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WHO Traditional Medicine Strategy 2002-2005



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This is the first global WHO Traditional Medicine Strategy. It was drafted following extensive consultation. However, given regional diversity in the use and role of traditional medicine, and complementary and alternative medicine, modifications may be necessary to take account of variations at regional levels. Additionally, it should be noted that difficulties persist in defining precise terminology for describing their therapies and products. The validity of related data is also frequently problematic. Methodologies used to collect data are often not comparable and parameters not clearly determined. The traditional medicine team at WHO Headquarters would therefore welcome comments on any of the data included in this strategy. They should be sent to: Dr Xiaorui Zhang, Acting Team Coordinator, Traditional Medicine, Department of Essential Drugs and Medicines Policy, World Health Organization, Avenue Appia 20, 1211 Geneva 27, Switzerland or emailed to: zhangx@who.int.



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Acronyms, abbreviations & WHO Regions

| | |
|-----------|---|
| AFRO | WHO Regional Office for Africa (see below for Member States covered) |
| AIDS | acquired immunodeficiency syndrome |
| AM | allopathic medicine |
| AMRO/PAHO | WHO Regional Office for the Americas/Pan American Health Organization (see below for Member States covered) |
| CAM | complementary and alternative medicine |
| CDS | Communicable Diseases Cluster |
| DGO | Director-General's Office |
| EGB | External Relations and Governing Bodies Cluster |
| EGB/ECP | External Relations and Governing Bodies Cluster/Department of External Cooperation and Partnerships |
| EIP | Evidence and Information for Policy Cluster |
| EIP/OSD | Evidence and Information for Policy Cluster/Department of Organization of Health Services Delivery |
| EMA | European Agency for the Evaluation of Medicinal Products |
| EMRO | WHO Regional Office for the Eastern Mediterranean (see below for Member States covered) |
| EURO | WHO Regional Office for Europe (see below for Member States covered) |
| FAO | Food and Agriculture Organization of the United Nations |
| FCH | Family and Community Health Cluster |
| FCH/RHR | Family and Community Health Cluster/Department of Reproductive Health and Research |
| FCH/WMH | Family and Community Health Cluster/Department of Women's Health |
| GMG | General Management Cluster |
| HIV/AIDS | human immunodeficiency virus/acquired immunodeficiency syndrome |
| HTP | Health Technology and Pharmaceuticals Cluster |
| NCCAM | National Center for Complementary and Alternative Medicine (USA) |
| NGO | nongovernmental organization |
| NMH | Noncommunicable Diseases and Mental Health Cluster |
| NMH/CCH | Noncommunicable Diseases and Mental Health Cluster/Department of Health Care |
| NMH/MNC | Noncommunicable Diseases and Mental Health Cluster/Department of Management of Noncommunicable Diseases |
| NMH/MSD | Noncommunicable Diseases and Mental Health Cluster/Department of Mental Health and Substance Dependence |
| RHR/TSC | Department of Reproductive Health and Research/Technical Support to Countries (part of Family and Community Health Cluster) |

| | |
|---------|--|
| SDE/HSD | Sustainable Development and Healthy Environments Cluster/Department of Health in Sustainable Development |
| SEARO | WHO Regional Office for South-East Asia (see below for Member States covered) |
| TCM | traditional Chinese medicine |
| TM | traditional medicine |
| UN | United Nations |
| UNAIDS | Joint United Nations Programme on HIV/AIDS |
| UNDP | United Nations Development Programme |
| UNESCO | United Nations Educational, Scientific and Cultural Organization |
| UNIDO | United Nations Industrial Development Organization |
| WKC | WHO Centre for Health Development (Kobe, Japan) |
| WHO | World Health Organization |
| WIPO | World Intellectual Property Organization |
| WPRO | WHO Regional Office for the Western Pacific (see below for Member States covered) |
| WSMI | World Self-Medication Industry |

WHO African Member States are: Algeria, Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Congo, Côte d'Ivoire, Democratic Republic of the Congo, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome & Principe, Senegal, Seychelles, Sierra Leone, South Africa, Swaziland, Togo, Uganda, United Republic of Tanzania, Zambia, Zimbabwe.


WHO Americas Member States are: Antigua & Barbuda, Argentina, Bahamas, Barbados, Belize, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, Dominica, Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Guyana, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Puerto Rico, Saint Kitts & Nevis, Saint Lucia, Saint Vincent & Grenadines, Suriname, Trinidad & Tobago, United States of America, Uruguay, Venezuela.

WHO Eastern Mediterranean Member States are: Afghanistan, Bahrain, Cyprus, Djibouti, Egypt, Islamic Republic of Iran, Iraq, Jordan, Kuwait, Lebanon, Libyan Arab Jamahiriya, Morocco, Oman, Pakistan, Qatar, Saudi Arabia, Somalia, Sudan, Syrian Arab Republic, Tunisia, United Arab Emirates, Yemen.

WHO European Member States are: Albania, Andorra, Armenia, Austria, Azerbaijan, Belarus, Belgium, Bosnia & Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Republic of Moldova, Romania, Russian Federation, San Marino, Slovakia, Slovenia, Spain, Sweden, Switzerland, Tajikistan, The former Yugoslav Republic of Macedonia, Turkey, Turkmenistan, Ukraine, United Kingdom, Uzbekistan, Yugoslavia.

WHO South-East Asian Member States are: Bangladesh, Bhutan, Democratic People's Republic of Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand.

WHO Western Pacific Member States are: Australia, Brunei Darussalam, Cambodia, China, Cook Islands, Fiji, Japan, Kiribati, Lao People's Democratic Republic, Malaysia, Marshall Islands, Micronesia, Mongolia, Nauru, New Zealand, Niue, Palau, Papua New Guinea, Philippines, Republic of Korea, Samoa, Singapore, Solomon Islands, Tokelau, Tonga, Tuvalu, Vanuatu, Viet Nam.



Key points: WHO Traditional Medicine Strategy 2002–2005

Traditional, complementary and alternative medicine attract the full spectrum of reactions – from uncritical enthusiasm to uninformed scepticism. Yet use of traditional medicine (TM) remains widespread in developing countries, while use of complementary and alternative medicine (CAM) is increasing rapidly in developed countries. In many parts of the world, policy-makers, health professionals and the public are wrestling with questions about the safety, efficacy, quality, availability, preservation and further development of this type of health care.

It is therefore timely for WHO to define its role in TM/CAM by developing a strategy to address issues of policy, safety, efficacy, quality, access and rational use of traditional, complementary and alternative medicine.

What is traditional medicine?

"Traditional medicine" is a comprehensive term used to refer both to TM systems such as traditional Chinese medicine, Indian ayurveda and Arabic unani medicine, and to various forms of indigenous medicine. TM therapies include medication therapies – if they involve use of herbal medicines,^a

animal parts and/or minerals – and non-medication therapies – if they are carried out primarily without the use of medication, as in the case of acupuncture, manual therapies and spiritual therapies. In countries where the dominant health care system is based on allopathic medicine, or where TM has not been incorporated into the national health care system, TM is often termed "complementary", "alternative" or "non-conventional" medicine.^b



Widespread and growing use

TM is widely used and of rapidly growing health system and economic importance. In Africa up to 80% of the population uses TM to help meet their health care needs. In Asia and Latin America, populations continue to use TM as a result of historical circumstances and cultural beliefs. In China, TM accounts for around 40% of all health care delivered.

Meanwhile, in many developed countries, CAM is becoming more and more popular. The percentage of the population which has

^a Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products, that contain as active ingredients parts of plants, or other plant materials, or combinations thereof.

^b Accordingly, in this document, "traditional medicine" is used when referring to Africa, Latin America, South-East Asia, and/or the Western Pacific, whereas "complementary and alternative medicine" is used when referring to Europe and/or North America (and Australia). When referring in a general sense to all of these regions, the comprehensive TM/CAM is used.

used CAM at least once is 48% in Australia, 70% in Canada, 42% in USA, 38% in Belgium and 75% in France.

In many parts of the world expenditure on TM/CAM is not only significant, but growing rapidly. In Malaysia, an estimated US\$ 500 million is spent annually on this type of health care, compared to about US\$ 300 million on allopathic medicine. In the USA, total 1997 out-of-pocket CAM expenditure was estimated at US\$ 2700 million. In Australia, Canada and the United Kingdom, annual CAM expenditure is estimated at US\$ 80 million, US\$ 2400 million and US\$ 2300 million respectively.

Why such broad use?

Accessible and affordable in developing countries

In developing countries, broad use of TM is often attributable to its accessibility and affordability. In Uganda, for instance, the ratio of TM practitioners^c to population is between 1:200 and 1:400. This contrasts starkly with the availability of allopathic practitioners, for which the ratio is typically 1:20 000 or less. Moreover, distribution of such personnel may be uneven, with most



being found in cities or other urban areas, and therefore difficult for rural populations to access.

TM is sometimes also the only affordable source of health care – especially for the world's poorest patients. In Ghana, Kenya and Mali, research has shown that a course of pyrimethamine/sulfadoxine antimalarials can cost several dollars. Yet per capita out-of-pocket health expenditure in Ghana and Kenya amounts to only

around US\$ 6 per year. Conversely, herbal medicines for treating malaria are considerably cheaper and may sometimes even be paid for in kind and/or according to the "wealth" of the client.

TM is also highly popular in many developing countries because it is firmly embedded within wider belief systems.

An alternative approach to health care in developed countries

In many developed countries popular use of CAM is fuelled by concern about the adverse effects of chemical drugs, questioning of the approaches and assumptions of allopathic medicine, and greater public access to health information.

At the same time, longer life expectancy has brought with it increased risks of developing chronic, debilitating diseases such as heart disease, cancer, diabetes and mental disorders. For many patients, CAM appears to offer gentler means of managing such diseases than does allopathic medicine.

Uncritical enthusiasm versus uninformed scepticism

Many TM/CAM providers seek continued – or increased – recognition and support for their field. At the same time many allopathic medicine professionals, even those in countries with a strong history of TM, express strong reservations and often frank disbelief about the purported benefits of TM/CAM. Regulators wrestle with questions of safety and efficacy of traditional herbal medicines, while many industry groups and consumers resist any health policy developments that could limit access to TM/CAM therapies. Reports of powerful immunostimulant effects for some traditional medicines raise hope among HIV-infected

^c TM practitioners are generally understood to be traditional healers, bone setters, herbalists, etc. TM providers include both TM practitioners and allopathic medicine professionals such as doctors, dentists and nurses who provide TM/CAM therapies to their patients – e.g. many medical doctors also use acupuncture to treat their patients.

individuals, but others worry that the use of such "cures" will mislead people living with HIV/AIDS and delay treatment with "proven" therapies.

So together with growing use of TM/CAM, demand has grown for evidence on the safety, efficacy and quality of TM/CAM products and practices. Interestingly, much of the scientific literature for TM/CAM uses methodologies comparable to those used to support many modern surgical procedures: individual case reports and patient series, with no control or even comparison group.



Nevertheless, scientific evidence from randomized clinical trials is strong for many uses of acupuncture, for some herbal medicines, and for some of the manual therapies.

In general, however, increased use of TM/CAM has not been accompanied by an increase in the quantity, quality and accessibility of clinical evidence to support TM/CAM claims.

Challenges in developing TM/CAM potential

To maximize the potential of TM/CAM as a source of health care, a number of issues must first be tackled. They relate to: policy; safety, efficacy and quality; access; and rational use.

Policy: basis of sound action in TM/CAM

Relatively few countries have developed a policy on TM and/or CAM – only 25 of WHO's 191 Member States. Yet such a policy provides a sound basis for defining the role of TM/CAM in national health care delivery, ensuring that the necessary regulatory and legal mechanisms are created for promoting and maintaining good practice, that access is equitable, and

that the authenticity, safety and efficacy of therapies are assured. It can also help to ensure sufficient provision of financial resources for research, education and training.

In fact, many developed countries are now seeing that CAM issues concerning safety and quality, licensing of providers and standards of training, and priorities for research, can best be tackled within a national policy framework. The need for a national policy is most urgent, however, in those developing countries where TM has not yet been integrated into the national health care system, even though much of their population depends on TM for health care.

An increased number of national policies would have the added benefit of facilitating work on global issues such as development and implementation of internationally accepted norms and standards for research into safety and efficacy of TM/CAM, sustainable use of medicinal plants, and protection and equitable use of the knowledge of indigenous and traditional medicine.

Safety, efficacy and quality: crucial to extending TM/CAM care

TM/CAM practices have developed within different cultures in different regions. So there has been no parallel development of standards and methods – either national or international – for evaluating them.

Evaluation of TM/CAM products is also problematic. This is especially true of herbal medicines, the effectiveness and quality of which can be influenced by numerous factors. Unsurprisingly, research into TM/CAM has been inadequate, resulting in paucity of data and inadequate development of methodology. This in turn has slowed development of regulation and legislation for TM/CAM.

National surveillance systems to monitor and evaluate adverse events are also rare. So although many TM/CAM therapies have promising potential, and are increasingly used, many of them are untested and their use not monitored. As a result, knowledge of their potential side-effects is limited. This makes identification of the safest and most effective therapies, and promotion of their rational use more difficult. If TM/CAM is to be promoted as a source of health care, efforts to promote its rational use, and identification of the safest and most effective therapies will be crucial.

Access: making TM/CAM available and affordable

Although many populations in developing countries are reported as depending heavily on TM to help meet their health care needs, precise data are lacking. Quantitative research to ascertain levels of existing access (both financial and geographic), and qualitative research to clarify constraints to extending such access, are called for. The focus should be on treatments for those diseases which represent the greatest burden for poor populations.

Also, if access is to be increased substantially, the natural resource base upon which certain products and therapies depends must be protected. Raw materials for herbal medicines, for instance, are sometimes over-harvested from wild plant populations.

Another major challenge concerns intellectual property and patent rights. The economic benefits that can accrue from large-scale application of TM knowledge can be substantial. Questions about how best these benefits can be shared between innovators and the holders of TM knowledge have not yet been resolved though.

Rational use: ensuring appropriateness and cost-effectiveness

Rational use of TM/CAM has many aspects, including: qualification and licensing of providers; proper use of products of assured quality; good communication between TM/CAM providers, allopathic practitioners and patients; and provision of scientific information and guidance for the public.

Challenges in education and training are at least twofold. Firstly, ensuring that the knowledge, qualifications and training of TM/CAM providers are adequate. Secondly, using training to ensure that TM/CAM providers and allopathic practitioners understand and appreciate the complementarity of the types of health care they offer.

Proper use of products of assured quality could also do much to reduce risks associated with TM/CAM products such as herbal medicines. However, regulation and registration of herbal medicines are not well developed in most countries, and the quality of herbal products sold is generally not guaranteed.

More work is also needed to raise awareness of when use of TM/CAM is appropriate (and cost-effective) and when it is not advised, and why care should be taken when using TM/CAM products.

The current role of WHO

WHO's mission in essential drugs and medicines policy is to help save lives and improve health by closing the huge gap between the potential that essential drugs have to offer and the reality that for millions of people – particularly the poor and disadvantaged – medicines are unavailable, unaffordable, unsafe or



improperly used. It does this by carrying out a number of core functions: articulating policy and advocacy positions; working in partnership; producing guidelines and practical tools; developing norms and standards; stimulating strategic and operational research; developing human resources; and managing information.

In terms of TM/CAM, WHO carries out these functions by:

- *Facilitating integration of TM/CAM into national health care systems*
by helping Member States to develop their own national policies on TM/CAM.
- *Producing guidelines for TM/CAM*
by developing and providing international standards, technical guidelines and methodologies for research into TM/CAM therapies and products, and for use during manufacture of TM/CAM products.
- *Stimulating strategic research into TM/CAM*
by providing support for clinical research projects on the safety and efficacy of TM/CAM, particularly with reference to diseases such as malaria and HIV/AIDS.
- *Advocating the rational use of TM/CAM*
by promoting evidence-based use of TM/CAM.
- *Managing information on TM/CAM*
by acting as a clearing-house to facilitate information exchange on TM/CAM.

