The Regional Strategy for Traditional Medicine in the Western Pacific (2011–2020)
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Preparation of this document would not have been possible without the support and dedicated work of these Governments.
Improved health is the overarching objective of public health policy across the Western Pacific Region and is critical for sustained economic and social development. All people have a right to quality health services that are available, accessible, affordable and acceptable. Traditional medicine is an important form of health care for many people in the Region. The use of safe and effective traditional medicine practices and products can make an important contribution to national and individual health care and the promotion of health equity.

The Regional Strategy for Traditional Medicine in the Western Pacific (2011–2020) provides guidance for countries and areas, WHO, development partners and other stakeholders on how to maximize the health potential of traditional medicine, and advance the cause of primary health care and universal access to health services for the people of the Region.

There is wide diversity of traditional medicine practices and products in the Region and they are integrated with Western medicine in national systems of health care to varying extents. As the forms, role and development of traditional medicine 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 needs and available resources of all countries and areas. Therefore, the challenges faced, the actions required and the support needed vary according to the needs and priorities of individual countries and areas.
Since the publication of the first regional strategy for traditional medicine, covering the period 2001 to 2010, there has been significant but variable progress by countries and areas in meeting the strategic objectives.

For some countries and areas the strategic objectives of the first regional strategy, their challenges, directions and actions, or parts of them, are still relevant to their health needs. For others, changes and advances in knowledge and technology may require some of the approaches to be updated.

The development of the Strategic Objectives took into account the advent of modern medical, analytical and information technologies, and the global strategic landscape including the United Nations Millennium Development Goals, the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and recent resolutions of the World Health Assembly.

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 recommended in the first regional strategy, and identifies and addresses new and emerging opportunities, challenges and directions that have since appeared.

Generally, the challenges for the future development of traditional medicine in the Region are related to framing policy, the development and enforcement of regulatory standards for practice and products, guidance for the assessment of quality, safety and efficacy, education and training, access and equity to traditional medicine products and services, and the safety monitoring of traditional medicine. An overarching challenge for all countries and areas is finding the required financial and human resources to meet these challenges.
The 10-year time frame provides a realistic period for countries and areas to plan and resource their activities. Emphasis has been given to:

- the values of primary health care and the contribution of traditional medicine to universal access;
- importance of cooperation and the sharing of information to support the quality, safety and efficacy of traditional medicine; and
- protection and conservation of indigenous health resources, including traditional knowledge and bio-resources.

The five key Strategic Objectives for 2011–2020 are:

- to include traditional medicine in the national health system;
- to promote safe and effective use of traditional medicine;
- to increase access to safe and effective traditional medicine;
- to promote protection and sustainable use of traditional medicine resources; and
- to strengthen cooperation in generating and sharing traditional medicine knowledge and skills.

The complex nature and the interdependence of many of the tasks, and the resources necessary to accomplish the Strategic Objectives for 2011–2020 have been taken into account in framing the directions and actions of the Regional Strategy for Traditional Medicine in the Western Pacific (2011–2020).

It is understood that, where and as appropriate, considerations with respect to the implementation of the Strategic Objectives for 2011–2020 will be based on national capacities, locally established priorities, relevant legislation, and on evidence of quality, safety and efficacy. Although the path to implementing the Strategic Objectives will be different in each country and area, where it is helpful, guidance based on groupings of countries facing similar challenges has been provided.
It is recommended that, where relevant and appropriate, countries and areas use the Regional Strategy for Traditional Medicine in the Western Pacific (2011–2020) as a framework for the development of specific national traditional medicine programmes. Country-specific strategic plans should be based on the principles of evidence-based traditional medicine and its respectful coexistence with Western medicine.

Each country and area is encouraged to carefully select and define a set of indicators to measure progress in implementing the Strategic Objectives which is appropriate for the contemporary and projected status of traditional medicine in their health system. It is intended that the indicators selected by countries and areas 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 enhancement of traditional medicine.

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

WHO can play a leading role to support regional initiatives, tailored to the current capacities, capabilities and aspirations of countries and areas, which offer scope for improving and harmonizing standards over time, avoiding duplication, sharing information and facilities, and promoting appropriate mutual recognition arrangements for traditional medicine standards within the Region.

WHO will continue to develop source materials for reference or adaptation by countries and areas.
I. Introduction

1.1 Purpose

The Regional Strategy for Traditional Medicine in the Western Pacific (2011–2020) provides guidance for countries and areas, WHO, development partners and other stakeholders on how to maximize the health potential of traditional medicine, and advance the cause of primary health care and universal access to health services for the people of the Region. The guidance provided in this document will need to be adapted to meet each country's situation and needs.

1.2 The Wide and Growing Use of Traditional Medicine

Traditional medicine is a health practice with strong historical and cultural roots. It is widely used, and is of increasing health and economic importance.

In some countries, the majority of the population continue to use traditional medicine to meet their health needs (Figure 1). It is an important primary care resource that can increase the availability and affordability of health care and contribute to improved health outcomes, including those mentioned in the Millennium Development Goals (MDGs). 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. This may, in part, be

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1 Achieving the health-related MDGs in the Western Pacific Region, World Health Organization, 2010.
2 Sometimes referred to as allopathic or conventional medicine.
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, illness, prevention and well-being.

The forms of traditional medicine practised 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 has a number of less complex traditional medicine practices that have developed within small and sometimes isolated ethnic groups. Such practices are based largely on local experience. The knowledge may not be documented and be transmitted orally from generation to generation.

Figure 1. Percentage of population using traditional medicine in selected countries in the Region.

