The use of traditional medicine (TM) and complementary and alternative medicine (CAM) has increased significantly over the past few years. However, as recent reports have shown, in addition to the many benefits there are also risks associated with the different types of TM/CAM. Although consumers today have widespread access to various TM/CAM treatments and therapies, they often do not have enough information on what to check when using TM/CAM in order to avoid unnecessary harm.

In this context, it is necessary to develop information to meet the needs of consumers. These Guidelines will provide governments and other stakeholders with an overview of the general principles and activities necessary for the development of reliable consumer information. The document will also be a useful reference to consumers in guiding them on the information they need to have in order to choose a TM/CAM therapy that is safe and effective.

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Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine

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Foreword

During the last decade, the use of complementary medicine (CM, referred to as CAM in the document) has increased in both developing and developed countries, and also within the Lombardy Region of Italy. Globalization has led to intercultural exchanges and widespread use of techniques and therapeutic products of CM often unknown to local communities. This phenomenon requires particular attention in order to avoid inadequate misunderstandings and inappropriate use that could be harmful to the individuals and subsequently affect entire communities.

For this reason, the Regional Government of Lombardy is focusing on the important and strategic sector of consumer protection, which has been considered as one of the priorities in economic health care planning as outlined in the

twenty objectives of the Government. This priority runs parallel to the most recent World Health Assembly Resolution on Traditional Medicine in 2003 which urged Member States of the World Health Organization to provide reliable information on traditional medicine (TM) and CM to consumers and providers in order to promote proper use. Therefore the Regional Government and the World Health Organization have established a four-year cooperation plan to develop technical guidelines and information on CM to help ensure the safety of consumers.

It is extremely important to create the conditions for the correct and appropriate use of CM methods which, if used correctly, can contribute to the protection and the enhancement of patients' health and well being. One such condition is the need to make sure that consumers are better informed and aware of CM strategies and treatments so as to enable them to make appropriate decisions on how to improve their health.

With this in mind, the Regional Government of Lombardy supported the development of the *WHO Guidelines on developing consumer information on proper use of traditional, complementary and alternative medicine* by outlining how governments and relevant non-governmental organizations can empower consumers to become active participants in the therapeutic choices for health care in the field of CM. The process of development of these guidelines included the WHO Consultation Meeting held in Milan in December 2003, which brought together experts, national authorities and professional organizations from all over the world. One of the conclusions of the Consultation was that these guidelines were appropriate as a resource not only for the Lombardy Region, but also for various country situations worldwide.

The Regional Government of Lombardy has also outlined various issues in its regional management plans, one of which involves the importance of consumer associations as an important bridge between authorities and the community. At one level, consumer associations can interact directly with patients and operate within the community by contributing to activities for increasing consumer awareness of all forms of health care. At another level, such entities can communicate the needs of consumers to regional authorities in order to create adequate regional policies.

Only through such cooperation can the consumers become more aware of the possibilities and of the issues relating to the use of TM/CM in health care and therefore assume responsibility for their own health.

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Preface

One of the main reasons for the increasing use of traditional medicine is a growing trend for patients to take a more proactive approach to their own health and to seek out different forms of self-care. In the process, many consumers have turned to natural traditional medicinal products and practices, under the assumption that "natural means safe". However, this is not necessarily the case. A number of reports have revealed examples of incorrect use of traditional medicines by consumers, including incidents of overdose, unknowing use of suspect or counterfeit herbal medicines, and unintentional injuries caused by unqualified practitioners. In an effort to prevent similar incidents, there is a need to ensure that consumers are well informed about the proper use of traditional medicine.

These guidelines are intended to provide technical guidance in order to assist Member States in developing context-specific and reliable consumer information promoting proper use of traditional medicine (TM) and complementary and alternative medicine (CAM). In developing the information, health authorities are recommended to collaborate with a wide range of stakeholders representing different perspectives, including NGOs, professional and consumer organizations and TM/CAM researchers.

The objectives of these guidelines are:

- To provide an overview of the key elements directly tied to consumers that must be in place in health systems in order to ensure proper use of TM/CAM;
- To describe general principles and activities for the development of reliable consumer information about TM/CAM;
- To outline the key elements that should be taken into consideration when developing consumer information promoting proper use of TM/CAM.

The long-term goal is to maximize the benefits and minimize the risks of TM/CAM use by empowering consumers to become active participants in health care and to make informed choices.

However, WHO recognizes that efforts to promote the proper use of TM/CAM through consumer education/training must be supported by other measures such as the establishment of national laws and regulations to control herbal medicines products, efforts to ensure the qualified practice of TM/CAM therapies, and, where appropriate, measures to control information about TM/CAM used in advertisements.

In a follow-up to the development of these guidelines, WHO is to organize a series of interregional, regional and national

workshops for national health authorities and relevant NGOs on how to develop consumer information on the proper use of TM/CAM and how to organize education/training programmes on this at a national level.

Since the use of TM/CAM varies from country to country, national health authorities and NGOs should rely on their own specific situation to develop appropriate consumer information and relevant training programmes. Some governments are already aware of the importance of consumer education in relation to the safe and effective use of TM/CAM and have developed consumer education information. It is important to note that such information should make use of engaging pictures and easily understood language so that it is easily accessible to a greater portion of the population. An excellent example of this can be found in Annex I: Leaflets promoting proper use of TM/CAM published by the Department of Health, Hong Kong SAR, China.

WHO believes that consumer information and education will help consumers to seek out appropriate types of self-care and, as a result, help them to obtain more benefits from TM/CAM and reduce unnecessary risks.

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Glossary

Adverse event Any untoward medical occurence that may appear during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with the treatment (*1*).

Conventional medicine For the scope of this document, conventional medicine refers to the broad category of medical practice that is sometimes called Western medicine, biomedicine, allopathic medicine, scientific medicine, or modern medicine.