But the challenges described earlier demand that WHO activities in this area be extended and increased.

Framework for action

The *WHO Traditional Medicines Strategy 2002–2005* reviews the status of TM/CAM globally, and outlines WHO's own role and activities in TM/CAM. But more importantly it provides a framework for action for WHO and its partners, aimed at enabling TM/CAM to play a far greater role in reducing excess mortality and morbidity, especially among impoverished populations. The strategy incorporates four objectives:



1. Policy – Integrate TM/CAM with national health care systems, as appropriate, by developing and implementing national TM/CAM policies and programmes.
2. 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.
3. Access – Increase the availability and affordability of TM/CAM, as appropriate, with an emphasis on access for poor populations.
4. Rational use – Promote therapeutically sound use of appropriate TM/CAM by providers and consumers.

Implementation of the strategy will initially focus on the first two objectives. Achieving the safety, efficacy and quality objective will provide the necessary foundation for achieving the access and rational use objectives.

Strategy implementation

Maximizing the potential that TM/CAM offers for improving health status worldwide is a daunting task, covering a diverse range of activities and demanding many types of expertise. Fortunately, WHO has established a global TM/CAM network, members of which include national health authorities, experts of WHO Collaborating Centres and research institutes, as well as other UN agencies and nongovernmental

organizations working on TM/CAM issues, and whose assistance WHO can call upon. Many organizations have contributed to development of the *WHO Traditional Medicine Strategy 2002–2005*, and many of them have agreed to be our partners in its implementation.

Use of critical indicators will facilitate monitoring of country progress under each of the strategy objectives.



Traditional medicine (TM) and complementary and alternative medicine (CAM) are attracting more and more attention within the context of health care provision and health sector reform. Many factors are contributing to widespread use of TM/CAM. But some important issues must be addressed if their potential is to be developed successfully.

1.1 What is traditional medicine? Towards a working definition

There are many TM systems, including traditional Chinese medicine, Indian ayurveda and Arabic unani medicine. A variety of indigenous TM systems have also been developed throughout history by Asian, African, Arabic, Native American, Oceanic, Central and South American and other cultures. Influenced by factors such as history, personal attitudes and philosophy, their practice may vary greatly from country to country and from region to region. Needless to say, their theory and application often differ significantly from those of allopathic medicine (Box 1).

Depending on the therapies involved, TM/CAM therapies can be categorized as medication therapies – if they use herbal medicines,^d animal parts and/or minerals – or non-medication therapies – if carried out primarily without using medication, as

in the case of acupuncture, manual therapies, qigong, tai ji, thermal therapy, yoga, and other physical, mental, spiritual and mind–body therapies.

Box 1

WHAT IS TRADITIONAL MEDICINE?

Traditional medicine may be codified, regulated, taught openly and practised widely and systematically, and benefit from thousands of years of experience.

Conversely, it may be highly secretive, mystical and extremely localized, with knowledge of its practices passed on orally. It may be based on salient physical symptoms or perceived supernatural forces.

Clearly, at global level, traditional medicine eludes precise definition or description, containing as it does diverse and sometimes conflicting characteristics and viewpoints. But a working definition is nevertheless useful. For WHO such a definition must of necessity be comprehensive and inclusive.

WHO therefore defines traditional medicine as including diverse health practices, approaches, knowledge and beliefs incorporating plant, animal, and/or mineral based medicines, spiritual therapies, manual techniques and exercises applied singularly or in combination to maintain well-being, as well as to treat, diagnose or prevent illness.

Complementary and alternative medicine

The terms "complementary" and "alternative" (and sometimes also "non-conventional" or "parallel") are used to refer to a broad set of health care practices that are not part of a country's own tradition, or not integrated into its dominant health care system.

^d Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products, that contain as active ingredients parts of plants, or other plant materials, or combinations thereof.

Acupuncture is a traditional Chinese medicine therapy. But many European countries define it and traditional Chinese medicine in general as CAM, because they do not form part of their own health care traditions. Similarly, since homeopathy and chiropractic systems were developed in

"To speak of "alternative" medicine is...like talking about foreigners – both terms are vaguely pejorative and refer to large, heterogeneous categories defined by what they are not rather than by what they are."¹

Europe in the 18th Century, after the introduction of allopathic medicine, they are not categorized as TM systems nor incorporated into the dominant modes of health care in Europe. Instead, they are regarded as a form of CAM.^c

Some common TM/CAM therapies, described in the 1999 *British Medical Journal* series on CAM, are shown in Table 1. The table is by no means exhaustive, and new branches of established disciplines are being developed continually.

Incorporation of TM/CAM into national health care systems

WHO has defined three types of health system to describe the degree to which TM/CAM is an officially recognized element of health care.

In an **integrative system**, TM/CAM is officially recognized and incorporated into all areas of health care provision. This means that: TM/CAM is included in the relevant country's national drug policy; providers and products are registered and regulated; TM/CAM therapies are available at hospitals and clinics (both public and private); treatment with TM/CAM is reimbursed under

Table 1

Commonly used TM/CAM therapies and therapeutic techniques

| | Chinese medicine | Ayurveda | Unani | Naturopathy | Osteopathy | Homeopathy | Chiropractic | Others |
|-------------------------|---------------------|----------|-------|-------------|------------|------------|--------------|-------------------------------|
| Herbal medicines | ● | ● | ● | ● | ■ | ● | | ● ^a |
| Acupuncture/acupressure | ● | | | | ■ | | | ■ ^b |
| Manual therapies | Tuina ^c | ● | ● | ■ | ● | | ● | Shiatsu ^d |
| Spiritual therapies | ● | ● | ● | ● | | | | Hypnosis, healing, meditation |
| Exercises | Qigong ^e | Yoga | | Relaxation | | | | |

● – commonly uses this therapy/therapeutic technique

■ – sometimes uses this therapy/therapeutic technique

■ – uses therapeutic touch

^a for example, many informal TM systems in Africa and Latin America use herbal medicines.

^b for example, in Thailand, some commonly used TM therapies incorporate acupuncture and acupressure.

^c type of manual therapy used in traditional Chinese medicine.

^d refers to manual therapy of Japanese origin in which pressure is applied with thumbs, palms, etc., to certain points of the body.

^e component of traditional Chinese medicine that combines movement, meditation and regulation of breathing to enhance the flow of vital energy (qi) in the body to improve circulation and enhance immune function.

^e Accordingly, in this document, "traditional medicine" is used when referring to Africa, Latin America, South-East Asia, and/or the Western Pacific, whereas "complementary and alternative medicine" is used when referring to Europe and/or North America (and Australia). When referring in a general sense to all of these regions, the comprehensive TM/CAM is used.

Table 2 Examples of countries with an integrative approach to TM/CAM

| | National policy on TM/CAM | TM/CAM unit or department within ministry of health | Regulation of herbal products and herbal products industry | Human TM resources | Practice at all levels including public hospitals, TM/CAM are integrated into national health system) | Health insurance coverage for treatment and products | TM/CAM research institutes | Official education at university level that covers both TM and AM for doctors, pharmacists and nurses |
|-------------------|---|--|--|---|---|--|--|---|
| China | 1949 constitution contains policy on TM | State Administration of Traditional and Complementary Medicine (TCM) | Regulation — Yes Pharmacopoeia includes herbs List of essential drugs includes herbal medicines Manufacturers 600 Herbal farmers 340 000 | TCM doctors 525 000 TCM/AM doctors 10 000 TCM pharmacists 83 000 TCM associate doctors 72 000 AM pharmacists 55 000 | TCM hospitals TCM/AM hospitals Total beds 35 000 TM hospitals for minority groups 127 | Full | 170 national and state research institutes | 30 TCM universities 3 TM colleges for minority groups 51 medical technology schools of TCM |
| Republic of Korea | National TM policy 1969 | Oriental Medicine Bureau | Regulation — Yes Pharmacopoeia includes herbs | Oriental doctors 9 914 Acupuncturists 4 500 | 107 oriental medical hospitals and 6 590 local oriental medical clinics | Full | 1 national research institute | 11 oriental medicine universities |
| Viet Nam | National TM policy 1955 | Department of TM | Regulation — Yes List of essential drugs includes herbal medicines State manufacturers 2 | TM doctors 25 500 Acupuncturists 20 000 TM practitioners 5 000 | 48 hospitals with TM department | Full | 3 national research institutes | TM faculty in 3 medical colleges, 2 medical technology schools of TM |

Sources: compiled from government reports to World Health Organization.

Table 3 Examples of countries with an inclusive approach to TM/CAM

| | National policy on TM/CAM | TM/CAM unit or department within ministry of health | Regulation of TM or herbal products or of both TM and herbal products | TM/CAM practised at all levels including public hospitals, TM/CAM are integrated into national health system) | Health insurance coverage for treatment and products | TM/CAM research institute at national or university level | Official education at university level, covering both TM + AM for doctors, pharmacists and nurses |
|----------------------|---------------------------|---|---|---|--|---|---|
| India | Yes | Yes | Both | Yes in some hospitals | No | Yes | Yes |
| Sri Lanka | Yes | Yes | Both | No | No | No | No |
| Indonesia | Yes | Yes | Both | Yes, in some state hospitals | No | Yes | No |
| Japan | No | No | Both | Yes, in some state hospitals | Yes | Yes, in some prefectures | No |
| Australia | No | Yes, in some states | Herbal products | Yes, in some state hospitals | Partial | No | Yes |
| United Arab Emirates | No | No | Both | Yes, in some state hospitals | No | Yes | No |
| Germany | No | No | Both | Yes, in some state hospitals | Partial | Yes | No |
| Norway | Yes | Staff in charge | Both | Yes, in some state hospitals | Partial | Yes, in one state university | No |
| United Kingdom | Yes | No | Both | Yes, in some state hospitals | Partial | No | No, in preparation |
| Canada | Yes | Yes | Both | Yes, in some state hospitals | Partial | Yes, in some state universities | No |
| USA | No | No | Both | Yes, in some state hospitals | Partial | Yes, NCCAM and in some state universities | No |
| Ghana | Yes | Yes | Both | No | No | Yes | No |
| Nigeria | Yes | Yes | Both | Yes | No | Yes | No |

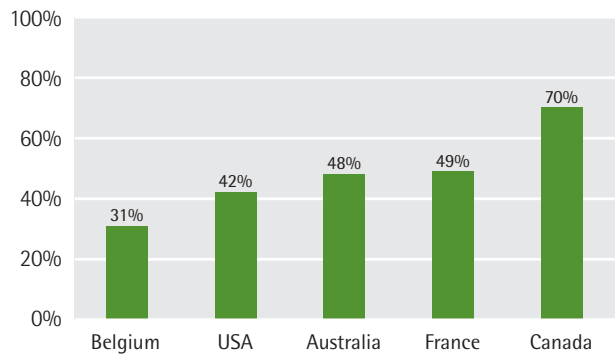
Sources: compiled from government reports to World Health Organization.

In many Asian countries TM continues to be widely used, even though allopathic medicine is often readily available. In Japan, 60–70% of allopathic doctors prescribe kampo medicines for their patients. In Malaysia, traditional forms of Malay, Chinese and Indian medicine are used extensively. In China, TM accounts for around 40% of all health care delivered, and is used to treat roughly 200 million patients annually.⁴ For Latin America, the WHO Regional Office for the Americas (AMRO/PAHO) reports that 71% of the population in Chile and 40% of the population in Colombia have used TM.⁵

In many developed countries, certain CAM therapies are very popular. Various government and non-government reports (Figure 3) state that the percentage of the population that has used CAM is 46% in Australia, 49% in France and 70% in Canada.^{6,7,8} A survey of 610 Swiss doctors showed that 46% had used some form of CAM, mainly homeopathy and acupuncture. This is comparable to the CAM figure for the Swiss

population as a whole.⁹ In the United Kingdom, almost 40% of all general allopathic practitioners offer some form of CAM referral or access.¹⁰ In the USA, a

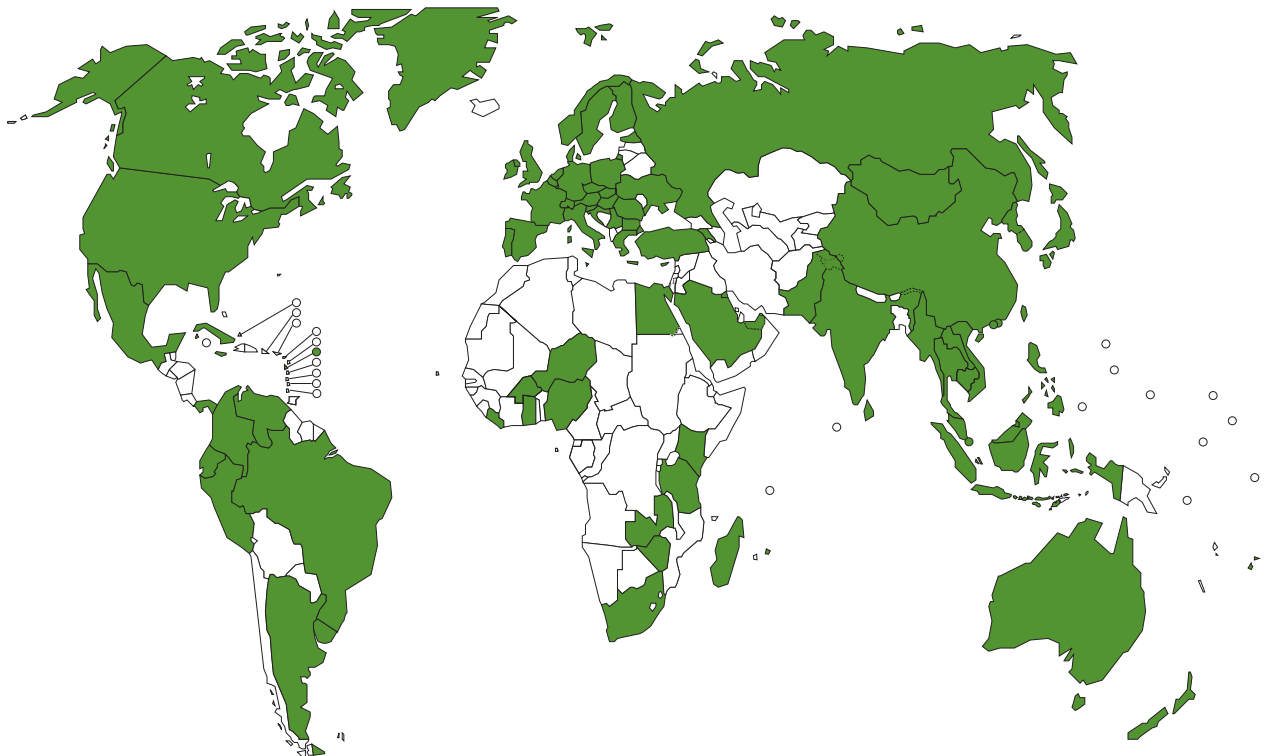
Figure 3
Percentage of population which has used CAM at least once in selected developed countries



Sources: Fisher P & Ward A, 1999; Health Canada, 2001, World Health Organization, 1998.^{7,8,6}

national survey reported in the *Journal of the American Medical Association* indicated that use of at least 1 of 16 alternative therapies during the previous year increased

Figure 4
Countries where acupuncture is practised by allopathic doctors only, or by both allopathic doctors and acupuncturists



Sources: World Federation of Acupuncture-Moxibustion Societies, 2000; World Health Organization, in press.^{11,12}

from 34% in 1990 to 42% in 1997.¹³ The number of visits to CAM providers now exceeds by far the number of visits to all primary care physicians in the US.

