CHAPTER 5

Traditional and complementary medicine policy

SUMMARY

For thousands of years, traditional medicine (TM) has been an important source of health care for much of the world, and many populations use and value TM not only as the source of their primary health care but also as part of their spiritual and cultural belief systems. Meanwhile, people in Europe, Australia, and North America have increasingly embraced TM, also referred to as complementary and alternative medicine (CAM), by using herbal medications to complement their standard health care.

Attractive features of TM practices include greater accessibility in many parts of the world, cultural acceptance in low- and middle-income countries, comparatively low cost and, often, a lesser need for modern technology. In developed countries, CAM is used for preventing disease and maintaining wellness, in addition to complementing conventional care for chronic and acute health conditions.

Although TM/CAM has a great influence on health care practices, there is wide variation from country to country in policies, laws, and regulations governing the safety, quality, and efficacy of TM/CAM therapies. Many consumers use herbal products to treat themselves—often without a health practitioner's knowledge or advice. Consumers and practitioners may not be adequately informed about potential adverse effects, drug interactions, and how to use herbal medicines safely. Lack of regulations on quality standards and evaluation for safety and efficacy of these products may cause problems, resulting in the marketing of unsafe or ineffective TM/CAM products.

Countries that already have a strong pharmaceutical regulatory structure in place should adapt their existing systems to include herbal medications, and countries that lack regulatory standards should work toward setting up a national system that encompasses both pharmaceuticals and herbal medicines. All countries should have some framework in place to review and monitor herbal medicines, including a regulatory agency, a national advisory committee, and a system to monitor adverse reactions from herbal medicines.

Expanding the credibility and integration of TM/CAM will require developing an evidence base for safety and efficacy, which means consolidating data from existing national and international studies and supporting new research to fill evidence gaps.

5.1 The changing role of traditional and complementary medicine in health care

For thousands of years, traditional medicine has been an important source of health care for much of the world, and many populations use TM not only as the source of their primary health care but also as part of their spiritual and cultural belief systems. Meanwhile, people in Europe, Australia, and North America have increasingly embraced alternative and complementary practices, such as the use of herbal medications, to supplement their standard health care.

The growing attention focused on TM has introduced a number of public health issues in developing and developed countries alike, including policy, safety and quality, efficacy, access, and appropriate use. Regulations that ensure the quality and safety of TM products and procedures are often lacking, and because herbal medicines are now marketed across regions and internationally, these issues have evolved from being local in scale and are now of global concern.

Definitions of traditional and complementary medicine

The World Health Organization (WHO) defines *traditional medicine* as—

> 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 (WHO 2002, 7).

Traditional medicine is a comprehensive term that refers to forms of medicine long-established in a country, whether developed or developing. Health care practices that are not part of a country's own tradition and that are not well established within the country's conventional health care system are often referred to as *complementary* and *alternative* medicine. Sometimes, the terms *complementary medicine* or *alternative medicine* are used interchangeably with *traditional medicine*, but CAM may include more recently developed technologies, unlike TM.

TM/CAM therapies are considered medication based if they use herbal medicines, animal parts, minerals, or homeopathic remedies. Herbal medicines include herbs, herbal materials, herbal preparations, and finished herbal products that contain therapeutically active ingredients that are plant based. Therapeutic interventions that are not based primarily on medications are procedure based. These therapies may include acupuncture; manual therapies, such as

massage and chiropractic, heat, or exercises; and qigong, tai chi, yoga, meditation, or spiritual practices. Box 5-1 includes a list of definitions developed by WHO related to TM/CAM and herbal medications.

Increasing popularity of traditional and complementary medicine

Traditional medicine has been used continuously in developing countries for centuries, but more recently, alternatives to conventional medicine have become increasingly popular in developed countries. TM and CAM have also attracted more attention within the context of the globalization of the health care sector, health sector reform, and health care provision. The popularity of TM/CAM is reflected in its worldwide economic importance: the global market for herbal medicines is estimated to be over 60 billion U.S. dollars (USD) and growing 10 to 20 percent a year (UNCTD 2000).

Traditional and complementary medicine usage is widespread. For example, according to WHO, up to 80 percent of people in Africa and Asia use TM as part of their primary health care; in China, traditional herbs make up 30

Box 5-1
WHO definitions related to traditional medicines

Traditional medicine. *Traditional medicine* is the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement, or treatment of physical and mental illness.

Complementary/alternative medicine. The terms *complementary medicine* and *alternative medicine* are used interchangeably with *traditional medicine* in some countries. They refer to a broad set of health care practices that are not part of that country's own tradition and are not integrated into the dominant health care system.

Herbal medicines. *Herbal medicines* are defined as plant-derived material or preparations with therapeutic or other human health benefits, which contain either raw or processed ingredients from one or more plants. In some traditions, material of inorganic or animal origin may also be present. Specific elements of herbal medicines are defined as discussed here.

- *Herbs,* including crude plant material such as leaves, flowers, fruit, seed, stems, wood, bark, roots, rhizomes, or other plant parts, which may be entire, fragmented, or powdered.
- *Herbal materials,* including, in addition to herbs, fresh juices, gums, fixed oils, essential oils, resins, and dry powders of herbs. In some countries, these materials may be processed by various local procedures, such as steaming, roasting, or stir-baking with honey, alcoholic beverages, or other materials.
- *Herbal preparations* are the basis for finished herbal products and may include comminuted or powdered herbal materials, or extracts, tinctures, and fatty oils of herbal materials. They are produced by extraction, fractionation, purification, concentration, or other physical or biological processes. They also include preparations made by steeping or heating herbal materials in alcoholic beverages and/or honey, or in other materials.
- *Finished herbal products,* consisting of herbal preparations made from one or more herbs. If more than one herb is used, the term *mixture herbal product* can also be used. Finished herbal products and mixture herbal products may contain excipients in addition to the active ingredients. However, finished products or mixture products to which chemically defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be herbal.

Traditional use of herbal medicines. This refers to the long historical use of these medicines. Their use is well established and widely acknowledged to be safe and effective, and may be accepted by national authorities.

Therapeutic activity. This refers to the successful prevention, diagnosis, and treatment of physical and mental illnesses; improvement of symptoms of illnesses; as well as beneficial alteration or regulation of the physical and mental status of the body.

Active ingredients. These are ingredients of herbal medicines with therapeutic activity. In herbal medicines where the active ingredients have been identified, the preparation of these medicines should be standardized to contain a defined amount of the active ingredients, if adequate analytical methods are available. In cases where it is not possible to identify the active ingredients, the whole herbal medicine may be considered as one active ingredient.

