Meeting Report

Experts’ Consultation Meeting on Regional Strategy for Traditional Medicine in the Western Pacific Region

Hong Kong Special Administrative Region (China) 18–19 November 2010

World Health Organization Western Pacific Region
REPORT

EXPERTS’ CONSULTATION MEETING ON REGIONAL STRATEGY FOR TRADITIONAL MEDICINE IN THE WESTERN PACIFIC REGION

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NOTE

The views expressed in this report are those of the participants in the meeting and do not necessarily reflect the policies of the World Health Organization.

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This report has been prepared by the World Health Organization Regional Office in the Western Pacific for those who participated in the Experts' Consultation Meeting on Regional Strategy for Traditional Medicine in the Western Pacific Region, 2011-2020 which was held in Hong Kong Special Administrative Region, China from 18 to 19 November 2010.
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SUMMARY

The Experts’ Consultation Meeting on Regional Strategy for Traditional Medicine in the Western Pacific Region was held in Hong Kong SAR, China from 18 to 19 November 2010. This meeting was organized by the World Health Organization (WHO) Regional Office for the Western Pacific and hosted by the Department of Health, Hong Kong SAR. Participants included temporary advisers and observers from 12 Member States in the Region and Macao SAR, short-term consultants, and WHO secretariat from WPRO (Manila) and HQ (Geneva).

The objectives of the meeting were:

1. To discuss developments, challenges, needs, gaps, and findings in traditional medicine.
2. To review the preliminary draft of the Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020.
3. To provide advice and recommendations on the preliminary draft document.

During the course of the meeting, WHO secretariat, the short term consultants and temporary advisers presented information on various aspects of the current situation of traditional medicine in the Western Pacific Region, including information from the on-going WHO Global Survey of Traditional Medicine, and country assessments. Following presentation of the preliminary draft document of the Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020, each of the five objectives, the strategic tools, the indicators and the way forward, were presented by the short-term consultants, and suggestions for revision were made by the participants following detailed discussion. The overall recommendation was to revise and circulate the document among the participants before presentation to the Intercountry Consultation meeting on the Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020 to be held in March 2011. The outcome of the meeting will be a first draft strategy of the Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020. The goal remains for the new strategy to be tabled for the 2011 Regional Committee Meeting.
1. INTRODUCTION

In September 2001, the fifty-second Session of the Regional Committee for the Western Pacific endorsed the *Regional Strategy for Traditional Medicine in the Western Pacific 2001-2010*, which sought to promote safe and appropriate use of traditional medicines in the Region. Significant developments and new challenges for traditional medicine have occurred in Member States since this strategy was developed, resulting in the need to consider future strategic guidance for traditional medicines in the Region.

On 4-5 May 2010, an Informal Meeting on Strategic Directions for Traditional Medicine in the Western Pacific Region was held in Manila. This meeting recommended that the existing Regional Strategy for Traditional Medicine in the Western Pacific be updated, building on the existing strategy. The meeting also recommended the utilization of the results of the WHO Global Survey on Traditional Medicine and a consultative process using regional experts in traditional medicine in order to develop a new strategy for the period 2011-2020. As a result of these recommendations, a preliminary draft strategy was developed. The Experts’ Consultation Meeting on Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020 was held on 18-19 November 2010, in the Hong Kong Special Administrative Region, China. The purpose of the meeting was to obtain guidance and advice from experts on the preliminary draft of the *Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020* (Annex 1).

1.1 Objectives

(1) To discuss developments, challenges, needs, gaps and findings in traditional medicine.

(2) To review the preliminary draft of the Regional Strategy for Traditional Medicine in the Western Pacific, 2011-2020.

(3) To provide advice and recommendations on the preliminary draft document.

2.1 Opening remarks

Dr Budiono Santoso, Team leader, Essential Medicines and Technologies (EMT), on behalf of the Director of the Department of Health Systems (DHS) for the Western Pacific, welcomed the participants (Annex 2) and delivered the opening remarks. He thanked the experts for their participation in the meeting and went on to thank Dr P Y Lam and his group for hosting and organizing the meeting. He spoke of the implementation of the *Regional Strategy for Traditional Medicine in the Western Pacific 2001-2010* and the importance of people-centred traditional medicine in the Western Pacific Region. He emphasized innovation and traditional medicine as essential aspects of primary health care. In addition, he expressed the hope that the meeting would have a productive outcome through the participation of all of the temporary advisers. Each of the participants then introduced themselves and provided some information about their respective backgrounds. Dr Narantuya Samdan, WHO Regional Adviser for Traditional Medicine, also thanked the participants and Dr P Y Lam for hosting and organizing the meeting. Dr Hendrik Bekedam, Director of Health Sector Development, Western Pacific Regional Office joined the meeting and welcomed the participants and thanked them for their involvement in the meeting.
In order to facilitate the meeting, Dr Budiono Santoso suggested two temporary advisers who were nominated as the Chairperson and the Vice-chairperson, of the group for the duration of the meeting. He proposed that the temporary advisor from the Hong Kong Special Administrative Region, China, Dr P Y Lam be nominated as the Chairperson of the meeting, and from Australia Dr Michael Smith was nominated as the Vice-chairperson. Dr Briggs and Dr Cordell were nominated as Rapporteurs for the meeting. Through consensus the participants agreed to these nominations.

2. PROCEEDINGS

Dr P Y Lam assumed his role as Chair of the meeting and asked for approval of the proposed agenda (Annex 3) and timetable (Annex 4) for the meeting, which was afforded by the participants. Dr. Samdan went on to introduce the objectives and expectations for the meeting (Annex 5.1). She briefly discussed the challenges and indicated that the Western Pacific Regional Office was seeking the opinion of the experts group of the Directions, Challenges and Actions of the Objectives, as well as the priorities, the way forward and the proposed indicators.

2.1 Global trend and perspective on traditional medicine

The presentation “Global trend and perspective on traditional medicine” (Annex 5.2) was provided as an introduction and overview by the Coordinator in Traditional Medicine for WHO HQ, Dr Zhang Qi. Global trends in traditional medicine were briefly reviewed. The challenges for traditional medicine globally were presented and include diversity of practices and a lack of reliable data, regulation of traditional medicine, implementation of regulations, and the degree of integration of traditional medicine into health systems, this was followed by the objectives and strategies. The priorities for traditional medicine were identified as:

1. Inclusion of traditional medicine into a national health plan
2. Strengthening of human resources needed
3. Development of herbal medicines and
4. Promotion of a healthy life-style through traditional medicine.

Finally, the approaches for traditional medicine to achieve the goals were presented. These included:

1. Expanding global network outside of WHO
2. Building up team work for traditional medicine within WHO and
3. Developing tools
2.2 The “Regional perspective on promoting traditional medicine - Overview of the implementation of the Regional Strategy for Traditional Medicine in the Western Pacific 2001-2010”

The “Regional Perspective on Promoting Traditional Medicine - Overview of the implementation of the Regional Strategy for Traditional Medicine in the Western Pacific 2001-2010" (Annex 5.3) was presented by the Regional Adviser in Traditional Medicine for the Western Pacific, Dr Narantuya Samdan. Objectives and strategic directions of the Regional Strategy for Traditional Medicine in the Western Pacific 2001-2010 were reviewed. The Western Pacific Regional Office traditional medicine activities were presented in terms of technical support to governments for traditional medicine policies, the safety, efficacy and quality of traditional medicine, and the development of the evidence base for traditional medicine. The activities related to standards, harmonization and education also were presented. Finally, the guiding principles and regional perspectives for traditional medicine of the Western Pacific Regional Office activities in traditional medicine were reviewed. These included:

1. Promoting integration, and evaluation of Traditional Medicine as a subsystem of national health systems
2. Strengthening research to promote the quality, safety and efficacy of traditional medicine and products
3. Capitalizing on the potential contribution of traditional medicine to people-centred primary care
4. Encouraging research and development in traditional medicine in accordance with national priorities and legislations, taking into account the relevant international instruments, including, as appropriate, those concerning traditional knowledge and the rights of indigenous people.

2.3 “Current status of Traditional Medicine in the Western Pacific Region” and “Selected Country Assessment”

The Technical Officer in Traditional Medicine for the Western Pacific, Dr Eunmi Seong, presented “Current status of Traditional Medicine in the Western Pacific Region” (Annex 5.4) as a general situational review of and the challenges for traditional medicine in the Western Pacific Region. The assessment was conducted according to nine criteria for the review and four criteria for the challenges. Data were collected through completion of the Second WHO Global Survey on National Policy and Regulation for Traditional Medicine Complementary and Alternative Medicine, country assessments and a review of selected publications on traditional medicine.

Under the criteria of Policy, 17 Member States and areas (47%) have a national policy on traditional medicine. A total of 17, 13 and 10 Member States and areas have a national office, laws and/or regulations, and a national research institute on traditional medicine, respectively. With respect to the criteria of the regulatory status of herbal medicine, there was a significant increase shown for those Member States indicating that they have Good Manufacturing Practices (GMP) for herbal medicines. In conclusion, the data showed the strengthening and growth of traditional medicine in the Region. A number of regional challenges were identified, which related to policy/regulation, safety, efficacy and quality, and rational use and access.

The “Selected Country Assessment” (Annex 5.5) of traditional medicine was presented by Professor Emeritus Geoffrey Cordell, Natural Products Inc., Evanston, IL USA. He reviewed the current status and challenges for traditional medicine in five selected countries: Cambodia,
China, Japan, Korea and Lao PDR. Country challenges identified included collaboration in the development of effective laws and regulations in the Region, a lack of commitment to the development of research resources, and strategies for quality, safety and efficacy determination.

2.4 Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020

The Regional Adviser in Traditional Medicine for the Western Pacific, Dr Narantuya Samdan presented the “Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020” (Annex 5.6). In the presentation she explained the need for revising the existing strategy, the basic framework of the updated strategy and the development process. Diversity and the unique culture of each form of traditional medicine in the Western Pacific Region were being considered in the process of updating the existing strategy.

Prof David Briggs, Centre of Complementary Medicine Research, University of Western Sydney, presented “Continuation of “Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020” (Annex 5.6) which further developed the background and overview of the Regional Strategy for Traditional Medicine 2011-2020. The existing global and regional strategies, the Beijing Declaration and the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) were described as important background materials for updating the strategy. Each Strategic Objective was presented, and the continuation and innovation on updating the strategy to provide better guidance for Member States were emphasized. The importance of developing respect for traditional medicine by other health professionals was mentioned. Key aspects of The Way Forward - Moving from Strategy to Action were presented for 2011-2020. These included:

- Need for government support and commitment
- Planning
- Implementation
- Monitoring and evaluation
- Financing

A discussion followed the presentation, in which there were comments made on the effects of environmental (climate) change, and population dynamics on traditional medicine, including the need to consider the importance of an ageing population; respect for cultural traditions in evaluating traditional medicine; strong partnerships within and between Member States to share expertise; the use of traditional medicine as a preventative, and the definition of traditional medicine.

2.5 Review of the Preliminary Draft Document

2.5.1 Review of the Strategic Objectives

The Strategic Objectives are:

- To include traditional medicine in the national health care system
- To strengthen the evidence base of traditional medicine
- To promote the safe and effective use of traditional medicine by health care providers and consumers
- To increase access to traditional medicine within the national health care system
To strengthen cooperation in generating and sharing traditional medicine knowledge and skills

**Strategic Objective 1. To include traditional medicine in the national health care system**

The review of the Objectives commenced with a discussion of Strategic Objective 1. The temporary advisers shared their experiences and their country situation regarding having a national policy on traditional medicine. Even though this objective was the same first Objective as the existing Regional Strategy, there was still a need for Member States to have national policy on traditional medicine as the top priority. A discussion of the different types and levels of integration of traditional medicine into the health system in each country followed in which all of the temporary advisers shared their knowledge and experience. China has a combined national health care system for traditional medicine, while Korea has a dual system, for Western medicine and for traditional medicine, which are viewed differently. Japan has one national license system only for Western medicine. Malaysia, the Philippines, Viet-Nam and Lao PDR also have different levels of recognition and integration of traditional medicine in their national health care system. Following discussion, there was a general consensus that development of a traditional medicine national policy should be an important task. The other sub-objectives of Objective 1 depended on respect for traditional medicine, the examination of the role, and the level of recognition of traditional medicine. Following discussion and consensus, two of the sub-headings of Objective 1 (Objectives 1.2 and 1.3) relating to regulations and standards (Objective 1.2) and qualifications and licensing of practitioners (Objective 1.3) were rearranged to be included in Objective 2. In addition, the group recommended the merging of Strategic Objectives 2 and 3.

**Strategic Objective 2. To strengthen the evidence base of traditional medicine and**

**Strategic Objective 3. To promote the safe and effective use of traditional medicine by health care providers and consumers**

Discussion of new Objective 2 commenced by amending and combining with Objective 3, and with Objectives 1.2 and 1.3. There was a consensus to change the title for the revised Objective 2 into "to promote the safe and effective use of traditional medicine". The four sub-objectives were determined to be:

- 2.1, to strengthen the evidence base of traditional medicine
- 2.2, the safe and effective use of traditional medicine products
- 2.3, the safe and effective use of traditional medicine by providers
- 2.4, the safe and effective use of traditional medicine by consumers

The evidence base of traditional medicine was separated into two categories, a scientific and a historical evidence base. Some ideas were suggested for actions under sub-objective 2.1, such as developing research guidelines to traditional medicine providers, strengthening the traditional research base, and harmonisation and cooperation. A discussion followed about the definition of traditional medicine providers, and the authorities for the accreditation of traditional medicine providers under sub-objective 2.3. Under the related sub-objective 2.4, the question was raised as to how the public could be better informed and what were the choices for informing consumers with respect to the safe and effective use of traditional medicine. Concerns
regarding the quality, safety and efficacy of traditional medicines on the e-market were expressed by several temporary advisers.

**Strategic Objective 4. To increase access to traditional medicine within the national health care system**

Following discussion with respect to Objective 4, to increase access to traditional medicine within the national health care system, it was suggested that the meaning of access should be included. This should refer to both sustainability of the resources used in traditional medicine, and to affordability and availability. Therefore, Objective 4 was divided into two separate objectives:

- Objective 3, to increase access the safe and effective traditional medicine, as appropriate to need.
- Objective 4, to promote and sustainable use of traditional medicine resources

Objective 3 was focused on the importance of universal coverage (affordability and availability to the consumer) as applied to traditional medicine, in particular on the insurance coverage (government and private) for those products and practices of traditional medicine which had a determined safety and efficacy. It was recognized that from a cost-aspect, access would be different for each Member State and for different insurance providers within each country.

Concerning Objective 4, and the sustainability of natural health resources, including indigenous knowledge and biodiversity, the continuing availability and, more recently, the scarcity of medicinal plant natural resources due to deforestation and over-use were discussed. Monitoring and conservation of natural resources as well as their habitats were emphasized, and some suggestions were made concerning intellectual property rights for traditional medicine. There was general consensus for sub-objectives of Objectives 3 and 4, which were financial, social, cultural, geographical and other factors as barriers to access for Objective 3, and baseline assessment of natural resources within a country, including knowledge and traditional medicine use for Objective 4.

**Strategic Objective 5. To strengthen cooperation in generating and sharing traditional medicine knowledge and skills**

Objective 5, to strengthen cooperation in generating and sharing traditional medicine knowledge and skills, was introduced. The responsibilities of high- and medium-income countries for the wider development of traditional medicine in the Region, particularly, the sharing and exchange of knowledge and experiences in all areas were discussed actively. There are some good models for networking, information collection and communication in the Region. However, some difficulties were recognized such as language barriers, linkages between, and access to, the scattered, existing portals, and the responsibility for maintenance of up-to-date information resources.

Two brief presentations were made by the temporary advisers from China and Japan. China presented of "The importance of prevention in traditional medicine" and the flow chart of "Patient-oriented integration" was presented by the temporary advisers from Japan in cooperation with the Korean temporary advisers. The participants appreciated these contributions to the discussion.

Followed these presentations, there was ongoing discussion about Directions, Challenges and Actions proposed for each Strategic Objective. There was a general consensus to review the
Directions, Challenges and Actions and to select only those indications which were regarded as being of the highest priority to the Member States present.

Under Objective 1, the priority direction was decided as a government commitment to recognise and explore the integration traditional medicine into health care planning. For the Challenges, the focus was on the absence of infrastructure and financial commitment at the national level. An addition was made to the Challenges in terms of the lack of traditional medicine information. For actions, the focus was on a systematic review of the status of traditional medicine, formulation of a comprehensive government policy, and producing an implementation plan and developing resources.

Under the Directions, Challenges and Actions of the revised Objective 2, the prioritised direction was strengthening capacity and capability to support the research and development of traditional medicine. Emphasis was also placed on the need to consider the nature of the traditional medicine paradigm in applying research methodology, establishing a regulatory and registration system for traditional medicine products and appropriate training program. Under Actions, the need to build and strengthen research capacity to promote research on the quality, safety and efficacy of traditional medicine was emphasized, as well as the introduction and monitoring of Good Agricultural and Cultivation Practices (GACP), Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), and Good Clinical Practice (GCP) standards.