Figure 1 “Percentage of population using traditional medicine in selected countries in the Region” contains data and references from the following four sources: (1) Country reports, Conference on traditional medicine in ASEAN countries, Bangkok, Thailand, 31 August–2 September 2009; (2) Xue C. et al. Complementary and Alternative Medicine Use in Australia: A National Population-Based Survey. The Journal of Alternative and Complementary Medicine, August 2007; 13(6):643–650; (3) Country reports, Informal meeting on strategic directions for traditional medicine in the Western Pacific Region, World Health Organization, Western Pacific Regional Office, Manila, 2010; and (4) Regional Strategy for Traditional Medicine in the Western Pacific, World Health Organization, Western Pacific Region, 2002.
1.3 Traditional Medicine in the Health System

Improved health is the overarching objective of public health policy across the Western Pacific Region and is critical for sustained economic and social development. While health status has improved greatly in many countries, particularly where governments have committed to universal coverage 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 reduce out-of-pocket expenses.

Traditional medicine has many contributions to make, especially in primary health care. The Declaration of Alma-Ata,4 which was adopted at the International Conference on Primary Health Care over 30 years ago, called for the inclusion of traditional medicine in primary health systems, and the recognition of traditional medicine practitioners as health workers, particularly at the community level.

Primary health care is now viewed more broadly than it was at the time of the Alma-Ata Declaration. The emphasis is on achieving universal health coverage and providing a continuum of care over a patient’s lifetime. There is also a focus on working within a mixed system of public and private health provision, acknowledging the need for a healthy global and local environment, and on recognizing that a primary health care approach provides value for money, not necessarily low-cost care.5

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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. Whether to include traditional medicine in a scheme of universal health coverage/access will be the decision of each country or area. Coverage could include access to all forms of traditional medicine or to specific, government-approved practices and products.

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. The framework promotes the use of 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. All of these building blocks are important components of a health system that can facilitate the delivery of traditional medicine services.

The World Health Assembly has urged countries and areas to include traditional medicine into their national health systems in accordance with national capacities, priorities, relevant legislation and circumstances, and based on evidence of safety, efficacy and quality.

There is wide diversity of traditional medicine practices in the Region and they are integrated with Western medicine in the national system of health care to varying extents. Some countries and areas have yet to take the step of recognizing traditional medicine in national health care, while others have fully integrated traditional medicine into their health system, with traditional medicine as an

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6 Regional Strategy for Health Systems Based on the Values of Primary Health Care, World Health Organization, Regional Office for the Western Pacific, 2010.

7 World Health Assembly resolution WHA62.13.
important partner in the provision of health care. Other countries and areas range between these two positions (Annex 1).

In countries and areas with full integration, traditional medicine is officially recognized and included in 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 and areas where traditional medicine is partially integrated 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 and areas where traditional medicine is not integrated, the national health system will not officially recognize, or exclude, traditional medicine. Although it may still be used, there are no government provisions supporting or controlling the use of traditional medicine beyond the general provisions of consumer protection.

The strategic objectives, directions and actions in this strategy outline measures to support the inclusion of traditional medicine in country health systems.

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8 The role of traditional medicine in national health care may be recognized by governments in different ways. For example, in a specific traditional medicine policy, or as part of a more general health or medicine policy.
1.4 Regional Progress in Traditional Medicine 2001–2010

Selected aspects of the developments in traditional medicine in the Region over the last 10 years are summarised below.

Government support on traditional medicine

The level of recognition and support for traditional medicine from governments varies considerably in the 37 countries and areas of the Western Pacific Region. To date, there are 18 countries and areas that had developed official government documents (including national policies, regulations or laws) applicable to traditional medicine, compared to 12 countries and areas having official documents before 2000. Examples of recent progress include Nauru, who developed a national policy in 2009, and Cambodia, who issued a policy on traditional medicine in 2010. Meanwhile, Fiji, Kiribati, Niue, New Caledonia and the Federated States of Micronesia are all in the process of establishing national policies on traditional medicine.

Across the Region there has been an increase in government activities in traditional medicine, including the establishment of a national office and/or a national expert committee. Fiji, Nauru and Tuvalu are in the process of establishing government bodies for traditional medicine. In the Philippines, the regulation of acupuncture providers was issued in 2008, and regulations...
on chiropractic and homeopathic providers were enacted in 2009. Within
the last few years, Fiji also enacted regulation for acupuncture providers. In
2007, the Lao People’s Democratic Republic established the regulation of
herbal medicine. Some countries and areas have specific regulations on herbal
medicine (Cambodia, China, Hong Kong (China), Macao (China), the Republic
of Korea, and the Philippines), and some have traditional medicine included
in regulations applicable to conventional pharmaceuticals (French Polynesia,
Japan, Mongolia, Malaysia and New Zealand) (Figure 2). While other countries
and areas are in the process of establishing regulations for herbal medicine
(Papua New Guinea) and regulations for traditional medicine providers (New
Caledonia).

Figure 2. Countries and areas with government bodies, regulation for herbal
medicine and practice for traditional medicine in the Western Pacific Region

![Graph showing the number of countries and areas with government bodies, regulation for herbal medicine, and practice for traditional medicine in the Western Pacific Region.]

Quality, safety and efficacy of traditional medicine

In the Western Pacific Region, some aspects of quality, safety and efficacy
of traditional medicine showed considerable improvement in the period
(GMP) for herbal medicines showed a significant increase. No countries and
areas in the Region reported applying GMP for traditional medicine products in
2001. There are now nine countries and areas with GMP implemented: Australia,
In addition, Macao (China) and Mongolia are in the process of establishing GMP for herbal medicinal products. Solomon Islands and Vanuatu have the same GMP rules as for conventional pharmaceuticals. These data indicate a significant increase in concern for the quality and safety of traditional medicines.

The establishment of national pharmacopoeias or monographs has also increased in the last decade, from four countries and areas with national pharmacopoeias in 2001 to nine by 2010. Rather than develop their own systems, several countries and areas have officially adopted or recognize the standards established by other countries in the Region. This facilitates international harmonization and mutual recognition.

Regarding the development of research institutes for traditional medicine, 13 countries and areas in the Region currently have a national institute. However, in some countries research may be carried out by other facilities. For example, Papua New Guinea does not have a separate traditional medicine research institute; the work is done by the national Department of Health in collaboration with the University of Papua New Guinea.