Sources: Adapted from WHO 2002, 2000.

to 50 percent of total medicine consumption; and 90 percent of Germans, 70 percent of Canadians, and 50 percent of Swedes have used a natural remedy at some time (WHO 2008b; Hanssen et al. 2005).

Even with the long history of TM use in most countries, however, and a sharp increase in TM/CAM in developed countries, a schism remains between traditional and conventional medical practice. Typically, both traditional and conventional practitioners are unaware or even suspicious of what the other can offer in terms of health care and services. In addition, patients can be reluctant to admit to health care providers that they are using both types of treatment, creating what could be a potentially alarming risk—especially for those patients taking certain herbal medications in combination with pharmaceuticals.

But barriers to addressing issues related to TM/CAM appear to be weakening in some areas, such as government recognition. More countries are considering ways to integrate TM/CAM into their national health care system, as some Asian countries, including China and South Korea, already do (Holliday 2003). For example, a recent report notes that increasing numbers of U.S. hospitals and physicians are offering CAM therapies; more insurers are covering alternative treatments; and integrative medicine centers now exist, many of which have ties to medical schools and teaching hospitals (IOM 2005). Developing countries, too, are acting on the need to officially recognize TM; for example, the government of Uganda has begun to integrate TM into its health system, and South Africa now legally recognizes traditional healers as health care professionals (Bianchi 2004).

5.2 Why people use traditional and complementary medicines

Positive features that attract people to TM/CAM include diversity, flexibility, greater accessibility in many parts of the world, extensive acceptance in developing countries, comparatively low cost, and a lesser need for modern technological capability.

Accessibility

Traditional medicine therapies are commonly used in developing countries because they are often more widely available and more affordable than conventional therapies. In addition, because TM practices are, often, woven into everyday life and belief systems, and because traditional healers are trusted members of the community, TM is often the first source of health care at the community level. Conventional health care may be a last resort, especially if the nearest primary health care facility is some distance from the community.

In resource-limited countries, especially in rural areas, there are usually fewer conventional health care practitioners than TM practitioners. In India, TM is the only available source of health care for a large part of the rural population (WHO 2002). This situation has been aggravated as large numbers of trained and licensed conventional health care workers leave their native countries for better opportunities elsewhere (the "brain drain" phenomenon); sub-Saharan Africa has been particularly hard hit (see Chapter 51).

In developed countries, patients have become more informed about their health and use print media, television, and the Internet to get information on which to base their health decisions. As a result, alternative therapies are appealing because they are perceived as more natural and therefore safer compared to "manufactured" pharmaceutical products (WHO 2004a). A perceptual difference between cultures may be that people in developing countries are more likely to view TM as their primary source of medical care, whereas people in developed countries generally view alternative treatments as complementary to, rather than competitive with, conventional medicine.

Affordability

Most poor people in developing countries buy their medicines out of pocket; even if the public health sector offers medicines at no charge, essential medicines may not be reliably stocked, or health facilities may be too far away. The rural poor often cannot afford the transportation costs to get to a public health facility. Herbal medicines in developing countries are often cheap, and the TM practitioner may accept a trade in-kind or offer a sliding payment scale. In addition, many herbal medications are available for purchase in stores, so patients may buy and take medication without ever incurring the cost of seeing a practitioner. A cost comparison of malaria treatments in Ghana showed that clinic treatment cost USD 1.60, self-treatment with medicines bought from a private drug shop (both chloroquine and herbal) was USD 0.35, and self-treatment with herbs cost USD 0.10 (Ahorlu et al. 1997). Recent evidence also suggests that the rising cost of conventional medicine in some developed countries is contributing to increased use of alternative medicines (Pagan and Pauly 2005).

Perceived safety

TM/CAM therapies are also popular because of the lower rate of adverse effects compared with some pharmaceutical-based therapies. For example, St. John's wort taken to treat mild depression generally causes fewer side effects than antidepressive pharmaceuticals; capsaicin cream, derived from hot *Capsicum* peppers and used to treat osteoarthritis, does not cause the gastrointestinal effects that nonsteroidal anti-inflammatory medications do. Evidence suggests that

some patients may choose an herbal medication over a conventional medication specifically to avoid adverse effects (Fraenkel et al. 2004). Although consumers may perceive herbal products as natural and therefore less likely to cause problems, these products are not without risk and are not necessarily safer than conventional pharmaceuticals.

Potential for treating disease

People also use TM/CAM because of its perceived efficacy, both in general (Sydara et al. 2005) and in particular for treatment of chronic, debilitating diseases that defy conventional pharmaceuticals. Indeed, plant extracts have been proved to have pharmacological effects on many conditions, both acute and chronic. Moreover, analysis from U.S. National Cancer Institute researchers showed that more than two-thirds of all drugs discovered in the previous quarter-century were derived from natural products, such as plants (Newman and Cragg 2007); for example, aspirin (salicylic acid) uses a compound derived from the white willow tree, and paclitaxel, a chemotherapy agent, is made using a substance found in the Pacific yew tree. As long-time treatments for the most severe form of malaria have become ineffective because of antimicrobial resistance, artemisinin compounds from *Artemisia annua,* an herb native to Asia, are now the first-line treatment for malaria in most countries.

Although research projects have investigated the effectiveness of herbal medicines to treat HIV/AIDS, thus far no equivalent to artemisinin for malaria has been found for HIV/AIDS. However, traditional healers have been targeted as essential partners in efforts to educate their communities and provide support for people living with HIV/AIDS (see Country Study 5-1), and many Africans use traditional herbal medications to treat AIDS symptoms and manage opportunistic infections (UNAIDS 2000, 2002). TM/CAM is also important to HIV/AIDS patients in developed countries; more than eighty percent of a sample of people living with HIV/AIDS in the United States reported regular use of alternative medicine therapies (Sparber et al. 2000).

5.3 Risks associated with herbal medications

Many people believe that, because herbal medications are "natural," or have been used in some parts of the world for generations, they must be safe. But, like modern pharmaceuticals, herbal medications can cause adverse effects (Farah et al. 2000). The causes of such adverse reactions are diverse: the use of inherently toxic herbal medicines or an overdose of herbs, conventional drug–herbal medicine interactions, and idiosyncratic reactions such as allergies. Most countries have no adverse drug reaction surveillance (pharmacovigilance) system for medicines at all, or the existing system may exclude herbal medicines.

