;CM practitioners</li> <li>■ Improved safe and effective use of T&amp;CM</li> </ul>	
4.3	To promote universal health coverage by integrating T&CM services into health care service delivery and self-health care	4.3.1	Capitalize on the potential contribution of T&CM to improve health services and health outcomes.	<ul style="list-style-type: none"> <li>■ Integration of T&amp;CM into the health system.</li> <li>■ Improved T&amp;CM services and accessibility.</li> <li>■ Improved communication between conventional medicine practitioners, professional bodies and T&amp;CM practitioners concerning the use of T&amp;CM.</li> </ul>	<ul style="list-style-type: none"> <li>■ Number of Member States reporting national plan/programme/approaches for integrating T&amp;CM service into the national health service delivery</li> <li>■ Number of Member States reporting consumer education project/programme for self-health care using T&amp;CM</li> </ul>
		4.3.2	Ensure consumers of T&CM can make informed choices about self-health care.	<ul style="list-style-type: none"> <li>■ Better awareness of and access to information about the proper use of T&amp;CM.</li> <li>■ Improved communication between conventional medicine practitioners and their patients about T&amp;CM use.</li> </ul>	

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## Annex A – Selected examples of notable T&amp;CM initiatives by region/country

WHO Region	Selected examples of notable T&CM initiatives
Africa	<ul style="list-style-type: none"> <li>■ Within the WHO African Region, progress has been made in policy development and provider education. The number of African countries with national T&amp;CM policies increased from eight in 1999/2000 to 39 in 2010, and those with national T&amp;CM strategic plans rose from zero to 18. Country regulatory frameworks increased from one in 1999/2000 to 28 in 2010, including various instruments such as the code of ethics and the legal framework for T&amp;CM practitioners. By 2010, eight countries had institutionalized training programs for T&amp;CM practitioners and 13 countries developed training programs for health science students and T&amp;CM (1).</li> <li>■ Since 2003, countries in the African Region have been hosting an annual African Traditional Medicine Day. Traditional health practitioners, conventional health practitioners, scientists, nongovernmental organizations (NGOs) and other stakeholders come together to engage on joint activities such as exhibitions, debates, symposia, seminars, panel discussions and cultural shows. These events have raised the profile of T&amp;CM and awareness of its activities. In 2010 some countries instituted a National Traditional Medicine Week (1).</li> <li>■ By 2010, 22 countries were conducting research on traditional medicines for malaria, HIV/AIDS, sickle-cell anaemia, diabetes and hypertension using WHO guidelines. Subsequently four countries included traditional medicines in their National Essential Medicines Lists (NEMLS) (1).</li> <li>■ Twelve countries issued marketing authorizations for T&amp;CM, ranging from three products in Cameroon and Congo to over 1000 in Ghana and Nigeria, compared to Mali alone at the time of the baseline survey.</li> <li>■ Guidelines for the protection of intellectual property rights (IPR) and traditional medicine knowledge (TMK) have been developed. By 2010, six countries had national tools for IPR and TMK protection versus zero in 1999/2000. Eight countries have established databases on traditional medicine practitioners, TMK and access to biological resources (1).</li> <li>■ Training tools were developed for health sciences students and traditional practitioners (AFRO, 2011).</li> </ul>
Americas	<p>Brazil:</p> <ul style="list-style-type: none"> <li>■ The Ministry of Health in Brazil has developed a National Policy on Integrative and Complementary Practices which was “implemented for political, technical, economic, social, and cultural reasons” (Retrieved from <a href="http://bvsmms.saude.gov.br/bvs/publicacoes/pnpic_access_expansion_initiative.pdf">http://bvsmms.saude.gov.br/bvs/publicacoes/pnpic_access_expansion_initiative.pdf</a>).</li> </ul> <p>Canada:</p> <ul style="list-style-type: none"> <li>■ A number of relevant policy, regulatory, and related issues and activities can be viewed at the Government of Canada’s “Health Canada” portal: <a href="http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php">http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php</a>.</li> <li>■ Comprehensive regulatory frameworks for natural health products including herbal and traditional medicines were introduced in Canada (<a href="http://www.hc-sc.gc.ca/dhp-mps/prodnatur/nhp-new-nouvelle-psn-eng.php">http://www.hc-sc.gc.ca/dhp-mps/prodnatur/nhp-new-nouvelle-psn-eng.php</a>, retrieved 3 August 2013).</li> </ul> <p>United States of America:</p> <ul style="list-style-type: none"> <li>■ In the USA, steps have been taken to strengthen provisions in the regulatory framework for dietary supplements especially in relation to Good Manufacturing Practices and adverse event reporting. (<a href="http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/dietarysupplements/ucm257563.htm">http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/dietarysupplements/ucm257563.htm</a>, retrieved 10 August 2012)</li> <li>■ The Office of Dietary Supplements, National Institutes of Health (NIH), has devoted considerable resources to developing validated analytical methods and reference materials to guide stakeholders on Quality Assurance (QA)/Quality Control (QC) of dietary supplements in its Analytical Methods/Reference Material (AMRM) program (<a href="http://ods.od.nih.gov/Research/AMRMProgramWebsite.aspx">http://ods.od.nih.gov/Research/AMRMProgramWebsite.aspx</a>).</li> <li>■ The FTC (Federal Trade Commission) has published guidelines and monitors commercial advertisements on dietary supplements, including botanicals (<a href="http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry">http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry</a>).</li> </ul>