Acupuncture is especially popular. Originating in China, it is now used in at least 78 countries and practised not only by acupuncturists, but also by allopathic practitioners (Figure 4). According to the World Federation of Acupuncture-Moxibustion Societies, there are at least 50 000 acupuncturists in Asia. In Europe, there are an estimated 15 000 acupuncturists, including allopathic doctors who also practise as acupuncturists. In Belgium, 74% of acupuncture treatment is administered by allopathic doctors. In Germany, 77% of pain clinics provide acupuncture. In the United Kingdom, 46% of allopathic doctors either recommend patients for acupuncture treatment or treat their patients with acupuncture themselves. The USA has 12 000 licensed acupuncturists – the practice of acupuncture is legal in 38 states and six states are developing acupuncture practice policies.^{11,14,15}

out-of-pocket expenditure for self-treatment with TM/CAM is even more scant. But some figures are available and, with TM/CAM gaining in use worldwide, public and private expenditure is clearly on the increase. In Malaysia, an estimated US\$ 500 million is spent annually on TM/CAM, compared to about US\$ 300 million on allopathic medicine.⁶ In the USA, total 1997 out-of-pocket CAM expenditure was estimated at US\$ 2700 million, which was comparable to the projected 1997 out-of-pocket expenditure for all physician services.¹³ In the United Kingdom, annual CAM expenditure is estimated at US\$ 2300 million respectively.¹⁶ In Canada, it is estimated that a total of US\$ 2400 million was spent in 1997–1998 on CAM.⁸

The world market for herbal medicines based on traditional knowledge is now estimated at US\$ 60 thousand million.¹⁷ In the USA, herbal sales increased by 101% in mainstream markets between May 1996 and May 1998. The most popular herbal products include ginseng, *Ginkgo biloba*, garlic, *Echinacea* spp. and St. John's wort (Table 4).¹⁸

Table 4

Increase in sales of the most popular herbal products in the USA 1997–1998

| Herb | Sales in US\$ million 1997 | 1998 | % increase in sales |
|--------------------------|-------------------------------|------|------------------------|
| Total herbal supplements | 292 | 587 | 101 |
| Echinacea | 33 | 64 | 96 |
| Garlic | 66 | 81 | 24 |
| <i>Ginkgo biloba</i> | 52 | 126 | 143 |
| Ginseng | 76 | 96 | 26 |
| St. John's wort | 1 | 103 | 102 |
| Other herbs | 64 | 118 | 85 |

Source: data from Scanner Data, FDM, Inc., USA.¹⁸

1.3 Expenditure

Reports on total national expenditure on TM/CAM are scarce. Information on national

1.4 Accounting for use and increasing interest

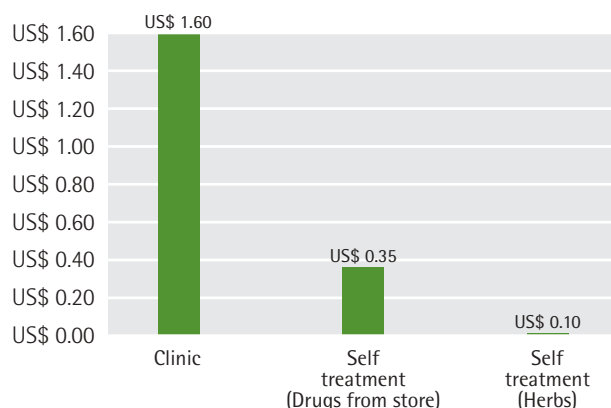
Accessible and affordable in developing countries

In some developing countries TM is much more widely available than allopathic medicine. In Tanzania, Uganda and Zambia, researchers have found a ratio of TM practitioners^f to population of 1:200–1:400. This contrasts starkly with the availability of allopathic practitioners, where the ratio is typically 1:20 000 or less.^{19,20} A 1991 survey by the US Agency for International Development found that, in sub-Saharan Africa, traditional practitioners outnumber allopathic practitioners by 100 to 1.²¹ Moreover,

^f TM practitioners are generally understood to be traditional healers, bone setters, herbalists, etc. TM providers include both traditional medicine practitioners and allopathic medicine professionals such as doctors, dentists and nurses who provide TM/CAM therapies to their patients. E.g. many medical doctors also use acupuncture to treat their patients.

allopathic practitioners are located primarily in cities or other urban areas. So for many rural populations TM is the only available source of health care. Surveys conducted by the WHO Roll Back Malaria Programme in 1998 showed that in Ghana, Mali, Nigeria and Zambia, more than 60% of children with high fever are treated at home with herbal medicines.^{22,23,24,25} One of the key reasons cited for this was the ready accessibility of herbal medicines in rural areas. (See also Figure 5.)

Figure 5
Malaria treatment in Ghana with herbal medicines is considerably cheaper than other forms of health care



Source: adapted from Ahorlu C et al., 1997.²⁶

TM is also sometimes the only affordable source of health care – especially for the poorest patients. In Ghana, Kenya and Mali, research has shown that a course of pyrimethamine/sulfadoxine antimalarials can cost several dollars. Yet total out-of-pocket health expenditure in Ghana and Kenya is only around US\$ 6 per capita per year. In other words, some populations simply cannot afford chemical drugs.²⁷ On the other hand, herbal medicines may be not only relatively cheap but payable in kind and/or according to the “wealth” of the client. Similarly in Salvador, the fee for treating a child for diarrhoea as an out-patient

at a public hospital – including consultation fee and medication – can be as high as US\$ 50. Treatment by a TM practitioner may be no more than US\$ 5 or payable in kind.²⁸

Greater accessibility to TM practitioners – and confidence in their ability to manage debilitating, incurable disease – probably explain why most Africans living with HIV/AIDS use traditional herbal medicines to obtain symptomatic relief and to manage opportunistic infections. Frequently, TM practitioners are well known in their communities for their expertise in health care and prevention of many sexually-transmitted diseases.⁹ At the same time, TM is often embedded in wider belief systems and continues to be an integral and important part of many people’s lives. UNAIDS is therefore advocating collaboration with TM practitioners in AIDS prevention and care in sub-Saharan Africa.^{29,30}

“It was argued at [a] UNAIDS-sponsored meeting in Kampala [in June 2000] that traditional medicine is in a real sense carrying the burden of clinical care for the AIDS epidemic in Africa. This trend has been largely overlooked by health ministries and international agencies.”³¹

TM is also commonly used in developing countries in Asia. The Indian Government has reported that for 65% of its population, TM is the only available source of health care. In some Asian countries, governments are actively promoting TM. The Ministry of Health of the Lao People’s Democratic Republic, is encouraging use of TM, including broad distribution among communities of the report, *Medicines in Your Garden*. In

⁹ Researchers in some countries have noted that some other illnesses and conditions not classified as sexually transmitted in biomedical nosology may be locally regarded as such by traditional healers and their clients.

Thailand, the Ministry of Health is working to enhance people's awareness and greater use of medicinal plants for primary health care. This has included publication of the *Manual of Medical Plants for Primary Health Care*.

An alternative or complementary approach to health care in developed countries

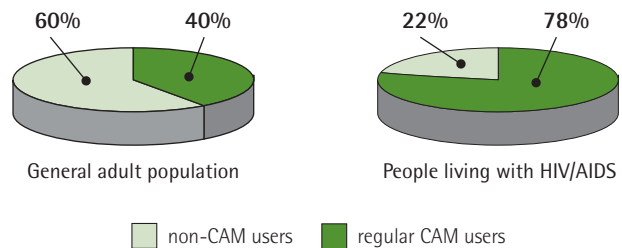
In many developed countries, increased use of CAM indicates that factors other than tradition and cost are at work. Concern about the adverse effects of chemical drugs, questioning of the approaches and assumptions of allopathic medicine, greater public access to health information, changing values and reduced tolerance of paternalism are just some of them.^{16,32}

“Traditional medicine is based on the needs of individuals. Different people may receive different treatments even if, according to modern medicine, they suffer from the same disease. Traditional medicine is based on a belief that each individual has his or her own constitution and social circumstances which result in different reactions to “causes of disease” and treatment.”⁶

At the same time, longer life expectancy has brought with it an increased risk of developing chronic, debilitating diseases such as heart disease, cancer, diabetes and mental disorders.²⁷ Although allopathic treatments and technologies are abundant, some patients have found that these have not provided a satisfactory solution. Treatments and technologies have not been sufficiently effective or have caused adverse effects. A national survey in the USA showed that the majority of CAM users do not in fact perceive CAM as “alternative to” but rather as “complementary to” allopathic medicine.³³

A recent survey showed that 78% of patients living with HIV/AIDS in the USA use some form of CAM (Figure 6).^{34,35,36}

Figure 6
Use of CAM by patients living with HIV/AIDS in the USA



Sources: Anderson W et al., 1993; Mason F, 1995; Ostrow MJ et al., 1997.^{34,35,36}

In developed country surveys of health-seeking behaviour and consumer satisfaction, a high degree of appreciation of the quality of care offered by CAM providers has been noted. The perceived relatively low risks associated with the use of procedural-based therapies of TM may also contribute to their

“It is imperative to acknowledge and affirm the essential role of conventional medicine with its capability to respond competently in the care of acute disease and trauma, its technical innovations in diagnosis and treatment and the escalating clinical applications of basic science discoveries. However, it is in the areas of comprehensive care and the management of chronic disease conditions that the more reductionistic, mechanistic, and organ-specific approach of conventional medicine can be lacking.”³⁷

popularity. In an analysis of data on malpractice for 1990–1996 in the USA, claims against chiropractors, massage therapists and acupuncturists were generally found to occur less frequently, and usually involved

less severe injury, than claims against medical doctors. In a worldwide literature search, only 193 adverse events following acupuncture (including relatively minor events such as bruising and dizziness) were identified for a 15-year period.³⁸

1.5 Responding to the popularity of TM/CAM

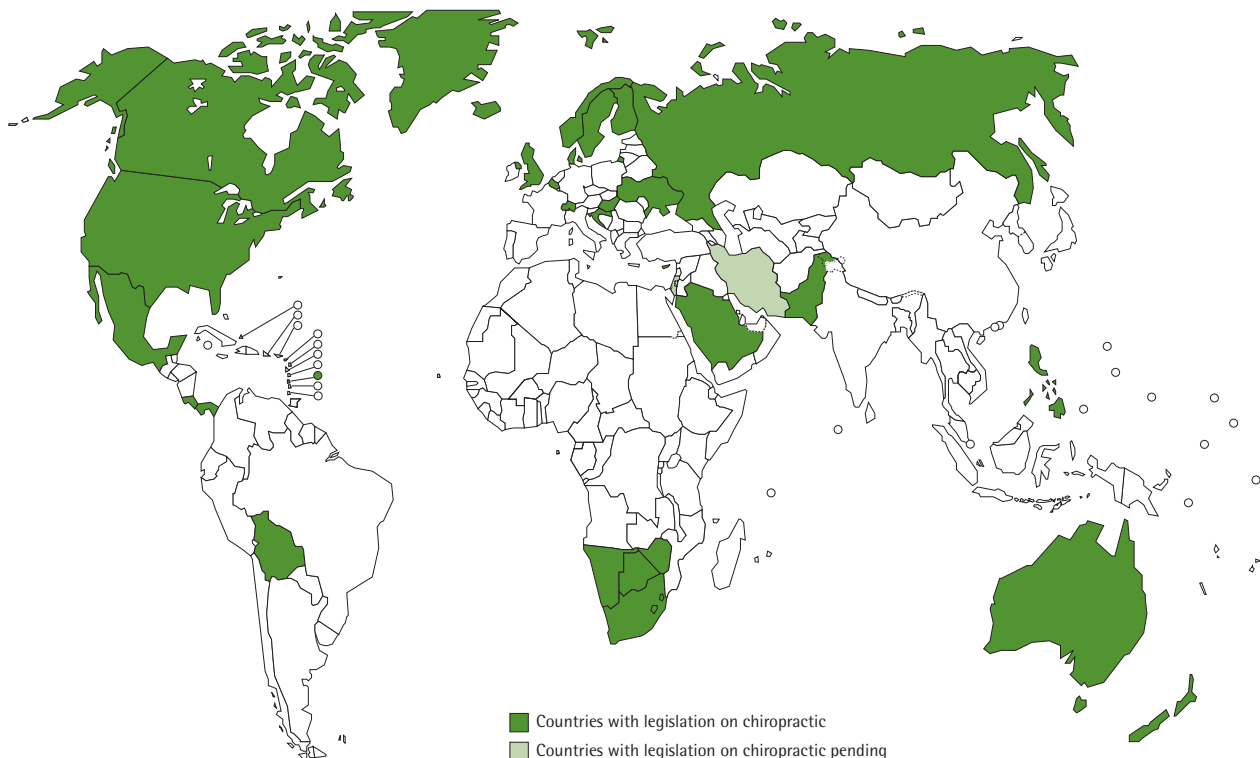
Governments are responding to the growing use of TM/CAM. Several countries are currently developing regulations for the practice of chiropractic, while 24 countries already have such regulations (Figure 7). Others are working to regulate herbal medicines – the number of WHO Member States with regulations related to herbal medicines increased from 52 in 1994 to 64 in 2000 (Figure 8). In 2000 alone, regulations on herbal medicines were developed by Australia, Canada, Madagascar, Nigeria

and the USA. (WHO assisted both Madagascar and Nigeria in developing its regulations.) In some countries, structures, budget and training in TM/CAM are growing steadily (Table 5).

The growing number of national TM research institutes in developing countries is also a sign of the growing importance of TM. In fact, most developing countries now have national TM research institutes. Notable examples are found in China, Ghana, the Democratic People's Republic of Korea, the Republic of Korea, India, Mali, Madagascar, Nigeria, Thailand, Indonesia, the Lao People's Democratic Republic, Sri Lanka and Viet Nam. (See also Figure 9.)

Meanwhile, in developing countries, responses to the popularity of CAM are becoming more and more extensive. In 1995, the Norwegian Parliament examined how CAM could best be incorporated into the Norwegian health service. This included

Figure 7
Chiropractic laws are now widespread



Source: reported by World Federation of Chiropractic and World Chiropractic Alliance in 2000.^{39,40}

Figure 8
More and more countries are regulating herbal medicines



Source: World Health Organization, 1998⁴¹ and data collected by World Health Organization during period 1999–2001.

consideration of: certification for professional training and education in CAM, and documenting CAM treatments. In 1997, the Ministry of Health and Social Affairs established a committee to look at various aspects of CAM. Its report proposed repeal of the Act Relating to Quackery, and creation of a registration system for CAM providers. It also proposed allocating funds over a five-year period, to increase knowledge of CAM, and promote cooperation between CAM providers and Norway's health care system.⁴² This last was followed up at international level in 1999 by the *Memorandum of Understanding on Cooperation in Health* signed by the Ministers of Health of the People's Republic of China and Norway. The agreement seeks to promote health and health services in both countries, focusing on TM/CAM and development, regulation and organization of hospitals.