Poor quality

A lack of strict standards for the production and manufacture of herbal medications can cause quality problems, such as adulteration, misidentification of ingredients, substitution of one herb with another, inclusion of pharmaceuticals without identification on the labels, contamination, and variability in the amount of active ingredient. For example, an analysis of different red yeast rice products on the market showed levels varying by 100-fold across ten products, and four were contaminated with a mycotoxin (ConsumerLab 2009). Heavy metals, fumigation agents, microbial toxins, and pharmaceutical substances have all been found in toxic concentrations in TM/CAM medications (Ernst 2001; Huang et al. 1997; Ko 1998). In 2009, a manufacturer recalled its herbal weight-loss product, which was found to actually contain the unlabeled prescription drug sibutramine, which can substantially increase blood pressure, and phenolphthalein, a suspected cancer-causing chemical that is not approved for marketing in the United States (FDA 2009).

Incorrect usage

Incorrect usage of herbal medication therapies can have fatal outcomes. The inappropriate long-term use of kava kava (*Piper methysticum*), for example, has been associated with serious cases of liver damage (Stevinson et al. 2002), and *Ginkgo biloba,* which stimulates circulation, may cause excessive bleeding during surgery (Ang-Lee et al. 2001). The U.S. Food and Drug Administration recalled all botanical products, marketed for a variety of ailments, that contained aristolochic acid, from the plant *Aristolochia,* after reports of adverse events showed a relationship with kidney failure. Problems also occur, when TM therapies are marketed and used in different cultures, with potentially hazardous changes in indicated uses and doses. *Ma huang* (*Ephedra sinica*), which contains ephedrine, has long been used in traditional Chinese medicine for respiratory symptoms, but its marketing at higher doses in the United States as a weight-loss product led to a number of severe effects and deaths (Ang-Lee et al. 2001).

Lack of information

Many consumers in both developed and developing countries use herbal products to treat themselves without a health practitioner's advice because of the availability and relatively inexpensive cost of such products. Consumers who treat themselves, however, may be uninformed about potential adverse effects and the safe use of herbal medicines.

Country Study 5-1
Using traditional practitioners in HIV/AIDS activities in sub-Saharan Africa

Kenya

Women Fighting AIDS in Kenya (WOFAK) is a nonprofit support organization started in 1994 by ten women affected by HIV/AIDS. WOFAK has incorporated traditional medical practices into its program because of a concern that conventional medicine is too expensive for WOFAK clients. WOFAK works to sustain and promote various forms of traditional medicine and beneficial cultural practices throughout the country, and it supports the exploration of traditional therapies for HIV and associated opportunistic infections.

To further its objectives, WOFAK established a collaboration with the Kenya Forestry Research Institute (KEFRI) to grow, process, and conduct safety assessments and analyses of medicinal herbs. Although collaboration between conventional and traditional practitioners in Kenya is rare, WOFAK encourages such partnerships to improve the quality of health services to people living with HIV/AIDS. For example, a KEFRI herbalist worked part-time at the WOFAK drop-in center treating clients with herbal medicine. The center has two clinic rooms—one for traditional medicine and one for conventional medicine—and the center employs one community nurse, one traditional healer, one part-time doctor, and two herbal nurses. Cross-referrals occur between the conventional health practitioners and the traditional medicine practitioners, according to the condition, the medicine available, or the patient's preference. Conventional screening methods are used to determine the problem before treatment begins. In addition, WOFAK conducts training sessions for traditional healers in HIV/AIDS issues, including patient counseling, the role of traditional healers in AIDS control, and the identification of herbs for treatment of opportunistic infections.

Tanzania

The Tanga AIDS Working Group (TAWG) was begun in 1990 after a traditional healer successfully used herbal medicines to treat a patient in a government hospital in the Tanga region of Tanzania. The doctors were so impressed that they initiated collaboration with healers to better provide services for their patients with HIV/AIDS. One of the first TAWG activities was to work with local healers to develop three herbal remedies to treat a variety of HIV/AIDS-related conditions. From that activity evolved a home-care service for patients and their families, a type of service that patients often prefer because it is more confidential than hospital-based services. These home visits are used to monitor general health, administer traditional therapies, and provide counseling services. Many hospital staff members refer patients to TAWG for HIV testing because they know that TAWG staff members have been trained as counselors on how HIV/AIDS is contracted, spread, and prevented.

In addition to home-based counseling, HIV testing services are provided at TAWG facilities. For patients who are hospitalized, TAWG prescribes herbal medicines collected by a healer and distributed by the hospitals, a process that allows patients to be monitored by conventional health care providers. TAWG's success is due to the trusting and collaborative relationship between clients, staff members, traditional healers, and conventional health practitioners.

Uganda

In the early 1990s, when the prevalence of HIV/AIDS in Uganda was among the highest in the world, the National AIDS Control Program, the Uganda AIDS Commission, and two nongovernmental organizations launched Traditional and Modern Health Practitioners Together Against AIDS and Other Diseases (THETA). THETA's first project was a collaborative clinical study to evaluate traditional herbal medicines for their effectiveness against HIV/AIDS-related symptoms, and its second project aimed to determine whether traditional healers could be trained as effective counselors on sexually transmitted infections and HIV/AIDS.

THETA's clinical studies showed that local herbal medications were just as efficacious in treating herpes zoster, which is especially problematic for people living with HIV/AIDS, as the conventional drug acyclovir. To increase access to these local products, THETA started an herbal processing-and-packaging demonstration laboratory, and grows medicinal herbs in a garden in Kampala. THETA also developed a Resource Center for Traditional Medicine and AIDS, which includes a library and a speakers bureau. To facilitate the exchange of information, the center has published booklets, training kits, educational videos, and a newsletter.

In addition, THETA's training program for traditional healers has been so successful that it has expanded to several districts. Healers who have gone through the intensive, two-year training and certification program serve as HIV/AIDS trainers for other traditional healers and

fill a gap in providing counseling services in geographic areas where counseling would not otherwise be available. Healers have been recognized for their unique education methods, which include song, dance, storytelling, and drama. Part of the training process includes workshops with conventional health practitioners to promote collaboration between traditional healers and health care providers.

> *I work together with fellow healers to educate the communities. When there are many of us, we can handle all the questions.*
>
> —Trained healer from Kiboga

South Africa

In South Africa, an estimated 80 percent of people regularly see *sangomas,* or traditional healers. The Nelson R. Mandela School of Medicine at the University of KwaZulu-Natal (KZN) in Durban has developed the Biomedical and Traditional Healing Collaboration Against HIV/AIDS to improve collaboration with traditional healers caring for people with HIV/AIDS. In 2003, a memorandum of understanding was signed between the school and the KZN Traditional Healers' Council (including the Ethekwini Traditional Healers' Council), as well as two other traditional healers' organizations, Mwelela Kwelihesheya and the Umgogodla Wesizwe Trust. The provincial health department helps run the project.