<p><b>Eastern Mediterranean</b></p>	<ul style="list-style-type: none"> <li>■ In the East Mediterranean Region (EMR), fifteen Member States (88%) use different types of T&amp;CM. Seven Member States (41%) had established a national policy on T&amp;CM by 2010 and three (18%) reported that a national T&amp;CM policy was being devised. A further seven Member States (41%) reported that they had national T&amp;CM regulation. The Council of the Arab Health Ministers is discussing a project for harmonizing legislation on traditional, complementary and alternative medicine in the Arab countries. The December 2011 Eastern Mediterranean Drug Regulatory Authorities Conference (EMDRAC) addressed regulatory harmonization, including T&amp;CM. Five Member States reported that they already had regulations for practitioners, with explicit regulations for different disciplines such as acupuncture, ayurveda, homeopathy and herbal medicine in four of them. The United Arab Emirates have made considerable progress in the regulation of T&amp;CM practitioners<sup>1</sup>.</li> </ul> <p>Saudi Arabia:</p> <ul style="list-style-type: none"> <li>■ Saudi Arabia has addressed the problem of widely available unregulated herbal products. The Saudi Food and Drug Administration (SFDA) will consider the registration of herbal products containing 1 to 5 herbal medicine components but not any herbal product containing more than five components<sup>1</sup>.</li> </ul>
<p><b>Europe</b></p>	<p>European Union:</p> <ul style="list-style-type: none"> <li>■ The three-year pan-European research network, CAMbrella (<a href="http://www.cambrella.eu">www.cambrella.eu</a>), aims to evaluate the conditions underpinning T&amp;CM use and provision in Europe and to develop a roadmap for future European T&amp;CM research. CAMbrella encompasses 16 academic research groups from 12 European countries and its major findings were presented at the European Parliament in November 2012 (2).</li> <li>■ T&amp;CM legislation is being developed with the intention of adopting a harmonized approach to the regulation of herbal medicines across the European Union (Association of the European Self-Medication Industry (AESGP), Legal and Regulatory Framework for Herbal Medicines, 2010 (<a href="http://www.self-medication.org/publications/countryProfiles.asp">http://www.self-medication.org/publications/countryProfiles.asp</a>).</li> </ul> <p>Belgium:</p> <ul style="list-style-type: none"> <li>■ Detailed information is available for homeopathy, acupuncture, osteopathy and chiropractic including scientific literature reviews, population surveys, product consumption patterns, sociological aspects, practices, legal frameworks, training, professional organizations, patients' associations and reimbursement policies (3).</li> </ul> <p>Switzerland:</p> <ul style="list-style-type: none"> <li>■ The Swiss Government is investigating if T&amp;CM can prove its worth as an insurable health cost (4). The Government of Switzerland has published a Health Technology Assessment (HTA) (5).</li> </ul> <p>Italy:</p> <ul style="list-style-type: none"> <li>■ A study of "Cost-effectiveness researches on traditional/complementary medicine in Lombardy region – Italy" in 2012 shows that for podalic malposition and labour pain the cost savings in using T&amp;CM therapy are at least 24.2% and 108.8 euros respectively compared to the common conventional medicine procedure (<a href="http://www.regione.lombardia.it/cs/Satellite">http://www.regione.lombardia.it/cs/Satellite</a>).</li> </ul>

<sup>1</sup> Communication with WHO from the WHO Eastern Mediterranean Regional Office, 2013.