With respect to the safe and effective use of traditional medicine, the need to increase the standards of education and training of practitioners was prioritized, together with increasing the ability of consumers to make informed choices about traditional medicine therapies. Some suggestions were made on the monitoring and reporting system of adverse drug reactions. A concern was also expressed, about consumer awareness of the potential risks from traditional medicine products and practices that are obtained outside of national regulatory controls, such as web-based purchases or products imported for personal use, where the quality, safety and efficacy may be unknown. For countries which already have a regulatory system for traditional medicine products, it was important to enhance the system. The need to strengthen communications between Western and traditional medicine practitioners was discussed.

Regarding the Directions, Challenges and Actions of Objective 3, the word “insurance” was rephrased into insurance or other subsidies according to the diverse practices of coverage and the various reimbursement systems of Member States. The main direction was to recognise traditional medicine as contributing to public health and its universal coverage. The main challenges were recognized as relating to access based on costs, over-servicing, including the over-use of traditional medicines, and the social, cultural and geographic perspectives.

With respect to Objective 4, the priority Directions were decided as the baseline assessment of existing natural health resources, including indigenous knowledge and traditions, developing and monitoring inventory, conservation and cultivation of traditional medicine resources, establishing policies for the protection and conservation of knowledge and resources, and the importance of intellectual property rights. Several countries in the Region indicated that destruction of habitat for medicinal resources was a major concern. There was some discussion about patents and intellectual property for traditional medicine products and practices. The importance, difficulties and economic implications were discussed and it was agreed that it was an area requiring careful consideration and adequate regulations and laws for the Member States. The need to develop conservation strategies for natural health resources was recognized as an Action.

Regarding the Directions, Challenges and Actions of Objective 5, the three sub-objectives were not changed. Interdisciplinary and regional collaboration for training in research methods
and contemporary technologies was strongly supported by the participants. It was recognized that consumers in many countries were increasingly self-medicating, and that governments should consider the use of traditional medicine where it has demonstrated quality, safety and efficacy. Education programs for Western health practitioners in traditional medicine were also supported. A fourth sub-objective was added “to facilitate international standardization” in the areas of terminology, classification, regulatory standards, and information sharing and access with a view towards greater cooperation and harmonization of traditional medicine standards and practices in the Region. It was recognized that standardization requires regular updating.

2.5.2 Draft Review - Priorities

The participants agreed that the priority areas for traditional medicine for the period 2011-2020 were national policy on traditional medicine, the inclusion of traditional medicine in a national health plan and the importance of a prevention and wellness role for traditional medicine. Other matters of inclusion were public support for traditional medicine and evaluation of progress of implementing the new Regional Strategy by Member States, such as a mid-term review.

2.5.3 Draft Review - Indicators

The general consensus, following a review of the indicators, was to revise and re-establish them Objective by Objective, since some of the Objectives were modified or newly created. Indicators were regarded as a good tool for measuring the progress of Member States at the national level.

It was generally not regarded as a good tool to indicate commitment at the national level. In support of this concept, the temporary advisers shared the country situation about their own national institute. Furthermore the temporary advisers shared information about the report and monitoring system for herbal medicines regarding safety. It was mentioned that there were no indicators for consumers under Objective 2, while most indicators were about providers. For consumer indicators, a number of ideas were suggested, including consumer education programmes, more informed consumer choice and media reports. Also added was the existence of information controls for advertising traditional medicine products and services. Indicators under initial Objective 3, the determination of the proportion of the population using traditional medicine should be reconsidered due to the different measuring tools used in the Member States. The indicator of the existence of a traditional medicine monitoring center should be deleted. For the initial Objectives 4 and 5, the temporary advisers shared their country situation concerning their licensing systems and available databases. Some good suggestions for monitoring systems were made.

2.5.4 Strategic Tools and WHO Support

This topic was mentioned and presented previously in the preamble discussion, and no further discussion was needed. It was stressed that the WHO Western Pacific Region will respond to requests related to enhancing policies, regulations and programmes in traditional medicine as generated by countries, based on a situation analysis with respect to the Strategic Objectives. Countries were encouraged to support all five of the Strategic Objectives.

2.5.5 Way Forward

The section on the Way Forward was intended to provide general guidance for Member States in order to consider, develop according to their specific prioritized needs, and implement the Regional Strategy. New evaluation tools developed to measure needs could be shared
between Member States. For more feedback based on the implementation of the Action points, it
will be necessary to reassemble as the Member States move forward with their initiatives.

2.5.6 Grouping Countries

There was a suggestion by Dr Narantuya Samdan, Regional adviser for traditional
medicine in the Western Pacific, to group the countries depending on their level of development
of traditional medicine programmes to show how different countries could proceed. However,
there were objections to the grouping idea due to the importance of Member States working
together and sharing resources. It was felt by the participants that the focus of the effort should
be targeted to support the Member States with clear criteria and ideas for moving forward in line
with the Regional Strategy.

3. CONCLUSIONS AND RECOMMENDATIONS

The temporary advisers agreed that there had been a thorough review of the preliminary
draft of the Regional Strategy for Traditional Medicines in the Western Pacific 2011-2020 and
recommended that the document be redrafted and circulated to the participants. It was
acknowledged that many of the issues and concerns discussed during the revision of document of
the Regional Strategy for Traditional Medicines in the Western Pacific 2011-2020 in this
Experts’ Consultation meeting will be reflected in the revised draft of the Regional Strategy for
Traditional Medicine on the Western Pacific 2011-2020. Recognizing the consensus nature of
the meeting and that all Member States were not represented, it was concluded agreed by the
temporary advisers present that the meeting was very successful, with all of the meeting
objectives met.

4. CLOSING

Dr Narantuya Samdan, Regional Adviser, Traditional Medicine, thanked all of the
participants for their active involvement in the review of the preliminary draft Regional Strategy
document, and indicated that a First Draft Regional Strategy document would now be prepared.
CONTENTS

INTRODUCTION

Wide and growing use of traditional medicine
A role for traditional medicine in promoting health care and health equity
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THE REGIONAL STRATEGY FOR TRADITIONAL MEDICINE IN THE WESTERN PACIFIC 2011-2020

Strategic Objectives

1. To include traditional medicine in the national health system
2. To promote safe and effective traditional medicine
3. To increase access to safe and effective traditional medicine
4. To promote protection and sustainable use of traditional medicine resources
5. To strengthen cooperation in generating and sharing traditional medicine knowledge and skills.

Mid-term review

THE WAY FORWARD

Prioritization
Moving from strategy to action
Strategic tools and WHO support
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ANNEXES
INTRODUCTION

The purpose of the *Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020* is to provide guidance for governments, WHO, development partners and other stakeholders on how to maximise the health potential of traditional medicine, and advance the cause of primary health care and universal coverage.

Wide and growing use of traditional medicine

Traditional medicine is an ancient and culture-bound health practice that has its origins before the application of modern science to health. Traditional medicine is widely used, and is of growing health and economic importance. In some countries, the majority of the population continue to use traditional medicines to meet their health needs. In addition, the use of traditional medicine is becoming more popular in other countries where it is used as an alternative to, or complementary with, Western medicine.

The forms of traditional medicine practiced in the Western Pacific region vary widely. Some forms are highly developed and well documented. They are based on systematized knowledge, comprehensive methodology and historical experience. The Region also includes a number of less complex traditional medicine practices that have developed within small and sometimes isolated ethnic groups. Such practices are based largely on an empirical experience of treatment. The knowledge may not be documented and is transmitted orally from generation to generation.

In low and middle-income countries, the continuing wide use of traditional medicine is often attributable to historical circumstances, cultural beliefs, and accessibility and affordability. The increasingly popular use of traditional medicine in many middle- and high-income countries can be attributed to increasing access to health information, concerns about the safety and approaches of Western medicine, the desire to take greater personal responsibility for one’s health, and an interest in a more holistic approach to health, prevention and wellbeing.

A role for traditional medicine in promoting health care and health equity

Improved health is the overarching objective of public health policy across the Western Pacific region and is critical to help underpin sustained economic and social development. While health status has improved greatly in many countries, particularly where governments have committed to universal coverage of health services based on the values and principles of primary health care, much remains to be done. Millions of people cannot afford to use health services, or they suffer financial hardship, or become impoverished because of the personal health costs. All countries can improve the efficiency and effectiveness of their health systems and thereby make available resources to provide coverage for more people, more services, or more of the out-of-pocket expenses. The utilization of high quality, safe and effective traditional medicine therapies can make an important contribution to national and individual health care and the promotion of health equity. The implementation of universal coverage for traditional medicine will be the decision of each Member State. Coverage may be general or selective. For example, use in prevention and wellness, in vulnerable groups such as children or the elderly or use for specific health conditions, disorders or diseases.

Traditional medicine and primary health care

Traditional medicine has many potential contributions to make to health care, but its greatest role is in primary health care. The Declaration of Alma-Ata¹, which was adopted at the International Conference on Primary Health Care over thirty years ago, called for the inclusion of traditional medicine in primary health systems, the recognition of traditional medicine practitioners as health workers, particularly for primary health care at the community level, the accommodation of proven (efficacious) and safe traditional remedies in national medicine policies and the need for regulatory measures.

Primary health care is viewed more broadly than it was since the original *Alma-Ata Declaration on Primary Health Care*.

Emphasis is now given to:

- achieving universal access/coverage;
• a focus on the entire population, especially the disadvantaged;
• recognition of the need for a healthy global and local environment;
• working within a mixed system of public and private health provision;
• providing a continuum of care over a lifetime; and
• recognizing that a primary health care approach provides value for money.

WHO recognizes that traditional medicine has an established, preventive, curative and rehabilitative role in health care.

**Traditional Medicine in the Health System**

A health system should be people-centred and respond to the medical and service needs of the population. WHO has promoted a framework of six building blocks for health systems; they include leadership and governance, health workforce, information, medical products and technologies, health financing, and service delivery. All of these building blocks are important components of a health system that can facilitate the delivery of traditional medicine services. A robust health system strives to ensure equitable access to essential products and technologies that are of assured quality, and are safe, efficacious and cost-effective. The system promotes the use of these essential products and technologies to provide the most effective therapy, based in either Western or traditional medicine, in an evidence-based and cost-effective manner.

Traditional medicine may range from being

- fully included,
- partially included,
- or excluded from the national health system.

In a **fully inclusive health system**, traditional medicine is officially recognized and incorporated into all areas of health provision. This means that traditional medicine is included in the country’s national health policy; providers of traditional medicine services are registered or otherwise publicly accountable; traditional medicine products, including manufacturers are regulated or otherwise controlled; therapies are available at hospitals and clinics (both private and public); treatment is reimbursed under public or private health insurance; relevant research is undertaken; and education in traditional medicine is available for health professionals and consumers, and is a requirement for practice.

In countries where traditional medicine is **partially included in the health system**, the government recognizes the role played by traditional medicine, supports its appropriate use, includes some forms of traditional medicine in its mainstream health provisions and takes varying measures to control the safe use of other forms of traditional medicine.

In countries where traditional medicine is **not officially recognized, or is excluded from the national health system**, traditional medicine may still be used, but there are no government provisions supporting or controlling its use beyond the general provisions of consumer protection.

**WHO supporting change for traditional medicine in the Western Pacific region**

The WHO Western Pacific Region Office will respond to the needs of Member States related to traditional medicine based on a situation analysis. To help identify national needs, the health plans of the requesting Member States should identify the development of traditional medicine as a need. To meet these requests, WHO’s role

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* Traditional medicine may be acknowledged by governments in a dedicated traditional medicine policy or be part of a more general health care or medicine policy.
will be identified through country cooperation strategies, the strategic planning process of WHO, and other relevant planning processes, such as the United Nations Development Assistance Framework. WHO will place emphasis on assisting Member States with the implementation of adopted Regional Strategies, including the Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020. WHO country offices should be involved in, and responsive to, national planning processes. WHO will mobilize support for countries subject to available resources.

The path to implementation of the Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020 will be different in each Member State. Where it is helpful, however, guidance based on groupings of countries [this could also be a grouping based on achievement] facing similar challenges is provided (see The Way Forward – Moving from strategy to action).

WHO will actively advocate and promote the Strategic Objectives of the Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020 in Member States and among development partners and other stakeholders at the regional and country level, in planning and in coordinating actions for country support. While the Strategic Objectives are important, ultimately, it is the health outcomes that follow from implementing the strategic actions that really matter.

Regional Trends in Traditional Medicine 2001-20104, 5, 6, 7, 8, 9

The WHO Regional Office for the Western Pacific Region has made significant efforts to increase understanding and to promote the appropriate use of traditional medicine. As a result of these efforts, improved progress has been achieved during the past 10 years, such as integration into national health care systems, and the promotion of quality, safety and effective use of traditional medicine, and strengthening evidence based medicine, etc. Aspects of the progress on traditional medicine made in the Region is summarised below.

Political support on traditional medicine

Traditional medicine continues to provide a major/alternative health option for populations in many Member States and areas. The level of recognition and support for traditional medicine from governments varies considerably in the 37 Member States in the Region. With respect to the development of official government documents (including a national policy, regulations/laws) applicable to traditional medicine, in 2001 there were 14 Member States and areas (38%). In 2010, four more Member States and areas for a total 18 Member States and areas (49%) had newly developed and adopted government official documents on traditional medicine. Most recently, Cambodia issued a national policy exclusively on Traditional Medicine of Kingdom of Cambodia, 2010. Furthermore, Nauru has developed a national policy in 2009. Fiji, Kiribati and the Federated States of Micronesia are in the process of establishing national policies on traditional medicine.

Regarding government activities, including having a national office and/or a national expert committee, there was a significant increase from seven Member States and areas (19%) in 2001 to 17 Member States and areas (46%) in 2010. Even more encouragingly, three more Member States, Fiji, Nauru and Tuvalu are in the process of establishing government bodies for traditional medicine.

From 2001 to 2010, the regulation of practice (practitioners) of traditional medicine was identified by five more Member States and areas for a total of 13 Member States and areas (35%). In the Philippines, the regulation on acupuncture providers was issued in 2008 and is now in the implementation stage, and regulations on chiropractic providers and homeopathic providers were enacted in 2009. Fiji also enacted a national level regulation for acupuncture providers.

Fifteen Member States and areas (41%) have regulations on herbal medicine in 2010, which is five more Member States and areas than in 2001. In 2007, the Lao PDR established the regulation on herbal medicine, Decree on Medicinal Natural Resources no 135/PM, which is now in the implementation stage. Some Member States and areas have exclusive regulations on herbal medicine (i.e. Cambodia, China, Hong Kong SAR, Macao SAR, Republic of Korea, and the Philippines), and some have traditional medicine included in regulations applicable to conventional pharmaceuticals (i.e. Japan, Mongolia, Malaysia). Papua New Guinea is in the process of establishing regulations for herbal medicine.
Even though the political support from government on traditional medicine is not increasing dramatically, the data show a gradual and steady increase in this area of support for traditional medicine in the Region over the past ten years.

**Evidence-based approach for the quality, safety and efficacy of traditional medicine**

An evidence-based approach to traditional medicine is an important factor towards enhancing the quality, safety and efficacy of traditional medicine, and in garnering respect from other health practitioners. In the Western Pacific Region, some aspects of the evidence based approach for traditional medicine showed significant improvement in the period 2001-2010.

In 2001, only four Member States and areas had national pharmacopoeia/monograph systems. By 2010, five more Member States and areas had developed national pharmacopoeia/monographs for a total of nine Member States and areas (24%). China and the Republic of Korea have published the 9th edition of their own national pharmacopoeias in 2010 and both documents are legally binding. The 16th Japanese Pharmacopoeia is anticipated in 2011.

With regard to the development of research institutes for traditional medicine, 13 Member States and areas (35%) have research institutes in 2010, representing an increase of only one Member States and areas since 2001. Even though Papua New Guinea does not have a research institute, research has been done by the national Department of Health in collaboration with University of Papua New Guinea.

The implementation of Good Manufacturing Practices (GMP) for herbal medicine showed a remarkable increase in the period. Compared with no Member States and areas implementing GMP in 2001, there are now eight Member States and areas with GMP implemented: Australia, China, Hong Kong SAR, Japan, Malaysia, Philippines, Singapore and Viet-Nam. In addition, Macao SAR, Mongolia and Tuvalu are in the process of establishing GMP for herbal medicine. These data indicate a significant increase in concern for the quality and safety of traditional medicines.
Education and training programs

Education on traditional medicine at the university level and related training programs should be provided to ensure the safe and effective use of traditional medicine by traditional medicine practitioners, as well as Western health care providers. Furthermore, regulatory systems are needed to assure the formal education and training standards and registration of traditional medicine practitioners.

In the Region, during past 10 years, 14 Member States and areas have a course on traditional medicine at the university level and 12 Member States and areas provide education on traditional medicine to at least the Bachelor degree level. Among 11 Member States and areas, seven provide PhD level education for research on traditional medicine (China, Hong Kong SAR, Japan, Macao SAR, Mongolia, Republic of Korea, and Viet-Nam). In Cambodia, even though there is no university level education for traditional medicine, there is a government recognized training program for indigenous traditional medicine practitioners.

Economic value of traditional medicine (for access)

There was significant economic value associated with the provision of traditional medicine in the Region in this period. Ten Member States and areas have health insurance coverage for traditional medicine provided by government and/or private sectors. In most cases, the health insurance covers is partial and covers specific areas such as acupuncture, chiropractic and herbal medicine. China and Republic of Korea have coverage in both the government and private sectors, and the Republic of Korea provides full coverage for acupuncture treatment. In Tuvalu, herbal medicine, osteopathy and chiropractic treatments are covered fully by private health insurance.