The project has trained hundreds of traditional healers on HIV/AIDS awareness, voluntary counseling and testing, home-based care, and antiretroviral therapy awareness. Membership in one of the councils is required for participation in the program. Traditional healers are recognized as effective counselors, and the project is developing strategies that use *sangomas* to deliver HIV prevention messages and behavioral counseling.

Sangomas are already treating many patients with HIV/AIDS while they are on the waiting list for antiretroviral therapy. They not only treat people's opportunistic infections, but also encourage patients' behavioral changes and advise them on good nutrition and healthy living. The project is working to improve two-way communication and referral between *sangomas* and conventional health practitioners. The *sangomas* already refer patients to health care facilities, but they feel that they do not receive reciprocal referrals because of hostility on the part of the conventional practitioners. The project is working with all parties to clarify patient confidentiality issues, which should help improve communication and information exchange.

In addition, the project supplies the traditional healers, who do not have the resources to buy supplies such as rubber gloves, with home-based care kits and helps them incorporate record keeping into their practices, which, although advocated by the healer councils, is challenging because of low literacy. Record keeping is seen as an important element of successful collaboration between the traditional and conventional health systems.

Biomedical and Traditional Healing Collaboration Against HIV/AIDS recognizes that the integration of traditional healers into care for patients with HIV/AIDS will help reduce workload, improve patient care, and give the HIV/AIDS treatment program partners within patients' communities.

Sources: Kenya, Tanzania, Uganda: UNAIDS 2002; South Africa: Smart 2005; IRIN PlusNews 2010.

Often, the labeling of herbal preparations contains inadequate or unclear information about usage or possible adverse effects, leading to improper use by consumers. In a fatal example, the label on a bottle of Chinese wintergreen oil indicated that it was primarily for external use but could be taken orally for enhanced efficacy, even though ingesting as little as 4 mL can be fatal. An elderly consumer seeking relief from arthritis drank the entire contents of the 60 mL bottle that she purchased in a grocery, resulting in her death (Hofman et al. 1998).

Another problem is that most people do not communicate with their health care providers about other medications they are taking. Studies show that up to 70 percent of people use TM/CAM therapies simultaneously with conventional medicine without telling their health care providers (Eisenberg et al. 2001). This lack of communication puts consumers at risk of suffering serious adverse effects caused by the interaction between herbal medicines and conventional medicines (Ernst 2001; Fugh-Berman 2000). Problems with herbal medicine–conventional medicine interactions can be prevented through improved communication between patients and health care providers and, in the case of self-treatment, better consumer information.

Clearly, issues related to herbal safety, herb-drug interactions, and health care provider and consumer education and communication are increasingly important for national and international authorities to address, given the growing popularity of herbal products in both developed and developing countries. WHO has published guidelines on developing consumer information for TM and CAM that discuss many of these issues (WHO 2004a).

5.4 Meeting the challenges of traditional medicine

Although TM has a great influence on health care practices worldwide, little reliable information exists regarding the safety, quality, and efficacy of TM/CAM medications, in part because most country governments do not regulate or officially recognize TM/CAM therapies. In the countries that do recognize TM, the scope of regulations varies considerably because of differences in history, culture, and product use. Some countries classify herbal products as medicines and some as food, and regulate accordingly. Generally, countries do not register herbal and other TM products the same way as conventional medicines, and evidence of quality, efficacy, and safety may not be required before marketing. Governments will continue to take different approaches in recognizing and classifying TM/CAM preparations unless an international framework is established for evaluating and regulating these products (Bast et al. 2002).

TM therapies have the potential to contribute to a better health care system in many places; however, a number of challenges must be met to avoid the emergence of more costly and less safe and effective health care (see Box 5-2). WHO has developed strategies to address these challenges through recent resolutions and through the publication of the *WHO Traditional Medicine Strategy: 2002–2005*. This overarching strategy includes four major objectives: (1) framing government policy; (2) ensuring safety, efficacy, and quality; (3) enhancing access; and (4) promoting proper use of TM/CAM, including herbal medicines (WHO 2002).

To share experiences and support the adoption of TM/CAM strategies, more than 1,500 representatives from member states and interested stakeholders attended the first WHO Congress on Traditional Medicine in 2008 in Beijing. Attendees shared national experiences and information on national TM/CAM policy, regulation of traditional and herbal medicines and TM/CAM practice, TM in primary health care, and research. The resulting Beijing Declaration calls on WHO member states and other stakeholders to take steps to integrate TM/CAM into national health systems (WHO 2008a).

Government policy on traditional medicine

TM is used widely to prevent, diagnose, treat, and manage disease, but considering TM's popularity, the development of regulation and legislation of the herbal medicines market has generally been inadequate. Public policies on TM differ significantly because countries and regions have diverse priorities; for example, the Chinese and Indian governments want to use TM to strengthen primary health care in remote areas; in Africa, many countries are looking for the best ways to use local TM resources and make TM an integrated part of minimal health care packages; and in Europe, licensing providers and creating standards of training and priorities for research have become crucial issues.

Box 5-2
Traditional, complementary, and alternative medicine challenges

National policy and regulatory frameworks

- 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

- Lack of research methodology
- Inadequate evidence base for 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

- 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 conventional practitioners
- Unsustainable use of medicinal plant resources

Rational use

- Lack of training for TM/CAM providers as well as for conventional practitioners on TM/CAM
- Lack of communication between TM/CAM and conventional practitioners, and between conventional practitioners and consumers
- Lack of information for public on appropriate use of TM/CAM

Source: WHO 2002.

Countries create policies that help characterize the role of TM in the national health care system and ensure that regulatory and legal mechanisms promote good practice, equitable access, and assurance of quality, safety, and efficacy. Unfortunately, a 2003 WHO survey found that only forty-five countries reported having enacted a national TM policy (WHO 2005). Fifty-one additional countries, however, reported having such policies in development. Without relevant policies, TM/CAM is practiced with little government oversight and without patient or consumer protection. Therefore, national policies should encompass legislation and regulation of practice and products; education, training, and licensing of providers; and research and development.

Before a country develops a national TM policy, it should assess TM use and practices and evaluate how TM can be used to improve the existing health care system. A national policy on TM/CAM must ensure the safety, efficacy, and quality of TM/CAM products and practices; at the same time, such a policy is not useful if it unduly hinders patient treatment options or leads to higher health care costs.