Complementary and alternative medicine (CAM) refers to a broad set of health-care practices that are not part of a country's own tradition and not integrated into the dominant health care system. Other terms sometimes used to describe these health care practices include 'natural medicine', 'non-conventional medicine' and 'holistic medicine' (*2*).

Herbal Medicines include herbs, herbal materials, herbal preparations and finished herbal products:

- *Herbs* Herbs include 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* include, 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* consist 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. (3)

Manufacturer For the purpose of these guidelines, the term manufacturer refers to the producer, importer, distributor or marketer of a finished TM/CAM medication product and, where applicable, to the holder of the marketing authorization or registration for that product in the country in question.

TM/CAM medication therapies For the scope of these guidelines, TM/CAM medication therapies include preparations commonly referred to as herbal medicines (see definition above), homeopathic remedies and dietary supplements.

TM/CAM procedure-based therapies For the scope of these guidelines, these include therapies that use various techniques primarily without the use of medication to provide health care. They include for example acupuncture and related techniques, manual therapies (e.g. massage, chiropractic, naprapathy and osteopathy, qi gong, tai ji quan), naturopathy, thermal medicine and other physical, mental, spiritual and mind-body based therapies.

TM/CAM provider refers to all persons who provide TM/CAM services to treat, diagnose or prevent any disease or disorder.

Traditional medicine (TM) This includes 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 (*2*).

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1 General Considerations

The use of traditional medicine (TM) and complementary and alternative medicine (CAM) is increasing throughout the world. Already, it accounts for a major part of the health care provided worldwide. In low- and middle-income countries, up to 80% of the population may rely on TM for their primary health care needs (*2*). In many high-income countries CAM utilization is becoming increasingly popular, with up to 65% of the population reporting that they have used this form of medicine (*2,4*).

In response to the challenges posed by the widespread use of TM/CAM, WHO has developed the *WHO Traditional Medicine Strategy: 2002-2005*. The Strategy has four major objectives: (i) framing policy; (ii) ensuring safety, efficacy and quality; (iii) enhancing access; (iv) promoting proper use of TM/CAM. While these guidelines focus on the issue of proper

use of TM/CAM, a number of WHO publications explore the other areas (see Annex V).

This document adopts the definitions of TM and CAM that have been established by WHO (see glossary).

1.1 THE BENEFITS OF TM/CAM

TM/CAM therapies are generally available, affordable and commonly used in low- and middle-income countries. 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 (*5–8*).

Many TM/CAM therapies are supported by empirical evidence on safety and effectiveness. Such evidence is usually based on sources such as traditional scriptures, pharmacopoeias and/or clinical experience collected over hundreds of years. An increasing number of scientific studies now support the use of certain TM/CAM therapies. The effectiveness of acupuncture, for example, a popular treatment for pain relief, has been demonstrated both through numerous clinical trials and laboratory experiments (*9,10*). Another example is artemisinin, a new antimalarial medicine, which is purified from a traditionally used medicinal plant. Other examples of TM/CAM therapies with a research-derived evidence base are: St John's Wort *(Hypericum Perforatum)* for mild depression; and Saw Palmetto (*Serenoa Repens*) for reducing symptoms of benign prostate hyperplasia (*11,12*).

TM/CAM therapies may cause fewer adverse events than conventional therapies such as treatment with conventional medicines (pharmacotherapy). For example, a National In-

stitutes of Health (NIH) panel issued a consensus statement on acupuncture stating that the incidence of adverse effects from acupuncture are extremely low and often lower than for conventional treatments (*13*).

Another reason why patients turn to TM/CAM for complementary care is the increasing cases of chronic and debilitating diseases for which there is no cure. Scientific studies of several TM/CAM therapies show that their use is effective, e.g. for HIV/AIDS and cancer patients (*14*,*15*). As a result, UNAIDS is advocating collaboration with TM practitioners in AIDS prevention and care in sub-Saharan Africa (*16*).

The advantages of TM/CAM include its diversity and flexibility; its availability and affordability in many parts of the world; its widespread acceptance in low- and middle- income countries; its comparatively low cost; and the relatively low level of technological input required. As a result, TM/CAM therapies have the potential to contribute to a better health care system in many countries (*2*). However, there is a need for an increase in research to improve the evidence base as regards the efficacy of most TM/CAM therapies. Measures needed to facilitate research efforts include the legal recognition of TM/CAM, an increase in funding for research, the development of appropriate research methods for evaluating some TM/CAM therapies, and the development of systems for intellectual property rights protection (*2*).

1.2 THE RISKS INVOLVED IN THE USE OF TM/CAM

TM/CAM medication therapies are commonly used as self-care treatments. However, TM/CAM products are unregulated

in many countries, and therefore many of the concerns about the risks for consumers relate to the safety and quality of TM/CAM medicinal products. Reported problems include sales of incorrect plant species and the contamination and adulteration of TM/CAM medication therapies. Heavy metals, fumigation agents, microbial toxins and pharmaceutical substances have been found in toxic concentrations in TM/CAM medication therapies (*17–19*). Problems involving the use of incorrect plant species and contamination can be prevented by the development and enforcement of herbal medicine regulations and by following good agricultural and collection practices (GACP) for medicinal plants and good manufacturing practices (GMP) respectively.

Uppsala Monitoring Centre, a WHO Collaborating Centre that monitors adverse reactions to medicines, has received reports from all over the world on adverse events following the use of TM/CAM medication therapies (*20,21*). The risks also include adverse events following sub-standard practices or the misuse of TM/CAM by unqualified practitioners. It is important to note that while TM/CAM procedure-based therapies are relatively safe, accidents do occasionally occur, for example when TM/CAM practitioners are not fully trained (*3*); when practitioners do not follow the professional code of ethics; or when the treatment is not adjusted or modified according to the condition or constitution of the patient. For example, although serious adverse events following acupuncture (e.g. pneumothorax) are rare, well-documented cases have occurred, including fatalities (*17*).