<p><b>South-East Asia</b></p>	<ul style="list-style-type: none"> <li>■ In the WHO South-East Asia Region (SEARO), the most notable progress concerns the introduction of new T&amp;CM policies and inclusion of T&amp;CM representation within government agencies (e.g., establishment of a new T&amp;CM division or delegation of government staff to T&amp;CM issues). Between 2002 and 2012, five countries developed national T&amp;CM policies: all SEARO Member States except Timor-Leste now have national policies in place, including T&amp;CM expert committees and offices in the respective Ministries of Health. Ten countries in the South-East Asia Region have national T&amp;CM programmes (6). In February 2013, the Government of India, in collaboration with the WHO South-East Asia Regional Office, organized an international conference on traditional medicine in New Delhi, at which participating countries agreed to cooperate, collaborate and mutually support each other in the field of traditional medicine by adopting the Delhi Declaration on Traditional Medicine<sup>1</sup>.</li> <li>■ In 2003, the WHO Regional Committee for South-East Asia developed a regional resolution on traditional systems of medicine (SEA/RC56/R6) in order to encourage the regional progress of TM. In several countries local T&amp;CM systems have been recognized by the respective governments, such as ayurveda and unani in Bangladesh, India, Nepal and Sri Lanka, sowa rigpa in Bhutan, jamu in Indonesia, koryo medicine in Democratic People's Republic of Korea, dhivehibeys in Maldives, Myanmar TM in Myanmar and Thai TM in Thailand. In Democratic People's Republic of Korea, koryo medicine is so integrated in the national health system that both TM and conventional health care are available in the same health facilities at all three levels of care. Both health systems are offered in separate facilities at secondary and tertiary levels in nine countries, of which eight have begun to integrate TM and conventional health care at the primary level (6).</li> <li>■ Since 2003, two countries have developed new regulations on traditional and herbal medicines and three Member States elaborated existing ones: nine countries therefore have regulations in place. Nepal established a National Formulary of herbal monographs in 2008, while another four countries updated their existing pharmacopoeias. In total, seven countries have national pharmacopoeias. Six countries have lists of essential traditional and herbal medicines. India and Indonesia contribute the International Regulatory Cooperation for Herbal Medicines (IRCH) (6).</li> <li>■ Efforts have been made to improve information exchange between Member States in order to promote the therapeutically sound use of TM and herbal medicine by providers and consumers. In Sri Lanka, the Central Department of Traditional Medicine, teaching institutions, hospitals and research institutions are involved in this process. A web site (HerbalNet) was launched by WHO in 2009 as an "digital repository" to encourage evidence-based information about national standards to be shared across the region; it is now accessed by other interested institutions around the world (6).</li> <li>■ Bhutan, Myanmar and Maldives have been assisted by WHO to carry out studies on public awareness of, attitude towards and practices in their respective TM systems. India undertook a systematic review of herbal medicines used for common chronic diseases and PHC diseases with encouraging results for TM integration in the national health system (6). In Bangladesh, there are 469 small factories (268 unani and 201 ayurvedic) producing traditional drugs worth approximately US\$ 100 million every year at present (7).</li> <li>■ In February 2013, regional Member States adopted the Delhi Declaration on Traditional Medicine, which has 9 items for cooperation, collaboration and mutual support. They include promoting national policies and strategies for equitable development and appropriate use of TM, pursuing a harmonized approach to TM education, practice, research, documentation and regulation, exploring the possibility of promoting mutual recognition of educational qualifications, pharmacopoeias and monographs, expanding common TM reference documents, encouraging sustainable development and resource augmentation of medicinal plants, and exchanging perspectives, experiences and experts in order to integrate traditional medicine into national health systems<sup>1</sup>.</li> </ul>
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<sup>1</sup> Communication with WHO from the Government of India, Ministry of Health and Family Welfare, 2013.