The annual sales expenditures on traditional medicines in China were USD 25 billion in 2008. From 2002-2008, the percentage of Chinese Materia Medica sales within the total pharmaceutical sales market ranged between 20-35% and the annual growth rate of Chinese Materia Medica sales is estimated to be about 23% over the past years. Chinese herbal companies account for about 25% of all pharmaceutical manufacturers. In Japan, the market size of herbal medicine (Kampo) increased gradually in the period 2007-2008, US $1, 42 billion, and US $1, 47 billion, respectively. In Korea, traditional medicine expenditures as a percentage of total health expenditures (%) were 14.9%, 12.8%, and 11.3% in 2003, 2005, and 2008, respectively. The data showed steady decrease for unknown reasons.

Need for support (challenges)

In summary the data show:

- Strengthening and growth of traditional medicine in the Western Pacific Region
- Expanded and increased use and recognition of traditional medicine in the Region, especially for quality and safety
- More Member States and areas are including traditional medicine into national health care services

However, more support is needed and many challenges regarding traditional medicine remain. There is a need for higher levels of government commitment and support for traditional medicine, more concern for the evidence-based quality, safety, and efficacy of traditional medicine, more information sharing on all aspects of traditional medicine across the Region, and an appropriate evaluation of the economic value of people-centered traditional medicine.

**Continuity and Change**

The *Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020* presents a balance between continuity and change, tradition and innovation. It provides for a continuation of the directions and actions detailed in the *Regional Strategy for Traditional Medicine in the Western Pacific 2001-2010* that remain relevant to the needs of Member States and WHO. The *Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020* also identifies and addresses new and emerging opportunities, challenges and directions that have appeared in the global and regionally since the development of the first Regional Strategy for Traditional Medicine in the Western Pacific.

**Regional Challenges for Traditional Medicine**

The regional significance of traditional medicine to Member States has been demonstrated in an assessment and survey of the situation of Traditional Medicine in Member States. These evaluation tools have identified a number of important facets of the use of traditional medicine where government can derive benefit from further development of traditional medicine as an inclusive component of their overall national health plans, particularly in preventive and primary health care.

Because the forms of traditional medicine practiced in the Western Pacific region vary widely, it is not possible to have a single approach, one model, or one set of standards to deal with the different systems of traditional medicine in the Region. However, there is considerable potential within a traditional medicine modality to set standards for quality, safety and efficacy that would be widely acceptable within the region and globally.

Quality, safe and efficacious traditional medicine products and practices, delivered by appropriately trained practitioners, should be recognized as full contributors to health care in order to provide optimal access to health care. However, government policies, regulations and funding initiatives in the past, have often favoured the promotion of Western medicine, even when the value of traditional medicine is recognized in the culture and the health system. The challenges, indicated below, are impediments to traditional medicine reaching its full potential in national health care. The challenges lead directly to the Strategic Objectives and the Strategic Actions and form the foundation of the *Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020* for Member States.

- Traditional medicine has a low priority in the national health care which results in a weak national commitment to develop policy and regulations to systematically review and monitor all aspects of traditional medicine products and practices.
- Different practices, terminology, philosophical outlooks, and products used in western and traditional medicine, and a limited interest in the standardization of products and practices, may limit the full engagement of, and communication between, all stakeholders. As a result, it may be difficult to advance the research strategies and technologies to provide an evidence base for traditional medicine, and may also limit a harmonious relationship and respectful co-existence between traditional and western medicine.
- Incomplete access to indigenous knowledge and limited evidence and enforcement of standards regarding the quality, safety, effectiveness of traditional medicine products and practices, hinders acceptance by governments, Western medicine practitioners and consumers.
- Different standards and regulations for traditional medicine across the region limit harmonization.
- Controversies regarding the inclusion of traditional medicine in universal health coverage.
Natural health care resources, including the knowledge of traditional practitioners, may not be assessed, monitored and conserved. As a result, they are open to exploitation, which may lead to loss of biodiversity, extinction of endangered species, destruction of natural habitats and resources, or the loss of intellectual property rights for indigenous groups or countries.

Information on traditional medicine practices is scattered, and may only be available in its original language, making access difficult.

Results from traditional medicine research and potential and real conflicts of interest are not always disclosed.

Absence of national organizations representing traditional medicine educators, practitioners and producers, limits reliable channels of communication between stakeholders and the government to enhance consumer public awareness of the safety, effectiveness and proper use of traditional medicine products and practices.

THE REGIONAL STRATEGY FOR TRADITIONAL MEDICINE IN THE WESTERN PACIFIC 2011-2020

It is apparent that since the Regional Strategy for Traditional Medicine in the Western Pacific 2001-2010 there has been significant progress in implementing its Strategic Objectives in the Western Pacific Region. However, progress has not been uniform in all Member States, and the challenges for some countries are greater than others. Some Member States have yet to take the step of recognizing traditional medicine in national health policies, while others have integrated traditional medicine into their health system with traditional medicine as an important partner in the provision of primary health care. Other Member States have advanced to varying degrees between these two extremes.

The WHO Western Pacific Regional Office and the Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020 recognizes that the needs and progress of individual Member States will depend on national needs, capacity, priorities, existing health policies, strategies, legislation, resources, culture and history. The complex nature and the interdependence of many of the tasks, and the resources necessary to accomplish the Strategic Objectives have been taken into account in framing the directions and actions of the Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020. The 10 year timeframe provides a more practical period for Member States to plan and resource their activities. It identifies challenges for the more advanced countries, while recognizing the challenges remaining ahead for the less advanced Member States.

It is recommended that, where appropriate, Member States should use the Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020 as a framework for the development of national traditional medicine programmes. Member States without a national health policy recognizing traditional medicine are strongly urged to formulate such a policy. Careful assessment should be made of the use and practice of traditional medicine in the country, and of the most appropriate means of using traditional medicine to help meet its health care goals.

To monitor progress, the WHO Western Pacific Regional Office will undertake a midterm review of the implementation of the Strategic Objectives and present progress of the Member States to a high-level meeting in 2015.

The Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020 builds on the Regional Strategy for Traditional Medicine in the Western Pacific 2001-2010 and identifies strategic objectives and actions that provide general principles and guidance for Member States and areas to use in responding to the challenges which they may face in considering of the unique situation applicable in each country or area. Countries will need to determine to what extent traditional medicine has been recognized and integrated into their national health system in order to formulate individual country or local strategic goals, action plans and time frames.

WHO will actively advocate and promote the Strategic Objectives of the Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020 in Member States and among development partners and other stakeholders at the regional and country level, in planning and coordinating actions for country support.

While the Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020 is an important guide for Member States, WHO, development partners and other stakeholders, it is the actions that lead from the Strategic Objectives that are more important. Ultimately, it is the health outcomes that follow from that action that really
matter. All actions that are proposed should be considered in the context of their ultimate impact, or potential to impact, on health care in the country.

STRATEGIC OBJECTIVES

In developing the Strategic Objectives for Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020, consideration was given to the resolutions of the World Health Assembly WHA 61.2110 and WHA 62.1311; the strategic objectives of the WHO Traditional Medicine Strategy 2002-2005 and the Regional Strategy for Traditional Medicine in the Western Pacific 2001-2010; and the provisions of the Beijing Declaration of 2008. Since the last document was approved, major developments facilitating access to local, national, regional, and global information systems have occurred. In addition, given the demands on limited financial and human resources, the need to utilize them optimally has become even more important. As a result, increased emphasis is given to:

- universal coverage
- the importance of cooperation and the sharing of information to support the quality, safety and efficacy of traditional medicine practices and products
- the protection and conservation of indigenous health resources, including traditional knowledge and bio-resources.

The five key Strategic Objectives for traditional medicine in the Western Pacific for the period 2011-2020 are:

1. To include traditional medicine in the national health system
2. To promote safe and effective traditional medicine
3. To increase access to safe and effective traditional medicine
4. To promote protection and sustainable use of traditional medicine resources
5. To strengthen cooperation in generating and sharing traditional medicine knowledge and skills.

It is understood that, where and as appropriate, considerations with respect to the implementation of the Strategic Objectives for 2011-2020 will occur based on national capacities, locally established priorities, relevant legislation, and on the evidence of quality, safety and efficacy.

OBJECTIVE 1

To include traditional medicine in the national health system

Formulate national policies which includes traditional medicine as part of national health care system

Traditional medicine is a major part of health care provision in many Member States within the region. The nature of the connections between the traditional and Western health care varies considerably across the region, with varying degrees of harmonization. There are potential benefits to free and open communication between practitioners of traditional medicine and Western medicine. Traditional medicine, as a part of a health system, has to function effectively alongside other demands on the system to fulfil its potential in health care.

A national policy is a statement of the Government. It should clearly indicate the view of Government on the role of traditional medicine in promoting and maintaining health and promulgate the Government’s position on its development, appropriate use and its relationship to its primary health care policy. The policy should define the role of traditional medicine in the national health care delivery systems, and provide a basis for promoting the

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* The World Health Assembly is the supreme decision-making body for WHO. It generally meets in Geneva in May each year, and is attended by delegations from all 193 Member States. Its main function is to determine the policies of WHO

** The Beijing Declaration was made by participants at the first WHO Congress on Traditional Medicine, Beijing, People's Republic of China, held 7-9 November 2008. Over 1100 participants from over 70 countries attended the Congress, as well as representatives from WHO Collaborating Centres for Traditional Medicine
Annex 1

rational use of traditional medicine as an affordable and cost-effective form of health care by ensuring there are supporting provisions for the quality, safety and efficacy of traditional medicine practice and products. The national policy on traditional medicine may stand alone, or be a part of a national health or medicine policy.

Directions

- Government commitment to recognise and integrate traditional medicine into their health system, in accordance with national capacities, priorities, relevant legislation and circumstances.
- Develop an explicit policy on the promotion of evidence-based traditional medicine with support from consumers, traditional medicine practitioners, academic institutions and industries.

Strategic Actions

- Formulate a comprehensive government policy on traditional medicine as a part of the national plan for health care.
- Produce a plan for implementation of the policy and assign financial resources for the implementation of the plan.
- Conduct a systematic review, regularly monitor outcomes and determine the resource needs for traditional medicine in the country.
- Establish, or strengthen, a lead government agency to take responsibility for implementing traditional medicine policy.
- As appropriate, promote harmonization of different national polices on traditional medicine (see also Objective 5).

OBJECTIVE 2

To promote safe and effective traditional medicine

It is important to create conditions where traditional medicine can be used safely and effectively. There are many partners who can help achieve this, including all levels of government, professional associations, industry, consumers and the media. There are four key contributing components to achieving this objective:

- To strengthen the evidence base of traditional medicine in terms of quality, safety and efficacy
- To have in place and enforce regulations and standards for traditional medicine products
- To establish systems for the qualification, accreditation or licensing of traditional medicine practitioners, and other providers, as appropriate
- To ensure that consumers are appropriately informed about the various traditional medicine modalities, their safety and their efficacy in order to optimize health outcomes.

To strengthen the evidence base of traditional medicine

In November 2008, WHO organized the first WHO Congress on Traditional Medicine in Beijing, China. The "Beijing Declaration" was adopted, promoting the safe and effective use of traditional medicine. It states, *inter alia*, that research and innovation on traditional medicine should be further developed in line with the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) (see Annex 1. WHO and Traditional Medicine).

Safe and effective use in this context refers to appropriate or rational use of a therapy. It sometimes also referred to as "quality use" or "rational use"
There is a need to develop and implement effective policies that will support health innovation in traditional medicine within an evidence-based framework. This includes clinical research in traditional medicine, the development of national inventories of medicinal plants for the preservation and protection of traditional medical knowledge. This will involve the setting of research priorities in traditional medicine in accordance with other national research priorities (see GSPOA, in Annex 1. WHO and Traditional Medicine).

The level of research, and therefore the regulatory aspects associated with the practice of traditional medicine, will depend on the extant knowledge, and the facilities, expertise, and financial resources available within countries. It is anticipated that through selective investment, the level of research associated with traditional medicine will continue to rise throughout the Region, including in those countries, which, at this time, are generally resource deficient. For more advanced countries in the Region, basic and applied scientific research on traditional medicine needs to be accompanied by clinical, social, political and economic research. These efforts will contribute directly to the development and the establishment of regulations and standards which will evolve in sophistication over time. In addition they will contribute to the enhancement of quality, safety and efficacy of traditional medicine, and thereby, improved health care.

Evidence-based research on traditional medicines should not rely entirely on any assumption of safety and efficacy. Many traditional medicines are derived from biological systems which typically show a high degree of chemical composition variability; this phenomenon leads to biological variability and thus uncertain therapeutic outcomes. As a result, not all preparations of the same traditional medicine are equally effective. Each of these factors, quality, safety and efficacy, individually and collectively, contribute to the establishment of an appropriate clinical outcome, and should be determined through the application of contemporary science and technology. In this way, evidence-based, regulatory standards can be promulgated. The consumer uses a traditional medicine to provide a health benefit, and as a human right has the expectation that it will be of high quality, safe and effective.

One of the effects of globalization is the migration of traditional medicine (or selected aspects of the traditional therapy) from its original social and cultural contexts to those that may be geographically and culturally removed. The translocation to a different environment may lead to modifications in response to local conditions that may impact on quality, safety and efficacy. The international scientific community is obliged to evaluate the safety and efficacy of these treatments because of their potential impact on public health.

To investigate traditional medicine with integrity, there is much to be gained from collaboration between researchers practising within the traditional social and cultural environments, and those practising within the ‘adoptive’ context.

In deciding what studies are necessary to substantiate safety and efficacy, each country will need to determine the minimum acceptable standard to meet their needs. This includes the role and standard of evidence from a therapy’s traditional (historical) use as well as the type of scientific evidence required. The type and rigour of the evidence (historical/scientific) required, may depend on the intended use of the therapy – whether intended for the management of a serious form of a disease, condition or disorder or for a minor, self-limiting condition.

The scientific evidence that underpin decisions on the acceptability of different therapies will vary. It is reasonable to expect that the evidence regarding the safety and efficacy of most medicinal products will be in the form of intervention studies. These studies include both randomised controlled clinical trials and controlled clinical trials. Randomised, double-blind, parallel group, placebo-controlled trials offer the greatest scientific rigour of assessing a relationship between a medicinal product and an outcome and are regarded as the ‘gold standard’ for assessing the effectiveness of an intervention or treatment. However, trials of this type may not always be possible, practical, or ethical. There are many systems available to rank scientific information. For example, see Table 1, which illustrates a hierarchy of scientific evidence, with the strongest evidence at the top. It should be noted that the relative strength of evidence will depend on its purpose. That is, whether the study is designed for intervention (treatment or prevention), diagnosis, aetiology or determining adverse effects.

Traditional therapies have an extensive history of use, sometimes measured over thousands of years. This history provides an accumulated repository of human observation that supports the current use of these therapies. For example, traditional medicines that have been prescribed over a long period of time usually result in preparations where the dosage and formulation have empirically evolved to maximise their therapeutic effectiveness and minimise risk. For most traditional medicines there is little or no contemporary scientific evidence to support their traditional role.
Table 1. Designation of levels of scientific evidence

<table>
<thead>
<tr>
<th>Type of Study</th>
<th>Level of Evidence</th>
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<tbody>
<tr>
<td>A systematic review of randomized studies</td>
<td>HIGH</td>
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<tr>
<td>A randomized controlled trial</td>
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<tr>
<td>Comparative study with concurrent controls:</td>
<td></td>
</tr>
<tr>
<td>• Non-randomized</td>
<td></td>
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<tr>
<td>• Cohort</td>
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<tr>
<td>• Case control</td>
<td></td>
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<tr>
<td>• Times series with control group</td>
<td></td>
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<tr>
<td>Comparative study without concurrent controls:</td>
<td></td>
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<tr>
<td>• Historical control</td>
<td></td>
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<tr>
<td>• Single arm study</td>
<td></td>
</tr>
<tr>
<td>• Time series without control group</td>
<td></td>
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<tr>
<td>Case series</td>
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<tr>
<td>Case-control</td>
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In using history of use to determine the quality, safety and efficacy of a traditional medicine product, it is important to establish that the product being evaluated is identical to the traditional form on which the assessment is being made, and that the method of preparation, dosage, dosage form and route and schedule of administration are consistent with the traditional product and its use. In assessing safety and efficacy, adverse effects that develop over time, occur infrequently, or are readily ascribed to an underlying disease are difficult to identify from historical data. A further consideration is that, in a modern context, traditional medicine is now often used concomitantly with Western medicine, and that there is a potential for new interactions to occur which may affect the safety and efficacy of either therapy.

Many traditional forms of medicine use medicinal products in a holistic context involving lifestyle changes, such as diet and behaviour. In those cases, holistic principles are usually part of the therapy and need to be considered in designing scientific studies to substantiate traditional evidence, for example, see Box 1.