**Education and training programmes**

The provision of university-level education and related training programmes in traditional medicine helps to ensure the safe and effective use of traditional medicine by health care providers. To date, 14 countries and areas in the Region have established a course on traditional medicine at the university level, 12 of these provide education to at least bachelor’s degree level. Seven of these countries and areas provide PhD level education for traditional medicine (China, Hong Kong (China), Japan, Macao (China), Mongolia, the Republic of Korea, and Viet Nam). In Cambodia, although not at university level, there is a government-recognized training program for indigenous traditional medicine practitioners.
**Economic value of traditional medicine services**

Due to the inconsistency of terminology and regulatory status in each country, it is difficult to establish precise data on the economic value of traditional medicine. However, it is clear that the use of traditional medicine is growing in the Region, and the economic value associated with the provision of traditional medicine services has risen in the last 10 years.

Sales of traditional medicine have seen a significant increase in the last decade. The annual industrial output for China listed on the herbal database Chinese Materia Medica was US$ 47.84 billion in 2010, up 29.5% from the previous year. Total profit reached nearly US$ 4.52 billion in 2010, up 33% over the previous year.

Complementary/alternative medicine sales in Australia totalled US$ 1.12 billion in 2008. In Japan, herbal medicine (Kampo medicine) sales increased from US$ 1.42 billion in 2007 to US$ 1.47 billion in 2008. The same trend can be seen in the Republic of Korea where annual expenditures on traditional medicine were US$ 4.4 billion in 2004, rising to US$ 7.4 billion in 2009 through gradual market expansion.

Health insurance coverage is an indicator of the level of government and/or community support for improved and comprehensive access to traditional medicine. Ten countries currently have health insurance coverage for traditional medicine provided by the government and/or private sectors. However, in most cases the health insurance is partial and only covers specific areas such as acupuncture, chiropractic and herbal medicine.

The position of traditional medicine in each of the countries and areas of the Western Pacific Region is summarized in Annexes 1 and 2.

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1.5 Continuity and Change, and Regional Challenges

It is apparent that since the publication of the Regional Strategy for Traditional Medicine in the Western Pacific (2001–2010)\textsuperscript{11} there has been significant, but variable, progress in implementing the Strategic Objectives by countries and areas across the Western Pacific Region.

The 2011–2020 strategy presents a balance between continuity and change, tradition and innovation. It provides for a continuation of the directions and actions that remain relevant to the needs of countries and areas and WHO. It also identifies and addresses new and emerging opportunities, challenges and directions that have appeared globally and regionally since the development of the first regional strategy.

The objectives, challenges, directions and actions of the first regional strategy will still be relevant to some of those countries and areas that have seen little advancement in the last decade. Equally, countries and areas that have made major advances may require some of the approaches taken at the time to be updated.

Challenges for the future development of traditional medicine in the Region are related to framing policy, the development and enforcement of regulatory standards for practice and products, guidance for the assessment of quality, safety and efficacy, education and training, access and equity to traditional medicine products and services and the safety monitoring of traditional medicine. An overarching challenge for all countries and areas is finding the required financial and human resources.

These challenges are addressed in the directions and actions proposed for each of the five key Strategic Objectives.

\textsuperscript{11} Regional Strategy for Traditional Medicine in the Western Pacific, World Health Organization, Western Pacific Region, 2002.
2. The Regional Strategy for Traditional Medicine in the Western Pacific (2011–2020)

The people of the Western Pacific Region 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 that are acceptable, accessible, affordable and available.12 The countries and areas of the Western Pacific Region, and WHO, are committed to the progressive realization of this strategy.


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12 Regional Strategy for Health Systems Based on the Values of Primary Health Care, World Health Organization, Regional Office for the Western Pacific, 2010.
This Strategy recognizes that the directions of individual countries and areas 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 outlined in this Strategy. The 10-year time frame provides a more practical period for countries and areas to plan and resource their activities.

As the forms, role and development of traditional medicine 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 needs and available resources of all countries and areas. Therefore, the challenges faced, the actions required and the support needed by countries and areas over the period 2011–2020 will vary according to their individual situations. It is recommended that, where appropriate, countries and areas should use this Strategy as a framework for the development of national traditional medicine programmes.

WHO will actively advocate and promote the Strategic Objectives of this Strategy in countries and areas, and among development partners and other stakeholders at the regional and country level, in planning and coordinating actions for country support.

17 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.

18 World Health Assembly resolution WHA61.21.

19 World Health Assembly resolution WHA62.13.
Strategic objectives

Since the first regional strategy 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. Hence, increased emphasis is given to:

- values of primary health care and the contribution of traditional medicine to universal health care access;
- importance of cooperation and the sharing of information to support the quality, safety and efficacy of traditional medicine; and
- protection and conservation of indigenous health resources, including traditional knowledge and bio-resources.

The five key Strategic Objectives are:

- to include traditional medicine in the national health system;
- to promote safe and effective use of traditional medicine;
- to increase access to safe and effective traditional medicine;
- to promote protection and sustainable use of traditional medicine resources; and
- to strengthen cooperation in generating and sharing traditional medicine knowledge and skills.

It is understood that, where and as appropriate, national implementation of these Strategic Objectives will be based on locally established priorities, national capacities, relevant legislation, and on evidence of quality, safety and efficacy.
Strategic objective 1
To include traditional medicine in the national health system

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

The nature and extent of the integration or operational harmony that exists between the traditional and Western systems of medicine varies considerably in the countries across the Region. Traditional medicine may be fully or partially integrated with other components of health care, including Western medicine. Traditional medicine, as a component of health care, has to be recognized and function effectively alongside other demands on the national health system, if it is to fulfil its potential in health care.