Although national TM policies have been, initially, slow to take shape, countries are increasingly aware of the importance of ensuring the safety and efficacy of TM, and those with some sort of regulations on herbal medicines increased from fourteen in 1988 to fifty-three in 2003 (WHO 2005). Another survey showed that eleven of twenty-six drug regulatory authorities in sub-Saharan Africa actually registered TMs (WHO 2010a). But, again, because national priorities differ, government approaches to legislation and regulations lack consistency (see Country Study 5-2).

Integration into national health care systems

The integration of TM within the national health care system generally follows four approaches (Bodeker 2001; WHO 2008a).

A *tolerant* health system is based on conventional Western medicine, but allows some TM/CAM practitioners to practice in some capacity. In the United Kingdom, only the practice of osteopathy and chiropractic are protected by statute; Canada's provinces individually regulate CAM practitioners, resulting in some CAM practitioners being regulated in some provinces but not others; in the United States, provider training, credentialing, and licensure requirements vary from state to state. Few national credentialing and licensing bodies are available to determine qualifications for a particular practice.

An *inclusive* system recognizes TM practices but does not fully integrate them into health care delivery, education, or regulation. Nigeria and Mali are examples of inclusive systems, where the governments have a national TM policy, but there is otherwise little regulation of products or practices. In some countries, such as Norway, Zimbabwe, and South Africa, authorities are giving substantial recognition to TM/CAM providers through national efforts designed to increase the integration of TM/CAM and conventional medical systems.

A *parallel* health care system has both conventional and TM as separate components of the national health system. For example, the government of India officially recognized the Ayurvedic and Unani medical systems through the Indian Medicine Central Council Act of 1970. More than 700,000 registered traditional medical practitioners are active in India and almost 500 colleges of Ayurvedic and other traditional medicine education exist (Joshi 2008).

An *integrated* system integrates conventional and TM systems at the level of medical education and practice. Integrative measures include government regulation and registration to control the safety, efficacy, and quality of herbal medicine products; registration of traditional healers and herbalists; and establishment of specialized hospitals, colleges, and universities. Worldwide, only China, the Democratic People's Republic of Korea, the Republic of Korea, and Vietnam are considered to have fully integrated systems (WHO 2002). The Association of Southeast Asian Nations recently committed to promoting the integration of TM/CAM into its members' national health care services, including drafting an Action Plan and Declaration on Traditional Medicine (ASEAN 2009).

Ensuring quality, safety, and efficacy

Many developing countries have a weak regulatory infrastructure for conventional pharmaceuticals, and most countries have no national regulations governing the quality, safety, and efficacy of herbal medications. To be registered as medicines, herbal products must undergo scientific study to assure their safety and efficacy, composition, dosage form, and claimed indications. However, in some countries, such as the United States, herbal products are regulated as foods rather than as medicines; manufacturers are not required to conduct safety or efficacy tests on their products and thus have little incentive to invest in research. Under U.S. law, the onus is on the Food and Drug Administration to prove toxicity in order to remove a product from the market.

Countries that do have a strong pharmaceutical regulatory structure in place should adapt their existing systems to include herbal medications, and countries that lack regulatory standards should work toward setting up a national system. All countries should have some framework in place to review and monitor herbal medicines, including a coordination agency, a national advisory committee, and a pharmacovigilance system for herbal medicines. WHO and its Regional Office for the Western Pacific have published a number of references and guidelines on assessing traditional therapies, and specifically herbal medicines, for use by government authorities and researchers. They are available

Country Study 5-2
The regulatory status of traditional medicine in eight countries

The creation of a national TM policy helps define the role of traditional medicine in a national health care system by putting mechanisms in place for ensuring availability, accessibility, safety, quality, efficacy, and appropriate use. Although more countries are recognizing and addressing the legal and policy issues surrounding TM and CAM, their efforts vary considerably in scope and approach. The following table summarizes the status of regulations, training, and insurance coverage in eight countries as of 2005 or before.

Country	Regulations and laws	Official training and education
Bolivia	• Regulation of herbal medicines was instituted in 1982; they are regulated in their own category as over-the-counter medications. • There are 52 registered herbal medicines. • A postmarketing surveillance system is planned. • Practice of TM was legally recognized in 1985. • TM practitioners must have a government license, although no registry exists. • No official program exists to integrate TM and conventional medicine.	• Ministry of Health established a training program for TM practitioners at conventional medical schools in 1982. • KUSKA, a research organization, runs two TM schools. • Formal courses, workshops, and seminars in TM are available through the government health sector.
Ethiopia	• Health, Drug, Science and Technology Policy of 1999 covers TM national policy. • Ethiopia does not regulate herbal medicine, and no regulatory status exists for herbal medicine. • There are no restrictions on the sale of herbal medicines. • Ethiopian Traditional Healers Association reviews practitioner qualifications in the absence of regulations.	None
Gambia	• No laws or regulations regarding TM exist, but a national policy is under development. • There are no restrictions on the sale of herbal medicines. • There is a licensing process for TM practitioners. • Some TM practitioners are involved in the primary health program.	• There is a training program for TM for health workers.
Kenya	• TM was incorporated into national health policy in the 1970s. • Herbal medicines are not regulated, and there are no restrictions on their sale. • TM practitioners must be registered. • Patent law was revised in 1999 to include protection for TM. • In 2004, Kenya announced that it would develop a national action plan on regulating and promoting TM. • A postmarketing surveillance plan is under development.	• Some training is available for traditional birth attendants.
Netherlands	• There is no national policy on TM/CAM. • Herbal medicines are regulated under the same laws as conventional pharmaceuticals. • There is no registration system for herbal medicines. They are sold in pharmacies and other outlets as over-the-counter products. • As of 1997, CAM practitioners can legally practice medicine, except for specific medical acts reserved for conventional physicians. • Legal registers exist for various categories of nonconventional practitioners who have satisfied specific requirements. Registration gives them the right to practice under a protected title, to ensure they are qualified in a specific field of health care.	• CAM institutions have organized training courses, developed standards of training and professionalism, and established national registration systems. • Most members of CAM organizations are trained as conventional physicians or nurses. • Courses on CAM are offered at conventional medical schools. • Three-year programs are offered in homeopathy, separate from conventional medical school curricula.
Philippines	• National policy on TM was established in 1997. • There is a TM division within the Department of Health. • Herbal medicines are regulated as over-the-counter medications, separate from conventional pharmaceuticals; medical claims may be made for herbals with supporting scientific proof. • The postmarketing surveillance system includes conventional and herbal medicines. • Traditional and Alternative Medicine Act signed in 1997 seeks to integrate TM into the national health care delivery system. • Philippines Institute of Traditional and Complementary/Alternative Health Care was created to promote research and integration of TM.	• Training in TM for conventional practitioners is a government priority.