Incorrect use of TM/CAM medication therapies can have fatal outcomes. For example, the Chinese herb ma huang (*Ephedra sinica*), which contains ephedrine and is used for breathing problems, has caused heart attacks and strokes

among some Americans using it as a dietary supplement (*22*); long-term use of kava kava (*Piper Methysticum*) can cause serious liver damage (*23*); and the use of ginkgo (*gingko biloba*), which stimulates peripheral circulation can result in bleeding during surgery (*22*).

In addition to adverse events, interactions have been described in the scientific literature (*17, 24*) as well as in WHO Monographs (*25, 26*). Interactions may pose a risk to patients who use TM/CAM medication therapies in conjunction with conventional drugs. Studies show that many patients use TM/CAM therapies concurrently with conventional medicine, often without informing their health care provider (*27*). Efforts are needed to improve communication between patients and health care providers and, in the case of self-care treatments, to ensure that consumers are better informed.

In summary, TM/CAM is unregulated in most countries, communication between patients and health care providers is generally poor, and there is an urgent need to develop consumer information in order to minimize the risks and maximize the benefits of TM/CAM use.

1.3 PROPER USE OF TM/CAM BY CONSUMERS

In view of the benefits and risks of TM/CAM therapies, efforts to ensure proper use of TM/CAM need to involve a wide range of stakeholders including consumers, governments, health authorities, NGOs, professional and consumer organizations, and TM/CAM researchers. Proper use of TM/CAM by consumers is a relative term that is influenced by the local culture and context (see section 2.1) and primarily depend-

ent on the individual's knowledge and ability to minimize the risks and maximize the benefits of TM/CAM use.

The following is a checklist of basic questions which may be used by consumers to help facilitate proper use of TM/CAM.

- Is the therapy suitable for treating the condition?
- Does the therapy have the potential to prevent, alleviate and/or cure symptoms or in other ways contribute to improved health and well-being?
- Is the therapy or herbal medicines provided by a qualified (preferably registered and certified) TM/CAM or health care practitioner with adequate training background, good skills and knowledge?
- Are the herbal medicinal products or materials of assured quality and what are the contraindications and precautions?
- Are the therapies or herbal medicinal products available at a competitive price?

1.4 ADDITIONAL IMPORTANT ASPECTS FOR THE PROPER USE OF TM/CAM

Although these guidelines focus mainly on the development and content of reliable information for consumers, there is also a critical need to ensure that key health systems structures and processes are in place when promoting proper use of TM/CAM. For instance, the presence of structures governing TM/CAM education, information and/or research and the existence of professional TM/CAM organizations are all important for the development, implementation and dissemination of activities promoting proper use of TM/CAM (*28*). The following sections describe some of these key areas.

(a) Quality control of herbal medicines

Herbal medicines are the most popularly used form of TM/CAM medication therapy. However, in some countries animal, mineral, or other materials may also be used. Therefore, in these cases, regulations should be specifically tailored to address each country's unique situation. Regulatory systems for the quality assurance and registration of herbal medicines will improve the quality of products and enable consumers to use high quality products (*2*). Quality control of herbal medicines involves complex issues, which have been described in a series of WHO documents such as *Quality control methods for medicinal plant materials* (*29*), *WHO monographs on selected medicinal plants* and *General guidelines for the methodology on research and evaluation of traditional medicine* (*3, 25, 26, 29*). It is important that regulations on the quality control of herbal medicines are developed and implemented appropriately so that small-scale manufacturers are able to comply and are not excluded from the market.

(b) Development of reliable treatment guidelines

The development of reliable information on the most commonly used TM/CAM therapies, based on results from clinical studies and other scientific studies, can offer clinically relevant information about these therapies to guide TM/CAM practitioners, conventional health care providers and the public. This will help prevent irrational use and improve the ability of consumers to make informed decisions on TM/CAM use.

(c) Training and qualified practice for TM/CAM practitioners

Adequate training and the licensing of TM/CAM practitioners will improve safety, promote the credibility of TM/CAM therapies and TM/CAM providers, and enhance consumer trust in their practitioners (*30, 31*). Guidelines for basic training and continuing education of TM/CAM practitioners have been developed by a number of organizations including WHO and a number of national governments and various professional organizations (*32*).

(d) Collaboration between conventional health care providers and TM/CAM practitioners

Since consumers often use both TM/CAM and conventional treatment simultaneously, it is necessary to improve collaboration between registered/licensed TM/CAM practitioners and conventional health care providers. Ideally, the training of conventional health care providers should include basic knowledge of commonly used TM/CAM. Likewise, the training of TM/CAM practitioners should include basic knowledge of relevant parts of conventional medicine, such as public health, hygiene, first aid and ethical issues. Moreover, TM/CAM practitioners should be encouraged to conduct research and submit reports to medical journals, in order to initiate information sharing between conventional and traditional medicine.

(e) Communication between TM/CAM consumers and their conventional health care providers and TM/CAM practitioners

Since conventional health care practitioners are sometimes sceptical about TM/CAM treatment, there is often a communication barrier between the consumers and doctors. Improved communication between TM/CAM consumers and their different health care providers, may promote greater trust between patient and providers and reduce the risks of adverse events and interactions in patients using TM/CAM medication therapies or using procedure-based therapies in conjunction with conventional treatment (*30, 31*).

(f) Organization of TM/CAM practitioners

Efforts to strengthen the organization of TM/CAM practitioners will help ensure better structures for self-regulated control mechanisms and contribute to increased professionalism (*30, 33*). There is a need to develop local organizations of TM/CAM practitioners which can become the backbone of future national organizations. The development of a professional code of ethics can further contribute to consumer trust and safety. Official recognition of relevant TM/CAM practitioners (e.g. through legal frameworks) should also take place.