A national policy should clearly indicate the view of government on the role of traditional medicine in promoting and maintaining health. The policy should define the role of traditional medicine in the national delivery of health care and provide a basis for promoting the rational use of traditional medicine as an affordable and cost-effective form of health care. The policy should ensure there are appropriate regulatory or other provisions to support the quality, safety and efficacy of traditional medicine practice and products.

Traditional medicine should be monitored using valid financial, social and health indicators, and its contribution to national health should be evaluated.
Directions

• Government commitment to recognize and include traditional medicine into the health system, in accordance with national priorities, capacities, relevant legislation and circumstances.

• Develop political support for a policy on the promotion of evidence-based traditional medicine with the advocacy of consumers, traditional medicine providers, other health professionals, academic institutions, industries and the media.

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, monitoring and evaluation of the policy and assign financial resources.

• Establish, or strengthen, a lead government agency to take responsibility for overseeing implementation of the traditional medicine policy.
Strategic objective 2
To promote safe and effective use of 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 components to this objective:

- to strengthen the evidence base of traditional medicine;
- 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
- to ensure that consumers are appropriately informed about the various traditional medicine modalities, their safety and their efficacy.

To strengthen the evidence base of traditional medicine

Research and innovation on traditional medicine should be further developed in line with the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA).20 The GSPOA aims to promote new thinking on innovation and access to medicinal products. It also provides a medium-term framework for securing needs driven essential health research and development that is relevant to diseases which disproportionately affect developing countries.

There is a need to develop and implement effective policies, regulations and standards for practice and products that will support health innovation in

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traditional medicine within an evidence-based framework. Generating and using information and research in a strategic fashion is critical to the development of this framework. It is anticipated that through selective investment, the level of research associated with traditional medicine will continue to rise throughout the Region to enhance the quality, safety and efficacy of traditional medicine, and confidence in its use.

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 minimize risk. However for most traditional medicines there is little or no scientific evidence to support their therapeutic role.

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 subsequent scientific studies to substantiate the safety and efficacy of the traditional medicine product. 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.21

In deciding the type and level of evidence necessary to substantiate safety and efficacy, each country will need to determine the minimum acceptable standard to meet their needs and circumstances.

Direction

Promotion and sponsorship of national programmes on evidence-based traditional medicine practices and products.

Strategic Actions

- Build and strengthen national research capacity and programmes.
- Establish prioritized, country-specific development programmes involving government, academic institutions and the private sector to enhance research on quality, safety and efficacy.
- Promote research with a view to establishing national regulations and standards for quality, safety and efficacy.
- Progress towards the implementation/introduction of Good Agricultural and Collection Practices (GACP), Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Clinical Practices (GCP), and Good Supply (distribution) Practices (GSP).
- Provide training opportunities on research methodology; develop technical guidelines and establish criteria for evaluating quality, safety, and efficacy.
- Document traditional medical knowledge while protecting the rights, including intellectual property rights, of the holders of this knowledge, and with their active participation and informed consent.
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 promote confidence in the safe and effective use of traditional medicine.

Regulations and guidelines for traditional medicine products should cover all aspects of production (growing, collection and storage), manufacture (practitioner certification, Good Manufacturing Practice, as appropriate), pre-market assessment of quality, safety and efficacy, product registration and post-market activities, including monitoring of adverse reactions; laboratory testing for quality and contamination (for example: heavy metals, adulteration with pharmaceutical drugs, microorganisms, microbial toxins, radionuclide, pesticide residues and solvent residues); surveillance in the market place; an effective and timely recall procedure; audit of Good Manufacturing Practice; and effective controls for advertising products.
Directions

• Develop standards for quality, safety and efficacy of traditional medicine products as a public health priority.

• Available and accessible traditional medicine products.

Strategic Actions

• Evaluate available historical and scientific information.

• Implement and enforce appropriate regulatory standards for traditional medicine products, including those for contamination and adulteration.

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

• Conduct regulatory impact assessments as part of the regulation of traditional medicine products.
The Safe and Effective Use of Traditional Medicine by Providers

Providers of traditional medicine can include traditional medicine practitioners, Western medicine practitioners, as well as health care workers such as dentists, nurses, midwives, pharmacists, physical therapists and others who provide traditional medicine services to patients, as appropriate with national laws. The integration of traditional medicine with Western medicine, particularly as part of primary health care, emphasizes the importance of respectful coexistence leading to the mutual referral.

To support the quality, safety and efficacy of traditional medicine there must be appropriate standards for practice and for the education and training of providers. 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. In 2005, the WHO Regional Office for the Western Pacific developed the WHO Guidelines for Quality Assurance of Traditional Medicine Education in the Western Pacific Region (see Annex 3) to assist Member States in this area. It is important that traditional medicine providers have sufficient knowledge to assess advantages and limitations, and have confidence in the quality, safety and effectiveness of traditional medicine.

Challenges in this area are at least twofold:

- ensuring that the knowledge, skills and competencies of traditional medicine practitioners are adequate; and
- that traditional medicine practitioners and Western medicine health professionals understand and appreciate the complementarities of the types of health care they offer, as well as its limitations and advantages.

To provide assurance of the safety-in-use of traditional medicine to consumers and health care providers, a national pharmacovigilance system must support and promote reporting and monitoring adverse events. WHO has issued guidelines on the safety monitoring of herbal medicines in pharmacovigilance systems which could be adapted for other traditional products and therapies.

**Directions**

- Develop regulations and standards for the qualification, accreditation or licensing of traditional medicine practitioners and other traditional medicine providers.
- Create awareness about the potential for adverse reactions to traditional medicine with consumers and health care providers, including Western medicine practitioners.

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Strategic Actions

• Conduct a national survey of practitioners as an initial step towards establishing regulations and standards for the practice of traditional medicine.

• Define the scope of practice and training for the diverse disciplines of traditional medicine and the relationship of traditional medicine practitioners to other health care professionals.

• Establish standards for the practice of traditional medicine including education, training and research.

• 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 professional associations or groups to facilitate education, including continuing education, and accreditation, licensing and registration of traditional medicine practitioners.