CAM provision and use has also been officially reviewed in the United Kingdom, following growing concerns about its

Figure 9
Many African countries have institutes that carry out TM research



Source: World Health Organization, 2000.³

Table 5

A growing number of African countries have established structures, budget and training in TM

| Country | A legal framework for TM | A national management or coordination body | Association(s) of traditional practitioners | Directory of traditional practitioners | National budget allocation for TM |
|------------------------|--------------------------|--|---|--|-----------------------------------|
| Angola | | ● | ● | ● | |
| Botswana | | | ● | | |
| Burkina Faso | ● | ● | ● | | |
| Cameroon | | | ● | ● | |
| Côte d'Ivoire | ● | ● | ● | | ● |
| Dem. Rep. of the Congo | ● | ● | | | |
| Equatorial Guinea | ● | ● | ● | | |
| Eritrea | | | | | ● |
| Ethiopia | ● | | ● | | ● |
| Gambia | | | | ● | |
| Ghana | ● | ● | ● | | ● |
| Lesotho | ● | ● | ● | ● | |
| Madagascar | ● | ● | ● | ● | |
| Malawi | | ● | ● | | |
| Mali | ● | ● | ● | ● | ● |
| Mauritania | | | ● | | |
| Mozambique | ● | | ● | | |
| Namibia | ● | ● | ● | | |
| Niger | ● | ● | ● | ● | |
| Nigeria | ● | ● | ● | | ● |
| Rwanda | | ● | ● | ● | ● |
| Sao Tome & Principe | ● | ● | ● | | |
| Senegal | | | ● | | ● |
| Zambia | ● | ● | ● | ● | |
| Zimbabwe | ● | ● | ● | ● | |

Source: World Health Organization, 2000.³

safety. Currently – with the exception of osteopathy and chiropractic, which are protected by statute – anyone can practise CAM without any training. In 1999, the House of Lords requested the Committee on Science and Technology to make a survey of this type of health care. The committee recommended creation of a central mechanism (funded by government and charitable resources) to coordinate, advise and oversee training on research into CAM. Secondly, it suggested that the National Health Service Research and Development Directorate, and

the Medical Research Council, dedicate research funding to create centres of excellence for CAM research, using the US National Center for Complementary and Alternative Medicine (see next page) as a model.¹⁶

Increased CAM training and education opportunities in the United Kingdom also reflect increased interest in this type of health care. Training in acupuncture, for example, is provided in more and more academic settings. And CAM courses are

also being offered to medical students, although they tend to provide an academic introduction only, rather than teach specific clinical skills. The proportion of medical schools in the United Kingdom offering such courses rose from 10% to 40% between 1995 and 1997.⁴³ In the USA, a large number of medical schools now have elective classes and CAM seminars.⁴⁴

In developed countries, funding and establishment of CAM research and research units at sites of research excellence is likewise increasing. In the United Kingdom, the National Health Service recently funded two trials of acupuncture for treating chronic pain, while in Germany, a centre for CAM research at the Technische Universität in Munich has produced a series of important systematic reviews.⁴³

In the USA, in 1992, US Congress established the Office for Alternative Medicine in the National Institutes of Health (see <http://nccam.nih.gov/>). The mandate of this Office

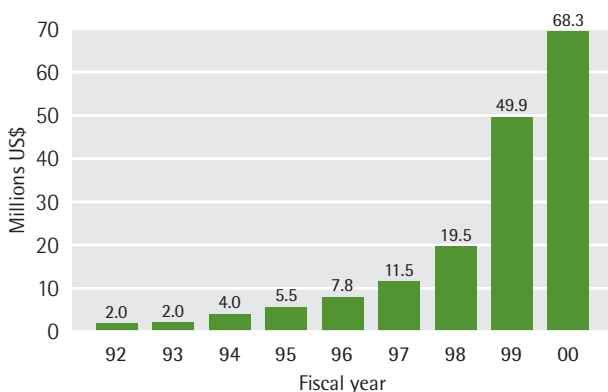
House Commission on Alternative Medicine. Created by an executive order on 8 March 2000, the Commission is charged with developing a set of legislative and administrative recommendations to maximize the benefits of CAM for the general public. It has ten members, including senators and experts.

The USA also has a large number of units for CAM research, based at research institutions such as the University of Maryland, Columbia University in New York, Harvard University in Massachusetts, and the Memorial Sloan-Kettering Cancer Center in New York.⁴³

International activity in TM/CAM is also becoming more prominent. The European Union (EU) recently completed a COST (European Cooperation in the field of Scientific and Technical research) project on "unconventional medicine". And in a 1999 EU Parliamentary Assembly (entitled *A European Approach to Non-conventional Medicines*), Member States were called upon to promote official recognition of CAM in medical faculties, to encourage its use in hospitals, and to encourage allopathic doctors to study CAM at university level.⁴⁶ Also in Europe, the European Agency for the Evaluation of Medicinal Products (EMA) works on the quality, safety and efficacy of herbal medicinal products. An Ad Hoc Working Group on Herbal Medicinal Products was established by the EMA in 1997. (See also Chapter 4).

More recently, the *Abuja Declaration on Roll Back Malaria*, signed by the African heads of state and governments of 53 countries in 2000, recognized the important contribution that TM makes to fighting malaria. The *Declaration* includes a request to governments to ensure the effectiveness of such treatment, and to make it available and accessible to the poorest groups in communities.

Figure 10
CAM funding is increasing significantly in the USA



Source: National Center for Complementary and Alternative Medicine, 2000.⁴⁵

was extended in 1999, with the Office becoming the National Center for Complementary and Alternative Medicine (NCCAM). NCCAM has received progressive budget increases – by 2000, its budget had risen to US\$ 68.4 million (Figure 10). Concurrently in 2000, the White House set up the White

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M/CAM has many positive features including: diversity and flexibility; accessibility and affordability in many parts of the world; broad acceptance among many populations in developing countries; increasing popularity in developed countries; comparatively low cost; low level of technological input; and growing economic importance. These can all be seen as opportunities to be maximized.

But other features of this type of health care can be regarded as challenges to be overcome. They include: the varying degree with which it is recognized by governments; the lack of sound scientific evidence concerning the efficacy of many of its therapies; difficulties relating to the protection of indigenous TM knowledge; and problems in ensuring its proper use.

WHO's broad range of TM/CAM expertise means that it is well placed to help tackle many of these challenges. Indeed, WHO Member States are increasingly and repeatedly requesting more assistance and guidance on TM/CAM issues – as expressed, for example, during WHO Regional Committee meetings, at the International Conferences of Drug Regulatory Authorities (ICDRAs) and at international government forums.

In 2000, the WHO Regional Committee for Africa, attended by 25 ministers of health, requested support for: creation of an enabling environment for TM; development of guidelines for formulating and evaluating national policies on TM; and development

of mechanisms for improving the economic and regulatory environments for local production of traditional medicines.² Similar requests were also made by WHO's Regional Office for South-East Asia (SEARO) in 1999⁴⁷ and by the Government Forum on Traditional Medicine in China in 2000, and by the 9th ICDRA meeting in 1999.

Some challenges are common to regions. For example, the Chinese and Indian Governments are concerned with how best to use TM to strengthen primary health care in remote areas. In Africa, many countries are seeking means of making best use of local TM resources and how to make TM an integrated component of minimal health care packages. For European WHO Member States, safety and quality, licensing of providers and standards of training, methodologies, and priorities for research, have rapidly become issues of great importance.

2.1 What needs to be done?

The most important issues to be tackled are outlined in Table 6 and fall into four categories:

- national policy and regulatory frameworks
- safety, efficacy and quality
- access
- rational use.

Table 6

TM/CAM challenges fall into four categories

| | |
|--|--|
| National policy and regulatory frameworks | <ul style="list-style-type: none"> • Lack of official recognition of TM/CAM and TM/CAM providers • TM/CAM not integrated into national health care systems • Lack of regulatory and legal mechanisms • Equitable distribution of benefits of indigenous TM knowledge and products • Inadequate allocation of resources for TM/CAM development and capacity building |
| Safety, efficacy and quality | <ul style="list-style-type: none"> • Lack of research methodology • Inadequate evidence-base for TM/CAM therapies and products • Lack of international and national standards for ensuring safety, efficacy and quality control of TM/CAM therapies and products • Lack of adequate regulation and registration of herbal medicines • Lack of registration of TM/CAM providers • Inadequate support for research |
| Access | <ul style="list-style-type: none"> • Lack of data measuring access levels and affordability • Need to identify safe and effective therapies and products • Lack of official recognition of role of TM/CAM providers • Lack of cooperation between TM/CAM providers and allopathic practitioners • Unsustainable use of medicinal plant resources |
| Rational use | <ul style="list-style-type: none"> • Lack of training for TM/CAM providers and on TM/CAM for allopathic practitioners • Lack of communication between TM/CAM and allopathic practitioners, and between allopathic practitioners and consumers • Lack of information for public on rational use of TM/CAM |

2.2 National policies and legal framework

Although TM/CAM is widely used in the prevention, diagnosis, treatment and management of disease, very few countries have developed a national TM/CAM policy.

“Without critical assessment of what should be integrated and what should not, we risk developing a health care system that costs more, is less safe, and fails to address the management of chronic disease in a publicly responsible manner.”³²

Yet such policies are needed in order to define the role of TM/CAM in national health care delivery systems and how it can contribute to health sector reform. They can also ensure that the necessary regulatory

and legal mechanisms are in place for promoting and maintaining good practice, that access to TM/CAM is equitable, and that the authenticity, safety and efficacy of any therapies used are assured. Without such policies, TM/CAM is practised without government oversight and without patient/consumer protection.

TM/CAM policies should therefore cover a range of issues, including: legislation and regulation for herbal products and practice of therapies; education, training and licensing of providers; research and development; and allocation of financial and other resources (Table 7.) In brief, sound TM/CAM policies can increase the types of safe and effective health care available to patients and consumers. To date, only 25 of WHO’s 191 Member States have developed a national TM/CAM policy.

Attention should also be paid to intellectual property issues if the country concerned has a wealth of indigenous TM knowledge and/or natural resources that are used in TM/CAM products. Some groups recommend protecting TM under existing or new forms of intellectual property rights. Others object to this suggestion for ethical or economic reasons. Nevertheless, "biopiracy" – the unauthorized appropriation of TM knowledge and materials – is largely condemned. Clearly, when drafting national TM/CAM policies, the objectives and implications of intellectual property right protection should be thoroughly considered.⁴⁸

Table 7

Key elements to include in a national policy on TM/CAM

- Definition of TM/CAM.
- Definition of government's role in developing TM/CAM.
- Provision for safety and quality assurance of TM/CAM therapies and products.
- Provision for creation or expansion of legislation relating to TM/CAM providers and regulation of herbal medicines.
- Provision for education and training of TM/CAM providers.
- Provision for promotion of proper use of TM/CAM.
- Provision for capacity building of TM/CAM human resources, including allocation of financial resources.
- Provision for coverage by state health insurance.
- Consideration of intellectual property issues.

Indeed, great caution generally should be exercised when developing TM/CAM policies. Careful assessment has first to be made of the use and practice of TM/CAM in the relevant country and the most appropriate means of using TM/CAM to help meet its health care goals. National policies should benefit patients using TM/CAM therapies. They fail to provide this benefit if they are: unable to ensure the safety, efficacy and quality of TM/CAM products and practices; unduly restrict the practice of TM/CAM; lead to higher health care costs; unjustifiably hinder patient treatment options; or reduce the ability of allopathic medicine practitioners to cross-refer patients.

2.3 Safety, efficacy, quality

Allopathic medicine is based on Western culture. Practitioners therefore emphasize its scientific approach, and contend that it is both value-free and unmarked by cultural values. TM/CAM therapies have developed rather differently, having been very much influenced by the culture and historical conditions within which they first evolved. Their common basis is an holistic approach to life, equilibrium between the mind, body and their environment, and an emphasis on health rather than on disease. Generally, the practitioner focuses on the overall condition of the individual patient, rather than on the particular ailment or diseases from which he or she is suffering.



"The quantity and quality of the safety and efficacy data on traditional medicine are far from sufficient to meet the criteria needed to support its use worldwide. The reasons for the lack of research data are due not only to health care policies, but also to a lack of adequate or accepted research methodology for evaluating traditional medicine. It should also be noted that there are published and unpublished data on research in traditional medicine in various countries, but further research in safety and efficacy should be promoted, and the quality of the research... improved."⁴⁹

This more complex approach to health care makes TM/CAM very attractive to many. But it also makes evaluation highly difficult since so many factors must be taken into account. And since TM/CAM practices have

developed within different cultures in different regions, there has been no parallel development of standards and methods – either national or international – for undertaking evaluation. Moreover, CAM providers may come from a cultural and philosophical background that differs radically from that surrounding the original development of a therapy. This can lead to problems of interpretation and application. Understandably, therefore, allopathic medicine practitioners in some countries have been reluctant to refer patients to CAM providers. (This in turn has made health insurance schemes unwilling to reimburse CAM treatments, effectively reducing patients' choice of health care.)

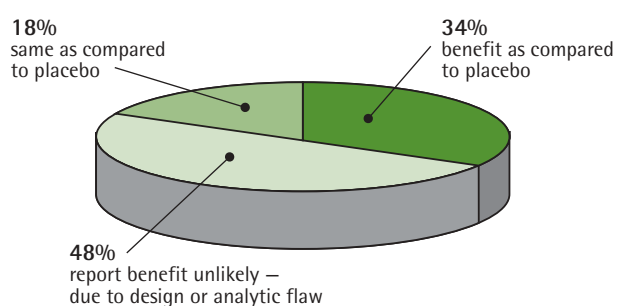
Evaluation of TM/CAM products, such as herbal medicines, is especially difficult. Accuracy of plant identification is essential, as is isolation of active ingredients. The latter is complex, though, because medicinal plant properties are influenced by the time of plant collection and area of plant origin (including environmental conditions). At the same time, a single medicinal plant can contain hundreds of natural constituents. Establishing which constituent is responsible for what effect can therefore be prohibitively expensive. Yet given the worldwide popularity of herbal medicines, a widely applicable, appropriate and effective means of evaluating herbal medicines with limited resources is urgently needed.

Research, research methodology and cost-effectiveness

It is perhaps not surprising that reviews have shown that clinical trials have been few, small and inadequately controlled. The Cochrane Complementary Field (see Chapter 4) found that articles indexed as "alternative medicine" formed only 0.4% of the total number of MEDLINE-listed articles for the period 1966–1996. (However, the annual total was steadily increasing during

this period and the growing proportion of reports of randomized clinical trials (RCTs) suggested a trend towards an evidence-based medicine approach.) Only some of the RCTs reported included costs (incurred for the therapy in question, and including cost of consultation, materials used, etc.). In fact, very few reliable and full economic analyses of TM/CAM have been made.

Figure 11
Good evidence of efficacy exists for some herbal medicines – but too often evaluation is inadequate



% of randomized clinical trials (RCTs) showing benefit of herbal medicines (based on 50 RCTs with 10 herbal medicines for 18 therapeutic indications)

Source: based on data in Herbal Medicines: an Evidence-based Look. Therapeutics Letter, Issue 25, June–July 1998.

The failure to support research in this area over recent years has resulted in a lack of data and development of methodology for evaluating the safety, efficacy and quality of TM/CAM. Yet there are indications that at least some commonly used alternative therapies – for instance, some herbal medicines, manipulative therapies and behavioural stress-reduction techniques, such as transcendental meditation – can provide effective management for chronic disease (Box 2). Box 3 indicates some of the more detailed cost-effective analysis that is beginning to be undertaken. More firm evidence along these lines would be of enormous assistance in presenting arguments for greater recognition and application of TM/CAM. Indeed, it will be a prerequisite if access to TM/CAM is to be promoted and extended, and rational use of this type of health care ensured.

Box 2

PROMISING POTENTIAL

Herbal medicines and acupuncture are the most widely-used TM/CAM therapies. Reports of investigations of their clinical efficacy have been published in prestigious international scientific journals. The efficacy of acupuncture in relieving pain¹⁰ and nausea,⁵⁰ for instance, has been conclusively demonstrated and is now acknowledged worldwide.

For herbal medicines, some of the best-known evidence for efficacy of a herbal product, besides that for *Artemisia annua* for the treatment of malaria, concerns St John's wort for the management of mild to moderate depression. Patients usually experience fewer side-effects than when treated with antidepressants, such as amitriptyline. Such findings have inspired research worldwide to establish the efficacy of other extensively-used TM/CAM. In laboratory settings, plant extracts have

been shown to have a variety of pharmacological effects, including anti-inflammatory, vasodilatory, antimicrobial, anticonvulsant, sedative and antipyretic effects.¹⁰ However, almost no randomized-controlled studies have been carried out to investigate the practice and treatment delivery of herbal practitioners in their everyday work. This also applies to most other TM/CAM therapies.