Country	Regulations and laws	Official training and education
United Kingdom	• Herbal medicines can be licensed or unlicensed; if licensed, they must meet the same manufacturing and safety requirements as conventional medicines. Unlicensed herbal products are not required to meet any specific quality or safety standards, but that may change in accordance with new EU directives. • The postmarketing surveillance system was expanded to include herbals in 1996. • CAM practitioners without a conventional medical degree are tolerated by law but not officially recognized. • No restrictions exist on registered physicians who also practice CAM if they have the required skills and/or qualifications.	• The British Medical Association recommends incorporating CAM into the undergraduate curriculum of medical schools and making accredited postgraduate training available. • Many professional CAM associations offer training in their specialties. • The Institute of Complementary/Alternative Medicines is working to establish national standards of training.
Vietnam	• A national TM/CAM policy is under development. • Laws and regulations on herbal medicines were established in 1989. They are regulated as prescription and over-the-counter medicines. • More than 1,500 herbal medicines are registered. • Safety requirements for herbal medicines include traditional use without demonstrated harmful effects and reference to documented scientific research on similar products. • The postmarketing surveillance system integrates conventional and herbal medicines. • Vietnam's constitution, as well as various laws and regulations, outlines the integration of conventional and traditional health care. Promotion of these objectives is a shared responsibility of the Ministry of Health, Vietnamese Traditional Medicine Association, and the Viet Nam General Union of Medicine and Pharmacy. • Regulations from 1991 specify qualifications for TM practitioners as well as procedures they are permitted to use. • The government entrusts an assessing committee with issuing licenses to TM practitioners.	• Government programs train community health workers to use TM methods to treat common diseases. • No college or university of traditional medicine exists, although the government plans to create one. • Hanoi Medical University has a department of traditional medicine. • Two secondary schools are the main seats of learning in TM.

Sources: WHO: 2001, 2005.

online at http://www.who.int/medicines/areas/traditional/en/index.html.

Expanding the credibility of TM will depend on developing an evidence base for safety and efficacy, which means consolidating existing national and international studies and supporting new research to fill evidence gaps. The increasing number of national TM/CAM research institutes in developed and developing countries is an encouraging sign that more research and collaboration is under way. Examples are found in China, Germany, Ghana, India, Indonesia, Mali, Nigeria, Norway, Thailand, the United States, and Vietnam.

Evaluating quality. Correct botanical identity is a critical step in ensuring the quality of herbal medicine. Formal procedures are needed, including retaining botanical voucher specimens for each raw material batch and using simple organoleptic tests. Increasingly, thin-layer chromatography and qualitative and quantitative high-performance liquid chromatography methods are being used to confirm the identity and quality of raw materials. Other strategies that help ensure the quality of herbal products include developing standard operating procedures for cultivation and manufacturing, quality standards, and assays for determining the pharmacological activity of the product.

Evaluating or even establishing quality standards for herbal medications is difficult because the properties of plants vary drastically according to the plants' genetic makeup and variability; where they are grown, climatic conditions, and time of harvest or collection; and post-harvesting treatment. Some products share more properties with food products, whereas others are potent medicines, and each plant may have hundreds of natural constituents that contribute to its therapeutic qualities.

Without any sort of manufacturing standard, herbal products range in composition from products that are virtually unprocessed, to extracts, to mixtures that include other chemicals. Given their natural complexity and the differences in formulation, isolating and identifying key active ingredient(s), establishing dosage levels, determining mechanisms of action, and weighing risks against benefits often prove difficult. Overall, the general lack of regulations governing quality-control standards and consistency among herbal products hinders the ability of health professionals to guide patients on product selection and use, as well as the ability of researchers to conduct studies that could further clarify product efficacy and appropriate uses.

To ensure that herbal products marketed to consumers are of adequate and consistent quality, national drug regulatory authorities must establish guidance on all elements

of quality assurance, including standard operating procedures, such as Good Agricultural and Collection Practices (GACPs), Good Manufacturing Practices (GMPs), and Good Laboratory Practices (GLPs). Guidelines have been published related to these standards, such as WHO's *Quality Control Methods for Medicinal Plant Materials*. These guidelines not only facilitate the technical work of drug regulatory authorities but also encourage countries to establish quality-control procedures for herbal medicines.

Evaluating clinical efficacy. A report from the U.S. Institute of Medicine (IOM 2005) stated that conventional and complementary medical treatments should be held to the same standards for demonstrating clinical effectiveness and that investigators should use common methods, measures, and criteria to generate and interpret the evidence necessary for making decisions about the use of complementary medicines. Because TM/CAM practices have developed within different cultural and regional contexts, there have been only limited efforts at parallel development of standards and methods—either national or international—for undertaking the type of evaluation that exists for conventional pharmaceuticals. Importantly, scientific research has increased on the chemistry and pharmacology of raw herbal materials and constituent phytochemicals. Despite this increase, however, many natural products on the global market lack clinical proof of safety and efficacy. Table 5-1 lists some herbal medicines that have been evaluated for clinical efficacy.

Additionally, TM/CAM practitioners often focus on the overall condition of the individual patient, rather than on the particular ailment or disease from which the patient is suffering. This more holistic approach to health care makes TM attractive to many people; to be evaluated, however, it requires an evidence base that uses innovative scientific approaches to include the many patient health factors, both specific and nonspecific, considered by TM practitioners. Therefore, the debate continues concerning the appropriateness of applying and combining accepted research methodologies to evaluations of TM/CAM.

Pharmacovigilance. Insufficient safety and efficacy research has hindered the development of national surveillance systems for monitoring and evaluating adverse reactions from herbal medicines. Pharmacovigilance needs to incorporate instruments to identify adverse reactions experienced by patients, studies to determine adverse reactions in specific settings, and a postmarketing quality surveillance system for herbal medicines.

Any adverse reaction reporting must document the product's specific batch number, identify the botanical ingredients present, and include other relevant information, when available. For example, an adverse reaction recorded for a product labeled "ginseng" could be incorrectly assumed to be caused by *Panax quinquefolius* (American or Western ginseng), whereas the product may actually be made from *Pfaffia paniculata,* which is sold as Brazilian ginseng. Monitoring adverse drug reactions requires some technical sophistication to differentiate crude-milled herbal material in tablet or capsule form from concentrated extracts; the latter may contain solvent residue that may be the cause of an adverse reaction, rather than the plant. Similarly, simultaneous conventional pharmaceutical and illicit drug use should be documented to help clarify causality.