• Establish appropriate education programmes in traditional medicine for health care providers and relevant researchers.

• Establish a responsive system for the reporting, monitoring and responding to adverse reactions and other safety issues.
The Safe and Effective Use of Traditional Medicine by Consumers

The type of information needed to support safe and effective use of traditional medicine by consumers is likely to vary depending on the individual context and utilization pattern in a country or region. For example, in some countries certain herbal medicines are only available following consultation with a practitioner. In other countries, the same product may be self-selected by a consumer and available over-the-counter. It is important to note that people who are using traditional medicine may also be using Western medicine and this may have implications for safety. Creating an environment that supports the safe and effective use by consumers is particularly challenging and requires information and education at the local level and/or point-of-sale.

Governments need to work with health care professionals, including traditional medicine and other health providers and other partners, to take an 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 health options and the importance of a healthy lifestyle. WHO has guidelines on developing consumer information for the proper use of traditional medicine.  

24 WHO guidelines on developing consumer information on proper use of traditional, complementary and alternative medicine, World Health Organization, 2004.
Direction

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 with their patients concerning the safe use of traditional medicine.
• Develop appropriate information and education tools to facilitate access to safe and effective traditional medicine.
• 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.
Strategic objective 3
To increase access to safe and effective traditional medicine

The utilization of safe, effective and high quality traditional medicine can make an important contribution to national and individual health care, and the promotion of health equity. Countries and areas will need to be assured that the traditional practice or product is quality assured, safe, effective and cost-effective. The cost of inappropriate or ineffective services is a drain on limited and precious resources. A solid evidence base permits decision-making regarding whether a traditional therapy is the most appropriate form of available health intervention. It is also recognized that for some people in the lowest-income countries, and those living in remote regions, traditional medicine may be the only form of health care accessible.

To help make decisions about the cost-effectiveness of traditional medicine practices and products, the following matters should be considered:

- whether the safe and effective use of a therapy should apply generally, or whether it should only have limited application. For example, the application of acupuncture for the treatment of specific conditions;
- the cost, availability and sustainability of supply; or
- whether the health system has the capacity and capability to support the delivery of the therapy to the target population.
Directions

• Government commitment to recognize and include traditional medicine into the health system, in accordance with national capacities, priorities, relevant legislation and circumstances.

• Use an evidence-based approach to allow decision-making for selecting a safe and cost-effective therapy for a particular health intervention.

• Ensure that the health delivery system is effective for delivering traditional medicine to the target population.

Strategic Actions

• Examine the feasibility of including traditional medicine (or selected forms of traditional medicine) as a component of universal access to health services.

• Examine and enhance the health system as necessary, to provide traditional medicine services as appropriate.

• Ensure that providers of traditional medicine services are well trained in primary health care, including healthy lifestyles, health promotion and infection control (see also Strategic Objective 2).
Strategic 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, traditional medical knowledge and natural resources 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 obligations.25

Each country has been encouraged to develop regulations and procedures to control access and protect genetic resources, and many countries now have such policies and regulations in place. These regulations vary significantly across the Region and it would be advantageous to examine the potential for harmonization.

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 to prevent exploitation and to protect and conserve indigenous health resources.

Strategic Actions

• Ensure that appropriate agencies are established and fully informed on issues related to the protection, conservation and promotion of traditional medicine, as well as issues related to intellectual property rights.
• 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 help ensure their 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.
Strategic objective 5
To strengthen cooperation in generating and sharing traditional medicine knowledge and skills

Globalization of health practices, technology and other health products has an impact on traditional medicine, including its availability, accessibly and affordability. Member States and areas should be encouraged to cooperate with each other in sharing traditional medicine knowledge and practices and in developing and exchanging scientific knowledge and training programmes on traditional medicine.

For traditional medicine to attain its potential 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 part of health care in which Western medicine is a dominant practice, greater communication and respect is needed between the respective systems.

There are three key components to achieving this Objective:

• To enhance cooperation and communication within and between countries and areas, at all levels of policy, regulation, education, practice and research related to traditional medicine
• To strengthen communication between Western and traditional medicine providers and with their patients
• To facilitate international standardization and harmonization
To enhance cooperation and communication within and between countries and areas

The diverse practices of traditional medicine are based on extensive empirical observations, and associated with numerous cultures in the Region. They 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.

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, much 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 resource.

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 countries and areas will also help identify areas for possible harmonization to promote and facilitate trade and promote the growth of traditional medicine.
**Directions**

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

**Strategic Actions**

- Prioritize policies, regulations and standards for harmonization of traditional medicine in the Region.
- 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.
- Respect and preserve indigenous healing practices and facilitate the sharing of this resource.
- Encourage the use of English for international communication in traditional medicine.
To strengthen understanding between Western medicine and traditional medicine providers and with their patients

There is generally an increased public awareness of, and improved access to, traditional medicine 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 national health services. From a patient perspective, health benefits may be enhanced by good communication between Western and traditional medicine practitioners, and by an open relationship between the patient and the respective health care provider. The harmonization of traditional and Western medicine practices 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 through improved communication between health providers and their patients.

Strategic Actions

- Promote mutual understanding and respect and facilitate referral between practitioners of traditional medicine and other health 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 programmes to enhance public awareness of traditional medicine.
**To facilitate international standardization and harmonization**

As the infrastructure to support an increasing role for traditional medicine in the Region develops and strengthens, the internationally acceptable standards for traditional medicine, including manufacture, registration of products, practices and practitioners, and post-market provisions, will become increasingly relevant and will provide models for international harmonization.

To avoid duplication of effort and to use limited resources more effectively, it is important to create and promote evidence-based standards for the harmonization of traditional medicine in the Region. This will also facilitate better understanding and respect for the different forms of traditional medicine as well as support its safe and effective use.