<p><b>Western Pacific</b></p>	<ul style="list-style-type: none"> <li>■ Government support for TM varies considerably across the 37 countries and jurisdictions of the WHO Western Pacific Region. In 2012, WPRO published its regional TM Strategy which Member States are in the process of implementing. In 2010, 18 countries and jurisdictions had developed official government documents (including national policies, regulations or laws) applicable to TM, compared to 12 countries and jurisdictions with official documents before 2000. The number of countries regulating herbal medicines was 10 in 2001; this had increased to 16 in 2010. The implementation of standards for Good Manufacturing Practices (GMP) for herbal medicines showed a significant increase from 2001 when no countries or jurisdictions in the region reported applying GMP for TM products; there are now nine countries and jurisdictions with active GMP in 2010. The establishment of national pharmacopoeias or monographs has also increased in the last decade: four countries and jurisdictions had national pharmacopoeias in 2001 compared to nine in 2010 (8).</li> <li>■ Examples of recent progress include Nauru, which developed a national policy in 2009, and Cambodia, which issued a policy on TM in 2010. Fiji, Kiribati, Niue, New Caledonia and the Federated States of Micronesia are all in the process of establishing national policies on TM (8).</li> <li>■ Singapore and New Zealand have introduced comprehensive regulatory frameworks for herbal and traditional medicines. New Zealand proposed legislation for the regulation of natural health products in 2010, as set out in the Natural Health and Supplementary Products Bill, which received its second reading in March 2013 (<a href="http://www.parliament.nz/en-NZ/PB/Legislation/Bills/b/c/8/00DBHOH_BILL11034_1-Natural-Health-Products-Bill.htm">http://www.parliament.nz/en-NZ/PB/Legislation/Bills/b/c/8/00DBHOH_BILL11034_1-Natural-Health-Products-Bill.htm</a> and <a href="http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/complementary_medicines.html">http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/complementary_medicines.html</a>). Australia is also reviewing and updating its existing regulatory framework for complementary medicines (<a href="http://www.anao.gov.au/publications/audit-reports/2011-2012/therapeutic-goods-regulation-complementary-medicines">http://www.anao.gov.au/publications/audit-reports/2011-2012/therapeutic-goods-regulation-complementary-medicines</a>, retrieved 1 August 2013).</li> <li>■ Across the region there has been an increase in government activities related to TM, including the establishment of a national office and/or a national expert committee. Fiji, Nauru and Tuvalu are in the process of establishing government bodies for TM. In the Philippines, regulation for acupuncture providers was issued in 2008.</li> <li>■ Regarding the development of research institutes for TM, 13 countries and areas in the region currently have a national institute, while research is carried out by other facilities elsewhere. To date, 14 countries and areas in the Region have established a university-level TM course, 12 of which provide instruction to at least bachelor-level while seven have doctoral programmes. Ten countries currently have health insurance coverage for TM provided by the government and/or private sectors. In most cases however, the health insurance is partial and only covers specific areas such as acupuncture, chiropractic and herbal medicine.</li> </ul> <p><b>Australia:</b></p> <ul style="list-style-type: none"> <li>■ The Council of Australian Governments (COAG) determined that all states and territories in Australia should regulate the practice of Traditional Chinese Medicine. Consequently, national registration of practitioners of Chinese herbal medicine and acupuncture and dispensers of Chinese herbal medicine commenced on 1 July 2012. The fastest growing group of T&amp;CM practitioners in the country are osteopaths, who tripled in number between 1996 and 2006 (9).</li> </ul> <p><b>Cambodia:</b></p> <ul style="list-style-type: none"> <li>■ In 2009, the Cambodian Government commissioned a national TM policy which set standards for the quality, safety and efficacy of herbal and other TM products and TM practices within Cambodia.</li> </ul> <p><b>New Zealand:</b></p> <ul style="list-style-type: none"> <li>■ New Zealand serves as an example of how the industrial sector for natural health products continues to increase. The New Zealand natural health product industry accounts for approximately NZ\$ 1.1 billion yearly, with 80% exported primarily to Australia, North America and parts of Asia. Growth has increased dramatically, from NZ\$ 400 million in 2004 to NZ\$ 760 million in 2007.</li> </ul>
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## Annex B – Information on selected global T&CM professional organizations