Regarding non-medication therapies, the 1999 *British Medical Journal* series on CAM commented that randomized controlled trials have provided good evidence that both hypnosis and relaxation techniques can reduce anxiety, and prevent panic disorders and insomnia. Randomized trials have also shown hypnosis to be of value in treating asthma and irritable bowel syndrome, yoga to be of benefit in asthma, and tai ji in helping elderly people to reduce their fear of falls.¹⁰

Box 3

STUDYING CAM COST-EFFECTIVENESS IN PERU

A study undertaken by Peru's National Programme in Complementary Medicine and the Pan American Health Organization compared CAM practices to allopathic medicine practices, as used in clinics and hospitals operating within the Peruvian Social Security System.

The relative effectiveness of CAM was evaluated in terms of:

- ❖ observed clinical efficacy
- ❖ user/patient satisfaction
- ❖ reduction of future medical risk associated with a lifestyle change.

Treatments were compared for selected pathologies, of the same degree of severity, as registered in case histories and/or clinical evaluations.

A total of 339 patients – 170 being treated with CAM and 169 with allopathic medicine – were followed for one year. Treatments for the following pathologies were analysed: moderate osteoarthritis; back pain; anxiety-based neuroses; light or intermittent asthma; peptic acid disease; tension migraine headache; exogenous obesity; and peripheral facial paralysis.

The conclusions (95% significance) can be summarized as follows:

1. The overall average of direct costs using CAM was less than that incurred using conventional therapy. (To evaluate the direct costs of both systems, costs actually incurred during treatment of each one of the selected pathologies were calculated and compared.)
2. For each of the criteria evaluated – clinical efficacy, user satisfaction and future risk reduction – CAM's efficacy was higher than that of conventional treatments, including:
 - ❖ fewer side-effects
 - ❖ higher correlation between patient perception of efficacy and clinical observation of efficacy
 - ❖ higher recognition among patients of the role played by medical systems in solving health problems.
3. The overall cost-effectiveness of CAM was 53–63% higher than that of conventional treatments for the selected pathologies.

Source: *EsSalud & Pan American Health Organization, 2000.*⁵¹

Ensuring safety and quality at national level

Low levels of research activity have also slowed development of national standards for ensuring the safety and quality of TM/CAM therapies and products. In particular, lack of technical guidance and information has hindered development of regulation and registration for herbal medicines. This in turn has slowed development of, for example, national surveillance systems for monitoring and evaluating adverse events. The fact that only 3% of 771 cases of counterfeit drugs reported to WHO by April 1997 involved herbal medicines might be a reflection of this low level of monitoring, rather than an indication that adverse effects from herbal medicines are few.⁵²

Table 8

Key needs in ensuring the safety, efficacy and quality of TM/CAM

At national level:

- National regulation and registration of herbal medicines.
- Safety monitoring for herbal medicines and other TM/CAM.
- Support for clinical research into use of TM/CAM for treating country's common health problems.
- National standards, technical guidelines and methodology, for evaluating safety, efficacy and quality of TM/CAM.
- National pharmacopoeia and monographs of medicinal plants.

At global level:

- Access to existing knowledge of TM/CAM through exchange of accurate information and networking.
- Shared results of research into use of TM/CAM for treating common diseases and health conditions.
- Evidence-base on safety, efficacy and quality of TM/CAM products and therapies.

Determining research needs

The 6th report from the Committee on Science and Technology to the House of Lords cites a number of problems relating to CAM research in the United Kingdom. They can be taken as applying to research problems in the field in general. The Committee found a poor research infrastructure

and concluded that research is often of poor quality because research ethics are not well understood, sound methodology is lacking, resources are in short supply and researchers are unwilling to evaluate evidence. A summary of key needs in ensuring the safety, efficacy and quality of TM/CAM is given in Table 8.

Some priority areas for research are outlined in Table 9.

Table 9

Priority areas for research

- Effects of each individual therapy: efficacy, safety and cost-effectiveness.
- Research into mechanisms of action of individual therapies, including patterns of response to treatment.
- Research into TM/CAM genre itself, including social research into motivation of patients seeking TM/CAM and usage patterns of TM/CAM.
- Research into new research strategies which are sensitive to the TM/CAM paradigm.
- Research into efficacy of diagnostic methods used.
- Research into implementation and effects of TM/CAM in specific health care settings.

Source: House of Lords, 2000.¹⁶

2.4 Access

Statistics demonstrate overwhelmingly that it is the world's poorest countries who are most in need of inexpensive, effective treatments for communicable diseases. Of the 10.5 million children who died in 1999, 99% came from developing countries. Over 50% of children's deaths in developing countries are due to just five infectious diseases. Similarly, 99% of the two million tuberculosis deaths each year occur in developing countries, and 80% of the current 30 million people living with HIV/AIDS live in sub-Saharan Africa.⁵³



At the same time, access to modern essential chemical drugs is lowest where people are suffering

most from communicable diseases. The reasons are well known and include inadequate financing and poor health care delivery. In developing countries, however, TM can be comparatively inexpensive. Additionally, TM practitioners may be widely trusted and respected providers of health care, albeit not necessarily officially recognized.

If access to TM is to be increased to help improve health status in developing countries, however, several problems must be tackled (Table 10). Firstly, reliable standard indicators to accurately measure levels of access – both financial and geographic – to TM must be developed. Qualitative research to help identify constraints to extending access should also be undertaken.

Table 10

Key needs in increasing availability and affordability of TM/CAM

At national and global levels:

- Identification of safest and most effective TM/CAM therapies and products (including: evidence that the therapy is effective; evidence that the therapy is safe; evidence that the therapy is cost-effective).
 - Research into safe and effective TM/CAM treatment for diseases that represent the greatest burden, particularly for poorer populations.
 - Recognition of role of TM practitioners in providing health care in developing countries.
 - Optimized and upgraded skills of TM practitioners in developing countries.
 - Indigenous TM knowledge protected and preserved.
 - Sustainable cultivation of medicinal plants.
-

Secondly, the safest and most effective TM therapies must be identified, to provide a sound basis for efforts to promote TM. The focus should be on treatments for diseases that represent the greatest burden for poor populations. This means focusing on the development of antimalarials, and HIV/AIDS treatment and prevention.

Evidently, increasing access to safe and effective TM should not mean displacing programmes to increase access to allopathic

medicine. Rather opportunities to improve cooperation between TM practitioners and allopathic medicine practitioners, should be created, to enable patients to draw upon both TM and allopathic therapies to best meet their needs. This is of course the case everywhere (and applies also to CAM). But it is particularly relevant in areas with poor access to allopathic medicine. Fortunately, in these areas, TM practitioners tend to be well established and well respected. Working with these practitioners can facilitate effective dissemination of important health messages to communities, as well as promotion of safe TM practices.

If access to TM is to be increased sustainably, the natural resource base upon which it often depends must be sustained. Raw materials for herbal medicines, for instance, are often collected from wild plant populations. Over-harvesting due to intensified local use or to meet export demand is a growing problem. In Eastern and Southern Africa, the sustainability of wild stocks of the African potato (*Hypoxis hemerocallidea* – formerly *H. rooperi*) is threatened because widespread publicity about the use of the plant in treatment of HIV/AIDS has boosted demand for it.³¹ Since the vast majority of plant genetic resources and other forms of biodiversity are found in or originate from developing countries with least capacity to protect them, such problems are in urgent need of resolution.

Unresolved intellectual property issues are another access problem. While research into TM is essential to ensuring access to safe and effective treatments, the knowledge of indigenous TM practices and products gained by researchers can be a source of substantial benefits to companies and research institutes. Increasingly, it appears that knowledge of TM is being appropriated, adapted and patented by scientists and industry, with little or no compensation to its original custodians, and without their informed consent.¹⁷

2.5 Rational use

In many countries, considerably more activity is required regarding: qualification and licensing of providers; proper use of products of assured quality; good communication between TM/CAM providers, allopathic medicine practitioners and patients; and provision of scientific information and guidance for the public.

Table 11

Key needs in promoting sound use of TM/CAM by providers and consumers

At national level:

- Training guidelines for most commonly used TM/CAM therapies.
- Strengthened and increased organization of TM/CAM providers.
- Strengthened cooperation between TM/CAM medicine providers and allopathic medicine practitioners.
- Reliable information for consumers on proper use of TM/CAM therapies and products.
- Improved communication between allopathic medicine practitioners and their patients concerning latter's use of TM/CAM.

Education and training

Challenges in this area are at least twofold (Table 11). Firstly, ensuring that the qualifications and training of TM/CAM providers are adequate. Secondly, using training to ensure that TM/CAM providers and allopathic medicine practitioners understand and appreciate the complementarity of the types of health care they offer. The first involves establishing, where possible, examination and licensing systems



for TM/CAM, and legislation – so that only those who are qualified can practice TM/CAM or sell TM/CAM products. The second requires modifying training programmes for

TM/CAM 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 TM/CAM.

Proper use of products of assured quality

Proper use of products of assured quality can also do much to reduce risks associated with TM/CAM products such as herbal medicines. However, regulation and registration of herbal medicines are not well developed in most countries. Products may be contaminated or vary tremendously in content, quality and safety. Garlic, for example, often claimed to have cholesterol-lowering effects, may fail to produce such effects if processed in certain

ways.⁵⁴ At the same time, standards to control labelling of and publicity for herbal medicines are few. Moreover, many are sold as over-the-counter or dietary supplements, 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 TM/CAM products and greater efforts to educate the public in this area.

Information and communication

Use of TM/CAM is increasing rapidly. But appreciation of its risks and how to avoid those risks has not kept pace. As a result, consumers may not understand why they should seek treatment only from suitably qualified and trained providers, or why they should exercise caution when using TM/CAM products. It is not commonly understood, for example, that side-effects following reactions between herbal medicines and chemical drugs can occur. On its own, for example, ginseng has few serious adverse

effects. But if combined with warfarin, its antiplatelet activity risks causing overanticoagulation.⁵⁵ Similarly, use of St John's wort as an antidepressant has been shown



to compare favourably with a standard antidepressant, imipramine. But if St John's wort is taken by subjects who are also taking indinavir, an HIV protease inhibitor, levels of indinavir in the blood are reduced below the level required to block HIV multiplication.^{56,57}

Without knowledge of the possibility of such interactions, patients may fail to inform their allopathic doctors about the

TM/CAM products they are using, while allopathic doctors may fail to ask. In the USA, for both 1990 and 1997, less than 40% of CAM therapies used were disclosed to a physician.¹³ At the same time, allopathic doctors, nurses and pharmacists, all of whom may be used as information sources by the general public, may not be informed about CAM and therefore unable to answer patients' queries about CAM treatment options.

Information, education and communication strategies could overcome some of these problems, and raise awareness of the potential benefits of TM/CAM.

The current role of WHO

W

HO's principal, current objectives in TM/CAM are to provide normative and country programme support so that Member States can:

- ▶ develop their own TM/CAM and integrate it into their national health care systems, as appropriate, and
- ▶ ensure appropriate, safe and effective use of TM/CAM.

It also seeks to:

- ▶ increase access – among Member States, the scientific community and the public – to accurate information on TM/CAM issues.

Some of WHO's achievements and current activities aimed at meeting these objectives are outlined below.

In carrying out its TM/CAM activities, WHO not only works directly with Member States, national and international organizations and regional bodies, but also with its network of Collaborating Centres.

3.1 Developing TM/CAM and integrating it into national health care systems

WHO is particularly active in supporting development of TM in Africa, South-East Asia and the Western Pacific. This includes helping Member States to develop national policy and regulations, facilitating regional information exchange on these issues, and

supporting efforts to ensure product safety, and availability of trained, qualified human resources.

Africa

As mentioned in Chapter 2 the WHO Regional Committee for Africa adopted a resolution, in 2000, on *Promoting the Role of Traditional Medicine in Health Systems: a Strategy for the African Region*.² The resolution recognized the importance and potential of TM for the achievement of *Health for All* in the African Region, and recommended accelerated development of local production of traditional medicines. The resolution further urged Member States to translate the strategy into realistic national TM policies, backed up with appropriate legislation and plans for specific interventions at national and local levels, and to collaborate actively with all partners in its implementation and evaluation.

Concrete results as a result of development of the strategy are now beginning to be seen. They include legal frameworks for TM in 16 African countries.

Americas

In 1999 an AMRO working group reviewed the situation and use of TM (including national policy and regulation) in its region, and proposed two meetings – on regulation of herbal products and research into indigenous medicine. The Regional Meeting on Regulatory Aspects of Herbal Products –

organized by WHO Headquarters and AMRO – was held in 2000 and analysed issues relating to national policy, economics, and regulation and registration of herbal products. Additionally, WHO guidelines for assessing the safety and efficacy of herbal medicines were introduced, and participants adopted a proposal on common requirements of registration of herbal products. The latter will facilitate further integration of TM into national health care systems in the Americas. Regulation and registration of herbal medicines, in particular, have been established in: Bolivia, Chile, Colombia, Costa Rica, Ecuador, Honduras, Guatemala, Mexico, Peru and Venezuela. The second meeting, on research into indigenous medicine, was held in March 2001 in Guatemala.

"Health policy-makers worldwide are recognizing that traditional medicine and the use of herbal medicinal plants continue to be a strong part of a country's culture, history and beliefs, and that those practices in most parts ought to be analysed as being part of the country's health system."⁵⁸

Europe

More than 12 Western European countries have established or revised their regulation on herbal medicines in accordance with the *WHO Guidelines for Assessment of Herbal Medicines*. WHO is increasingly active in advising European countries on regulation of TM/CAM and how to evaluate their safety and efficacy.

South East Asia

TM is widely used and respected throughout South-East Asia. In 1998, the South-East Asian Meeting of Ministers of Health recommended that this "rich heritage" and

"important resource" be used more effectively in implementing primary health care in the countries of the region. In response, SEARO organized a regional consultation on development of traditional medicine, in the following year. The consultation focused on strengthening national TM programmes, and the role of TM expertise in improving district health systems. Additionally, information on national policy and regulations on TM was shared. SEARO continues to actively support individual countries in their efforts to develop national policy on TM and to integrate TM into their national health care systems.

In particular, WHO has supported the activities of the Department of Indian Systems of Medicine and Homeopathy, which was established within India's Ministry of Health and Family Welfare in 1995. During 1998 and 1999, the Department increased efforts to standardize and promote quality control of ayurvedic, unani, siddha and homeopathic medicines. It also finalized good manufacturing practice guidelines for ayurvedic medicines and promoted education in Indian TM.

Western Pacific

The Western Pacific also has a rich TM heritage, which its countries are keen to optimize. At the 1997 and 1999 Meetings of Ministers of Health of the Western Pacific, participants iterated their full support for the wider application and development of TM in efforts to improve health status.

The Regional Office for the Western Pacific (WPRO) not only supports countries in drafting national TM policy and regulations, but also facilitates integration of TM into health service systems. For example, WHO helped draft legislation, signed on 8 December 1997, that created the Philippine Institute of Traditional and Alternative Healthcare. It also assisted Papua New Guinea in preparing a national TM policy that has since been

incorporated into the country's 2001–2010 health plan. This policy identifies research into TM as a top priority. In Singapore, the Traditional Chinese Medicine Practitioners Act – incorporating a number of recommendations made by WPRO on regulation of practitioners – was passed by Parliament in 2000.

“More and more governments from countries and areas within the Region [WHO's Western Pacific Region] have shown a willingness to promote the proper use of traditional medicine and bring it into the formal health service system... There are now 14 countries and areas in the Region that have developed official government documents which recognize traditional medicine and its practice. This is in contrast to a few years ago, when only four countries (China, Japan, the Republic of Korea and Viet Nam) officially recognized the role of traditional medicine in formal health care systems.”⁵⁹

Meanwhile, full-time TM degree courses are being offered at universities in Australia, China, Hong Kong (China), Japan, the Republic of Korea and Vietnam, many of which have benefited from WPRO input.