Standardization of data collection and storage will aid access to traditional medicine information and assist in its inclusion in evolving healthcare applications, including computerized health information systems, reimbursement policies, treatment, health care funding allocation and public health programmes. Standardization in this context relates to the use of common terms for access to the literature, as a building block for electronic health records and as the basis for a classification system to enable collection of uniform data concerning traditional medicine practice and utilization. It aims to create economies of scale, raise the standard of traditional medicine in clinical practice, public health, research, clinical trials, education, policy development, resource allocation and to allow exchange of health records and inclusion of traditional medicine data in health information systems in a manner compatible with data collected in the practice of Western medicine. It is intended that the standardization of traditional medicine will be internationally accepted and become part of the WHO Family of International Classifications, such as the International Classification of Diseases (ICD).
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, analysis and interpretation of traditional medicine data across the Region.
• Support for the development and update of international standards for evidence-based traditional medicine classification and terminology, in collaboration with interested stakeholders, nationally and internationally.
• Implement national systems for the collection and analysis of traditional medicine data and harmonize with international standards where appropriate.
• Integrate evidence-based traditional medicine standards in the current health information systems.
3. The Way Forward

3.1 Moving from Strategy to Action

This Strategy has been developed to provide a general framework or model for the strategic development of national traditional medicine programmes. While the Strategy is an important guide for countries and areas, WHO, development partners and other stakeholders, it is the directions and actions that lead from the Strategic Objectives that are more important, and it is the subsequent health outcomes that really matter. All directions and actions that are proposed should be considered in the context of their ultimate impact, or potential to impact, on improvements in health care and health outcomes.

The path to implementing the Strategic Objectives will be different for each country and area. Where it is helpful, however, guidance based on groupings of countries facing similar challenges is provided below. The groupings are very broad and based on the primary need for each country and area to first have an effective traditional medicine policy in place. A robust policy is needed to ensure that traditional medicine activities within the health system are country led. It is also important that with a wide variety of internal and external stakeholders in traditional medicine and health care, such as government agencies, consumers, traditional medicine providers, Western health professionals, academic
institutions, industries, WHO and development partners, that there be a unifying national position on traditional medicine.

The task to formulate a policy should be assigned to a lead agency that will take responsibility for coordinating input from stakeholders.

To realize the full contribution that traditional medicine can make to health care in countries and areas, irrespective of individual country progress, it is critical to gain the appropriate political, social and financial support of all stakeholders as appropriate. Countries and areas will have to decide to what extent traditional medicine will be included in their health system—in parallel with other forms of health care, complementary to, or a component with other forms of health care in a fully unified or integrated system.

**Countries and areas with an existing traditional medicine policy** need to make certain that subsequent priorities are in accordance with their specific needs and resources to ensure that the policy is implemented. 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. For these countries, the following actions should be considered:
• Inclusion of traditional medicine into national health planning
• Regular monitoring and assessment of the role of traditional medicine in health care
• Based on evidence of safety, efficacy and cost-effectiveness, include or expand the traditional medicine practices and products that are covered by health insurance
• Strengthen the capacity for research and information gathering to improve the evidence base of traditional medicine and advance standards for quality, safety and efficacy
• Include traditional medicine into national pharmacovigilance systems
• Use international standards to manage traditional medicine services and information, including the use of e-health systems
• Establish or strengthen, as appropriate, the policy and regulations on the sustainable utilisation of traditional medicine resources.

Countries and areas without an existing traditional medicine 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 outcomes identified in the policy. It reflects the particular needs of the countries and areas in relation to traditional medicine. Countries and areas will need to determine how the traditional and Western medical systems should respectfully and cooperatively exist - in parallel, complementary, or as a unified stream of health care. The policy may be a separate traditional medicine policy or part of a national health or medicine 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.
The Way Forward

The following actions are encouraged:

- Developing and implementing a national policy for traditional medicine
- Collecting information on traditional medicine services provided in the country
- Including or extending health insurance coverage towards the inclusion of traditional medicine practices and products with approved safety and efficacy
- Introducing formal training and licensing for traditional medicine practitioners.

Countries and areas not yet ready to develop a traditional medicine policy or develop and implement a national strategic plan for traditional medicine are encouraged to:

- Undertake a situational analysis of the current status of traditional medicine and its role in health care
- Support professional development of traditional medicine practices
- Move towards voluntary self-regulation as a stepping-stone towards mandatory regulation at a later date
- Initiate and support greater collaboration between traditional medicine providers, Western medicine practitioners and other health professionals
- Encourage collaboration between traditional medicine and Western medicine researchers
- Document traditional medicine knowledge, taking into consideration the implications with regard to intellectual property rights.
Developing a national strategic plan for traditional medicine

For those countries and areas that are ready to include traditional medicine into national health care, a country-specific strategic plan should be developed. The development of a country-specific strategy is important, as it uses a range of health care approaches to address national health care issues. The strategy should be based on the principles of evidence-based traditional medicine and its respectful coexistence with Western medicine. In developing the national strategic plan, a consideration of the following matters is helpful:

1) A situational analysis of the current status of traditional medicine and its current role in health care.
   - The analysis will provide information on the current status of traditional medicine in the country, its role in health care, its utilization in public and private health care (including socioeconomic status and rural and urban accessibility), its cultural and social significance, and the level of government commitment to a role for traditional medicine in health care.

2) Formulation of the strategic plan.
   - Identify a national focal point for the development of the plan. The national health authority is generally the most appropriate body to take the lead in developing the national plan, although this could also be a national academic institution.

3) A national advisory committee could be set up to assist the health authority or lead body in developing the plan. The advisory committee could be supported by subcommittees to advise on specific or specialised aspects, if required.
   - An implementation plan should be developed as part of overall planning. Following identification of problems and benefits, priorities can be set and the country-specific strategic objectives better defined.
4) Consultation with the community and interested parties is essential. This should include institutions both within and outside of government and with the private sector. Where necessary, expert opinion can be obtained from international agencies and other countries. The public can be consulted when a draft strategic plan is prepared. The integration of traditional medicine in the health care system requires Government endorsement and support, as well as acceptance by Western health professionals.