2

Development of Consumer Information

Although consumer information cannot compensate for poor TM/CAM products or inadequate TM/CAM practices, it can help consumers gain increased knowledge about the benefits and potential risks of TM/CAM therapies and where to find reliable sources of information. Public information about TM/CAM serves the purpose of spreading knowledge about the health benefits of TM/CAM as well as the potential risks. However, it is important that information strategies provide a well-balanced message containing reliable, well-supported information tailored to the specific local context. A recent report from Hong Kong SAR, China, on the impact of a number of publicity measures in reducing the incidence of herb-induced aconitine poisoning underlines the effectiveness of public information campaigns

about the risks involved in the use of TM/CAM (*34*). In addition, experiences from public education strategies promoting rational use of conventional medicine support the use of public interventions for behavioural change (*35*).

The importance of developing and disseminating reliable TM/CAM information has been addressed in a number of reports (*2, 33, 36, 37*).

WHO has proposed six steps for the development of effective communication strategies promoting rational drug use: (i) investigation; (ii) activity planning; (iii) development of materials; (iv) material testing and revising; (v) activity implementation and monitoring; (vi) activity evaluation and reassessment (WHO, 2002). While the present guidelines focus mainly on steps (ii) and (iii) (see sections 3 and 4 respectively), it is recommended that stakeholders developing information promoting proper use of TM/CAM should pay attention to all six steps, possibly with guidance from the WHO work on the promotion of rational use of medicines.

The type of information needed when promoting proper use of TM/CAM may vary from country to country depending on a number of factors such as cultural and traditional influences, health system structure, the TM/CAM utilization pattern and the development of all additional aspects of proper use as outlined in section 1.4.

2.1 CULTURAL INFLUENCE

It is essential that an information campaign promoting proper use of TM/CAM is undertaken with knowledge of the social, cultural, religious and spiritual context in which it is

based. Each country has its own set of medical knowledge based on the local culture and past experience. As a result, medical concepts and understandings can vary significantly from one country to the next. For instance, a traditional Chinese medicine for the heart will not treat the same conditions as heart medications in conventional medicine. This is because the term 'heart' in traditional Chinese medicine does not only mean the physical organ 'heart', but also includes some functions conventional medicine would attribute to the brain. This is an example of how simple cultural misunderstanding can easily occur.

When medicines are being traded in foreign markets, the domestic consumers often wrongly apply their own medical concepts and understanding to the imported traditional medicines, often resulting in misunderstanding and subsequent misuse.

2.2 HEALTH SYSTEM STRUCTURE

The structure of the health system in the country is important for the development of information about TM/CAM as it may determine the need for information as well as the kind of information suitable for different groups (*2*).

The extent to which TM/CAM is an officially recognized element of health care depends largely on the structure of the health system in individual countries. WHO has identified three types of health system structures in relation to TM/CAM: an *integrative* health system, an *inclusive* health system and a *tolerant* health system (*2*).

In an *integrative* health system (e.g. China, the Republic of Korea and Viet Nam) TM/CAM is officially recognized and

incorporated into all areas of health care provision. There are a series of regulations and registration to control the safety, efficacy and quality of herbal medicine products. The TM doctors must receive a university education which includes both knowledge of TM and modern medicine, and they must be licensed to practise. Patients/consumers are free to consult both TM/CAM providers and medical doctors, the health insurance system covers both forms of treatment, and there are no communication barriers between TM/CAM practitioners and medical doctors. In addition, the government often provides consumer education. (See Annex I for an example of consumer information developed by the Department of Health, Hong Kong SAR, China.) The benefit of an integrative health system is that many of the necessary elements that are important when promoting proper use of TM/CAM already exist.

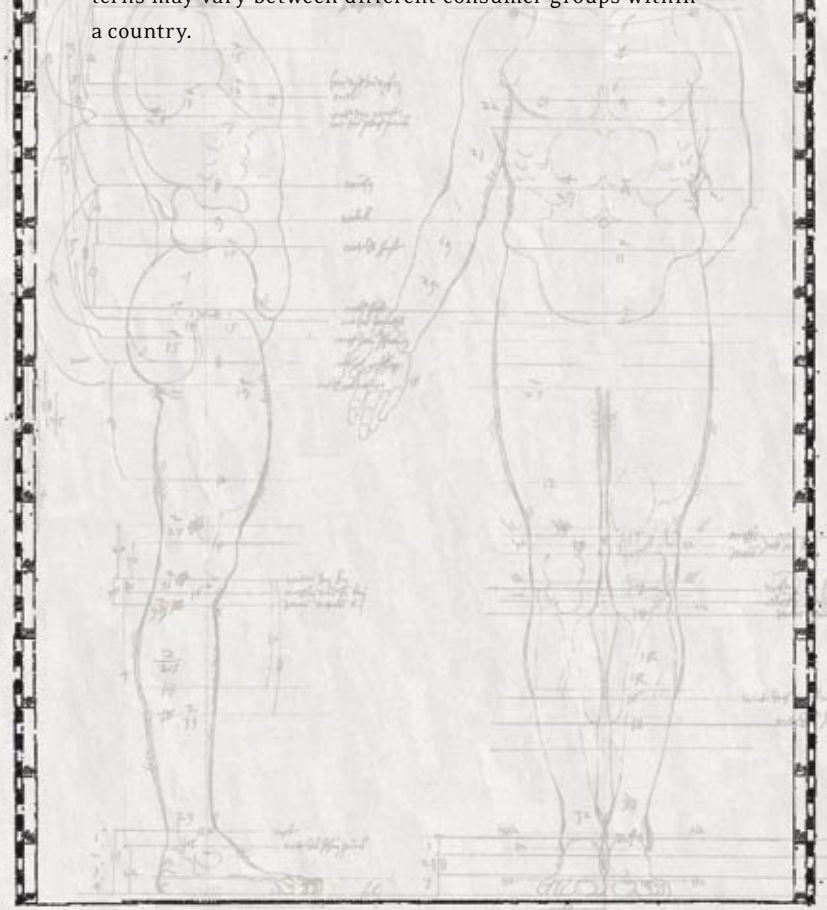
The other systems are an *inclusive* health system, which recognizes TM/CAM, but has not yet incorporated it into all aspects of health care (e.g. in health care delivery, education and training, regulation or research). This situation exists in many countries including Australia, Canada, Germany, Ghana, India, Indonesia, Iran, Madagascar, Malaysia, Mali, Singapore, Switzerland, Thailand, Ukraine, United Arab Emirates and the United States. In a *tolerant* health system, health care is based entirely on conventional medicine and TM/CAM practices are not officially recognized as therapeutic methods or as health enhancement practices within the national health care system. At present, most countries have a health system structure that belongs to this third category (*2*). The type of information developed will have to address the specific needs demanded by the individual health system.