Other WPRO activities have included development, in 1997, of *Guidelines for the Appropriate Use of Herbal Medicine*, to promote appropriate use of herbal medicines by countries in the region. The guidelines can be used to help formulate national policies and programmes on herbal medicines. Creation and implementation of national TM policies is in fact an area in which WPRO is becoming more and more involved. In 1999, a WHO workshop on developing national TM policies reviewed

the role of TM in the Western Pacific and identified problems in drafting relevant government policy. In late 1999 a WHO consultation on TM and allopathic medicine examined how to harmonize the two types of health care to achieve maximum health impact. In 2000, a WHO regional workshop on TM practice and health sector development drafted an action plan on traditional medicine for the 20 Pacific Island countries.

3.2 Ensuring appropriate, safe and effective use of traditional medicine

TM/CAM therapies often develop within a very specific cultural environment. Yet, increasingly, they are transferred to other cultural environments. This raises safety and efficacy issues. For instance, are the transferred therapies applied with the same degree of training, skill and knowledge as in their original environment? Acupuncture is a case in point. Now widely practised in many countries other than China

– its country of origin – acupuncture has probably become one of the world's most popular TM/CAM therapies. WHO has accordingly worked with experts in acupuncture to propose a standard international nomenclature. This is now widely accepted. WHO has also developed *Guidelines on Basic Training and Safety in Acupuncture* and *Guidelines for Clinical Research on Acupuncture*. These guidelines strongly encourage national health authorities to regulate acupuncture practice and research.

Similarly, TM/CAM products, particularly herbal medicines, are now traded inter-regionally and internationally. Many health authorities are concerned as to whether they are used rationally and safely, particularly if relevant regulations are lacking, and



the quality and safety of these products cannot be assured. WHO has responded by producing reference documents such as *Quality Control Methods for Medicinal Plant Materials*, to not only facilitate the technical work of drug regulatory authorities but also to encourage countries to undertake quality control of herbal medicines.

WHO tools and assistance

In most developing countries, national TM institutes have been established – as in China, the Democratic People's Republic of Korea, Ghana, India, Indonesia, the Lao People's Democratic Republic, Mali, Madagascar, Nigeria, the Republic of Korea, Sri Lanka, Thailand and Viet Nam. WHO provides not only guidelines and scientific information to support their research, but also grants for research into the safety and efficacy of use of TM/CAM. In Africa, WHO is supporting a total of 21 countries in their



research into TM therapies. For example, it has provided research grants to support clinical research on herbal antimalarials that is being carried out by Kenya's Medical Research

Institute, Ghana's National Centre for Scientific Research into Plant Medicine, and Nigeria's National Institute for Pharmaceutical Research and Development. The research is following the *WHO General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine*.

Collaboration with other organizations

WHO's work to promote appropriate, safe and effective use of TM/CAM benefits from technical input from a number of organizations, both national and international. NCCAM in the USA, for example, was designated a WHO Collaborating Centre for Traditional Medicine in 1996. It has provided not only technical comments on developing the

WHO Monographs on Selected Medicinal Plants and Guidelines on Basic Training and Safety in Acupuncture, but also financial support for development of documents such as the *General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine*.

At European level, collaboration has taken place with EMEA's Ad Hoc Working Group on Herbal Medicinal Products. The group has assisted with the preparation of *WHO Monographs on Selected Medicinal Plants, General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine*, and *Guidelines for the Assessment of Herbal Medicines*. As a result, European countries are further encouraged to use WHO technical documents on TM/CAM.

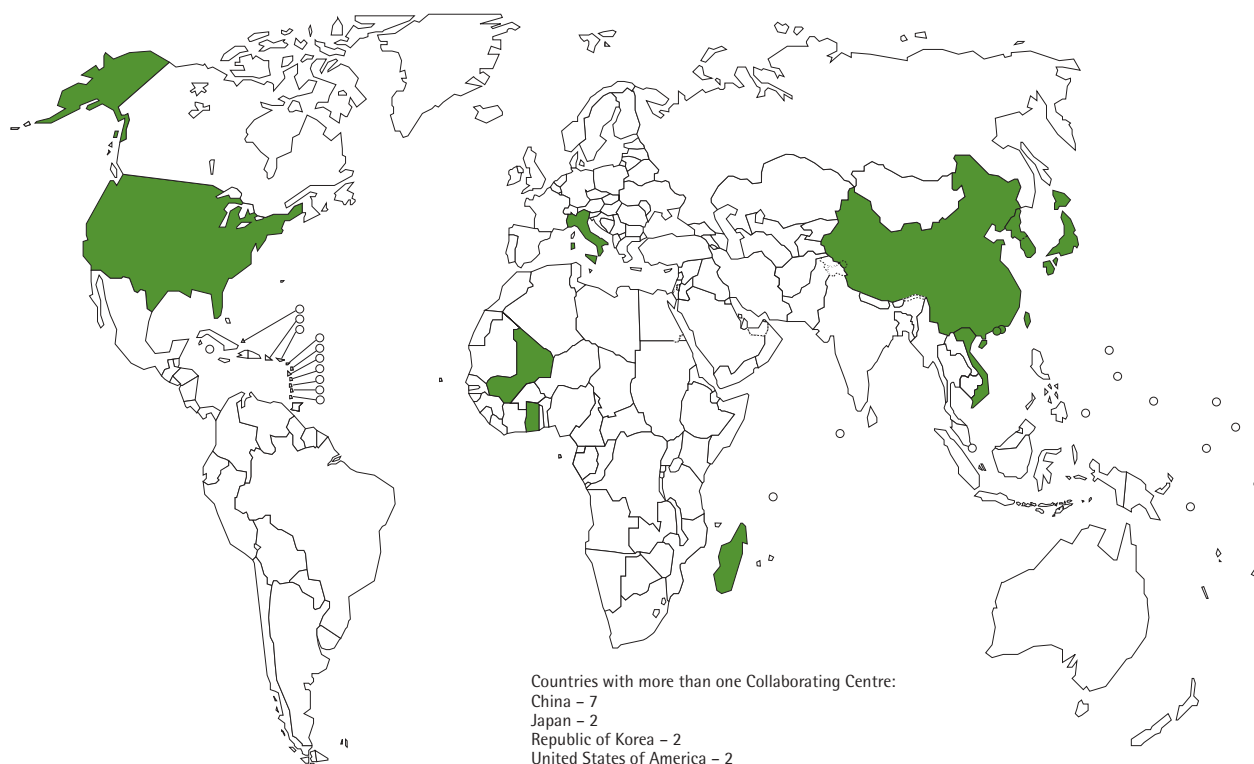
WHO also works with its Collaborating Centres for Traditional Medicine to carry out national, regional and global activities. (A full list of these WHO Collaborating Centres is given in Annex 1.) WHO Collaborating Centres for Traditional Medicine agree to promote their national TM through their research and training programmes (Figure 12). They also agree to provide technical comments and information to support development of WHO technical guidelines and documents, and to provide training, at WHO's request, for experts in acupuncture and on research skills for investigating the safety and efficacy of herbal medicines.

3.3 Increasing access to TM/CAM information

With 191 Member States, involvement in a range of TM activities and direct access to expertise on many TM issues, WHO is well placed to help increase access to accurate information on TM. This includes producing authoritative reference works – for example on medicinal plants – and guidance on

Figure 12

WHO Collaborating Centres for Traditional Medicine – a growing resource



national policy, training, good practice, and selection and use of therapies (see Annex 2). The Organization also increasingly facilitates information exchange.

Authoritative information

The *WHO Monographs on Selected Medicinal Plants* provide scientific information on the safety, efficacy and quality control of widely-used medicinal plants. This includes concise summaries of the botanical features of medicinal plants, listings of the plants' major chemical constituents and instructions on how to ensure quality control of herbal materials derived from the plants. The *Monographs* also summarize medicinal use in three categories: pharmacology; posology; contraindications; and precautions against potential adverse reactions. A key reference for national health authorities, scientists and pharmaceutical companies, they are also used by lay persons to guide them in rational use of herbal medicines. Additionally, WHO Member States as diverse

as Benin, Mexico, South Africa and Viet Nam have used the *Monographs* as a model when developing their own national monographs or formularies. Volume 1 has been recommended by the European Commission to its own Member States as an authoritative reference.

Although overall responsibility for the content and production of the *Monographs* rests with WHO, they nevertheless represent a collaborative effort which has enhanced their accuracy and reliability. To date, more than 200 experts, in addition to members of WHO's Expert Advisory Panels on Traditional Medicine and more than 50 national drug regulatory authorities, have been involved in their preparation. Volume I of the *Monographs* was published in 1999 and has since been widely distributed. Volume II was published in 2001 and Volume III was finalized in late 2001.

The Regulatory Situation of Herbal Medicines: Worldwide Review was also a collaborative

effort – between WHO and many of its Member States. Providing information from 50 countries on the regulation of herbal medicines, this reference work serves as a guide to health authorities in other countries now seeking to develop their own systems for regulation and registration of herbal medicines. Research institutes and the pharmaceutical industry also find the *Review* helpful. *Quality Control Methods for Medicinal Plant Materials* is another key reference recently produced by WHO.

Facilitating information exchange

In addition to making its own publications and documents widely available, WHO also facilitates information exchange through

The WHO Collaborating Centre for Traditional Medicine at the College of Pharmacy at the University of Illinois at Chicago, has a database on medicinal plants that contains coded information on natural products from 150 750 references. These include references relating to ethnomedicine, pharmacology of extracts and pure compounds, and phytochemistry. Since 1994, the Centre has provided valuable assistance for the drafting of all three volumes of the *WHO Monographs on Selected Medicinal Plants*. It has also been providing information free of charge to developing countries. In 2000, it responded to 10 182 requests received from developing countries by WHO Headquarters and WHO Regional Offices by providing 407 840 references (Table 12).

Additionally, WHO Collaborating Centres for Traditional Medicine in China (the Institute of Clinical Science and Information, China Academy of Traditional Chinese Medicine, Beijing), the Republic of Korea (Natural Products Research Institute, Seoul National University) and the USA (The National Center for Complementary and Alternative Medicine, Institutes of Health, Bethesda, Maryland) also maintain databases of information on TM/CAM which play an important and visible role in providing scientific information for both providers and the public.

Last but not least, web-sites on TM/CAM are being established at WHO Headquarters and the WHO Regional Offices to provide information on national TM/CAM policies, regulations governing practice and use of TM/CAM, and research data on the safety, efficacy and use of TM/CAM therapies.



Table 12

Information exchange through WHO Collaborating Centre for Traditional Medicine at the College of Pharmacy at the University of Illinois at Chicago

| WHO Headquarters or Regional Office | Number of requests received | Number of references supplied in response |
|---|-----------------------------|---|
| Headquarters | 171 | 17 396 |
| Regional Office for Africa | 1 759 | 31 238 |
| Regional Office for the Eastern Mediterranean | 28 | 1 784 |
| Regional Office for the Americas/Pan American Health Organization | 5 135 | 131 760 |
| Regional Office for South-East Asia | 2 801 | 179 113 |
| Regional Office for the Western Pacific | 288 | 46 549 |

its Collaborating Centres for Traditional Medicine. Queries received from national health authorities, scientists and the public are responded to in cooperation with these WHO Collaborating Centres.

International and national resources for traditional medicine

Maximizing the potential that TM/CAM offers for improving health status worldwide is a daunting task, covering a diverse range of activities and demanding many types of expertise. Fortunately, the

“The recognition by governments of the importance of traditional medicine for the health of the populations in the Region and the creation of an enabling environment are the basis for the optimization of the use of traditional medicine. Sustainable political commitment and support from policy-makers, traditional medicine practitioners, NGOs, professional associations, the community, teaching and training institutions and other stakeholders, created through advocacy and utilization of social marketing and participatory methods are required.”²

number of organizations working on TM/CAM issues, and whose assistance WHO can call upon, is growing. Some of these organizations are described below. An indication is also given of any collaboration between these organizations and WHO that has already taken place.

4.1 UN Agencies

The Convention on International Trade in Endangered Species of Flora and Fauna (CITES) (<http://www.cites.org/index.html>) entered into force in July 1975 and now has a membership of 125 countries. These countries act by banning commercial exploitation of an agreed list of endangered species of flora and fauna, and by regulating and monitoring trade in others that might become endangered. The Secretariat of the Convention is administered by the United Nations Environment Programme and helps countries to implement CITES by providing interpretation of its provisions, and implementation advice. The Secretariat also runs projects to help improve implementation, such as training seminars, and to examine the status of species in trade, to ensure that their exploitation remains within sustainable limits.

The mandate of the Food and Agriculture Organization of the United Nations (FAO) (<http://www.fao.org/>) is to raise levels of nutrition and standards of living, improve agricultural productivity, and better the conditions of rural populations. A specific priority of the organization is to encourage sustainable agriculture and rural development, including a long-term strategy for the conservation and management of natural resources. Since the 1980s, FAO's Forestry Department has been producing a series of documents on non-wood forest products – some of which include medicinal plants – with information on national

policies, conservation, and related research data and activities. FAO has collaborated with WHO on developing the latter's *Monographs on Selected Medicinal Plants* by providing research data.

The principal goals of the **United Nations Conference on Trade and Development (UNCTAD)** (<http://www.unctad.org/>) are to maximize the trade, investment and development opportunities of developing countries, and to help them face challenges arising from globalization. Many of the world's products are based on traditional knowledge and represent major sources of income, food and health care. Likewise, most plant genetic resources and other forms of biodiversity originate from or are found in developing countries. UNCTAD is accordingly heavily involved in the issue of protection of traditional knowledge. Currently, it is responding to concern that TM knowledge is at times misappropriated. Collaboration between UNCTAD and WHO is still at an early stage but in 2000 included WHO attendance at UNCTAD's Expert Meeting on Systems and National Experiences for Protecting Traditional Knowledge, Innovations and Practices, and UNCTAD representation at the WHO Interregional Workshop on Intellectual Property Rights in the Context of Traditional Medicine, held in Bangkok.

The **United Nations Industrial Development Organization (UNIDO)** (<http://www.unido.org/>) helps developing countries and transition economies to pursue sustainable industrial development. In particular, it seeks to address concerns relating to competitive economy, sound environment and productive employment at the policy, institutional and enterprise levels. In 1986, a UNIDO meeting of experts recommended that research, development and distribution of herbal medicines be widely encouraged and incorporated into health delivery systems, especially in developing countries.

The UNIDO Third Consultation on the Pharmaceutical Industry, in 1987, recommended that UNIDO support industrial use of medicinal plants, including factory production of herbal medicines, improved technology for producing herbal medicines, and development of technology for standardizing production of herbal medicines. UNIDO currently supports developing countries in their efforts to build industrial capacity to produce herbal medicines. UNIDO has participated in a WHO consultation to develop the *WHO Monographs on Selected Medicinal Plants*.

The **World Intellectual Property Organization (WIPO)** (<http://www.wipo.org/>) is "dedicated to promoting the use and protection of works of the human spirit." It administers 21 international treaties dealing with different aspects of intellectual property protection. In 1998, WIPO Member States requested the Organization to initiate a work programme on intellectual property and traditional knowledge. Since then, WIPO has conducted the Asian Regional Seminar on Intellectual Property Issues in the Field of Traditional Medicine (in New Delhi, in October 1998), and worked with UNEP on two case studies on the role of intellectual property rights in the sharing of benefits arising from use of medicinal plants and associated TM knowledge. It has also undertaken fact-finding missions on intellectual property and traditional knowledge (1998–1999) and conducted two roundtables on intellectual property and traditional knowledge. It has also developed a sample Traditional Knowledge Digital Library (TKDL), including information on about 50 medicinal plants and associated traditional knowledge. WIPO has invited WHO to participate in its meetings and requested WHO cooperation in developing TKDLs.