- The contents of the draft plan should be revised following consultation and before the draft is finalized and submitted for formal endorsement by the government.

5) Implementation.

- A national agency of appropriate size (health authority/academic institution) should be identified to coordinate the implementation of the strategic plan. The agency will be responsible to ensure that the plan adopted by the Government is translated into operational activities at different levels. It will work closely with related government departments, health care providers, the private sector, teaching and research establishments and non government organizations.

- Funds from the government and other sources should be allocated to support the implementation of the plan.

- As with the implementation of any health intervention, the implementation of the national strategic plan for traditional medicine must be monitored and evaluated to assess whether it is meeting its strategic objectives and health outcomes. Evaluative criteria include therapeutic and cost-effectiveness, equity in terms of access and environmental and cultural impact. Depending on the evaluation results, modification of the strategic plan may be necessary to better achieve the stated objectives and health outcomes.
3.2 Strategic Tools and WHO Support

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

The WHO Western Pacific Regional Office will respond to requests from countries and areas related to enhancing policies, regulations and programmes in traditional medicine, based on a situation analysis with respect to the Strategic Objectives. The core documents to help identify needs are the national health plans of countries and areas, 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 countries and areas 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 countries and areas, which offer scope for improving and harmonizing standards over time, avoiding duplication, sharing information and facilities, and promoting appropriate mutual recognition arrangements for traditional medicine standards within the Region. In particular, WHO can continue to develop source materials for reference or adaptation by countries and areas 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 3 for details of selected WHO publications relevant to traditional medicine).

WHO will provide support to countries and areas, as appropriate, in order to:

1) Implement the resolution of the Sixty-second World Health Assembly on traditional medicine (WHA 62.13) including the Beijing Declaration;

2) Give assistance in implementing the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and the WHO Global Strategy for Prevention and Control of Noncommunicable Diseases;

3) 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;

4) 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;

5) Develop international standards for classifying traditional medicine;

6) Assist in creating computerized information systems for traditional medicine;

7) Facilitate regional cooperation to develop infrastructure; and

8) Support regional meetings of researchers, policy makers and regulators to exchange information, ideas and experiences.

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

It is important for countries and areas, and WHO, to be able to monitor and measure the progress of their efforts towards achieving the Strategic Objectives. Each country and area 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 indicators chosen should be objective and their progress measurable.

It is hoped that the indicators selected by countries and areas will provide useful guidance in decision-making, in identifying needs with respect to requests to WHO, and provide a basis for future planning for individual countries and areas. It must be recognized that not all measures are in the control of the health sector and that other stakeholders will need to be consulted in developing a comprehensive and valid set of indicators.

The following table provides some example indicators. Countries and areas should identify additional indicators that are relevant for their own setting.
Table 1: 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 having:</td>
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<td>- a national policy</td>
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<td>- a national plan/program</td>
<td>- a lead government agency/office</td>
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<td>- review and monitoring system</td>
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<td>- information systems</td>
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<td></td>
<td>- lead government agency/office</td>
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<td>To promote the safe and effective use of traditional medicine</td>
<td>Existence and implementation of:</td>
<td>Number of countries having:</td>
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<td>- programmes to build and strengthen national research capacity</td>
<td>- GACP, GMP, GLP, GCP and GSP standards</td>
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<td>- national regulation and registration system for products</td>
<td>- national regulation and registration system for products</td>
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<td>- national pharmacovigilance system</td>
<td>- national pharmacovigilance system</td>
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<td>- standards for the scope of practice, training, licensing and registration for providers</td>
<td>- organizations of professional groups</td>
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<td>- training programmes for Western health professionals in traditional medicine</td>
<td>- national medicinal plants monographs</td>
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<td>- national medicinal plants monographs</td>
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<td>- education programmes for consumers</td>
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<td>To increase access to safe and effective traditional medicine</td>
<td>Existence and implementation of:</td>
<td>Number of countries having:</td>
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<td>- insurance coverage for products and practices of traditional medicine with established</td>
<td>- insurance coverage for products and practices of traditional medicine with established</td>
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<td>safety and efficacy</td>
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<td>- controls for advertising traditional medicine products and services</td>
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<td>To promote protection and sustainable use of traditional medicine resources</td>
<td>Existence and support of:</td>
<td>Number of countries having:</td>
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<td>- conservation and cultivation programs</td>
<td>- conducted an assessment of existing resources</td>
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<td>- programmes for educating indigenous groups regarding their intellectual property rights</td>
<td>- programmes for educating indigenous groups regarding their intellectual property rights</td>
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<tr>
<td>To strengthen cooperation in generating and sharing traditional medicine knowledge and skills</td>
<td>Existence of:</td>
<td>Participation at the Regional level in:</td>
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<td>- a national research institution or centres of excellence</td>
<td>- collaborative programmes supporting the harmonization of policies, regulations and</td>
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<td>- national standards for classification of terminologies</td>
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<td>- WHO programmes and meetings supporting collaboration</td>
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<td>- international training and research programmes</td>
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Annex 1: Supporting Infrastructure for Traditional Medicine in the Western Pacific Region

<table>
<thead>
<tr>
<th>Country</th>
<th>Government Official Documents (Policy/Law and/or Regulation)</th>
<th>National Office 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>
<th>GMP on Herbal Medicine</th>
<th>Health Insurance and/or other subsidies</th>
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Annex 2: Development of Policies on Traditional Medicine in the Western Pacific Region

**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.

**Brunei Darussalam**

The national policy on traditional medicine was issued and government body for traditional medicine exists. Also, regulation for herbal medicine was issued. Recently, the regulation of traditional medicine providers was issued in 2010.

**Cambodia**

The National Policy on Traditional Medicine of the 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

In 1986 the State Administration of Traditional Chinese Medicine (SATCM) was established, setting a solid organizational framework for Traditional Chinese Medicine (TCM). The commitment to develop both modern and traditional medicines was written into the Chinese constitution in 1982. National health policy gives equal weight to Western medicine and traditional Chinese medicine.