(side box)Box 1

In traditional Indian medicine, the prakriti (in Ayurveda) or mijaj (in Unani medicine) determines the effectiveness of a particular herbal medicine. Prakriti could be described as the temperament or the psychomotor character of the individual – a person could have one of three prakriti and the treatment varies according to the prakriti. In designing scientific studies, the prakriti would need to be assessed and used as an inclusion/exclusion criterion in clinical studies. Similarly, in traditional medicine the choice of therapy may vary with concomitant symptoms. For example, an asthmatic patient with GI symptoms will respond to one medicine and a patient without GI disturbance will respond to another.

Directions

- Promotion and sponsorship of national programmes on evidence-based traditional medicine practices and products.
- Develop regulations, standards, and guidelines for traditional medicine products and practices based on research findings.

Strategic Actions

- Build and strengthen national research capacity and programmes on traditional medicine,
- Promote research on traditional medicine with a view to establishing national regulations and standards for quality, safety and efficacy.
• Progress towards the implementation of Good Agricultural and Collection Practices (GACP), Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), and Good Clinical Practices (GCP).

• Provide training opportunities on research methodology and develop technical guidelines and establish criteria for evaluating quality, safety, and efficacy.

• Establish prioritized, country-specific development programs involving government, academic institutions and the private sector to enhance research on quality, safety and efficacy.

The Safe and Effective Use of Traditional Medicine products

Health care programmes compete with other policy areas for critical financial and other resources, including the development of regulations and standards. In addition, there is a general reluctance on the part of governments to finance research on, and the development of health programmes for which the health and economic benefits are uncertain. This has important implications for traditional medicine because there may be limited scientific studies and economic data with which to justify the inclusion of selected traditional medicine products into mainstream health services. Evidence-based assessment and registration of quality controlled products within a country will enhance the status of traditional medicine and increase Western medicine practitioner and consumer confidence regarding their safety and efficacy.

Regulations and guidelines to help support the quality, safety and efficacy of traditional medicine products should cover all aspects of production (growing, collection and storage), manufacture (practitioner certification, Good Manufacturing Practice (GMP), as appropriate), pre-market assessment of quality, safety and efficacy, product registration and post-market activities, including monitoring of adverse reactions; laboratory testing; surveillance in the market place; an effective and timely recalls procedure; audit of GMP; and effective controls for advertising products.

Directions

• Improve the quality, safety and efficacy of traditional medicine products as a public health priority, and consideration for inclusion in national essential medicines lists.

• Implement Regulatory Impact Assessment prior to decision-making on product regulation.

Strategic Actions

• Develop criteria and indicators related to the cost-effectiveness of traditional medicine products using appropriate tools, and relevant to the country.

• Conduct regulatory impact assessments for changes to the regulation of traditional medicine products.

• Evaluate available historical and scientific information with respect to quality, safety and efficacy which might support the inclusion of traditional medicine, or aspects thereof, in health care, insurance programs, and in essential medicine lists.

• Implement and enforce regulatory standards for contamination and adulteration.

The Safe and Effective Use of Traditional Medicine by Providers

Providers of traditional medicine can include traditional medicine practitioners (including traditional birth attendants), Western medicine practitioners, as well as health care workers such as dentists, nurses, midwives, pharmacists and physical therapists who provide traditional medicine services to their patients. The integration of traditional medicine with Western medicine, particularly in the context of Primary Health Care, emphasizes the importance of respectful co–existence.

The quality, safety and efficacy of traditional medicine also relates to the establishment of appropriate standards for aspects of practice and for the education and training of practitioners. Implementation of professional standards, when supported through regulation, enhances the learning base of practitioners, evokes confidence from patients and consumers in the provider, enhances the stature of practitioners, and ultimately leads to improved health care outcomes. In 2005, the Western Pacific Region developed *WHO Guidelines for Quality*
Assurance of Traditional Medicine Education in the Western Pacific Region (see Appendix 2. WHO Traditional Medicine Publications for details) to assist Member States in this area.

Regulatory options range from national professional organizations imposing standards on their members, to the recognition of these standards, either directly or indirectly, by the government, including statutory support for accreditation, certification programs, licensing bodies which impose standards, or the formal government registration of practitioners. However, in countries where traditional medicine practitioners are not trained in formal education systems, licensing may not be practical. In such countries, national surveys of practitioners could be an initial step towards more structured regulation.

It is important that both traditional medicine providers and Western medicine professionals have a sufficient knowledge of traditional medicine to allow them to assess its advantages and limitations, and to have confidence in the quality, safety and effectiveness of traditional medicine products. The advantages and limitations of traditional medicine practice should be determined through the application of methodologically sound research by applying the principles of evidence-based medicine to traditional medicine research and practice. Research should also aim to establish the value of traditional medicine in the management of disease, and also in promoting health and wellness through the application of various modalities. It is recognized that the inclusion of traditional medicine may provide alternative effective therapies for some, but not all, disease states subject to treatment with Western medicine.

Challenges in this area are at least twofold: firstly, ensuring that the knowledge, skills and competency of traditional medicine providers are adequate and secondly, using training to ensure that traditional medicine providers and Western medicine practitioners understand and appreciate the complementarities of the types of health care they offer. The first involves establishing, where possible, examination and licensing systems for traditional medicine, and legislation — so that only those who are qualified can practice traditional medicine or provide traditional medicine products. The second requires modifying training programmes for traditional medicine providers to include basic elements of primary health care and public health, and ensuring that pharmacy, medical and public health degrees include a component on traditional medicine.

Proper use of products of assured quality can also do much to reduce the risks associated with traditional medicine products, such as herbal medicines. Many are sold as over-the-counter medicines with little advice offered on their appropriate use. Consumers may then be unaware of potential side-effects, and how and when herbal medicines can be taken safely. Reversing this situation will necessitate much more stringent control of traditional medicine products, and greater efforts to educate the public in this area.

Information, education and communication strategies could overcome some of these problems, and raise awareness of the potential benefits of traditional medicine.

To provide assurance in the safety-in-use of traditional medicine to consumers and health care practitioners, the regulatory system must support and promote a system for monitoring adverse events. WHO has issued a set of guidelines on the safety monitoring of herbal medicines in pharmacovigilance systems. (See Box 2.)

A critical element in reporting adverse events is good communication between patients and their health professional and between the health professional and the body responsible for receiving the reports.

* An adverse event is defined as "any untoward medical that may present during treatment with medicine, but which does not necessary have a casual relationship with this treatment". An Adverse Drug reaction, in contrast to an event, is characterised by the fact that a casual relationship between the drug and he occurrence is suspected. In some countries, for reporting purposes, if an event is reported, even though the relationship is unknown or unstated, it meets the definition of an Adverse Drug Reaction.
In the management of adverse events, WHO has recommended that countries focus on four areas in the management of adverse events associated with traditional medicines:

- Clear identification of the nature of the adverse events.
- Management of risks.
- Institution of measures to prevent adverse events.
- Good communication of the risks and benefits of herbal medicines.

**Direction**

- Establish systems for the qualification, accreditation or licensing of traditional medicine practitioners.

**Strategic Actions**

- Define the scope of practice and training for the diverse disciplines of traditional medicine, and the relationship of traditional medicine practitioners to other health professionals.
- Foster cohesiveness among traditional medicine practitioners and empower them to organize into associations or groups.
- Establish formal channels of communication between government and traditional medicine practitioner professional associations or groups for the education, including continuing education, and accreditation, licensing and registration.
- Establish appropriate training programmes in traditional medicine for Western health professionals and relevant researchers.
- Establish a responsive system for the reporting, monitoring and responding to adverse reactions.

**The Safe and Effective Use of Traditional Medicine by Consumers**

The type of information needed to support safe and effective use is likely to vary depending on the individual context and utilization pattern in a country or region. It is important to note that people who are using traditional medicine may also be using Western medicine. In addition, as the proportion of older people increases, there will be greater pressure on health services, including the demand for traditional medicine products and practices. Creating an environment that supports the safe and effective use by consumers is particularly challenging and requires information and education at the local level.

Governments need to work with health professionals, including traditional medicine providers and other partners, to take a more active role in ensuring that consumers have access to reliable information, and importantly, the skills to interpret information and make informed decisions about their health choices. Consumers need to be aware of the risks and benefits of traditional medicine (and other) therapies, the possibility of non-medical options and the importance of a healthy lifestyle.

**Directions**

- Increase the capacity of consumers to make informed decisions about traditional medicine practices and products.

**Strategic Actions**

- Strengthen cooperation and communication between traditional medicine and Western medicine practitioners and their patients concerning their use of traditional medicine. (see also Strategic Objective 5)
- Facilitate access to safe and effective traditional medicine through informed consumer choice by developing appropriate information and education tools.
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- Create consumer awareness about the potential risks of traditional medicine products and practices that
  are obtained outside of national regulatory controls, such as web-base purchase or imported for personal
  use, where the quality, safety and efficacy may be unknown.

OBJECTIVE 3

To increase access to safe and effective traditional medicine

People deserve to live out their lives in the highest state of health possible. While there can be no guarantee of
individual health, all people have a right to quality health services, including traditional medicine, that are
available, accessible, affordable, and acceptable. Traditional medicine can potentially provide an affordable and
cost-effective form of health care, including the poor and populations in remote areas17.

The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) is
designed to promote innovation, build capacity, improve access and mobilize resources (see Annex 1. WHO and
Traditional Medicine for guidance on implementing these aspects of development).

The utilization of safe, effective and high quality traditional medicine therapies can make an important
contribution to national and individual health care, and the promotion of health equity. It is recognized that
people in some of the poorest countries, and those living in remote regions, may have access to traditional
medicine. Without an evidence base on which to make decisions, it is not known if such therapy is the most
appropriate form of health intervention available, or if it is effective in its intended purpose. The cost of
inappropriate or ineffective services is a drain on limited and precious resources.

The extent to which traditional medicine is included under universal health coverage will be a decision of each
Member State. In making decisions about the cost-effectiveness and access to traditional medicine, governments
will need to consider matters such as the:

- evidence base for the safe and effective use* of traditional therapy (see also Objectives 2 and 5).
- use of specific therapy generally, or limiting its use, for example, for prevention and wellness;
  to support the health of vulnerable groups such as children or the elderly; or to manage specific
  health conditions, disorders or diseases
- cost-effectiveness, availability and sustainability of supply (see Objective 4)
- capability and capacity of the health system to support the delivery of traditional medicine to the
target population.

Directions

- Develop an evidence base to allow decisions for selecting the most cost-effective therapy for a particular
  health intervention.
- Strengthen the health system to facilitate delivery of traditional medicine as appropriate to the target
  population.

Strategic Actions

- Examine and enhance the health system as necessary, to provide traditional medicine services.
- Develop the evidence base (as described in Objectives 2 and 5)
- Examine the options for inclusion of selected traditional medicine modalities under universal health
  coverage

* This includes ensuring that the therapy is the most appropriate for its intended use, and is the minimum
  intervention necessary to achieve the desired outcome. This does not preclude the combined use of traditional and
  Western therapies.
OBJECTIVE 4

To promote protection and sustainable use of traditional medicine resources

To help assure sustainable access to traditional medicine, measures to protect, preserve and to improve, if necessary, traditional medical knowledge and natural resources for sustainable development of traditional medicine are needed. Depending on the circumstances in each country; such measures might include, where appropriate, the intellectual property rights of traditional medicine practitioners over traditional medicine formulas and texts, as provided for under national legislation consistent with international obligations18.

An awareness of the need to maintain Earth’s resources has grown in recent years. The term “sustainability” was introduced as a concept to recognize and emphasize that, as a global society; there is a critical need to reconsider on a continuous basis whether our individual and collective actions result in the permanent depletion of the resources of the planet.

Each country has been encouraged to develop regulations and procedures to control access to genetic resources and many countries now have such policies and regulations in place. These regulations vary significantly across the Region and there would advantages from examining the potential for harmonization of regulations and procedures to access biodiversity.

The safety and efficacy of herbal medicines is closely correlated with the quality of the source materials used in their production. There are also concerns related to local, regional and global over-harvesting, and the protection of threatened or endangered species. Monitoring of medicinal plant availability, accessibility and usage in the country is therefore important.

Directions

- Undertake baseline national assessments of existing indigenous natural health resources and the monitoring of their exploitation.
- Develop, monitor and enforce policies and regulations for the protection and conservation of the environment and for indigenous health resources and intellectual property rights.
- Offer programmes to educate and empower the community on the protection and conservation of their indigenous health resources.

Strategic Actions

- Enforce intellectual property rights and ensure that appropriate agencies are established and fully informed on issues related to the protection, conservation and promotion of innovation of traditional medicine.
- Develop collaborative, inventory, conservation and cultivation programmes, at the national and local levels, for important natural health resources, especially those included in national essential medicines lists, to assure long term availability and accessibility.
- Educate and empower indigenous people and communities on their rights and the use of, and access to, their natural health resources.
- Examine the potential for harmonization of regulations and procedures to access indigenous knowledge and biodiversity.

OBJECTIVE 5

To strengthen cooperation in generating and sharing traditional medicine knowledge and skills

Globalization of health practices, technology and other health products has had an impact on traditional medicine, including its availability, accessibility and affordability. In addition, there have been major advances in traditional medicine including setting, implementing and monitoring standards for practice and products, the requirement for evidence to support quality, safety and efficacy and approaches to intellectual property protection for traditional medicine. To cooperate in sharing knowledge and practices of traditional medicine and also in exchanging training programmes on traditional medicine, consistent with national legislation and relevant international
obligations is essential. No single government, industry group, research institute, hospital or university can justify the resources for, or access to, the range and depth of expertise required to meet the total future needs for traditional medicine research and development without cooperation or collaboration to share expertise, equipment, or build capacity and capability.

For traditional medicine to attain an appropriate place in health care in the Region, effective communication about traditional medicine within stakeholder groups, and productive cooperation within and between nations having common interests in traditional medicine, are essential. In this regard, given the global ease of on-line access to information, including some on traditional medicine, communication also embraces the availability of information resources. In addition, for traditional medicine to evolve as an integral aspect of systems in which Western medicine is a dominant practice, greater communication and respect is needed between the respective systems.

There are three key contributing components to achieving Objective 5:

- to enhance cooperation and communication within and between member states, at all levels of policy, regulation, practice and research related to traditional medicine
- to strengthen communication between Western and traditional medicine providers and with their patients
- to facilitate international standardization

To enhance cooperation and communication within and between member states, at all levels of policy, regulation, practice and research related to traditional medicine

The diverse practices of traditional medicine associated with the numerous cultures in the Region, evolved, and were developed, over extended periods of time. They are based on extensive empirical observations, and are a result of human experience in maintaining health and curing illness, in part, through various philosophies and spiritual practices and the use of natural resources. As an integral part of developing the experimental techniques and technologies for establishing an evidence base for some aspects of traditional medicine in its diversity, it is important to maintain those essential philosophical and spiritual components.

The outcomes of most international scientific research (basic, applied, clinical and economic) in traditional medicine are communicated in English, and most websites are developed in English also. Consequently, the construction of websites, or the writing of papers, solely in a native language limits access and may diminish the value of the research, or the information being presented to the larger global community.

Many practices of traditional medicine and many herbal medicines are used in several countries in the region as a part of their health care. Research on various aspects of the quality, safety and effectiveness of that plant may have been conducted in the country, in the Region, or elsewhere. The inherited information on traditional medicine practices and herbal medicines from various countries is an important cultural resource to be treasured. However, at the present time, all of this information is highly scattered, in the Region, and globally. If compiled and accessible at the national or regional level, it would serve as an important, indeed invaluable, global health care resource for Government regulators, researchers, industry, and consumers/patients. At a time when medicinally significant genetic resources are disappearing, information regarding their potential location gained from national herbaria could be extremely important in assuring long-term availability and access to a traditional medicine.

Enhancing cooperation, including the establishment and maintenance of databases between the nations would also facilitate conditions conducive to the rational use of traditional medicine, thus enabling and encouraging individuals, families, and communities to make appropriate health choices in establishing comprehensive treatment plans throughout their lifespan. Databases on existing international and regional regulatory regimes and the technical infrastructure in Member States will also facilitate identification of areas for possible harmonization to promote and facilitate trade and promote the growth of traditional medicine.

Directions

- Enhance international cooperation to facilitate harmonization of traditional medicine policies, regulations and standards.
• Develop and maintain databases and information systems and facilitate access as the foundation for evidence-based traditional medicine research.

**Strategic Actions**

• Prioritize policies, regulations and standards for harmonization of traditional medicine in the Region.

• WHO to support regional meetings of researchers, policy makers and regulators to exchange ideas and experiences regarding the use of traditional medicine in health care.

• Encourage interdisciplinary and regional collaboration for training in research methods and contemporary technologies in traditional medicine research.

• Create national and regional centres of excellence as resources for training, research, and information.

• Governments should respect and preserve indigenous healing practices and facilitate the sharing of this resource.

• Increase the use of English for international communication in traditional medicine

**To strengthen communication between Western and traditional medicine providers and with their patients**

There is increased public awareness of, and improved access to, various modalities of traditional medicine in all countries in the Western Pacific Region. Such awareness depends, in part, on the government’s attitude towards traditional medicine, particularly if traditional medicine is included as an integral part of health services. From a patient perspective, health benefits may be enhanced by good communication between Western medicine and traditional medicine practitioners, and by an open relationship of the patient with the respective health care provider. The harmonization of traditional and Western medicine will help ensure their proper and effective use in health care.