4.2 International organizations

The Commonwealth Secretariat (<http://www.thecommonwealth.org/>) is the principal organization of the Commonwealth, a voluntary association of independent sovereign states, including both developed and developing nations. As well as seeking to promote democracy and good governance, and serving as a platform for global consensus building, the Commonwealth is a source of practical help for sustainable development. This last has recently included promotion of production of herbal medicines. The Secretariat has provided limited funds to support African Anglophone countries in manufacturing herbal medicines and in late 2000 organized a Medicinal Plants Forum in Cape Town, South Africa. The Forum explored ways of improving and encouraging cultivation and conservation of plants in order to increase production of herbal remedies to provide affordable medicine, particularly in Africa. The Forum also covered trade-related issues such as non-tariff barriers, regulation and licensing, patents and quality. The Secretariat launched *A Guide to the European Market for Medicinal Plants and Extracts* at the Forum. Detailing the growth and development of the European herbal industry, the guide includes practical information for producers and exporters of medicinal plants.

The European Agency for the Evaluation of Medicinal Products (EMA) (<http://www.emea.eu.int/>) contributes to the protection and promotion of public and animal health through its efforts to: ensure high-quality evaluation of medicinal products; develop efficient and transparent procedures to facilitate timely access by users to innovative medicines; and control the safety of medicines for human and

animals, particularly through its pharmacovigilance network. In 1997, EMA established an Ad Hoc Working Group on Herbal Medicinal Products. The group acts as a forum for Member States to exchange information and experience regarding herbal medicinal products. It also promotes the development of a common interpretation of existing legislation in this area and provides guidance for national drug regulatory authorities on herbal medicines issues. Additionally, the Group is preparing proposals for revising and developing new guidance and requirements for ensuring the quality, safety and efficacy of herbal medicinal products.

Founded in 1989, the European Scientific Cooperative on Phytotherapy (ESCOP) (<http://info.ex.ac.uk/phytonet/escop.html>) aims to advance the scientific status of phytomedicines^h and to assist with the harmonization of their regulatory status at the European level. ESCOP's Scientific Committee has completed a number of European monographs summarizing the medicinal uses of plants (including their safety). ESCOP considers this activity essential for harmonization. Fifteen monographs had been published by 1992. Since then, attention has focused on producing summaries of product characteristics on individual plant drugs, primarily those for which European or national pharmacological monographs already exist. The sequence of topics in each summary is designed to highlight clinical aspects of the relevant plant drugs, including pharmacodynamics, pharmacokinetics and pre-clinical safety data.

The European Union (EU) (<http://userpage.chemie.fu-berlin.de/adressen/eu.html>) is a union of 15 independent states based on the European Communities and was

^h ESCOP defines phytomedicines as "medicinal products containing as active ingredients only plants, parts of plants or plant materials, or combinations thereof, whether in the crude or processed state".

founded to enhance political, economic and social co-operation. Member States delegate sovereignty for certain matters to independent institutions which represent the interests of the EU as a whole, its member countries and its citizens. The EU focuses on two aspects of TM/CAM: policy and regulation, and research into "non-conventional" medicine. A recently completed COST (European Cooperation in the field of Scientific and Technical research) project examined differences between so-called conventional and non-conventional medicine in terms of concepts, research and practice, reasons for the growing popularity of non-conventional medicine and the implications of these for conventional medicine, and the current state of research in non-conventional medicine.

The **World Bank** (<http://www.worldbank.org/>) is the world's largest source of development assistance, providing nearly US\$ 17 thousand million in loans annually to its client countries. Using its financial resources, staff and knowledge-base it seeks to help developing countries attain stable, sustainable and equitable growth in the fight against poverty. Currently, this includes assisting a number of developing countries with policies and strategies for medicinal plant conservation, cultivation, processing and marketing. Additionally, the Bank operates an Indigenous Knowledge (IK) Program (see <http://www.worldbank.org/afr/ik/index.htm>), which aims to mainstream indigenous/traditional knowledge in agriculture, health care, food preparation, education, natural resource management and many other areas of concern to communities, into the activities of development partners. Different strategies are being used to achieve this goal. They include a database on indigenous/traditional knowledge and practices, and a series of "IK Notes". The Program also supports resource centres

across Africa that focus on identification and dissemination of indigenous/traditional knowledge and practices. Working with governments and local partners, the Program has also begun to help mainstream the application of IK in World Bank projects and in national development programmes.

The **World Trade Organization (WTO)** (<http://www.wto.org>) is the international organization charged with setting the legal ground rules for international trade. Although WTO became officially operational only in January 1995, it is the successor to the General Agreement on Tariffs and Trade multilateral trading system founded in 1947. Its objectives are to promote: non-discrimination; progressive liberalization of barriers to trade; predictable policies and transparency; competition; and special provisions for developing countries. WTO's Council for the Agreement on Trade-Related Aspects of Intellectual Property Rightsⁱ accorded WHO observer status on an ad hoc basis. WHO can now monitor all relevant issues under discussion at the WTO that may have implications for the health sector. (As of May 1999 WHO was mandated to monitor and analyse the public health implications of trade agreements on pharmaceuticals.) In 2000, WHO and WTO held an international workshop on Differential Pricing and Financing of Essential Drugs.

4.3 Nongovernmental organizations

Worldwide, many nongovernmental organizations (NGOs) are working on TM/CAM. Only a few examples are given below.

By preparing, maintaining and promoting the accessibility of systematic reviews of the effects of healthcare interventions, the **Cochrane Collaboration** (<http://hiru.mcmaster.ca/cochrane/>) aims to help people

ⁱ The Agreement is commonly known as "TRIPS".

make well-informed decisions about healthcare. Cochrane Fields are Cochrane groupings that focus on dimensions of health care other than health problems, such as the setting of care (e.g. primary care), the type of consumer (e.g. older people), the type of provider (e.g. nurses), or the type of intervention (e.g. physical therapies). People working in a Field hand-search specialist journals, help to ensure that priorities and perspectives in their field of interest are reflected in the work of collaborative review groups, compile specialist databases of reviews, coordinate activities with relevant agencies outside the Collaboration, and comment on systematic reviews relating to their particular area. The Cochrane Complementary Medicine Field was established in 1996 to produce, maintain and disseminate systematic reviews on TM/CAM topics.

The mission of the Ford Foundation (<http://www.fordfound.org/>) is to "decrease poverty and promote justice throughout the world". It supports NGOs, schools, universities, research institutes, cultural groups and government organizations. It is particularly concerned about the HIV/AIDS epidemic in Africa, and believes that the AIDS epidemic in Africa cannot be addressed without the active involvement of traditional healers and TM organizations. One of its major grantees is PRO.ME.TRA (see below), with which it works to carry out TM activities in anglophone and francophone Africa.

Based in Dakar, Senegal, and with offices in Benin, Cameroon and the USA, PRO.ME.TRA – the Association for the Promotion of Traditional Medicine (<http://www.prometra.org>) – works to advance the use and acceptance of TM. As well as running an association of 450 certified healers and a research treatment clinical site in Fatick, Senegal, it produces health education information for the fight against HIV/AIDS. Its communications strategy incorporates

use of print, electronic media and digital satellite technology and is being implemented with the help of Foundation du Présent in Geneva, Switzerland and the World Space Foundation in the USA.

The World Wide Fund for Nature (WWF) (<http://www.panda.org/>) is the world's largest independent conservation organization. Like the World Conservation Union (IUCN) (<http://www.iucn.org/>), WWF works to assist societies throughout the world to conserve the integrity and diversity of nature, and to ensure that any use of natural resources is equitable and ecologically sustainable. This includes projects and research on sustainable management of non-timber forest products, which commonly include medicinal plants. Both organizations have shown how the massive demand for bark, roots, and whole plants from wild

populations of medicinal plants can cause critical declines in the population numbers of some species, potentially leading to

extinction. Highlighting such concern the two Organizations have brought conservationists and resource users together to investigate possible solutions and to research sustainable harvesting of medicinal plants. Both Organizations have developed guidelines on how to conserve medicinal plants.



4.4 Global professional associations

The Liga Medicorum Homeopathica Internationalis (LMHI) (International Homeopathic Medical League) (LMHI) (<http://www.lmhi.net/>) was established in 1925 and represents about 8000 homeopathic practitioners in 50 countries. Its objectives are to: support member countries

in their efforts to secure legal recognition of homeopathy; create links among licensed homeopaths with medical diplomas; and provide help and support to national homeopathic organizations on education in homeopathy, research into homeopathy and documentation of homeopathic practices. It also promotes reimbursement of homeopathic treatment within health insurance schemes.

Established in 1987, the **World Federation of Acupuncture-Moxibustion Societies (WFAS)** (<http://www.who.int/ina-ngo/ngo/ngo194.htm>) has nearly 60 000 members from 73 acupuncture organizations from 40 countries in several regions. Of those members, 70% (35 000) are either medical doctors, or have graduated from TM colleges and universities that are officially recognized by national government (as in China, the Republic of Korea and Viet Nam). The remaining members are acupuncturists who are licensed to practise. WFAS promotes understanding and cooperation among acupuncture-moxibustion groups throughout the world, strengthens international academic exchanges on acupuncture-moxibustion and contributes to the development of the science of acupuncture-moxibustion. WFAS has worked with WHO to develop WHO technical guidelines and international standards relating to acupuncture-moxibustion. This has included contributing to a number of WHO technical documents on acupuncture.

The **World Federation of Chiropractic (WFC)** (<http://www.wfc.org/>) works with national and international organizations to provide information and other assistance in the fields of chiropractic and world health; promotes uniform high standards of chiropractic education, research and practice; works to develop an informed public opinion among all peoples with respect to chiropractic; and upon request provides advice on appropriate legislation for chiropractic in member countries. Current

activities with WHO include research on low back pain and collection of information on the regulation and registration of the practice of chiropractic by countries. The latter will assist WHO in reviewing and documenting the legal status of TM.

A federation of 54 member associations, the **World Self-Medication Industry (WSMI)** (<http://www.wsmi.org/guide.html>) was founded in 1970, and represents manufacturers and distributors of nonprescription medicines – that is, over-the-counter medicines, a large proportion of which are herbal medicines. Many companies that develop, manufacture and market herbal medicines belong to WSMI's member associations. WSMI encourages the development of self-medication industry associations to promote the understanding and development of responsible self-medication. Indeed, it requires member associations to develop and implement voluntary codes of advertising practice and encourages consumer-friendly labelling. WSMI has been in official relations with WHO since 1977 and worked with the Organization to develop guidelines for assessing herbal medicines, and methodology for research and evaluation of herbal medicines. It has also contributed research data to support development of the *WHO Monographs on Selected Medicinal Plants*.

4.5 International and national professional associations

Many different international professional associations support WHO activities. The **Islamic Organization for Medical Sciences (IOMS)** (<http://www.who.int/ina-ngo/ngo/ngo192.htm>), for example, plans to work with WHO on preparation of a manual on the use of medicinal plants. Islamic medicine incorporates modern Western medicine but its fifth criterion of "utilizing all useful resources" means that it is also willing to consider any potentially useful treatment

therapies, including TM/CAM therapies, such as treatment with herbal medicines. IOMS established the Centre for Research on Herbal Medicine in Kuwait. A non-profit organization it extends its services to all those who seek treatment with herbal medicines and other products.

Many national professional organizations also work with WHO. National professional organizations include TM practitioners associations in Africa and Asia. For example, there are 22 TM practitioners associations in sub-Saharan Africa. In China, national professional associations exist for those who practise both allopathic medicine and TM, for practitioners of manual therapy, and for specialists in nutrition and health foods. In India, professional associations have long existed for practitioners of ayurveda, unani, sidha and homeopathy.

4.6 Specific initiatives

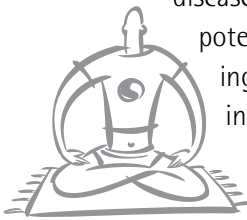
The Global Initiative for Traditional Systems (GIFTS) of Health (<http://users.ox.ac.uk/~gree0179/>) is supported by the Commonwealth Secretariat (see Section 4.2). It seeks to raise international awareness of the role of traditional health systems and to promote policy development to ensure their continued use. This work includes developing linkages between traditional health systems, biodiversity conservation and economic development.

The Research Initiative on Traditional Antimalarial Methods (RITAM) (http://mim.nih.gov/english/partnerships/ritam_application.pdf) was launched in 1999 as a collaboration between WHO, the Global Initiative for Traditional Systems of Health (GIFTS), the University of Oxford, and researchers and others throughout the world who are investigating or interested in the antimalarial properties of plants, with a view to developing or validating local herbal medicines to prevent and/or treat malaria. RITAM held its inaugural meeting in December 1999 in Moshi, Tanzania.

Strategy and plan of action
2002–2005

Reducing excess mortality, morbidity and disability, especially in poor and marginalized populations is one of WHO's strategic directions for 2002–2005.⁶⁰ Since TM is a highly accessible and affordable form of health care in many low-income countries, WHO is promoting its inclusion – where proven safe and effective – in plans for improving health status.

At the same time, global population ageing is bringing greater incidence of chronic disease and TM/CAM offer a



potential means for managing such disease. Indeed, in developed countries, more and more people are using TM/CAM – in combination with or instead of allopathic medicine – to help relieve chronic pain and/or to improve quality of life.

But several objectives must be attained to ensure optimal use of TM/CAM. At the same time, WHO's resources are limited and its efforts must be directed towards securing the greatest public health gains for the greatest number. Specific objectives in TM/CAM for 2002–2005 are accordingly to support countries to:

- integrate TM/CAM with national health care systems, as appropriate,^j by developing and implementing national TM/CAM policies and programmes

- 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
- increase the availability and affordability of TM/CAM, as appropriate, with an emphasis on access for poor populations
- promote therapeutically sound use of appropriate TM/CAM by providers and consumers.

Each of these objectives incorporates two or three components, with expected outcomes (Table 13). A critical indicator has also been included for each objective and will be used to help evaluate WHO's work in this area. Additionally, several surveys relating to TM/CAM policy, and regulation and use of TM/CAM, will be carried out in cooperation with Member States and NGOs to assess progress.

Over the next four years, WHO will make the first two objectives – development and implementation of national TM/CAM policies, and promoting the safety, efficacy and quality of TM/CAM – a priority. This will include work on regulation of herbal and other TM/CAM products. It will also include focusing on strengthening research methodologies, and on increasing the

^j "Appropriate" is taken to refer to TM/CAM health care that does not cost more and which is no less safe and efficacious than recommended allopathic care for the disease or health problem.

quality, quantity and accessibility of clinical evidence to support claims for TM/CAM effectiveness.

“The wealth of accumulated clinical experience and knowledge within traditional medicine deserves to be acknowledged and combined with methodologically sound research into the extent and limitations of traditional practice. Patients, governments, traditional practitioners and practitioners of modern medicine all stand to benefit from evidence-based practice of traditional medicine. The support of the scientific community and practitioners of modern medicine will be needed if traditional medicine is to be brought into mainstream health services.”⁶¹

5.1 Policy: Integrate TM/CAM with national health care systems, as appropriate, by developing and implementing national TM/CAM policies and programmes

Components

- Recognition of TM/CAM. Help countries to develop national policies and programmes on TM/CAM.
- Protection and preservation of indigenous TM knowledge relating to health. Help countries to develop strategies to protect their indigenous TM knowledge.



WHO strategy

WHO will encourage governments to recognize the important contribution certain forms of TM/CAM can make to improving and maintaining health. It will also strengthen collaboration between its Headquarters and Regional Office TM programmes, in order to elaborate and carry out common tasks effectively and efficiently. It will continue to cooperate with other relevant UN agencies and explore the possibility of working with new partners. This will include organizing a series of regional and interregional workshops for national health authorities on policy and use of TM/CAM.