NGO	Activities
<b>World Federation of Hydrotherapy and Climatotherapy (FEMTEC)</b> (1)	<p><b>Progress:</b></p> <ul style="list-style-type: none"> <li>In many European countries, Hydrotherapy (HT) is widely used and therapies are included in national health care systems. These countries have a regulation on the use of HT and specific educational programmes.</li> <li>In North Africa and South-East Asia, HT is part of a long tradition and increasing demand is driving legislative and regulatory development.</li> <li>In many Latin American countries, ministries of health recognize HT.</li> </ul> <p><b>Challenges:</b></p> <ul style="list-style-type: none"> <li>In several countries, HT is considered as being either a complementary medicine with no reimbursement options, or a leisure and wellness activity. It has proved difficult to evaluate the efficacy of HT. This limits the ability of authorities to fund these therapies, as well as the ability of consumers to obtain information on HT. Research is mostly limited to European studies.</li> </ul>
<b>World Federation of Acupuncture-Moxibustion Societies (WFAS)</b>	<p><b>Progress:</b></p> <ul style="list-style-type: none"> <li>According to the result of a survey conducted by the World Federation of Acupuncture and Moxibustion Societies, acupuncture was used in 183 out of 202 surveyed countries. Of the 192 Member States of the United Nations, 178 (93%) have acupuncture practice and 59 acupuncture organizations.</li> <li>Legislation: in many countries, partial or complete insurance cover is available for acupuncture. Between 1998 and 2000, the coverage rate of acupuncture insurance rose from 12% to 17%.</li> <li>Education: several countries offer acupuncture courses and degrees. More and more governments are adopting official licensing systems for acupuncture practitioners which require academic training, examination and registration. Between 2002 and 2011, 91 medical colleges in the US integrated complementary and alternative medicine into their compulsory educational curriculum for conventional medicine.</li> </ul> <p><b>Challenges:</b></p> <ul style="list-style-type: none"> <li>Acupuncture has not yet gained an equal footing with conventional medicine in some countries, and often only conventional medical doctors are allowed to practise acupuncture.</li> <li>International standards on acupuncture are lacking.</li> <li>There is a dearth of evidence due to scarce funding for scientific research on acupuncture.</li> <li>Associated practices like moxibustion and blood-letting are disappearing.</li> </ul>
<b>World Federation of Chiropractic (WFC)</b> (3)	<p><b>Progress:</b></p> <ul style="list-style-type: none"> <li>Since 2000, the chiropractic profession has expanded from North America and the United Kingdom to all world regions, due to new educational programmes, legislation to regulate the profession and publication of WHO guidelines. Common international standards are now widely maintained, both in the educational and legislative fields, owing to the support of international associations.</li> <li>Increased numbers of chiropractic graduates and increasing funding in Europe and North America have resulted in increasing research opportunities and a stronger evidence base.</li> <li>Significant steps have been made to encourage collaboration and integration between chiropractic and medical professions.</li> </ul> <p><b>Challenges:</b></p> <ul style="list-style-type: none"> <li>In countries where practices are unregulated, other health providers claim to offer chiropractic services.</li> <li>Funding is generally limited to education and research, whereas it is required to increase policy input.</li> <li>Patients experience barriers in accessing chiropractic services (limited offer of chiropractic services outside of North America and financial disincentive, since chiropractic is excluded from most private and government health plans).</li> </ul>