In cases where a national pharmacovigilance system for conventional pharmaceuticals exists, it should be enhanced and broadened in ways that will include surveillance of herbal medicines. Knowledgeable researchers and practitioners of TM should be consulted during the development of such systems. WHO has published guidelines on how to include herbal medicine monitoring in pharmacovigilance systems (2004b). Chapter 35 provides more information on pharmacovigilance monitoring.

Enhancing access

Poor countries are the most in need of inexpensive, effective treatments for diseases and access to essential medicines. In these regions, some form of TM is often the most widely available and affordable source of health care. Creating linkages between traditional and conventional medicine through collaboration and communication may help improve health care access and services for all people, and especially for those in resource-limited, rural areas. Such linkages may also promote the acceptance of TM as part of the overall health care system.

Other access issues relate to the protection of TM knowledge and intellectual property rights and the sustainable use of natural resources. Many methods can be used to protect TM knowledge, such as creating a national policy on protecting indigenous knowledge and formalizing the record of information on medicinal plants.

Promoting acceptance of TM in the health care system. One strategy is to develop local professional organizations of TM/CAM practitioners that can form the basis of future national organizations. A strong organization of TM/CAM practitioners will help create better mechanisms for self-regulation and contribute to enhanced professional standards and increased consumer trust and safety. Establishing such professional organizations also facilitates outreach and communication within the health care community.

Countries in Asia that have better-integrated health care systems experience more professional information exchange and cooperation between the TM and conventional health sectors, partly through links in their educational systems (Holliday 2003). Recognizing the effect that TM has on the lives of most Africans, Uganda has added traditional healing studies to its university curriculum to

Table 5-1 Select examples of clinical effectiveness based on meta-analyses of clinical TM/CAM therapy research

Therapy	Medical condition	Conclusion
Artemether	Severe malaria	Equally effective as quinine, but more effective in quinine-resistant areas
Ginkgo biloba	Peripheral arterial disease	More effective than placebo
St. John's wort	Mild depression	More effective than placebo, as effective as (and safer than) synthetic antidepressants
Kava kava	Anxiety	More effective than placebo
Saw palmetto	Prostate hyperplasia	Effective in relief of symptoms
Horse chestnut *(Aesculus hippocastanum L)* seed extract	Chronic venous insufficiency	Effective in short term at reducing leg pain and swelling
Glucosamine sulfate	Osteoarthritis	Decreased pain and increased function

Sources: Ernst 2001; Pittler and Ernst 2008, 1999; Schneider 1992; Towheed et al. 2008.

show that TM has a role in the health care system. In some countries, more informal links are being made between TM practitioners and primary health care providers—especially through efforts to increase access to HIV/AIDS treatment and counseling (Kaboru et al. 2006). But in many other countries, the two types of health care providers work in isolation from each other. Creating opportunities to improve cooperation between TM practitioners and conventional medicine practitioners may allow patients to use both TM and conventional therapies to best meet their needs while improving patient safety. WHO has published the results of a workshop on how to help traditional health practitioners become more involved in primary health care (WHO 2009a).

Protecting medicinal plants. A key to guaranteeing access to traditional medicines is the protection and sustainable use of medicinal plant resources. Raw materials for herbal medicines are often collected from wild plant populations, and overharvesting for local use or to meet export demand is a growing problem. For example, when countries affected by chloroquine-resistant malaria began turning to artemisinin-based antimalarials, China, which exports raw material and extracts of the source plant, *Artemisia annua,* could not fulfill the need. Fortunately, *Artemisia annua* can readily be grown from seed as an annual crop, and many countries, including Kenya, Nigeria, and Tanzania, are establishing commercial plantations.

To help protect its resources, Kenya has banned the export of an endangered tree, *Prunus africana,* that has medicinal properties. The Republic of Kiribati is promoting resource management, conducting agricultural research on medicinal plants to help improve crops and yield, as well as offering registered traditional healers seeds and advice on growing conditions (B. Snell, *E-drug,* Feb. 7, 2005). As part of national TM strategies, other countries are compiling national inventories of medicinal plants to help focus efforts on natural resource management and sustainability.

Protecting indigenous knowledge and intellectual property. Use of herbal medicines requires access not only to biological resources, but also to community knowledge about plants' therapeutic properties. However, rights to indigenous knowledge and resources have, for the most part, been overlooked by Western intellectual property systems, where the components of TM have been treated as part of the public domain and available to anyone. Although research into TM is essential to ensuring access to safe and effective treatments, the knowledge of TM practices and products can be a source of substantial economic benefit to companies and research institutes.

Currently, TM knowledge is being appropriated, adapted, and patented by scientists and industry, with little or no compensation to its original creators or holders, and without their informed consent. Because of such appropriation and because of the focus on intellectual property rights and pharmaceuticals in general, growing attention is being paid to the issue of protecting TM knowledge and products. But, because intellectual property rights are usually given to individuals or organizations, whereas indigenous knowledge is community based, determining what can and should be protected may be difficult.

Country Study 5-3 describes a unique collaboration between the University of California, Berkeley, and Samoa that is designed to protect indigenous knowledge while exploiting modern research and development capabilities.

WHO encourages countries to adopt systems that compile a national inventory of medicinal plants and create records to preserve TM knowledge and enable its correct and continuous use over generations. For example, the Ministry of Health in Côte d'Ivoire has conducted a knowledge survey among traditional practitioners and recorded more than 2,000 traditionally used plants (WHO 2002); traditional healers, lawyers, and scientists are some of the stakeholders in Zambia working to create a national policy specifically to protect and document knowledge and biological resources (Ngandwe 2005); and India has developed a digital library of knowledge and formulations used in Ayurveda that is organized to help international patent offices to avoid granting inappropriate patents. Other countries, such as China, are

Country Study 5-3
Innovative indigenous knowledge research agreement: Samoa and the University of California, Berkeley

In the 1980s, an ethnobotanist from the United States was searching for a cure for breast cancer among the flora in Samoa. As part of the project, he interviewed two *taulasea* (traditional healers) who had used the bark of the indigenous mamala tree (*Homalanthus nutans*) as a treatment for hepatitis. Later tests of mamala showed that it contained prostratin, a previously known substance that showed powerful effects against HIV in the laboratory. The hope is that prostratin will become an effective treatment for HIV/AIDS. However, the supply of prostratin is limited to mamala tree bark, found wild in Samoa and a few other South Pacific islands. To make prostratin more widely available without endangering its source in the rain forest, researchers at the University of California, Berkeley (UC Berkeley), are using genetic engineering to clone the tree's genes and insert them into microbes to mass-produce the substance.