Most importantly, WHO will help Member States to develop and implement national TM/CAM policies and regulations, and to promote safe and effective forms of indigenous TM in accordance with WHO guidelines. WHO will also facilitate information sharing on TM/CAM among countries.

Critical indicator

| Strategy objective | Number of WHO Member States reporting a national TM/CAM policy/ Total number of WHO Member States | 1999 status | 2005 target |
|--|--|-------------|-------------|
| WHO Member States with national policy on TM/CAM | 25/191 | 13% | 25% |

Expected outcomes for 2002–2005

- Increased government support for TM/CAM, through comprehensive national policies on TM/CAM.
- Relevant TM/CAM integrated into national health care system services.
- Increased recording and preservation of indigenous knowledge of TM, including development of digital TM libraries.

Table 13

WHO Traditional Medicine Strategy 2002–2005 – objectives, components and expected outcomes

| Objectives | Components | Expected outcomes |
|--|--|---|
| POLICY: Integrate TM/CAM with national health care systems, as appropriate, by developing and implementing national TM/CAM policies* and programmes | 1. Recognition of TM/CAM Help countries to develop national policies and programmes on TM/CAM | 1.1 Increased government support for TM/CAM, through comprehensive national policies on TM/CAM 1.2 Relevant TM/CAM integrated into national health care system services |
| | 2. Protection and preservation of indigenous TM knowledge relating to health Help countries to develop strategies to protect their indigenous TM knowledge | 2.1 Increased recording and preservation of indigenous knowledge of TM, including development of digital TM libraries |
| 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 | 3. Evidence-base for TM/CAM Increase access to and extent of knowledge of the safety, efficacy and quality of TM/CAM, with an emphasis on priority health problems such as malaria and HIV/AIDS | 3.1 Increased access to and extent of knowledge of TM/CAM through networking and exchange of accurate information 3.2 Technical reviews of research on use of TM/CAM for prevention, treatment and management of common diseases and conditions 3.3 Selective support for clinical research into use of TM/CAM for priority health problems such as malaria and HIV/AIDS, and common diseases |
| | 4. Regulation of herbal medicines Support countries to establish effective regulatory systems for registration and quality assurance of herbal medicines | 4.1 National regulation of herbal medicines, including registration, established and implemented 4.2 Safety monitoring of herbal medicines and other TM/CAM products and therapies |
| | 5. 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/CAM products and therapies | 5.1 Technical guidelines and methodology for evaluating safety, efficacy and quality of TM/CAM 5.2 Criteria for evidence-based data on safety, efficacy and quality of TM/CAM therapies |
| ACCESS: Increase the availability and affordability of TM/CAM, as appropriate, with an emphasis on access for poor populations | 6. Recognition of role of TM/CAM practitioners in health care Promote recognition of role of TM/CAM practitioners in health care by encouraging interaction and dialogue between TM/CAM practitioners and allopathic practitioners | 6.1 Criteria and indicators, where possible, to measure cost-effectiveness and equitable access to TM/CAM 6.2 Increased provision of appropriate TM/CAM through national health services 6.3 Increased number of national organizations of TM/CAM providers |
| | 7. Protection of medicinal plants Promote sustainable use and cultivation of medicinal plants | 7.1 Guidelines for good agriculture practice in relation to medicinal plants 7.2. Sustainable use of medicinal plant resources |
| RATIONAL USE: Promote therapeutically sound use of appropriate TM/CAM by providers and consumers | 8. Proper use of TM/CAM by providers Increase capacity of TM/CAM providers to make proper use of TM/CAM products and therapies | 8.1 Basic training in commonly used TM/CAM therapies for allopathic practitioners 8.2 Basic training in primary health care for TM practitioners |
| | 9. Proper use of TM/CAM by consumers Increase capacity of consumers to make informed decisions about use of TM/CAM products and therapies | 9.1 Reliable information for consumers on proper use of TM/CAM therapies 9.2 Improved communication between allopathic practitioners and their patients concerning use of TM/CAM |

* With the exception of China, the Democratic People's Republic of Korea, the Republic of Korea and Viet Nam, such integration has nowhere taken place. This underlines the fact that in some countries national assessment is needed to ascertain which TM/CAM modalities can be best integrated with the national health care system.

5.2 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

Components

- Evidence-base for TM/CAM. Increase access to and extent of knowledge of the safety, efficacy and quality of TM/CAM, with an emphasis on priority health problems such as malaria and HIV/AIDS.
- 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/CAM products and therapies.

WHO strategy

WHO will strengthen and expand its existing global expert TM/CAM network, members of which include WHO Collaborating Centres, national health authorities, academic and scientific institutions, and other relevant international agencies such as EMEA, the European Pharmacopoeia, FAO, the Organization of African Unity and UNIDO. Working with these partners it will continue to develop technical guidelines and scientific information, particularly on herbal medicines. The Organization will also expand its TM/CAM evidence-base, with a view to identifying which TM/CAM therapies are of proven safety and efficacy, and to generate greater public health credibility for TM/CAM. It will do this through technical review of clinical use of TM/CAM in the prevention, treatment and management of common diseases and conditions, and

further support to clinical research into the safety and efficacy of TM/CAM.

WHO Headquarters and Regional Offices will establish a global regulatory network of safety monitoring systems on herbal medicines and other TM/CAM therapies. This will include helping countries establish post-marketing surveillance for herbal medicines. WHO will continue to cooperate with relevant professional associations and academic institutions to develop and provide guidelines for basic training in certain manual therapies. It will also organize training programmes and workshops for national authorities to upgrade their knowledge of safety and efficacy issues regarding herbal medicines.

Critical indicator

| Strategy objective | Number of WHO Member States reporting laws and regulations on herbal medicines/Total number of WHO Member States | 1999 status | 2005 target |
|---|--|-------------|-------------|
| WHO Member States with laws and regulations on herbal medicines | 65/191 | 34% | 40% |

Expected outcomes for 2002–2005

- Increased access to and extent of knowledge of TM/CAM through networking and exchange of accurate information.
- Technical reviews of research on use of TM/CAM for prevention, treatment and management of common diseases and conditions.
- Selective support for clinical research into use of TM/CAM for priority health problems such as malaria and HIV/AIDS, and common diseases.
- National regulation of herbal medicines, including registration, established and implemented.

- Safety monitoring of herbal medicines and other TM/CAM products and therapies.
- Technical guidelines and methodology for evaluating safety, efficacy and quality of TM/CAM.
- Criteria for evidence-based data on safety, efficacy and quality of TM/CAM therapies.

5.3 Access: Increase the availability and affordability of TM/CAM, as appropriate, with an emphasis on access for poor populations

Components

- Recognition of role of TM/CAM practitioners in health care. Promote recognition of role of TM/CAM practitioners in health care by encouraging interaction and dialogue between TM/CAM practitioners and allopathic practitioners.
- Protection of medicinal plants. Promote sustainable use and cultivation of medicinal plants.

WHO strategy

Most countries that suffer from widespread malaria, HIV/AIDS and other common communicable diseases have less than US\$ 15 per capita per year to spend on health. In some countries only US\$ 0.75 per capita per year is available for drugs expenditure. WHO will explore the potential for using accessible and affordable TM/CAM resources to combat common communicable diseases. This will include research into the most effective herbal medicines, and encouraging governments to develop strategies for protecting wild populations of medicinal plants and sustainable cultivation of such plants. (This will contribute not only to

access to health care, but also to protecting the environment and generating income.) Protection of indigenous TM knowledge relating to health and equitable sharing of its benefits will be promoted within the context of any research undertaken.

WHO will also encourage dialogue and interaction between TM/CAM practitioners and allopathic practitioners to promote recognition of the role of TM/CAM in health care provision. In developing countries it will work with TM practitioners associations and NGOs so that the role of TM practitioners in preventing and managing common communicable diseases is optimized.

Critical indicator^k

| Strategy objective | Number of WHO African Member States reporting professional recognition of TM practitioners/Total number of WHO African Member States | 1999 status | 2005 target |
|---|--|-------------|-------------|
| African WHO Member States with professional recognition of TM practitioners | 21/46 | 45% | 60% |

Expected outcomes for 2002–2005

- Criteria and indicators, where possible, to measure cost-effectiveness and equitable access to TM.
- Increased provision of appropriate TM/CAM through national health services.
- Increased number of national organizations of TM providers.
- Guidelines for good agriculture practice in relation to medicinal plants.
- Sustainable use of medicinal plant resources.

^k Data is available for the African region only.

5.4 Rational use: Promote therapeutically sound use of appropriate TM/CAM by providers and consumers

Components

- Proper use of TM/CAM by providers. Increase capacity of TM/CAM providers to make proper use of TM/CAM products and therapies.
- Proper use of TM/CAM by consumers. Increase capacity of consumers to make informed decisions about use of TM/CAM products and therapies.

"...we must broaden the knowledge base of CAM and conventional health care practitioners to encompass the full repertoire of safe and effective health care practices — truly expanding the horizons of health care. These practices can then be integrated into optimal interdisciplinary treatment plans developed in cooperation with patients. These imperatives dictate serious efforts in research, training, education and communication..."⁴⁵

WHO strategy

WHO will encourage countries to organize training programmes for allopathic practitioners to enable them to acquire basic knowledge of TM/CAM and to promote licensed practice of therapies.

WHO will continue to develop authoritative references for Member States, such as the *WHO Monographs on Selected Medicinal Plants*. It will also develop information and education materials (including translations) and a TM/CAM web-site to raise awareness of the need for rational use of TM/CAM, and to guide the public in their safe use.

Critical indicators

| Strategy objective | Number of WHO Member States with national research institute ¹ for TM/CAM/Total number of WHO Member States | 1999 status | 2005 target |
|---|--|-------------|-------------|
| WHO Member States with national research institute for TM/CAM | 19/191 | 10% | 18% |

Expected outcomes for 2002–2005

- Basic training in commonly used TM/CAM therapies for allopathic practitioners.
- Basic training in primary health care for TM practitioners.
- Reliable information for consumers on proper use of TM/CAM therapies.
- Improved communication between allopathic practitioners and their patients concerning use of TM/CAM.

¹ A national research institute is here defined as a government-supported national research institute.



List of WHO Collaborating Centres for Traditional Medicine

Total number of Collaborating Centres: 19

Regional breakdown

| | |
|--------------------------|----|
| African Region: | 3 |
| Americas Region: | 2 |
| European Region: | 1 |
| South-East Asian Region: | 1 |
| Western Pacific Region: | 12 |

African Region

- Centre for Scientific Research in Plant Medicines, Mampong-Akwapim, Ghana
- Centre National d'Application des Recherches Pharmaceutiques (CNARP), Antananaviro, Madagascar
- Institut National des Recherches en Santé Publique, Bamako, Mali

Americas Region

- National Center for Complementary and Alternative Medicine (NCCAM), National Institutes of Health, Department of Health and Human Services, Bethesda, USA
- College of Pharmacy, University of Illinois at Chicago, Chicago, USA

European Region

- Centre of Research in Bioclimatology, Biotechnologies and Natural Medicine, State University of Milan, Milan, Italy

South-East Asian Region

- Academy of Traditional Korean Medicine, Pyongyang, Democratic People's Republic of Korea

Western Pacific Region

- Institute of Acupuncture and Moxibustion, China Academy of Traditional Chinese Medicine, Beijing, People's Republic of China
- Institute of Clinical Science and Information, China Academy of Traditional Chinese Medicine, Beijing, People's Republic of China
- Institute of Medicinal Plant Development, Chinese Academy of Medical Sciences, Beijing, People's Republic of China
- Institute of Chinese Materia Medica, Chinese Academy of Traditional Chinese Medicine, Beijing, People's Republic of China

- Nanjing University of Traditional Chinese Medicine, Nanjing, People's Republic of China
- Institute of Acupuncture Research, Fudan University, Shanghai, People's Republic of China
- Shanghai University of Traditional Chinese Medicine, Shanghai, People's Republic of China
- Oriental Medicine Research Centre, The Kitasato Institute, Tokyo, Japan
- Department of Japanese Oriental Medicine, Toyama Medical and Pharmaceutical University, Toyama, Japan
- East-West Medical Research Institute, Kyung Hee University, Seoul, Republic of Korea
- Natural Products Research Institute, Seoul National University, Seoul, Republic of Korea
- Institute of Traditional Medicine, Hanoi, Viet Nam



Selected WHO publications and documents on traditional medicine

Publications and documents listed below are available in English. If publications and documents are also available in French and/or Spanish, this is indicated by F and/or S.

National policy and monitoring

Apia Action Plan on Traditional Medicine in the Pacific Island Countries. Manila, WHO Regional Office for the Western Pacific, 2001.

Development of National Policy on Traditional Medicine. Manila, WHO Regional Office for the Western Pacific, 2000.

Legal Status of Traditional medicine and Complementary/Alternative Medicine: a World-wide Review. Geneva, World Health Organization, in press.

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

Regulatory Situation of Herbal Medicines: a World-wide Review. Geneva, World Health Organization, 1998 (document reference WHO/TM/98.1) (F in press/S).

Report of the Inter-regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine. Geneva, World Health Organization (document reference WHO/EDM/TRM/2001.1).

The Role of Traditional Medicine in Primary Health Care in China (Based on an Inter-Regional Seminar Sponsored by the WHO in Association with the Ministry of Public Health of the People's Republic of China, 9–21 October 1985). Geneva, World Health Organization, 1986 (document reference WHO/TM/86.2).

Traditional Health Systems in Latin America and the Caribbean: Baseline Information. Washington, DC, Pan American Health Organization/World Health Organization, 2000.

Traditional Medicine and Health Care Coverage. Geneva, World Health Organization, 1983. Reprinted 1988.

Traditional Practitioners as Primary Health Care Workers. Geneva, World Health Organization, 1995 (document reference WHO/SHS/DHS/TM/95.6).

Quality, safety and efficacy

Medicinal plants

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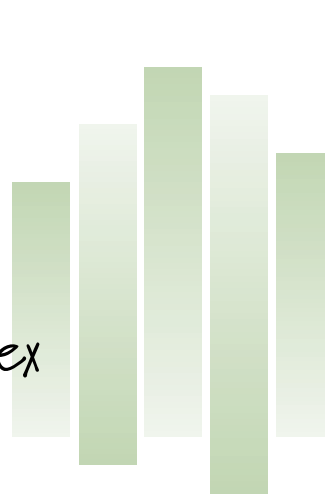
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A traditional medicine strategy is **relevant**:

Traditional medicine continues to play an important role in health care. In many parts of the world, it is the preferred form of health care. Elsewhere, use of herbal medicines and so-called complementary and alternative therapies is increasing dramatically. There is no single determinant of popularity. But cultural acceptability of traditional practices, along with perceptions of affordability, safety and efficacy, and questioning of the approaches of allopathic medicine, all play a role. In view of this broad appeal, the general lack of research on the safety and efficacy of traditional medicines is therefore of great concern.

A traditional medicine strategy is **urgently needed**:

International, national and nongovernmental agencies continue to make great efforts to ensure that safe, effective and affordable treatments for a wide range of diseases are available where they are most needed. WHO estimates, however, that one-third of the world's population still lacks regular access to essential drugs, with the figure rising to over 50% in the poorest parts of Africa and Asia. Fortunately, in many developing countries, traditional medicine offers a major and accessible source of health care. Use of traditional medicine in primary health care, however, especially in the treatment of deadly diseases, is cause for concern. An evidence-base supporting its safe and efficacious use has yet to be developed.

A traditional medicine strategy has been developed:

In response to these challenges, WHO has developed a strategy for traditional medicine to enable this form of health care to better contribute to health security. It focuses on working with WHO Member States to define the role of traditional medicine in national health care strategies, supporting the development of clinical research into the safety and efficacy of traditional medicines, and advocating the rational use of traditional medicine.