2.3 UTILIZATION

Utilization of TM/CAM is complex and varies among Member States. Therefore it is important to take into consideration the utilization pattern of a country to ensure that the information developed will be effective and appropriate to the specific country situation. Three broad types of utilization patterns can be recognized. The first is prevalent in countries where TM is used as the *primary source* of health care. Typically for these countries, the availability and/or accessibility of conventional medicine are generally limited and TM is used mainly by poor populations, as in many African countries and some Asian countries. This situation is found mainly in countries with either a tolerant or an inclusive health system structure. The second type of TM utilization, involving a few countries, entails the use and prescription of TM in conjunction with conventional medicine due to cultural/historical influence. This *dual utilization pattern* is found in integrative systems such as in China, Viet Nam, and the Republic of Korea or in *inclusive* systems in many countries in Asia and South America. The third type involves the use of TM/CAM in a complementary or alternative role with conventional medicine. This *selective utilization* is common in high-income countries where the health system structure is usually inclusive or tolerant as in North America and many European countries.

In countries where TM is the primary source of health care or is used in conjunction with conventional medicine, consumers are likely to be familiar with the general concepts of

TM therapies. However, when TM is practised outside the context where it was first developed, consumers may not have the same knowledge about the general concepts of TM/CAM. As a result, the type of information needed is likely to vary depending on the individual context and utilization pattern in a country or region. In addition, TM/CAM utilization patterns may vary between different consumer groups within a country.



3

General Principles and Activities for Ensuring Reliable TM/CAM Information

Before developing and disseminating consumer information on how to use TM/CAM properly, it is necessary to carefully plan how to develop information, how the information is going to be disseminated, and what regulatory mechanisms are needed to ensure reliability.

3.1 HOW TO DEVELOP RELIABLE INFORMATION

It is essential that national and/or local governments play an important role in controlling and supporting the development and dissemination of various information initiatives ensuring proper use in the field of TM/CAM. However, in order to develop contextually appropriate TM/CAM informa-

tion, there is a need for collaboration and exchange of ideas among different stakeholders including: international organizations; regional, national and local authorities; manufacturers and suppliers of TM/CAM; TM/CAM researchers; professional organizations; consumer organizations; and NGOs involved in TM/CAM. Before starting to develop consumer information, it may be useful to examine what other countries have achieved (e.g. what kind of TM/CAM information and how this has been disseminated). Organizations or stakeholders in the same country but in other fields may also have useful experiences and information relevant for the development of TM/CAM consumer information.

3.2 DISSEMINATION OF INFORMATION

In order to ensure the success of information initiatives promoting proper use of TM/CAM, it is important to attract the attention and interest of consumers. In order to reach as many TM/CAM consumers as possible, the information provided should be in plain and simple language, if possible in each of the main languages spoken in the country and with alternative forms for those unable to access the written form. To meet the various needs of consumers and to ensure that information is both accessible and understandable, information also needs to be presented in a variety of ways and through different activities as suggested in the following sections.

3.2.1 TM/CAM information centre

A TM/CAM information centre can be a useful way of facilitating the dissemination of reliable information. Such

a centre can be separate or part of an independent national research institute, either within an existing health or drug information centre. Public hospitals and primary health care centres can also serve as local TM/CAM information centres, possibly working under the supervision of a national centre. The staff at a TM/CAM information centre should include TM/CAM representatives, preferably designated by national health authorities.

A TM/CAM information centre can provide consumers, the media, health care providers and others with guidance on TM/CAM issues including:

- National regulations and registrations involving TM/CAM;
- Contact details of relevant TM/CAM professional organizations (e.g. a free local directory);
- Lists of TM/CAM therapies covered by national or private health insurance;
- Locally appropriate information regarding the safety, quality and efficacy of different TM/CAM therapies (House of Lords, 2000);
- Systems for reporting benefits as well as suspected adverse events or interactions.

3.2.2 TM/CAM surveillance system

A surveillance system is essential in order to improve the safety of TM/CAM therapies in general and to learn more about potential harmful adverse events and interactions following TM/CAM use. In countries with a national surveillance system for conventional medicines, the same system, adapted for collecting reports on TM/CAM medication therapies, could be used for the reporting of suspected adverse

events following use of TM/CAM medication therapies. TM/CAM experts should be involved in all TM/CAM surveillance systems in order to verify reports. The context in which a surveillance system functions will determine the appropriate structure of the system, including the means of reporting. For instance, different pathways of reporting may be used for TM/CAM medication therapies depending on their mode of delivery, as proposed in the *Guidelines on the safety monitoring and pharmacovigilance of herbal medicines* (*38*). For TM/CAM procedure-based therapies, similar surveillance systems can be developed, tailored to the particular TM/CAM therapy in question.