This research is conducted under an innovative agreement between the university and the nation of Samoa, which asserts national sovereignty over the gene sequence. The intellectual property agreement was made after scientists visited tribal chiefs to give a presentation on genetic engineering. The contract gives Samoa and UC Berkeley equal shares of any royalties that the university might ultimately derive from the use of the genes. Samoa's portion will be allocated to the government, villages, and the families of the *taulasea* who first showed the American ethnobotanist how to use the plant. In addition, if the research results in a marketable product, UC Berkeley and Samoa will establish a distribution process that will allow access to developing countries at a cost including no or minimal profit.

A separate agreement was established in 2001 between the Samoan government and the AIDS Research Alliance (ARA), allowing clinical research on prostratin, with 20 percent of the ARA's profits to be returned to the Samoan people. ARA planned to finish its preclinical trials in 2010, paving the way to begin human clinical trials.

Sources: ARA 2010; Black 2004.

using the Indian database as a template for developing their own knowledge libraries (Hepeng 2005). The information generated by these inventories should be used by national patent offices worldwide to evaluate the novelty and innovation of patent applications. In South Africa, the Patents Amendment Act of 2005 requires that every patent application state whether the invention is based on or derived from traditional knowledge.

Promoting rational use

As with the rational medicine use concept promoted for conventional pharmaceuticals (Chapter 27), appropriate use of TM and herbal medicines is dependent on qualified practitioners, proper prescribing and use of high-quality products, and reliable information and guidance for practitioners and patients. The degree to which traditional or alternative medicine is integrated into the conventional health care system will affect the type of information about TM/CAM needed in the community. In many countries, additional work is needed to raise awareness of safe and appropriate use of TM, but unfortunately there is a shortage of organized networks of traditional practitioners to help promote safe TM practices.

Reliable information based on results from high-quality scientific studies is crucial in guiding TM/CAM practitioners, conventional health care providers, and the public in the most appropriate use of herbal medicines. The *WHO Monographs on Selected Medicinal Plants* is an important reference for national health authorities, scientists, and pharmaceutical companies, providing technical information on the safety, efficacy, and quality control of widely used medicinal plants (WHO 1999, 2004, 2007, 2009).

Proper use by providers. Training for TM practitioners should ensure that their knowledge and qualifications are adequate in their area of expertise. Without appropriate training or accompanying qualification and licensing schemes, it is difficult for national authorities and consumers alike to identify qualified TM providers. In the few countries that integrate TM and conventional medicine into one health care system, TM practitioners benefit from university education, which should include study of both TM and conventional medicine. Subsequently, these practitioners can become part of staff at hospitals of conventional medicine, promoting the use of TM in combination with conventional medicine practices. In the absence of formal education, TM practitioners or healers who receive basic training in primary health care can help disseminate important health information, especially in areas where people rely predominantly on TM.

Also, because TM/CAM use is becoming more widespread, all doctors, nurses, pharmacists, and other conventional health care providers should receive education about TM treatments during their professional education. Parallel

ASSESSMENT GUIDE

TM/CAM national policy, laws, and regulations

- Is there a national policy on TM/CAM?
- Are there any laws or regulations relating to TM/CAM? How are the laws enforced?
- Do any laws or regulations pertain specifically to herbal medicines?
- If so, are herbal medicines regulated separately from conventional medicines? Are they classified as prescription or over-the-counter, or are they given another status, such as food?
- Is there a national program or expert advisory group that has responsibility for TM/CAM issues?

Evaluating the quality, safety, and efficacy of herbal medicines

- What regulatory requirements apply to the manufacturing of herbal medicines?
- What are the regulatory requirements for the safety assessment of herbal medicines?
- What type and level of evidence, if any, is required to prove the efficacy of herbal medicines?
- Is there a registration system for herbal medicines?
- Is there a postmarketing surveillance system for herbal medicines? Does it include reporting for adverse reactions?

TM/CAM research

- Is there a national research institute devoted to TM/CAM?
- Are there any policies in place to compile an inventory and/or protect traditional medicine resources, such as endangered plants? Is there any system to document indigenous knowledge and resources?

Integration of TM/CAM into the conventional health system

- Is TM/CAM officially recognized by the government as part of the health care system? Is there any integration with the national health care system? Are there any herbal medicines on the national essential medicines list?
- Is the practice of TM/CAM regulated both for health care providers and TM/CAM providers?
- Are there any training programs for TM/CAM practices?

Use of TM/CAM

- How do consumers typically use herbal medicines? Where do they buy herbal medicines? From pharmacies or other medicine outlets? From licensed or unlicensed practitioners?
- How are consumers informed about the benefits and risks of herbal medicines? Are there any regulations related to medical or health claims or labeling?

education helps TM providers and conventional health care professionals understand how their roles can complement each other for the benefit of the patient.

Proper use by consumers. Because many consumers use herbal medicines without consulting a health care professional, they must have access to reliable information and product labeling to make informed decisions on the safe use of herbal medicines. Without knowledge of the potential for adverse reactions, patients may fail to inform their doctors about the TM/CAM products they are using, and doctors may fail to ask.

Public information about TM/CAM helps spread knowledge about the health benefits as well as the possible risks, but the information must be reliable and adapted to the specific local context. An information campaign on herbal medicines should consider the local social, cultural, religious, and spiritual contexts, because medical concepts and understanding can vary significantly. Consequently, efforts to ensure that consumers use TM/CAM properly must involve a range of stakeholders, including government representatives, health authorities, professional and consumer organizations, and TM/CAM researchers. An important resource related to consumer education is *Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine* (WHO 2004a).

Currently, few standards exist to control the labeling and advertising of herbal medicines. The regulatory framework for TM/CAM products should include guidelines on how to educate the public, including restrictions on information and advertisements. Such regulations can be issued either by national authorities, in the form of enforceable controls, or by local organizations, such as professional groups, in the form of voluntary controls. These kinds of regulations help secure the trustworthiness of the information, prevent false health claims and misleading advertisements, and ensure the appropriate labeling of TM/CAM products.

Consumers also need to be reminded that information on the Internet is not easily controlled or regulated and that special attention is needed when evaluating online information (see Chapter 34). Some countries have special regulations to control the publication of health information on the Internet, but product marketing and advertising are mostly unrestricted. ■

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