Improved electronic data transmission and global communications have fostered consumer understanding of traditional medicine. Community-based information exchange systems in low and middle-income countries also provide a mechanism for improving public understanding of traditional medicine.

**Direction**

• Promote people-centred health care for better health outcomes through improved communication between health providers and their patients.

**Strategic Actions**

• Promote mutual understanding and respect and facilitate referral between practitioners of traditional and Western medicine.

• Provide access to Western medical technology for appropriately trained traditional medicine practitioners.

• Provide formal education to Western medicine practitioners and other health providers to increase awareness and respect for the health-related cultural backgrounds, beliefs and benefits of traditional medicine.

• Develop programs to enhance public awareness of traditional medicine.

**To facilitate international standardization**

Many of the internationally acceptable standards for traditional medicine, including manufacture, registration of products, practices and practitioners, and post-market provisions, currently lack relevance to the priorities and needs of many countries in the Region. However, as the infrastructure to support a role for traditional medicine in
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the Region develops and strengthens, such standards will become increasingly relevant and will provide models to facilitate international harmonization and mutual recognition.

In the Western Pacific Region, traditional medicine is used to provide health care to a significant proportion of the population. To avoid duplication of effort and to use limited resources more effectively, it is important to create and promote evidence-based harmonization of traditional medicine standards in the Region. This will facilitate better understanding and respect for the different forms of traditional medicine in the Region as well as support its safe and effective use.

Several countries have already created their own national standards for the classification of traditional medicine. Historically, however, there has been no platform on which to harmonize the collection of data on the clinical, epidemiological and other aspects of traditional medicine utilization. For this reason, there is a lack of knowledge and information exchange regarding the utilization of traditional medicine globally. There is a need for this information, especially in the fields of primary health care and patient safety to allow clinicians, regulators, researchers and policy makers to comprehensively monitor utilization, spending and trends in traditional medicine care as in other forms of health care. Standardization of data collection will facilitate the inclusion of traditional medicine in evolving healthcare applications, including computerized health information systems, reimbursement policies, treatment, health care funding allocation and public health programmes.

Direction

- Continue to develop traditional medicine infrastructure to support strengthening of standards and facilitate harmonization within the Region and globally.

Strategic Actions

- Develop harmonized standards for the collection and interpretation of traditional medicine data across the Region.
- Support for the development and update of international standards for classification and terminology, in collaboration with interested stakeholders, nationally and internationally.

THE WAY FORWARD

Priorities for moving forward

The Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020 has been developed to provide a general framework or model for the strategic development of national traditional medicine programmes.

A country-specific strategic plan should be developed in the context of the nation’s health system and its aspirations, priorities, capabilities and capacities to initiate, maintain or further develop traditional medicine programs. This will generally require a systematic review of the current role and status of traditional medicine in the country, and will include an assessment of the scope of traditional medicine (the different forms of traditional medicine), its utilization in public and private health care (including socioeconomic status and rural and urban accessibility), the size of the workforce, standards for practitioner education, manufacturing standards, the scope of natural medicinal resources, their management and economic potential, etc). This assessment will better define the strategic objectives, directions and actions to meet national needs. The development of a country-specific strategy is very important, as it may involve choosing between several approaches to address the issues that have been identified.

Moving from strategy to action

The critical first step in realizing a formal role for traditional medicine in the health system of a Member State is to gain the appropriate political, social and financial support for the government to formulate a policy that recognizes traditional medicine in the nation’s health care. This task should be assigned to a lead agency that will take responsibility for coordinating input from stakeholders and provide secretariat support for a Steering Committee established to advise the Government on traditional medicine. The Steering Committee will be responsible for agenda setting and advocacy; policy formulation; planning and costing policy implementation; consultation (government, public and private stakeholders) and the monitoring and review of action plans and implementation. Any actions to be taken must be evaluated for their potential effects on the functioning of the entire health system and for their effect on health outcomes. The Steering Committee should be supported by
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subcommittees to advise on specific or specialised aspects, as required. Where necessary, expert opinion can be obtained from international agencies and other countries.

The Member States that do not have a policy in place should consider the development of a national policy on traditional medicine as a priority. A national policy provides a plan of action for government and guides management and organizational decisions to achieve the goals and outcome(s) identified in the policy. It reflects the particular needs of the Member State in relation to traditional medicine. Member States will need to determine how the traditional and Western medical systems should respectfully and cooperatively exist - in parallel, complementary, or even as unified streams of health care. The policy may be a separate traditional medicine policy or part of a national health policy. Quality, safety and efficacy should be stated as the guiding principles of the policy. The policy should also include a vision and mission, as well as the goals and objectives of the policy. For Member States with an existing traditional medicine policy, the subsequent priorities should be in accordance with their needs and capability. The policy should be supported by laws and regulations that establish the legal conditions under which traditional medicine should be organized to be consistent with the national policy and also other relevant government policies, such as health, environment and manpower. For example, traditional medicine laws may cover matters on professional education standards, licensing of practitioners, manufacture and trade in products and services. Regulations, like laws, are developed through government legislative processes and provide the legal machinery to achieve the administrative and technical goals of a law. Many traditional medicine activities should be covered by regulations, such as a description of obligations and responsibilities of licensed practitioners, the penalties and sanctions if these are not respected, and the obligation of manufacturers of traditional medicine products.

Strategic tools and WHO support

WHO has an important role to play, in collaboration with stakeholders, in helping to strengthen development of regulatory infrastructure for traditional medicine with the ultimate aim of improving regulatory standards and the harmonization or convergence of standards within the Region.

The WHO Western Pacific Region will respond to requests related to enhancing policies, regulations and programmes in traditional medicine as generated from countries, based on a situation analysis with respect to the Strategic Objectives. The core documents to help identify needs are the national health plans of Member States, the strategic planning process of WHO, and other relevant planning processes, such as the United Nations Development Assistance Framework. WHO will place emphasis on assisting Member States with the implementation of adopted Regional Strategies, including the Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020.

WHO can play a leading role to support regional initiatives, tailored to the current capacities, capabilities and aspirations of Member States, which offer scope for improving and harmonizing standards over time, avoiding duplication, sharing information and facilities, and promoting appropriate mutual standardization. In particular, WHO can continue to develop source materials for reference or adaptation by Member States wishing to establish or strengthen their standards for traditional medicine. WHO has accomplished much in this area with, for example, the publication of monographs for herbal medicines, practitioner training standards, good agricultural and collection practices, good manufacturing practices, standard terminology in traditional medicine in the Western Pacific Region, development of consumer information for the use of traditional medicines, the safety and appropriate use of herbal medicines, public health and intellectual property (see Annex 2 for details of WHO publication relevant to traditional medicine).

WHO country offices must be involved in and responsive to, national planning processes. The ability of the WHO Western Pacific Regional Office to respond to requests for assistance will be subject to available resources.

WHO will provide support to Member States, as appropriate, in order to:

- Implement the Beijing Declaration on Traditional Medicine;
- Give due consideration to the specific actions related to traditional medicine in the implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and the WHO Global Strategy for Prevention and Control of Non-Communicable Diseases;
- Continue providing policy and technical guidance to countries on how to include traditional medicine into health systems, especially to promote, where appropriate, the use of traditional/indigenous medicine for primary health care, including disease prevention and health promotion, in line with evidence of quality, safety, and efficacy taking into account the traditions and customs of indigenous peoples and communities;
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- Strengthen cooperation with WHO Collaborating Centres, research institutions and non-governmental organizations in order to share evidence-based information and support training programmes for national capacity building in traditional medicine.
- To continue to develop source materials for reference or adaptation by Member States.
- To facilitate cooperation between Member States to share information and develop infrastructure.

Indicators

It is important for Member States and WHO to monitor and measure the progress of efforts, and their impact, towards the Strategic Objectives on a regular basis, in order to assess the improvement of the status of traditional medicine within the health system and the Region. Each Member State is encouraged to carefully select and define a set of indicators which is appropriate for the contemporary and projected status of traditional medicine in their health system. The chosen indicators should be objective and be capable of measuring progress in evaluating achievements towards the five objectives of the Regional Strategy for Traditional Medicine for the Western Pacific 2011-2020. The set of indicators presented below is intended for application in countries which have an adequate implementation infrastructure for traditional medicine and for those which currently have limited capacity in this regard. This set of indicators should be considered as a starting point for the development of a diverse set of indicators which are well-accepted, straightforward to measure and interpret. It is hoped that the selected indicators will provide useful guidance in decision-making, in identifying needs with respect to requests to WHO, and provide a basis for future planning for the continuing enhancement of traditional medicine within the context of the health system of the individual Member State. The validity, reliability and sensitivity of any selected indicators are therefore important considerations for inclusion in the overall analysis.

The WHO Western Pacific Regional Office will undertake a mid-term review of the implementation of the Strategic Objectives and the development of traditional medicine in the Member States at a high-level meeting in 2015.

The following Table provides examples of indicators to measure progress in meeting the Strategic Objective that might initially be considered by Member States.

**Table: Indicators to measure progress in implementing the Strategic Objectives**

<table>
<thead>
<tr>
<th>STRATEGIC OBJECTIVE</th>
<th>COUNTRY LEVEL INDICATORS</th>
<th>REGIONAL LEVEL INDICATORS</th>
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<tbody>
<tr>
<td>To include traditional medicine in the national health system</td>
<td>Existence and implementation of:</td>
<td>Number of countries</td>
</tr>
<tr>
<td></td>
<td>- a national policy on traditional medicine</td>
<td>- having a national policy on traditional medicine</td>
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<td></td>
<td>- national regulations on traditional medicine</td>
<td>- having national regulations on traditional medicine</td>
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<td></td>
<td>- a national plan for the development of traditional medicine</td>
<td>- having a national plan for the development of traditional medicine</td>
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<td></td>
<td>- a systematic review and monitoring system for outcomes of the national plan for traditional medicine</td>
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<td></td>
<td>Existence and support of a lead government agency/office for traditional medicine</td>
<td>Number of countries having a lead government agency/office for traditional medicine</td>
</tr>
<tr>
<td>To promote the safe and effective use of traditional medicine</td>
<td>Existence and implementation of:</td>
<td></td>
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<tr>
<td></td>
<td>- programmes to build and strengthen national research capacity in traditional medicine</td>
<td>- having programmes to build and strengthen national research capacity in traditional medicine</td>
</tr>
<tr>
<td></td>
<td>- GACP, GMP, GLP and GCP as standards for traditional medicine</td>
<td>- having GACP, GMP, GLP and GCP as standards for traditional medicine</td>
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<tr>
<td></td>
<td>- formal training programmes in research methodologies for traditional medicine</td>
<td>- having formal training programmes in research methodologies for traditional medicine</td>
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</table>

The selected indicators are intended as a starting point for the development of a diverse set of indicators which are well-accepted, straightforward to measure and interpret.
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<th>COUNTRY LEVEL INDICATORS</th>
<th>REGIONAL LEVEL INDICATORS</th>
</tr>
</thead>
<tbody>
<tr>
<td>To increase access to safe and effective traditional medicine</td>
<td>Collaborative programmes to enhance research on the quality, safety and efficacy of traditional medicine</td>
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<td></td>
<td>A national regulation and registration system for traditional medicine practices and products</td>
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<td></td>
<td>Indicators for the cost-effectiveness of traditional medicine products and practices in the health system</td>
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<td>Regulatory impact assessment protocols for proposed changes in regulations applied to traditional products and practices</td>
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<td></td>
<td>Review procedures for historical and scientific information for consideration of traditional medicine in insurance programs or on essential medicines lists</td>
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<td>Regulatory standards for contamination and adulteration of traditional medicine products</td>
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<td></td>
<td>Standards for the scope of practice, training, licensing and registration of traditional medicine providers</td>
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<td></td>
<td>Organizations of professional groups in traditional medicine</td>
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<td></td>
<td>Training programmes for Western health professionals in traditional medicine</td>
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<td></td>
<td>A responsive adverse reaction reporting system</td>
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<td>National medicinal plant monographs</td>
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<td></td>
<td>Programmes to strengthen cooperation and communication between Western and traditional medicine providers and their patients</td>
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<td></td>
<td>Programmes to enhance informed consumer choice with respect to traditional medicine</td>
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<td></td>
<td>Having a national regulation and registration system for traditional medicine practices and products</td>
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<td></td>
<td>Having regulatory standards for contamination and adulteration of traditional medicine products</td>
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<td>Having a responsive adverse reaction reporting system</td>
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<td></td>
<td>Having national medicinal plant monographs</td>
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<tr>
<td></td>
<td>Number of countries:</td>
<td></td>
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</table>
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<thead>
<tr>
<th>STRATEGIC OBJECTIVE</th>
<th>COUNTRY LEVEL INDICATORS</th>
<th>REGIONAL LEVEL INDICATORS</th>
</tr>
</thead>
</table>
| To promote protection and sustainable use of traditional medicine resources | - governance
- insurance coverage for traditional medicine products and practices with established safety and efficacy
- medical claims controls for advertising traditional medicine products and services | - having insurance coverage for traditional medicine products and practices
- having medical claims controls for advertising traditional medicine products and services |

Exists and support of:
- designated agencies to oversee conservation and promotion of innovation of traditional medicine
- assessment of existing traditional medicine resources
- conservation and cultivation programs for the sustainable development of priority traditional medicines
- a system for educating indigenous groups regarding their intellectual property rights
- efforts towards harmonization of regulations related to the CBD

Number of countries:
- conducting an assessment of existing traditional medicine resources
- having a system for educating indigenous groups regarding their intellectual property rights

### To strengthen cooperation in generating and sharing traditional medicine knowledge and skills.

Exists and implementation of programmes to promote:
- mutual respect and understanding between Western and traditional medicine practitioners
- access to modern technologies to trained traditional medicine providers
- the sharing of information and development of infrastructure for traditional medicine, including a national research institution or centres of excellence
- the development of standards for classification of terminology in traditional medicine

Participation at the Regional level in:
- procedures to cooperate for the harmonization of policies, regulations and standards for traditional medicine
- WHO programmes and meetings to enhance traditional medicine
- training and research programmes in traditional medicine
ANNEX 1. WHO Framework for Traditional Medicine

Overview

WHO recognizes that traditional medicine has an established, preventive, curative and rehabilitative role in health care. It can be the main form of health care or an integrated component of mainstream health care, or an alternative or complement to the main form of health care in a particular country.

WHO and its Member States cooperate to promote the use of traditional medicine for health care. The collaboration aims to:

- support and integrate traditional medicine into national health systems in combination with national policy and regulation for products, practices and providers to ensure safety and quality
- ensure the use of quality, safe, and effective products and practices, based on available evidence
- acknowledge traditional medicine as part of primary health care, to increase access to care and preserve knowledge and resources
- ensure patient safety by upgrading the skills and knowledge of traditional medicine providers

Research and development in traditional medicine is part of the WHO global strategy and plan of action on public health, innovation and intellectual property. Apart from setting out a research agenda for traditional medicine, the action plan also addresses the need to prevent misappropriation of health-related traditional knowledge. WHO, together with the World Intellectual Property Organization, is also providing support in this area.

The First Global WHO Traditional Medicine Strategy 2002-2005

In 2002, following extensive consultation, WHO released the first global WHO traditional medicine strategy 2002-2005. The Strategy identified and addressed a range of challenges and provided direction for Member States to maximize the potential of traditional medicine as a source of health care. In the WHO Traditional Medicine Strategy 2002-2005, the four key objectives relating to traditional medicine are policy; safety, efficacy and quality; access and the rational use of traditional medicine. WHO regards an evidence-based approach to traditional medicine to be an important step if traditional and modern medicines are to work effectively side-by-side in the health care system.

WHO Traditional Medicine Strategy 2002-2005 — Objectives

| Policy | Integrate TM/CAM* with national health care as appropriate, by developing and implementing national TM/CAM policies and programmes |
| Safety, Efficacy and Quality | Promote the safety, efficacy and quality of TM/CAM by expanding the knowledge-base on TM/CAM, and by providing guidance on regulatory and quality assurance standards |
| Access | Increase the availability and affordability of TM/CAM, as appropriate, with an emphasis on access for poor populations |
| Rational | Promote therapeutically sound use of appropriate TM/CAM products by providers and consumers |

* Traditional, complementary or alternative medicine

The WHO Traditional Medicine Strategy 2002-2005 recommended to Member States that countries develop a national traditional medicine policy which includes the registration and licensing of providers, national
regulation for herbal medicines, including the registration of herbal medicines, and a system for the safety monitoring of herbal medicines and other traditional medicine therapies. Without such a policy, traditional medicine could be practised without government oversight and without patient/consumer protection. Traditional medicine policy needs to be supported by laws and regulations to:

- Regulate and control the manufacturing of traditional medicine products and the practice of therapies.
- Regulate and control the trading of traditional medicine products.
- Prevent over-harvesting of medicinal plants and protect the environment.
- Protect indigenous traditional medicine knowledge.
- Regulate and control the education, training and licensing of traditional medicine practitioners.
- Support traditional medicine research and development.
- Regulate and control allocation of national financial and other resources.

In a fully integrated health system, traditional medicine is officially recognized and incorporated into all areas of health care provision. This means that traditional medicine is included in the country’s national health policy:

- providers of traditional medicine services are registered or otherwise publically accountable;
- traditional medicine products, including manufacturers are regulated or otherwise controlled;
- therapies are available at hospitals and clinics (both private and public);
- treatment is reimbursed under health insurance;
- relevant research is undertaken; and
- education in traditional medicine is required.