3.2.2.1 PATHWAYS OF SURVEILLANCE FOR TM/CAM MEDICATION THERAPIES

The setting in which an adverse reaction is noted and the status of the person noting the reaction will determine the most appropriate means of reporting. It is recognized that in some countries a pharmacovigilance programme may consist of a network of national and regional centres. Reports should be sent to the appropriate regional or national centre in line with individual countries' reporting guidelines. In the absence of a centre, it may be appropriate to report directly to the regulatory authority.

The different pathways for reporting are as follows:

1. Health professionals and providers of TM/CAM medication therapies should report to the national pharmacovigilance centre.
2. Patients/consumers should normally report to their physicians or providers of TM/CAM medication therapies. They may also report directly to the national pharmacovigilance centre, consumer organizations or to companies (or their representatives.
3. Manufacturers and importers/distributors of TM/CAM medication products could be a source of information on adverse events involving their products. Some countries have included this source of information as part of their regulatory framework. Manufacturers should report directly to the national pharmacovigilance centre or to the regulatory authority.

3.2.3 The media

The media play an important role in providing consumers with information on TM/CAM therapies. In order to ensure that the TM/CAM information they provide is accurate, journalists – especially health journalists – should have ready access to reliable information. They also need to be informed about the importance of ensuring accuracy, credibility, balance, legitimacy and responsibility, as well as knowing who to consult in case of uncertainty.

Different forms of media serve different purposes and have special characteristics in relation to their ability to reach and actively involve their audience. Various types of media may therefore be used in combination to get across a distinct message in a tailored way, to reach a particular audience, and to improve communication between different groups of people (39). Furthermore, since standards, language, cultures,

technical capacity, literacy and logistics all vary according to country and location, the message needs to be tailored to the local audience when different forms of media are selected.

The use of the mass media (radio, TV and newspapers) is one of the major ways of disseminating information to consumers. Because they target a large audience, the mass media have the potential to raise public awareness about different issues. However, they do not always offer the possibility to explore issues in depth. TV and radio programmes with a health content can be used as well as sections in newspapers that focus on health issues. Another way of reaching consumers is through information campaigns using advertisements and commercials on the radio and TV and in newspapers.

Journals, reports, books, documentaries and the printed media often provide more in-depth information than the more immediate and faster forms of communication provided by the mass media. However, in addition to the longer production time, their major drawback is that they reach fewer people, and that those who are illiterate, for example, will not be able to access the information. Journals and reports on TM/CAM-related issues play an important role in meeting certain consumer needs, while the printed media such as leaflets and booklets are another useful means of communication, easily distributed at health care facilities (conventional as well as TM/CAM-oriented health care centres) and retail outlets, for example.

3.2.4 Other information activities

Informative and educational approaches can also be made available through schools. Wherever possible, national authorities should support the use of reliable and independent

educational materials targeted to young consumers. Both printed material and videos can be effective outreach strategies for use in schools. Information can also be provided to consumers through consumer organizations and other NGOs working in the field of TM/CAM.

Although the Internet offers easy access and a wider target audience, the disadvantages include lack of access by the poor and the fact that electronic communication and publishing is not always reliable (*39*). To counter these problems, several approaches can be used, including a website controlled by national or local authorities or by officially approved TM/CAM organizations, and the use of certified sites on the Internet where the information has been approved by TM/CAM organizations and consumer organizations. Another approach is the use of peer-reviewed sites, where the information has been approved by experts (*33*). One way of overcoming the problem of the lack of access to electronic communication is to transfer the information in digital form to local printing and distribution outlets.

Workshops and seminars may be an additional way of providing consumer information. Other methods such as the use of theatre and promotional events related to TM/CAM may also be considered (*35*).

3.2.5 Activities promoting rational use of medicines

The most appropriate choice of media for information outreach may vary according to the country's needs. In a WHO survey on public education in rational medicine use, it was found that in developing countries use of the mass media was the most popular channel of communication, followed by workshops and the distribution and display of printed mate-

rials. In developed countries, the most popular communication activities were printed materials followed by the mass media. Other popular activities used in both developing and developed countries included community meetings, health centre talks, school programmes, traditional or street theatre, puppet shows and telephone services. Many projects included in the study used a mixed approach of activities (*35*). The experiences of information initiatives on rational use of medicines may serve as a useful reference for consumer education on the proper use of TM/CAM.

3.3 REGULATORY MECHANISMS FOR INFORMATION AND ADVERTISEMENTS

In addition to regulations for TM/CAM therapies, there is also a need for regulations controlling TM/CAM-related information and advertisements. Such regulations can be issued either by national authorities, in the form of statutory controls, or by local organizations such as professional organizations, in the form of voluntary controls (*33*). These kind of regulations, such as those recommended by the World Health Medication Industry (*40*), may control the reliability and ethical content of the information, prevent false health claims and misleading advertisements,[1] and ensure the appropriate labelling of TM/CAM products (both medication- and procedure-based). Ideally, legal mechanisms should be established to control both non-commercial

[1] False health claims are those that are not supported by adequate evidence and misleading advertisements are ones that may lead the consumer to act unreasonably.

and commercial information in advertising and on product packages. These could involve the issuing of permits for advertisements and information, based on evaluation of the contents. 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 web-based information as compared to printed information (see Annexes II and III). Some countries have special regulations controlling the publication of health information on the Internet.

4 Topics to Consider when Developing Consumer Information Promoting Proper Use of TM/CAM

Information/education about the advantages and the disadvantages of certain TM/CAM therapies is key to enabling consumers to make an informed choice. This information may include issues such as methods of diagnosis and treatment, benefits, risks, philosophy of the TM/CAM therapy concerned, health promotion and maintenance strategies. However, the content will vary depending on the country-specific features of TM/CAM. For example, the structure of the health system and rate of TM/CAM utilization will influence the degree of familiarity with this kind of medicine and the level of knowledge among consumers.