The regulations of the People’s Republic of China on Traditional Chinese Medicine was issued in 2003 by the Chinese State Council and the State Council’s opinions concerning supporting and promoting the development of Traditional Chinese Medicine was promulgated in 2009. In 2011, the 12th Five-Year Plan on TCM (2011–2015) was released, ensuring that TCM is actively protected, supported and developed. According to a nationwide investigation on development of traditional Chinese medicine from 2006 to 2010, there were about 440 700 institutions providing TCM services, 520 600 patient beds, 907 million out-patients per year, including those from rural health centers, 408 600 TCM-certified doctors and assistant doctors, 32 TCM universities and colleges with 500 000 students, 24 768 research personnel, and 388 level-three laboratories.

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, the government recognises the need for traditional medicine. The way forward for traditional medicine in Fiji is recognition of traditional medicine to complement Western medicine, development of a national policy for traditional medicine and working towards the development of a working committee.
French Polynesia

The national laws and regulations on traditional medicine exist in the country, including regulations for herbal medicine and traditional medicine providers.

Hong Kong (China)

The Chinese Medicine Ordinance was enacted in 1999 to establish a statutory regulatory framework to control the practice, use, manufacture and trading of Chinese medicine in Hong Kong. The Chinese Medicine Council of Hong Kong was also set up in 1999 to implement various regulatory measures on the basis of the Chinese Medicine Ordinance. Under the Chinese Medicine Ordinance, licensing system on Chinese medicines trading, and registration system on Chinese medicine practitioners and proprietary Chinese medicines have been established to safeguard the health of public. Besides, the Chinese Medicine Division of the Department of Health was set up in 1997 and tasked with enforcing the Chinese Medicine Ordinance, promoting the development of Chinese medicine, and providing professional and executive support to the Chinese Medicine Council of Hong Kong. Hong Kong Chinese Materia Medica (HKCMM) Standards Office was set up in 2001 under the Chinese Medicine Division in the Department of Health to manage and coordinate the development of monographs for commonly used and important herbs in Hong Kong. An International Advisory Board (IAB) consisting of renowned experts from local, the Mainland and overseas was established to give advice on the principles, methodologies, parameters and analytical methods for the development of HKCMM Standards. The monograph coverage will be increased from the current 60 CMM to about 200 by 2012.

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 exists.

**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)**

Law and regulation on traditional medicine was issued in 1994. Exclusive policy on traditional medicine was introduced in 2001. There is an office and expert committee for traditional medicine, and an 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. Macao University of Science and Technology established the School of Chinese Medicine and began to offer 5-year full-time Chinese Medicine Undergraduate Programme in 2000.

**Malaysia**

A National Policy on Traditional and Complementary Medicine was issued in 2001 and revised in 2007. The Government recognizes traditional medicine as an integral part of the health care system. Since then nine government hospitals
integrated traditional medicine and 13 standards and curriculum had been introduced in 2008. Currently 7 universities are offering courses in traditional medicine. 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. Since 1992 traditional medicine products have to be registered with the Drug Control Authorities before being marketed in Malaysia. The regulation on licensing for traditional manufacturers and importers was enforced in 1999 and licensing of traditional wholesalers in 2002.

**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, the Federated States of**

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 46th: Policy for Mongolian Traditional Medicine. There is a 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 TM Science, Technology and Manufacture. Herbal medicine and traditional medicine providers are regulated.
New Caledonia

Currently, there is no national policy on traditional medicine.

New Zealand

The Ministry of Health published Standards for Traditional Maori Healing in 1999. A national programme for supporting the selective provision of traditional Maori Healing was established in 2006 and an expert 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 as an integral part of 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 the process. There are no national research institutes on traditional medicine. There is no regulation on herbal medicines.

Papua New Guinea

A national policy on traditional medicine was issued in 2007, laws and regulations 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 in the 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 Department of Health of the Philippines established Traditional Medicine Unit in 1993 to advocate the practice of Traditional and Alternative Health Care. The National policy on Traditional Medicine was enacted in 1997 as
the Traditional and Alternative Medical Act of 1997 that created Philippine Institute of Traditional and Alternative Health Care (PITAHC). There are National Institutes that collaborate with PITAHC programs such as National Institute for Health (NIH), National Integrated Research Program on Medicinal Plants (NIRPROMP) and the Philippine Council for Health Research and Development (PCHRD). The Food and Drug Administration (FDA) regulates herbal medicine manufacturing and products. In June 2009, a guideline for regulating the practice of acupuncture was introduced.

Republic of Korea

86% of Koreans have experience of using traditional medicine. Traditional medicine services account for 5.8% out of total medical services used. Western and traditional hospitals are separately operated in Korea. As of December 2009, there were 158 traditional medicine hospitals with 8,694 beds. The number of traditional medicine clinics is 11,705. With the revision of the Medical Service Act allows joint consultation between western and traditional medicine in 2010. Traditional medicine is covered by the National Health Insurance. Currently, acupuncture, moxibustion, cupping, 68 kinds of herbal medicine, 56 prescriptions and 3 physical therapies are covered. The licence system for Korean traditional medicine doctors was institutionalised in 1951 and a specialist system for Korean traditional medicine doctors in 1999. Currently, over 800 students graduate from 11 Korean traditional medicine universities nationwide every year. Schools have 5000 plus hour programs.

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 subcomponent 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**

Traditional Medicine was captured in the national medicines policy, 2009; however there is no specific traditional medicine policy formulated since then. A national programme on traditional medicine has 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 medicine.
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.
## Annex 3: Selected WHO Traditional Medicine Publications

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<td>WHO Guidelines for Quality Assurance of Traditional Medicine Education in the Western Pacific Region</td>
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<td>WHO Guidelines on Basic Training and Safety in Chiropractic</td>
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