The WHO Traditional Medicine Strategy 2002-2005 recognized that in some countries in the Western Pacific Region, the integration of traditional medicine into the national health care system had already taken place.

In a partially integrated system, the government recognizes the role played by traditional medicine, supports its appropriate use, includes some forms of traditional medicine in its mainstream health services and takes varying measures to control the safe use of other forms of traditional medicine.

Some governments may allow the use of traditional medicine but there are no government provisions that support or control traditional medicine. In such circumstances, support for traditional medicine and any provisions to control access and use may be limited. These provisions could range from private sector providers with a self-regulating professional organization to unsupported and isolated local healers or family members.

Regional Strategy for Traditional Medicine in the Western Pacific Region

In October 1999, the WHO Regional Office for the Western Pacific organized a Workshop on the Development of National Policy on Traditional Medicine in Beijing for those countries in the Region who expressed a willingness to initiate efforts for policy development. The workshop highlighted the importance of having a national policy on traditional medicine and the significant role of Governments in developing action plans for their own traditional medicine programmes.

The WHO Regional Committee for the Western Pacific adopted two resolutions, WPR/RC36.R6 in 1985 and WPR/RC38.R16 in 1987 recognizing that traditional medicine practices, particularly herbal medicine and acupuncture, constituted appropriate health practices that could be integrated into national health strategies.

During the development of the first global WHO Traditional Medicine Strategy 2002-2005 it was recognized that given regional diversity in the use and role of traditional medicine, it may be necessary to take account of the variations and needs at regional levels. To meet the needs of the Region, the WHO Regional Office for the Western Pacific prepared the Regional Strategy for Traditional Medicine in the Western Pacific. It was adopted by the WHO Regional Committee for the Western Pacific during its 52nd Session held in Brunei Darussalam in September 2001 (WPR/RC52.R4).

The Regional Strategy, for the period 2001 to 2010, established a blueprint for the development of traditional medicine in the Western Pacific Region that has served as a guide to national governments, WHO and other partners. It encouraged Member States to develop an appropriate, scientifically sound, evidence-based,
practical and sustainable national strategy for strengthening the role of traditional medicine within their national health systems.

The Regional Strategy for Traditional Medicine in the Western Pacific 2001-2010 provides guidance concerning seven key objectives for traditional medicine (see Box below) and the activities that need to be performed, as appropriate, to meet specific needs of countries. It was acknowledged that ‘one size does not fit all’, and that each country’s strategy for traditional medicine should be adopted in accordance with national capacity, priorities, health policies, strategies, legislation, resources and culture.

Key strategic objectives in the Regional Strategy for Traditional Medicine for the period 2001-2010

- to develop a national policy for traditional medicine;
- to promote public awareness of and access to traditional medicine;
- to evaluate the economic potential of traditional medicine;
- to establish appropriate standards for traditional medicine;
- to encourage and strengthen research into evidence-based practice of traditional medicine;
- to foster respect for the cultural integrity of traditional medicine; and
- to formulate policies on the protection and conservation of health resources

The Regional Strategy for Traditional Medicine in the Western Pacific 2001-2010 recognized many challenges for traditional medicine, including the need to develop standards and regulations for training and traditional medicine practice, broadening research to encompass the holistic nature of many forms of traditional medicine, establishing the economic and health benefits of traditional medicine, and to develop and implement policies and programmes that help ensure that traditional medicine benefits the people who need it most.

The Regional Strategy for Traditional Medicine in the Western Pacific 2001-2010 was designed to help ensure that traditional medicine in the Western Pacific Region was developed and used appropriately, would contribute to building healthy populations and communities, and combat ill health. It also identified the partners who could work together to ensure the use of cost-effective traditional medicine for the benefit of the people of the Region.

The WHO Regional Office for the Western Pacific has made significant efforts to increase understanding and to promote the rational use of traditional medicine both in the region and globally. It has organized international meetings on traditional medicine, provided technical support and advice to Member States, organized regional and national activities and contributed to the development of policy, technical guidelines and standards, and published books and documents on traditional medicine (refer to the Annex 2 associated with Chapter 5, Regional Trends in Traditional Medicine 2001-2010).

To continue with its work to promote the appropriate use of traditional medicine and encourage its integration into the Region’s health care systems, the WHO Regional Office for the Western Pacific, in consultation with development partners and other stakeholders, and to reflect WHO traditional medicine policy since 2002, has developed a Regional Strategy for Traditional Medicine for the period 2011 to 2020 (Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020).

RECENT WHO RESOLUTIONS RELATING TO TRADITIONAL MEDICINE

At the global level, the World Health Assembly of the WHO has adopted the following resolutions on traditional medicine: WHA40.33 (1987), WHA42.43 (1989), WHA44.34 (1991), WHA54.11, WHA56.31 (2003) and WHA61.21 (2008). In 2009 the World Health Assembly (WHA62.13) requested:
Annex 1

- Member States:

1. to consider adopting and implementing the Beijing Declaration\textsuperscript{26} on Traditional Medicine in accordance with national capacities, priorities, relevant legislation and circumstances;
2. to respect, preserve and widely communicate, as appropriate, the knowledge of traditional medicine, treatments and practices, appropriately based on the circumstances in each country, and on evidence of safety, efficacy and quality;
3. to formulate national policies, regulations and standards, as part of comprehensive national health systems, to promote appropriate, safe and effective use of traditional medicine;
4. to consider, where appropriate, including traditional medicine into their national health systems based on national capacities, priorities, relevant legislation and circumstances, and on evidence of safety, efficacy and quality;
5. to further develop traditional medicine based on research and innovation, giving due consideration to the specific actions related to traditional medicine in the implementation of the Global strategy and plan of action on public health, innovation and intellectual property\textsuperscript{24};
6. to consider, where appropriate, establishing systems for the qualification, accreditation or licensing of traditional medicine practitioners and to assist traditional medicine practitioners to upgrade their knowledge and skill in collaboration with relevant health providers, on the basis of traditions and customs of indigenous peoples and communities;
7. to consider strengthening communication between conventional and traditional medicine providers and, where appropriate, establishing appropriate training programmes with content related to traditional medicine for health professionals, medical students and relevant researchers;
8. to cooperate with each other in sharing knowledge and practices of traditional medicine and exchanging training programmes on traditional medicine, consistent with national legislation and relevant international obligations.
ANNEX 2. Traditional Medicine publications from the WHO Regional Office for the Western Pacific and Guidelines updated by WHO/HQ

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<td>Traditional and Modern Medicine: Harmonizing the Two Approaches</td>
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**ANNEX 3. Supporting Infrastructure for Traditional Medicine in the Western Pacific Region**

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<tr>
<th>Country</th>
<th>Government Official Documents (Policy/Law and/or Regulation)</th>
<th>Government Bodies for Traditional Medicine</th>
<th>National Program</th>
<th>National Advisory/Expert Committee</th>
<th>Regulation of Traditional Medicine Providers</th>
<th>Regulation of Herbal Medicines</th>
<th>Research Institutes</th>
<th>Pharmacopoeia/Monograph</th>
<th>Courses on traditional medicine in universities</th>
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* The countries who participated and completed the Second WHO global survey on national policy and regulation for TM/CAM are listed above the table with updated data
* Blank box represented "No, don't have"
ANNEX 4. Development of Policies on Traditional Medicine in the Western Pacific Region (could be shrunk)

**Australia** The Australian Commonwealth Government recognizes that the role played by traditional medicine and includes some forms of traditional medicine in its mainstream health services. In July 2010, a National Registration and Accreditation Scheme for health practitioners came into force and replaced the scheme operating in individual Australian states. The practice of traditional Chinese medicine is to be included in the scheme from 1 July 2012. There is no standardized national system for regulating other forms of traditional medicine practice. There is a national scheme for the regulation of all traditional medicine products supplied in or exported from Australia, including requirements for quality, safety and efficacy, as well as advertising, labelling, and access.

**Cambodia** The national policy exclusively on traditional medicine, *Policy on Traditional Medicine of Kingdom of Cambodia*, was issued in 2010 and national regulation for herbal medicine, “Production Import and Export on Traditional Medicine for Health Care Service” was issued in 1998. In addition, a national level regulation for traditional medicine providers was issued in 1998, *Declaration No.570*.

**China** The TCM Division of the Ministry of Health was established in 1951, and was upgraded to a Department in 1954. In 1957, a programme of integrated TCM and modern medicine was initiated within the Ministry of Health. In 1986 the State Administration of TCM (SATCM) was established, and in 1988, the State Council established SATCM as a separate administrative body. As a result, over 200 statutes and policies relating to the development of TCM have been promulgated in order to establish a solid organizational framework for TCM. In 2005, the SATCM produced “Collections of Laws, Regulations and Documents on Traditional Chinese Medicine” which summarizes laws regarding the TCM enterprise in China; including *The Regulations on Traditional Chinese Medicine of the People’s People’s Republic of China* implemented 2003. The national policy was updated in 2009 "The State Council's Opinions concerning Supporting and Promoting development of Traditional Chinese Medicine”

**Cook Islands** The Cook Islands do not have a national policy, laws, regulations, a national programme, a national office, an expert committee or national research institutes on traditional medicine, nor are there currently any plans to establish these. There are no regulations on herbal medicines, nor do herbal medicines have any regulatory status.

**Fiji** There is no national policy, law or regulation or national programme for traditional medicine in Fiji, however, there is in process the establishment of a national policy and a national programme for traditional medicine. Currently, there is no national office, expert committee or national research institute for the study of traditional medicine. Fiji does not regulate herbal medicines, and herbal medicines are sold with health claims. There are regulations for acupuncture providers and chiropractic providers at the national level.

**French Polynesia** The government does not recognise traditional medicine. However, there are various practitioners such as herbalists, masseurs and shamans.

**Hong Kong (China)** The Chinese Medicine Ordinance was passed by the Legislative Council in July 1999. National regulation on traditional medicine was updated in 2002 and there are two traditional medicine programs: Establishment of Chinese Medicine Council of Hong Kong (1999) and Establishment of Public Chinese Medicine clinics (2003). *The Hong Kong Jockey Club Institute of Chinese Medicine* was established in 2001 as a national research institute.

**Japan** In 1960, a regulation on herbal medicine was issued and it was the same regulation as conventional pharmaceuticals. In 1967, Kampo extracts were first added to the National Health Insurance Drug Tariff in Japan, and in 1976 prescriptions of Kampo medicines received health insurance coverage. All of the 148 Kampo prescription formulas and six acupuncture treatments...
are covered by the national health insurance plans. The regulations for acupuncture and herbal medicine were issued in 1947 and 1960, respectively.

**Kiribati** No national policy on traditional medicine has been issued, but currently it is in the process of being established. The national office of traditional medicine is the Maurin Kiribati Traditional Healers Federation. There are no national research institutes on traditional medicine. There is currently no regulation of herbal medicine and no safety requirement currently exists.

**The Lao People's Democratic Republic** The Revised National Medicine Policy, based on earlier decree in 1995 is at the implementation stage. The Policy defines the role of traditional medicine in national health care delivery systems and provides a basis for promoting the rational use of traditional medicine. A law on traditional medicine was issued in 2000 and there is a regulation for traditional medicine "Decree on Medicinal Natural Resources". A national office for traditional medicine was established in 1976 as the Institute of Traditional Medicine under the Ministry of Health.

**Macao (China)** National law and regulation on traditional medicine was issued in 1994. Exclusive national policy on traditional medicine was introduced in 2001. There is a national office and expert committee for traditional medicine, and a national institute was established in 2002 as the "Institute of Chinese Medical Sciences, University of Macao". The practice of traditional Chinese medicine and herbal medicine is regulated and legally protected.

**Malaysia** A National Policy on Traditional and Complementary Medicine was issued 2001 and revised in 2007. The Government recognizes traditional medicine as an integral part of the health care system. There are a national office, an expert committee, and a national programme. A national research institute for traditional medicine was established in 2000 as the Herbal Medicine Research Centre, Institute for Medical Health.

**Marshall Islands** Traditional medicine is often used as initial treatment because of the cost of modern medicine. The Government has no policy on traditional medicine.

**Micronesia, Federated States** A national policy on traditional medicine is currently in the process of being established. There are no laws, regulations or national programmes on traditional medicine, nor are there currently any in development. There is no national office, national expert committee or national research institute on traditional medicine. There are no regulations on herbal medicines.

**Mongolia** State policy on the development of Traditional Mongolian Medicine was adopted by the State Great Khural (Parliament) in 1999, *Mongolian Parliament act of 46*: Policy of Polity for Mongolian TRM. There is national regulation and an office for traditional medicine (Medical Care Policy Implementation and Coordination Department of Ministry of Health established in 1992). There is also a national research institute established in 1959, Corporation of TRM Science, Technology and Manufacturer. Herbal medicine and traditional medicine providers are regulated.

**New Zealand** The Ministry of Health published Standards for Traditional Maori Healing in 1999. A national programme for traditional Maori Healing was established in 2006 and an experts committee was established for traditional Maori Healing. Traditional medicine products may be regulated as therapeutic-type dietary supplements or medicines. The regulations for chiropractors and osteopathy were issued in 1960 and 2004, respectively.

**Nauru** In 2009, the national policy for traditional medicine was issued in an integrated form into other national policies. National laws, regulations and a national programme on traditional medicine are being established. No expert committee has been established, but it is in process.
There are no national research institutes on traditional medicine. There is no regulation of herbal medicines.

**Papua New Guinea** A national policy on traditional medicine was issued in 2007, laws and regulations on are currently in development. The national programme was issued in 2001 as part of the *National Health Plan, 2001-2010*. A national office was established in 1999, National Health Department. A national expert committee was established in 1999 as the Traditional Medicine Task Force. No national research institutes have been established. No national regulations on herbal medicines have been issued, but are now in process.

**Philippines** The national policy on traditional medicine was enacted into legislation in 1997 as *The Traditional and Alternative Medicine Act*. In 1993, the Department of Health of the Philippines created a Traditional Medicine Unit and issued national program (Philippines Institute of Traditional and Alternative Health Care: PITAHC). There are a few national institutes in Philippines such as the National Institute for Health, National Integrated Research Program on Medicinal Plants, and the Philippine Council for Health Research and Development. Regulations on herbal medicine and practitioners have been issued. In June 2009, a standardized curriculum for acupuncture certification was introduced.

**Republic of Korea** Exclusive national policy on traditional medicine was issued in 1951 as part of the *National Health Act*. A law fostering the development of Oriental Medicine was enacted in 2003. Very recently, a national regulation of traditional medicine was issued in 2010. The Oriental Medicine Division in the Ministry of Health and Welfare was upgraded to bureau level in 1996. The Republic of Korea has a dual medical system of KOM (Korean oriental medicine) and Western Medicine established in 1952. The licensure system for KOM doctors was institutionalized in 1953 and after a stimulation program in 1999 by the Korean Government. There are now 11 KOM universities and one special KOM graduate school (2008) and a Specialist system for KOM (1999). An insurance system for long-term care insurance was started in 2008. An regulation exclusively on herbal medicine was enacted in 1995.

**Samoa** There is no legislation on traditional medicine. Although the Medical Practitioner's Act states that only registered persons can practice medicine, practitioners of traditional medicine are not considered to be breaking the law. The Health Sector Reform has included traditional medicine as a sub-component for institutional strengthening/reform.

**Singapore** New regulations were developed in 1998 requiring documentation, labelling and quality control of Chinese proprietary medicines (finished products). Currently, other traditional medicines (e.g. traditional Malay and Indian medicines) and homoeopathic medicines are not subject to pre-marketing approval and licensing for their import, manufacture and sale in Singapore. The enactment of Health Products Act in 2007 is providing an opportunity to review the regulation of complementary healthcare products, including traditional medicines. The Traditional Chinese Medicine Practitioners Board is a statutory board established in 2001 under the Traditional Chinese Medicine Practitioners Act 2000 and The Board registers TCM practitioners (both acupuncturists and TCM physicians).

**Solomon Islands** A national policy on traditional medicine was issued in 1994. Laws, regulations and a national programme on traditional medicine have not been developed, nor are they in development. There is also no national office, expert committee or national research institute. There are no national laws or regulations on herbal medicines; herbal medicines are classified for self medication only. Herbal medicines are not sold with claims.

**Tonga** Traditional medicine is practiced in all of the islands. There is no national policy, law, or national office on traditional medicine. Herbal medicines are sold with medical, health, nutrient content claims, and not regulated by law.
Vanuatu No national policy, laws, regulations or national programmes have been issued. A national policy is being developed. There is no national office, expert committee or national research institute. There are no national laws or regulations on herbal medicines.

Tuvalu No national policy, laws, regulations and national research institute on traditional medicine have been developed. There is also no national office, expert committee, but it is now in process. There are no national laws or regulations on herbal medicine.