National or local authorities need to decide which specific TM/CAM therapies should be included in the information initiatives. The popularity of TM/CAM therapies as well as safe-

ty, quality and efficacy concerns will determine which ones should be included. The national or international evidence base for a certain therapy may also influence its inclusion. The following sections outline different topics to consider when developing consumer information. These are summarized in table 1.

4.1 GENERAL INFORMATION

Decisions about individual health care are important, including the decisions about whether to use TM/CAM.

General consumer information regarding TM/CAM may include the following key issues:

- The importance of the need to take charge of one's own health by being an informed consumer.
- The need for all providers, both conventional health care providers and TM/CAM practitioners, to be aware of the major TM/CAM and conventional therapies in use in order to promote the best treatment strategy to meet the patient's specific needs and prevent potentially dangerous interactions.
- The importance of ensuring that the provider is competent and provides TM/CAM services and products of quality.
- Where relevant, the need for consumers to find out about standard charges and possible health insurance coverage for TM/CAM therapies.

Table 1. Elements relevant for consumer information on TM/CAM.

Section	Main topics	Specific issues
4.1	***General information***	~ Being an informed consumer ~ Informing health care providers and TM/CAM practitioners about therapies being used ~ Engaging qualified TM/CAM practitioners and utilizing quality assured TM/CAM medication therapies ~ Where relevant, information regarding health insurance coverage
4.2	***Where to find reliable information***	~ Institutions and authorities representing TM/CAM and/or conventional medicine ~ Registered TM/CAM providers, conventional health care providers ~ Certain publications and websites
4.3	***How to identify reliable information***	~ Purpose ~ Relevance/accuracy ~ Sources ~ Updated information ~ Objectivity
4.4	***TM/CAM medication therapies***	~ Therapeutic claims and corresponding level of evidence ~ Quality ~ Precautions ~ Adverse events ~ Potent and/or toxic therapies ~ Interactions and contraindications ~ Posology ~ Methods of administration ~ Self-medication ~ Preparation ~ Children, pregnant or lactating women and the elderly
4.5	***Procedure-based therapies***	~ Therapeutic claims and corresponding level of evidence ~ Precautions
4.6	***Practitioners***	~ How to identify qualified practitioners ~ Certification of practitioners ~ Surveillance system for malpractice
4.7	***Pricing/ health insurance coverage***	~ Where to access information about standard charges and health insurance coverage

4.2 WHERE TO FIND RELIABLE INFORMATION

Consumers need to know where and how to find and freely access reliable TM/CAM information (*41*). Reliable information should also be available and accessible in various ways (e.g. for those unable to access the written form), depending on the needs and capacity of each Member State.

Conventional health care providers, TM/CAM practitioners, and other consumers using the TM/CAM therapy in question may be important sources of information. Valuable information about TM/CAM can also be obtained from national health authorities, research institutes, professional organizations, consumer organizations, pharmacies, libraries, websites, bookstores, health food stores, drug information centres, universities/pharmacy schools that offer training courses and certification programmes for TM/CAM providers, or societies representing specific diseases/conditions. One obvious resource for reliable TM/CAM information is a national or local centre for TM/CAM that critically evaluates information before making it available to consumers. In addition, consumers can be advised to consult different kinds of reliable publications and types of product information to find out more about TM/CAM.

The following key concepts could be considered when producing consumer guidelines on how to assess the reliability of TM/CAM information[2]:

- Purpose. Any reliable information source should have clear and transparent goals. It should be clear for whom and for what purpose the information is intended. For example, is it intended to educate the consumer or sell a product?

- Relevance/accuracy. Good information meets the needs of the consumer and is relevant to his/her lifestyle and situation. It should not give unrealistic recommendations and should be written in a language that is easy to understand and does not contain obvious errors such as misspellings and grammatical mistakes.

- Sources. Credible information states clearly who is responsible for the information, who is financially supporting the information and where the information comes from (i.e. the original source). It should be clear whether the information is opinion-based or factual.

- Updated information. Information needs to be updated and reviewed on a regular basis. The publication date on written information should always be easy to find.

- Objectivity. A good source of information provides unbiased and balanced information. Such information should be honest about areas of uncertainty and enable consumers to make therapy choices that are in his/her best interest. In case of commercial information, relationships to product manufacturers, for example, should be clearly stated.

[2] List adapted from various sources including the Discern Instrument, http://www.discern.org.uk (accessed 25 January 2004); and http://nccam.nih.gov/health/decisions/index.htm (accessed 25 January 2004).

4.3 HOW TO IDENTIFY RELIABLE INFORMATION

Governments have a key role in the control of information on TM/CAM, irrespective of whether a national TM/CAM centre exists. However, in most countries the majority of consumers may not have access to information controlled by either a national TM/CAM centre or by the government. In any case, consumers are likely to collect information from a variety of sources. Hence there is a need to help consumers understand how to evaluate information about TM/CAM.

WHO has published guidelines entitled *Medical products and the Internet: a guide to finding reliable information*. The principles of these guidelines could also be used for finding reliable information on TM/CAM (See Annex III) (*42*).

It is important for the consumer to be able to evaluate critically the information by means of an independent source. Both reliability and quality need to be assessed. Instruments for testing the reliability and quality of general health care information may be developed to help consumers with this evaluation. One notable example is the Discern Instrument in the United Kingdom which is designed to help consumers and others to evaluate information in order to identify reliable and high quality information (*41*).

4.4 TM/CAM MEDICATION THERAPIES

TM/CAM medication therapies include therapies commonly referred to as herbal medicines (see glossary), homeopathic remedies and dietary supplements. TM/CAM medication

therapies are used with or without prescription from a TM/CAM provider or a conventional health care provider.

4.4.1 Therapeutic claims

Statements about the efficacy and/or benefits of a TM/CAM therapy made by manufacturers, health care providers or TM/CAM practitioners may or may not be supported by an evidence base. The claims on legally registered TM/CAM products can be expected to be reliable. However, in most countries, TM/CAM has not been integrated into mainstream health care and there is a lack of research information and, in particular, a lack of clinical studies. The efficacy of TM/CAM could be divided into different categories based on research data and studies.