<p><b>World Federation of Chinese Medicine Societies (WFCMS) (4)</b></p>	<p><b>Progress:</b></p> <ul style="list-style-type: none"> <li>• Chinese Medicine has spread to more than 100 countries and has grown into an international industry. There are about 100 000 Chinese medicine clinics, about 300 000 Chinese medicine practitioners and no less than 1000 Chinese medicine education institutes worldwide. Research has profited from the largesse of funding.</li> <li>• Of the various Chinese medicine modalities, acupuncture is the most used worldwide. In the United States it has acquired legal status in 43 States.</li> <li>• In China itself, Chinese medicine has been nationally and locally integrated into the health system: from a government perspective Chinese medicine and conventional medicine have an equal ranking. The export of Chinese medicinal products has registered a constant increase since 1999.</li> </ul> <p><b>Challenges:</b></p> <ul style="list-style-type: none"> <li>• In some countries, national regulatory frameworks now require Chinese medicine products to be sold only as health products or non-medicinal foods.</li> <li>• Chinese medicine needs to obtain legal status in some countries.</li> </ul>
<p><b>Osteopathic International Alliance (OIA) (5)</b></p>	<p><b>Progress:</b></p> <ul style="list-style-type: none"> <li>• Osteopathy is currently used in over 80 countries: there are an estimated 120 000 osteopaths and osteopathic physicians, which is twice the figure of ten years ago.</li> <li>• In the United States, the number of osteopathic physicians increased 73% between 2000 and 2012: they account for more than 6.5% of the total physician population.</li> <li>• There has been a significant increase in the number of universities and colleges offering training in osteopathy, as well as in students attending these courses.</li> <li>• Regulation of providers has been increasing.</li> <li>• Osteopathy is partly funded within national health systems.</li> </ul>

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## Annex C – Selected WHO publications on T&CM

As of May 2013, the following abbreviations are used to indicate the availability of language editions:

[A] Arabic; [C] Chinese; [F] French; [R] Russian; [S] Spanish.

An asterisk\* indicates a language edition in preparation.

Bold type face indicates publication and language versions made available since 2002.

### Policy

#### **POLICY DIRECTION AND STRATEGY**

**The *WHO Traditional Medicine Strategy 2014-2023*, WHO, Geneva.**

***WHO Western Pacific Regional Strategy on traditional medicine: 2011–2020.* Manila, WHO Regional Office for the Western Pacific, 2012. (ISBN 978 92 9061 559 0)**

***Development of traditional medicine in the South-East Asia region: Report of a regional consultative meeting.* Pyongyang, Democratic People's Republic of Korea, 22-24 June 2005. WHO Regional Office for South-East Asia, New Delhi, 2005. (document reference SEA-Trad.Med.84).**

***WHO Policy Perspectives on Medicines, Traditional Medicine - Growing Needs and Potential.* Geneva, WHO, 2002. (document reference WHO/EDM/2002.4) [A], [C], [F], [R], [S]**

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***The Promotion and Development of Traditional Medicine: Report of a WHO Meeting.* Geneva, WHO, 1978 (WHO Technical Report Series, No. 622).**

#### **NATIONAL POLICY AND REGULATION MONITORING**

***National policy and regulation of traditional medicine: report of the second WHO global survey.* Geneva, WHO (in preparation).**

***Regulatory situation of manual therapies; a worldwide review.* Geneva, WHO, (in preparation).**

***National policy on traditional medicine and regulation of herbal medicines: report of a WHO global survey.* Geneva, WHO, 2005 (ISBN 92 4 159323 7).**

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## **PROMOTION AND PRESERVATION OF TRADITIONAL MEDICINE KNOWLEDGE**

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## **Quality, safety and efficacy**

### **HERBAL MEDICINES - QUALITY AND SAFETY**

*WHO guidelines on good processing practices for herbal medicines.* Geneva, WHO, (in preparation).

*WHO guidelines on safety management of toxic medicinal plants and monographs on selected toxic medicinal plants.* Geneva, WHO (in preparation).

*WHO guidelines on selection of substances of herbal origin for quality control of herbal medicines.* Geneva, WHO (in preparation).

*Quality control methods for herbal materials* (updated edition of 1998 publication). Geneva, WHO, 2011 (ISBN 978 92 4 150073 9).

*Safety issues in the preparation of homoeopathic medicines.* Geneva, WHO, 2010 (ISBN 978 92 4 159884 2).

*WHO guidelines on assessing quality of herbal medicines with reference to contaminants and residues.* Geneva, WHO, 2007 (ISBN 978 92 4 159444 8). [F]\*, [S]\*

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## **HERBAL MEDICINES - REGULATION**

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