Viet Nam In 2003, the Government approved the national policy on traditional medicine and pharmacy until 2010. Traditional medicine is integrated into the national health care system with the establishment of traditional medicine hospitals and traditional medicine departments in general hospitals.
LIST OF TEMPORARY ADVISERS, CONSULTANT AND SECRETARIAT

1. TEMPORARY ADVISERS

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Manila, Philippines, Telephone: (632) 528 9046, Fax: (632) 521 1036,
Email: seonge@wpro.who.int
PROVISIONAL AGENDA

1. Opening session and election of chairperson
2. Introduction: meeting objectives and expectations
3. Global trend and perspective on traditional medicine – Introduction and overview
4. Regional prospective on promoting traditional medicine - Overview of the implementation of the Regional strategy for traditional medicine in the Western Pacific (2001-2010)
5. Current status of traditional medicine in the Western Pacific Region
   – Review of country assessment on traditional medicine in selected countries
6. Regional strategy for traditional medicine in the Western Pacific 2011-2020
7. Draft review - Objective 1: To include traditional medicine in the national health care system
8. Draft review - Objective 2: To strengthen the evidence base of traditional medicine
9. Draft review - Objective 3: To promote the safe and effective use of traditional medicine by health care providers and consumers
10. Draft review - Objective 4: To increase access to traditional medicine within the national health care system
11. Draft review - Objective 5: To strengthen cooperation in generating and sharing traditional medicine knowledge and skills
12. Draft review – Priorities, indicators, strategic tools and WHO support and the way forward - Moving from strategy to action
Annex 3

13. Overall review – Introduction, Regional strategy for traditional medicine in the Western Pacific 2011-2020

14. Conclusion and recommendations

15. Closing session
EXPERTS’ CONSULTATION MEETING ON THE REGIONAL STRATEGY FOR TRADITIONAL MEDICINE IN THE WESTERN PACIFIC REGION, 2011-2020
HONG KONG SAR, CHINA, 18-19 NOVEMBER 2010

TENTATIVE TIMETABLE

<table>
<thead>
<tr>
<th>TIME</th>
<th>Thursday, 18 November</th>
<th>Time</th>
<th>Friday, 19 November</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:30</td>
<td>Registration</td>
<td>08:30</td>
<td>9. Draft review - Introduced by two consultants (Prof Briggs and Prof Cordell):</td>
</tr>
<tr>
<td>09:00</td>
<td>1. Opening session and election of chairperson</td>
<td></td>
<td>Objective 3: To promote the safe and effective use of traditional medicine by health</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>care providers and consumers</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Discussion</td>
</tr>
<tr>
<td>09:30</td>
<td>C O F F E E  B R E A K</td>
<td>10:00</td>
<td>10. Draft review - Introduced by two consultants (Prof Briggs and Prof Cordell):</td>
</tr>
<tr>
<td>10:00</td>
<td>2. Introduction: meeting objectives and expectations (Dr Samdan)</td>
<td></td>
<td>Objective 4: To increase access to traditional medicine within the national health</td>
</tr>
<tr>
<td>to 12:00</td>
<td></td>
<td></td>
<td>care system</td>
</tr>
<tr>
<td>12:00</td>
<td>3. Global trend and perspective on traditional medicine – Introduction and overview (Dr Zhang)</td>
<td></td>
<td>- Discussion</td>
</tr>
<tr>
<td></td>
<td>4. Regional prospective on promoting traditional medicine - Overview of the implementation of the Regional strategy for traditional medicine in the Western Pacific (2001-2010) (Dr Samdan)</td>
<td></td>
<td>11. Draft review - Introduced by two consultants (Prof Briggs and Prof Cordell):</td>
</tr>
<tr>
<td></td>
<td>5. Current status of traditional medicine in the Western Pacific Region (Dr Seong)</td>
<td></td>
<td>Objective 5: To strengthen cooperation in generating and sharing traditional medicine</td>
</tr>
<tr>
<td></td>
<td>- Review of country assessment on traditional medicine in selected countries (Prof Cordell)</td>
<td></td>
<td>knowledge and skills</td>
</tr>
<tr>
<td></td>
<td>6. Regional strategy for traditional medicine in the Western Pacific 2011-2020 (Dr Samdan and Prof Briggs)</td>
<td></td>
<td>- Discussion</td>
</tr>
<tr>
<td></td>
<td>- Discussion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12:00</td>
<td>C O F F E E  B R E A K</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>L U N C H  B R E A K</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TIME</td>
<td>THURSDAY, 18 NOVEMBER</td>
<td>TIME</td>
<td>FRIDAY, 19 NOVEMBER</td>
</tr>
<tr>
<td>-------</td>
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<td>---------------------</td>
</tr>
</tbody>
</table>
| 13:30 to 15:00 | 7. Draft review-Introduced by two consultants (Prof Briggs and Prof Cordell):  
Objective 1: To include traditional medicine in the national health care system  
- Discussion | 13:00 | 12. Draft review - Priorities, indicators, strategic tools and WHO support, and the way forward-moving from strategy to action  
- Discussion |
| 15:00 | 8. Draft review - Introduced by two consultants (Prof Briggs and Prof Cordell):  
Objective 2: To strengthen the evidence base of traditional medicine  
- Discussion | 15:15 to 16:30 | 13. Overall review – Introduction, Regional strategy for traditional medicine in the Western Pacific 2011-2020  
14. Conclusions and recommendations  
15. Closing session |
| Evening | Gala dinner hosted by the Hospital Authority of Hong Kong |       | Dinner hosted by the Department of Health, Hong Kong Special Administrative Region |
OBJECTIVES OF THE EXPERTS' CONSULTATION MEETING

Objectives

- Discuss the main challenges, directions, actions, way forward, and country and regional indicators for 2011-2020
- Provide advice and recommendations on the preliminary draft of the Regional Strategy for Traditional Medicine in the Western Pacific Region, 2011-2020

Related presentations

- Global trends and perspectives on TM
- Regional perspectives on promoting TM- Overview of the implementation of the Regional Strategy for Traditional Medicine in the Western Pacific 2001-2010
- Current status of TM in the Western Pacific Region
- Review of country assessment on TM in selected countries
- Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020

We are seeking your valuable input on the following:

1. Review the preliminary draft of the Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020
2. Main objectives, directions, challenges and actions should be undertaken for 2011-2020
3. Advise and give recommendations on the preliminary draft, including omissions
4. Identify the way forward
5. Identify the main country and regional indicators which would help to monitor the implementation of the strategy
Overview on my presentation

- Trend and challenges
- Strategies and priorities
- Approaches

Global trend and perspective on traditional medicine

Dr Zhang Qi
Traditional medicine programme

Trend: Populations Using TM/CAM Worldwide

<table>
<thead>
<tr>
<th>Country</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethiopia</td>
<td>70%</td>
</tr>
<tr>
<td>Mali</td>
<td>70%</td>
</tr>
<tr>
<td>Myanmar</td>
<td>70%</td>
</tr>
<tr>
<td>Rwanda</td>
<td>70%</td>
</tr>
<tr>
<td>Tanzania</td>
<td>50%</td>
</tr>
<tr>
<td>Uganda</td>
<td>30%</td>
</tr>
</tbody>
</table>

Trend in developed countries:

<table>
<thead>
<tr>
<th>Country</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>70%</td>
</tr>
<tr>
<td>France</td>
<td>70%</td>
</tr>
<tr>
<td>Germany</td>
<td>70%</td>
</tr>
<tr>
<td>Australia</td>
<td>46%</td>
</tr>
<tr>
<td>USA</td>
<td>44%</td>
</tr>
</tbody>
</table>

Number of countries before 1990: 5
Number of countries in 2007: 48
31% of respondents have national policy
Number of Member States with national policy pending: 51

Challenges

- TM is diversified and lack of reliable data
- How to develop regulation on TM
- Implementation of regulation on TM
- How and to what extent to integrate TM into health systems
Annex 5

Objectives

• To broaden the scope of TRM
  Herbal medicines → Integration of TM into health systems
• To reprioritize the projects/activities

Strategies

• Support countries on evidence-based policies and regulations of TM, and integration of TM into health systems
• Monitor global progress on TM and assess the trend of TM

Priorities

• Inclusion of TM in national health plan/strategy/program
• Human resources & non-medicines therapies
• Herbal medicines
• Promotion of healthy life-style through TM

Approaches

• Expanding global network outside of WHO
• Building up team work: with WHO regional and country offices, with other programs in WHO/HQ. within TRM
• Developing tools
Regional perspective on promoting Traditional Medicine

Overview on implementation of the Regional Strategy for Traditional Medicine in the Western Pacific 2001-2010

Dr. Narantuya Samdan
Regional Adviser in Traditional Medicine
World Health Organization
Western Pacific Regional Office

Use of Traditional Medicine in WPR

- Long history of use
- TM is still popularly used in PHC and other levels of health care
- Rapidly growing health system and economic importance.
- Government commitment and support for the development and promotion of TM
- Governments are keen to further promote use of TM
- Development and level of integration are quite different between countries

Regional Strategy for Traditional Medicine in the Western Pacific (2001-2010)

52nd session of the Regional Committee (Brunei Darussalam, 2001)

First regional strategy for traditional medicine in the Western Pacific
Identified needs and addressed directions, challenges and actions should be taken

Regional Strategy for Traditional Medicine in the Western Pacific (2001-2010)

Strategy designed to ensure that Traditional medicine in the Western Pacific Region is:

- Developed and used appropriately
- Contributes to building healthy populations and communities
- Combats ill health

Population Use of TM

<table>
<thead>
<tr>
<th>Country</th>
<th>% of Country Populations using TM/CAM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viet Nam</td>
<td>50</td>
</tr>
<tr>
<td>Singapore</td>
<td>30</td>
</tr>
<tr>
<td>Philippines</td>
<td>20</td>
</tr>
<tr>
<td>New Zealand</td>
<td>15</td>
</tr>
<tr>
<td>Mongolia</td>
<td>10</td>
</tr>
<tr>
<td>Malaysia</td>
<td>10</td>
</tr>
<tr>
<td>Lao PDR</td>
<td>10</td>
</tr>
<tr>
<td>Republic of Korea</td>
<td>10</td>
</tr>
<tr>
<td>Japan</td>
<td>10</td>
</tr>
<tr>
<td>Fiji</td>
<td>10</td>
</tr>
<tr>
<td>China</td>
<td>10</td>
</tr>
<tr>
<td>Brunei Darussalam</td>
<td>10</td>
</tr>
<tr>
<td>Australia</td>
<td>50</td>
</tr>
</tbody>
</table>

World Health Organization

Mission

Attainment by all peoples of the best possible level of health
Annex 5

### Western Pacific Region main approaches
- Establish clear policies on TM to clarify the government role
- To establish or update regulations governing TM

**Identify need for:**
- Political support
- Establishing appropriate standards
- Promoting evidence-based approach
- Protecting and conserving indigenous health resources

### Regional Strategy for Traditional Medicine in the Western Pacific 2001-2010

#### Objectives:
- To develop a national policy for TM
- To promote public awareness of and access to TM
- To evaluate the economic potential of TM
- To establish appropriate standards for TM
- To encourage and strengthen research into evidence-based practice of TM
- To foster respect for the cultural integrity of TM
- To formulate policies on the protection and conservation of health resources

### Regional Strategy for Traditional Medicine in the Western Pacific 2001-2010

**The Regional Strategy for Traditional Medicine was prepared to guide national governments, WHO and other partners:**
- to help ensure the proper use of TM in maintaining health and fighting diseases in the Region.
- to identify directions and actions that provide general principles and guidance responding to the challenges of TM use in each country and area.

### WHO/WPRO/TRM Activities

**Policy: technical support and advice to governments**
- Regional Meeting on Network for Policy and Programme Development in Traditional Medicine (Shanghai, 2003)
- Cambodia TM Policy
- Consultative workshop on TM policy in Cambodia
- Lao PDR’s national policy TM and regulation of herbal medicine
- Assessment of the current situation and the policy of TM in China, Japan, Korea, Mongolia, Philippines
- Mongolia National Plan of Implementation of the National policy on TM
- Meeting of directors of WHO CCs for TM in the Western Pacific Region (Melbourne, 2009)
- Informal meeting on STRATEGIC DIRECTIONS OF TRADITIONAL MEDICINE (THE WESTERN PACIFIC REGION) (Manila, 2010)

**Organized international meetings on traditional medicine; provided technical support and advice to governments.**

**Organized regional and national activities; developed technical guidelines and standards, and published books and documents on TM.**

**WHO works directly with countries, national and international organizations and regional bodies and with its network of Collaborating Centres.**
**Annex 5**

**Safety, Efficacy and Quality**

Promote the safety, efficacy and quality of TM by expanding the knowledge-base on TM, and by providing guidance on regulatory and quality assurance and standards.

**Evidence-base for TM**
- Increase access to and extend of knowledge of the safety, efficacy and quality of TM, with an emphasis on priority health problems.

**Regulation of herbal medicines**
- Support countries to establish effective regulatory systems for registration and quality assurance of herbal medicines.

**Guidelines on safety, efficacy and quality**
- Develop and support implementation of technical guidelines for ensuring the safety, efficacy and quality control of herbal medicines and other TM products and therapies.

**WHO/WPRO/TRM Activities**

**Standardization**
- English version in 2008 (first edition)
- 2009 (revised second edition)
- Japanese version 2008
- Korean version 2008
- Chinese version 2009

**Evidence based TM, safety, quality and scientific documentation:**
- WHO International standard terminologies on TM in the Western Pacific Region (2008)
- 1st and 2nd revised publication of “WHO standard acupuncture point locations in the Western Pacific Region” (2008, 2009)
- Medicinal Plants in Papua New Guinea (printed 2009), Mongolia, Lao PDR (editing)
- Regulation of quality control and safety of herbal medicines (Cambodia, Lao PDR, Mongolia, Philippines)

**International Classifications in Traditional Medicine (ICTM)**

- The significant use of TM worldwide makes it essential to gather information about the provision of TM particularly with respect to use, cost and outcomes.
- Joint project at WHO: Classification and Terminology; Traditional Medicine; and the Quality and Safety of Medicines
- Joint project at WHO: Establishment of Forum on Harmonization of Herbal Medicine (FHH) (Beijing, 2002)

- Standardization of the clinical language used by providers of TM
- The integration of TM into general health information systems

**WHO/WPRO/TRM Activities**

**Establishment of Forum on Harmonization of Herbal Medicine (FHH) (Beijing, 2002)**

- to promote public health by recognizing and developing standards and technical guidelines that aim to improve the quality, safety and efficacy of herbal medicines
Annex 5

WHO/WPRO/TRM Activities

Harmonization

*Harmonizing the Two Approaches:*

- 1st Consultation on Traditional and Modern Medicine  (Beijing, 2001)
- 2nd Consultation on Traditional and Modern Medicine (Gyeongju, 2003)

WHO/WPRO/TRM Activities

WPRIM

1st Informal Consultation for Developing Western Pacific Regional Index Medicus (WPRIM) (Manila, March 2006)
2nd Informal Consultation for Developing WPRIM (Beijing, Dec 2006)
WHO/HQ: Global Health Library (Jan 2007)

WHO/WPRO/TRM Activities

Education in TM

- Working Group Meeting on Quality of Academic Education in TM  (Melbourne, November 2003)
- WHO Guidelines for Quality Assurance of Basic Traditional Medical Education in the Western Pacific Region (February 2006)

Guiding Principles of WPRO Activities

- Recognition of TM diversity
- Based on the needs of Member States
- Tradition and innovation

Regional perspectives for TM

- Promoting integration, and evaluation of Traditional Medicine as a subsystem of national health systems.
- Strengthening research to promote the quality, safety and efficacy of traditional medicines and products
- Capitalizing on the potential contribution of traditional medicine to people centered primary care
- Encourage research and development in traditional medicine in accordance with national priorities and legislations, taking into account the relevant international instruments, including, as appropriate, those concerning traditional knowledge and the rights of indigenous people.

Thank You
# CURRENT STATUS OF TRADITIONAL MEDICINE IN THE WESTERN PACIFIC REGION

## Current Status of Traditional Medicine in the Western Pacific Region

**Dr Eunmi Seong**
Technical Officer, Traditional Medicine
WHO Western Pacific Regional Office

## Methodology

### Study challenges
- The completed Second Global Survey is still under way (18 Member States and areas responded by 12th Nov 2010)
- Limited information for some Member States and areas

### Purpose of the assessment
- Identify the situation of TM in the Region
- Identify the challenges to update the Regional Strategy for Traditional Medicine in the Western Pacific 2011-2020

### Data collection
- Completion of the Second WHO Global Survey on National Policy and Regulation for TM/CAM
- Country assessment
- Review of selected publications on TM

## The WHO Global Survey of National Policy on TM/CAM and Regulation of Herbal Medicine (First WHO Global Survey)

In 2003: The WHO Global Survey was conducted to monitor the countries’ progress and evaluate the implementation of WHO Traditional Medicine Strategy 2002-2005
- Global response 142/193 member countries
- Regional response 22/28 member countries

The summary report published in 2005: National Policy on Traditional Medicine and Regulation of Herbal Medicine

## The Second WHO Global Survey on National Policy and Regulation for TM/CAM (The Second WHO Global Survey)

**Conducted in 2010 – awaiting completion**

### Purpose of the Second Global Survey:
- Expanded and increased use of TM globally
- More Member States recently included TM into national health care services
- Resolution WHA 62.13 on TM (adopted 2009)
- To update the WHO Traditional Medicine Strategy 2002-2005-based on countries’ progress and current new challenges
- To evaluate the progress of implementation of Regional Strategy for Traditional Medicine in the Western Pacific 2001-2010: Provision of information for updating the Regional Strategy


- Provided useful information
- Addressing the challenges related to the appropriate use of TM/CAM

[http://apps.who.int/medicine/docs/en/d/1s7916e/](http://apps.who.int/medicine/docs/en/d/1s7916e/)
### Criteria Identified for Review

- **National Policy on TM**
  - National Policy
  - Law and Regulation
  - TM National office
  - National Research Institute

- **Regulatory Status of Herbal Medicines**
  - Regulation of herbal medicine
  - National pharmacopoeia/monograph
  - Safety (manufacturing-GMP)

- **Practice, Providers, Education and Health Insurance**
  - Education of TM Providers
  - Health Insurance and TM

### National Policy on TM: National Policy

<table>
<thead>
<tr>
<th>National Policy</th>
<th>(17 Member States and areas: 47%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Cambodia, China, China, Cambodia,</td>
</tr>
</tbody>
</table>

### List of the Member States and areas

- **Law and Regulation (13 Member States):**
  - Australia, Brunei Darussalam, Cambodia, China, Fiji, Hong Kong SAR, Korea, Lao PDR, Macao SAR, Malaysia, Philippines, Singapore, Viet-Nam

- **National Office and/or Expert Committee (17):**
  - Australia, Brunei Darussalam, Cambodia, China, Hong Kong SAR, Kiribati, Korea, Macao SAR, Malaysia, Mongolia, Nauru, New Zealand, Niue, Philippines, Papua New Guinea, Singapore, Viet Nam

- **National Research Institute (Government funded and supported) (10):**
  - Australia, Macao SAR, China, Korea, Hong Kong SAR, Laos, Malaysia, Mongolia, Philippines, Viet Nam

### List of the Member States and areas

- **Regulation of HM (14):**
  - Australia, Brunei Darussalam, Cambodia, China, Hong Kong SAR, Japan, Korea, Lao PDR, Macao SAR, Malaysia, Mongolia, Philippines, Singapore, Viet Nam

- **National Pharmacopoeia/monograph (10):**
  - Australia, China, Hong Kong SAR, Japan, Korea, Malaysia, Mongolia, Philippines, Papua New Guinea, Viet Nam

- **GMP on HM (8):**
  - Australia, China, Hong Kong SAR, Japan, Malaysia, Philippines, Singapore, Viet Nam
  - (3 Member States and areas in progress: Tuvalu, Mongolia, Macao SAR)
**Regulatory Status of Herbal Medicine: Market**

Market is very various - such as pharmacies, outlet, by licensed practitioners and no restriction of selling herbal products.

**Annual market sale of HM**
- For Hong Kong SAR and Japan: the currency rate used was that of 17th in November 2010
- Reference
  - Korea: estimation made by Korean Pharmaceutical Traders Association

<table>
<thead>
<tr>
<th></th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hong Kong SAR</td>
<td>US $ 4,728,200</td>
<td>US $ 4,898,700</td>
<td>US $ 4,943,600</td>
</tr>
<tr>
<td>Japan</td>
<td>US $ 1,422,791,204</td>
<td>US $ 1,467,563,128</td>
<td></td>
</tr>
<tr>
<td>Korea</td>
<td>US $ 88,340,000</td>
<td>US $ 70,597,000</td>
<td>US $ 67,907,000</td>
</tr>
</tbody>
</table>

**Practice, Providers, Education and Health Insurance : Education and Health Insurance**

- **Education**
  - University level of education: 11 Member States and areas (6 provide Ph D level)

- **Health Insurance**
  - 10 Member States and areas: health insurance covers TM (through government agency and/or private health insurance)

**List of the Member States and areas**

- **Education (11):** Australia, China, Hong Kong SAR, Japan, Korea, Malaysia, Macao SAR, Philippines, Singapore, Mongolia, Viet Nam.
- **Health Insurance (10):** Australia, China, Japan, Korea, Hong Kong SAR, Malaysia, Singapore, Mongolia, Tuvalu, Viet Nam.

**Summary**

- Overall, the data show the strengthening and growing of TM in the Western Pacific Region
- Expanded and increased use and recognition of TM in the region (especially safety concerns: the rapidly growing number of countries using GMP. In 2001, no countries had GMP for HM)
- More Member States and areas included TM into national health care services

**Criteria for Identifying Regional Challenges**

- **Based on:**
  - WHO Traditional Medicine Strategy 2002-2005
  - Regional Strategy for Traditional Medicine 2001-2010 in WPR
  - Strategic Objectives from Global as well as Regional Strategy
  - 2nd Global Survey
  - Country analysis

**Challenges related to Policy and Regulation**

- Insufficient government support and commitment on TM program
- Inability to develop, implement and enforce policy
- Limited appropriate mechanisms to control and regulate herbal products
- Limited appropriate mechanisms to monitor and regulate TM providers
- Limited mechanisms to control and regulate TM advertising and claims
- Limited cooperation between national health authorities
### Challenges related to Safety, Efficacy and Quality

<table>
<thead>
<tr>
<th><strong>Safety and Quality Control of Herbal Medicines</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>- Limited mechanisms to monitor safety of TM products, including HM</td>
</tr>
<tr>
<td>- Registration of herbal medicine (Inclusion HM into Essential Medicines List)</td>
</tr>
<tr>
<td>- Limited manufacturers in compliance with GMP</td>
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<tr>
<td>- Limited post-marketing surveillance</td>
</tr>
<tr>
<td>- Limited national capacity to establish regulations for HM</td>
</tr>
<tr>
<td>- Limited pharmacopoeia, monograph</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Research and Establishment of Evidence Base for TM</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>- Low priority of TM research</td>
</tr>
<tr>
<td>- Limited research database</td>
</tr>
<tr>
<td>- Limited financial support for research on TM</td>
</tr>
<tr>
<td>- General technical guidance for research and evaluation of TM related to safety, efficacy and quality</td>
</tr>
</tbody>
</table>

### Challenges related to Appropriate and Rational Use

<table>
<thead>
<tr>
<th><strong>Practice, Education</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>- Limited appropriate mechanisms to monitor and regulate TM providers</td>
</tr>
<tr>
<td>- Limited education and training for TM providers</td>
</tr>
<tr>
<td>- Limited mechanisms to monitor safety of TM practice</td>
</tr>
<tr>
<td>- Registration and regulation of practitioners</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Information</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>- Limited sharing and dissemination of information within national health systems on TM</td>
</tr>
</tbody>
</table>

### Challenges related to Access

<table>
<thead>
<tr>
<th><strong>Limited mechanisms to control and regulate TM advertising and claims</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Limited health insurance coverage for TM</strong></td>
</tr>
<tr>
<td><strong>Cost-effectiveness analysis not undertaken</strong></td>
</tr>
</tbody>
</table>

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**Thank You for Your Attention**
Annex 5

SELECTED COUNTRY ASSESSMENT

Selected Country Assessment

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Selected Country Assessment

- Countries assessed
  - Cambodia
  - China
  - Japan
  - Korea
  - Lao PDR

Selected Country Assessment –
Strengths and New Initiatives

- Cambodia
  - National Policy in place 2010
  - TM is an encouraged and important aspect of health care
  - Products of existing system are available and at low cost
  - As an ASEAN member, committed to harmonization and product safety

Selected Country Assessment –
Some Challenges

- Cambodia
  - Implementation of policy
  - Expanded research on quality, safety, and efficacy through NCTMR
  - Research on market demand and sustainability

Selected Country Assessment –
Strengths and New Initiatives

- China
  - SATCM, SFDA and CACMS
  - Dynamic, visionary, and well-funded approach to TCM
  - Monitoring TCM practices and use
  - Quality in manufacturing improving
  - Pharmacopoeia, Monographs and Essential medicines list
  - University-level education programs

Selected Country Assessment –
Some Challenges

- China
  - Upgrade the development of TCM industry (too many small producers with poor QC)
  - Indiscriminate TM plant and animal collection
  - Foster research on safety and efficacy
  - Strengthen the training programs for young scientists
  - Expanded teaching of TCM in English
### Selected Country Assessment – Strengths and New Initiatives

**Japan**
- Prescription Kampo medicine list
- Japan Liaison for Oriental Medicine (JLOM) est. 2005
- Good QC for manufacturing of Kampo medicine and acupuncture needles

**Korea**
- Ministry-level representation for TKM
- Series of laws and regulations covering TKM
- Pharmacopoeias
- Korea Institute of Oriental Medicine
- Collaborative Studies of TKM Plants

**Lao PDR**
- National policy encourages TM
- TM products on essential medicines list
- As an ASEAN member, committed to harmonization and product safety

### Selected Country Assessment – Some Challenges

**Japan**
- Policy and enhanced Government recognition of TM in the Pharmaceutical and Food Safety Bureau of MHLW
- National regulations for contaminants in imported plants
- Limited funding of innovative basic and clinical research on Kampo medicine
- National centre(s) of excellence for Kampo medicine
- Four-year training program in Kampo medicine
- Increase four-year acupuncture programs

**Korea**
- Stronger vision for development of TKM
- Commitment to research on safety and efficacy
- Test imported plant materials for pesticides, heavy metals and adulterants
- Access of TKM practitioners to Western medicine technology and testing methods
- More specialised TKM doctors

**Lao PDR**
- Research on market demand and sustainability
- Expanded research on quality, safety, and efficacy
- Information systems support
### Selected Country Assessment – Country Challenges

- Collaboration in the development of effective laws and regulations in the Region
- Lack of commitment to research resources (infrastructure and financial)
- Strategies for Quality, Safety and Efficacy determination
- Enhanced collaboration with Western medicine
- Conservation and database(s) of ethnomedical records
- Sustainable development of TMs
- More TM information on-line and in English
- Publication bias and/or conflict of interest
- Monitoring the e-commerce of TMs (quality??)
- Enhanced communications (e.g. Standardization of disease state terminology) is needed at many levels
REGIONAL STRATEGY FOR TRADITIONAL MEDICINE IN THE WESTERN PACIFIC 2011-2020

Regional Strategy 2011-2020

Provides a continuation of the directions and actions from the Regional Strategy 2001-2010 that remain relevant

Identifies and addresses new and emerging opportunities, challenges and directions that have subsequently appeared globally and regionally

Needs for revising the existing strategy

• Significant progress has been made in the Region
• New opportunities appeared
• New challenges appeared caused by environmental changes
• Vast developments in science and communication
• Globalisation

Regional Strategy 2011-2020

The strategy identifies:
• challenges
• objectives
• directions
• actions
• ways forward
• main indicators

Regional Strategy 2011-2020

Considering:

• diversity of TM in the Region
• unique culture of each form of TM

Underpinning principles:

– Balance between continuity and change
– Balance between tradition and innovation
– People-centeredness
– Sustainability
– Scientifically sound
– Evidence based
– Diversity
– Countries have to decide how to apply this strategy to their situation
Annex 5

Regional Strategy 2011-2020

The following were considered in revision of the Strategy:

- development, monitoring and review of national policies on TM;
- recognizing TM as an important resource in the health system;
- an evidence-based approach for quality, safety and efficacy;
- strengthening of capacity building and capability;
- cultural integrity of TM and the preservation of traditional knowledge.

Development Process

- Informal Meeting on Strategic Directions for Traditional Medicine in the Western Pacific Region, May 2010, Manila, Philippines
- Experts consultation meeting on the Regional Strategy for Traditional Medicine in the Western Pacific, 2011-2020, Nov. 2010, Hong Kong
- Draft strategy V 1
- Intercountry consultative meeting on the Regional Strategy for Traditional Medicine in the Western Pacific, 2011-2020, March 2011
- Draft strategy V 2
- RCM, Sep 2011

Thank You
CONTINUATION OF REGIONAL STRATEGY FOR TRADITIONAL MEDICINE IN THE WESTERN PACIFIC 2011-2020

CONTINUATION

REGIONAL STRATEGY FOR TRADITIONAL MEDICINE IN THE WESTERN PACIFIC 2011 – 2020

Prof David Briggs
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Australia

PRESENTATION OUTLINE

➤ Background and Context
  — WHO and Traditional Medicine
    • Strategies
    • Beijing Declaration
    • Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property
  ➤ Regional Strategy 2011–2020
    — Overview
      • Preamble
      • Purpose
      • Approaches
      • Key Objectives

WHO and Traditional Medicine

➤ Strategies
First global strategy for TM released in 2002


WHO Traditional Medicine Strategy 2002-2005

Key Objectives 2002-2005

➤ Policy
  Integrate TM with national health care
➤ Safety, Efficacy and Quality
  Expand the knowledge-base and provide guidance on regulatory and QA standards
➤ Access
  Increase availability and affordability of TM
➤ Rational use
  Promote sound use of appropriate TM products by providers and consumers

WHO and Traditional Medicine

➤ Strategies
Given regional diversity in the use and role of TM, the WHO Regional Office for the Western Pacific prepared the:

Regional Strategy for Traditional Medicine in the Western Pacific for the period 2001- 2010

Regional Strategy for Traditional Medicine 2001-2010

Key Objectives 2001-2010

➤ develop a national policy for TM
➤ promote public awareness of and access to TM
➤ evaluate the economic potential of TM
➤ establish appropriate standards for TM
➤ encourage and strengthen research into evidence-based TM practice
➤ foster respect for the cultural integrity of TM
➤ formulate policies on protection and conservation
WHO and Traditional Medicine

Beijing Declaration – November 2008

- Member States asked to consider adopting and implementing the Beijing Declaration on TM
- Recognizes TM as a resource of PHC to increase availability and affordability and to contribute to improved health outcomes including those in the Millennium Development Goals
- Recognizes Member States have different domestic legislation, approaches, regulatory responsibilities and delivery models

WHO and Traditional Medicine

- Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA)
  - Aims to promote new thinking on innovation and access to medicines, as well as provide a medium-term framework for securing enhanced and needs driven research and development relevant to diseases which disproportionately affect developing countries

Regional Strategy 2011-2020

- Provides a continuation of the directions and actions from the Regional Strategy 2001-2010 that remain relevant
- Identifies and addresses new and emerging opportunities, challenges and directions that have subsequently appeared globally and regionally
  - Presents a balance between continuity and change, tradition and innovation.

Strategy Overview 2011-2020

- Preamble
  - Significant progress in advancing 2001-2010 objectives
  - Progress not uniform and future challenges for some countries greater than others
  - Complex nature of many tasks and resources required were taken into account
  - 10 year period provides more realistic timeframe to plan and resource activities
  - Mid-term review to monitor implementation planned.
Strategy Overview 2011-2020

- **Purpose**
  - To guide Member States, WHO, development partners and other stakeholders in their efforts to promote quality and the safe and effective use of TM, and to fulfil its potential in health care.
  - Provides a framework for the development of national TM programmes.
    - Careful assessment should be made to help determine the most appropriate means of using TM to help meet national health care goals.

Strategy Overview 2011-2020

- **Approaches** - the Regional Strategy encourages Member States to:
  - Formulate policies, regulations and standards to promote quality, and the safe and effective use of TM
  - Respect, preserve and widely communicate the knowledge of, and the resources for, TM treatments and practices
  - Further develop TM based on research and innovation

Strategy Overview 2011-2020

- **Key Strategic Objectives 2011-2020:**
  1. To include TM in the national health care system.
  2. To strengthen the evidence base of TM.
  3. To promote the safe and effective use of TM by health care providers and consumers.
  4. To increase access to TM within the national health care system.
  5. To strengthen cooperation in generating and sharing TM knowledge and skills.

Strategy Overview 2011-2020

- **Key strategic objectives 2011-2020:**
  1. To include TM in the national health care system.
    - Formulate national policies which include TM as part of the national health care system
    - Formulate regulations and standards which apply to TM products and practices and are enforced
    - Establish systems for the qualification, accreditation or licensing of TM practitioners
Strategy Overview 2011-2020

- Key strategic objectives 2011-2020:
  1. To strengthen the evidence base of TM.
  2. To promote the safe and effective use of TM by health care providers and consumers.
  3. To increase access to TM within the national health care system.
  4. To strengthen cooperation in generating and sharing TM knowledge and skills.

- Priorities for 2011-2020:
  First step is a national policy recognizing TM
  • provides a plan of action for government and guides management and organizational decisions to achieve the goals and outcomes identified in the policy.
  • reflects the particular TM needs of a Member State
  • may be separate and distinct or included in a national health or medicine policy.
  • need to determine to what degree traditional and Western medical systems will co-exist

- Indicators for 2011-2020:
  • Important to monitor and measure the progress of efforts and their impact on health status.
  • Each Member State should select and define a set of indicators
  • should be objective and capable of measuring progress

Safe and effective use refers to appropriate or rational use of a therapy - sometimes also referred to as “quality use”
Strategic Tools and Support

- WHO will support, as appropriate, Member States to:
  - Implement the WHA resolutions including the Beijing Declaration, TM aspects of the GSPOA and the WHO strategy for prevention and control of non-communicable diseases
  - Continue providing policy guidance on how to integrate TM
  - Continue providing technical guidance on the quality, safety and efficacy of TM
  - Strengthen cooperation to share evidence-based information and support national capacity building

Way Forward – Moving from Strategy to Action

- Key Stages for 2011-2020:
  1. Need for government support and commitment
  2. Planning
  3. Implementation
  4. Monitoring and evaluation
  5. Financing