For example, in the *WHO monographs on selected medicinal plants*, the information on medicinal use has been divided into the following three categories (*25, 26*):

Use supported by clinical data

This category includes medical indications which are well established in some countries and which have been validated by clinical works documented in the world's scientific literature. Clinical trials may be controlled, randomized, double-blind studies, open trials, cohort studies, or well-documented observations on therapeutic applications.

Uses described in pharmacopoeias and in traditional systems of medicine

This category includes medicinal uses which have been well established in many countries and are included in official pharmacopoeias or governmental monographs. Uses hav-

ing a pharmacologically plausible basis are included as well as information resulting from clinical studies which clearly need to be repeated because of conflicting results.

Uses described in traditional medicine, not supported by experimental or clinical data

This category refers to indications described in non-official pharmacopoeias and other literature or traditional uses. Their appropriateness could not be assessed because sufficient data to support the claims could not be found in the literature.

Consumers need to be aware of the different levels of efficacy and the different legal status of medicinal products, which have a major impact on the safety, efficacy and quality of the products and treatment.

Claims for TM/CAM medication therapies should be appropriately stated on the label. Statements about claims for TM/CAM procedure-based therapies may be provided by bodies such as approved TM/CAM professional organizations. In addition, it is important to ensure that when a product is claimed to be marketed for its traditional use, it is used in accordance with the traditional method of use (e.g. the same dosage, duration of treatment and dosage instructions).

Many Member States have regulatory agencies or licensing boards for certain types of TM/CAM practitioners and therapies that may also provide information about evidence and claims (*43, 44*). In addition, licensing, accreditation and regulatory laws for TM/CAM practices help ensure that TM/CAM practitioners are competent and provide services that correspond to stated claims.

When it is possible to have access to conventional medicines, it is widely agreed by doctors and medical researchers that

certain serious diseases or disorders cannot or should not be diagnosed or treated except under medical advice, and that claims for the treatment of such diseases/disorders must be specially evaluated by conventional health care providers and TM/CAM practitioners (3). In countries where such circumstances apply, consumers need to know where to find proper information. The WHO document *Acupuncture: Review and analysis of reports on controlled clinical trials*, for example, lists symptoms and diseases for which acupuncture may be used (30). It also emphasizes that some symptoms and diseases may only be treated provided that the practitioner has special knowledge in conventional medicine and access to adequate monitoring equipment.

4.4.2 Quality

Consumers may need guidance on how to identify quality assured TM/CAM medication therapies. For example, information about quality can be found on the package, label or leaflet that is provided with the medication or given by the provider/retailer. Information that could help the consumer to check the quality of a product include GMP standards, the product registration number and information about the product given by a TM/CAM information centre.

Depending on the regulatory status of TM/CAM medication therapies, the quality of the products may be more or less difficult to assess. In many countries, TM/CAM medication therapies are marketed as food supplements. In such situations no rigorous regulation exists comparable to that of the pharmaceutical sector. As a result, it becomes even more important to empower consumers to make an informed choice in relation to quality.

The following information should always be available when purchasing a quality TM/CAM medication therapy.

(a) Information about the product

Identification of the product/active ingredients is an important step when assuring the quality of most TM/CAM medication products. It involves identification of the plant/animal species (sometimes also including minerals and/or vitamins), when relevant through botanical verification. It is also important to check the quantitative composition of the product. For many Member States it may be relevant to inform consumers of the need to pay attention to the composition and the local and scientific (Latin or equivalent national terminologies) name of all active ingredients (*45*). Identification of a species both by its local and Latin name may be important since local names are occasionally used for several different species with different biological activities. Latin binomial names are constructed in two parts, the first part identifying the genus and the second part describing the particular species. Since different parts of a species might also have different biological activities, consumers also need to identify the parts of the plant/animal material (e.g.. bark, leaves, blossoms) used for the preparations (*25, 26*) in order to ensure that the correct part of the species is used. Information about the identity of ingredients can be either presented on labels or explained verbally by the retailer at the time of purchase.

(b) Recognition of quality standards

A product of quality can be identified through recognition of official quality standards. Where available, national or local quality standards and/or registra-

tion/licensing systems for TM/CAM medication therapies can guide the consumer to choose quality products by, for instance, labelling quality controlled products with a specific label, such as the licence symbol used by Swissmedic (see Annex IV). Such standards can be based on recommendations in national or international pharmacopoeias, national registration and regulation procedures or according to suggestions from registered TM/CAM providers. Where product quality certifications are not available, certified TM/CAM practitioners or conventional health care providers providing TM/CAM services should be able to provide or recommend products of quality.

It is also important to be able to identify the holder of the market authorization as well as GMP standards and site registration in order to know whom to contact in case of questions about the product, for example. Different rules might apply to nationally produced products and imported products.

With regard to quality standards of raw plant material (or animal and mineral material), it is the responsibility of the registered TM/CAM practitioner or the registered provider of the raw materials to ensure the quality of the material.

(c) Storage and expiry date

Consumers need to pay attention to the manufacturer's instructions concerning storage and expiry date. Following the storage instructions may be crucial, for example to prevent early ageing and/or destruction of a product. It is also important that consumers are aware that they should not purchase or use a product beyond its expiry date, since the efficacy of TM/CAM medication therapies can be age-related (*45*).

(d) Quality control of raw materials

Most of the issues cited above also apply to raw materials, which are used by a majority of those who have limited access to high-quality medicines. Good cultivation and preparation are some of the additional areas that need to be addressed in relation to quality assurance of raw materials.

4.4.3 Precautions

Consumers need to be informed about the risks associated with the use of TM/CAM medication therapies. Awareness and vigilance are valuable first steps towards minimizing risks such as direct toxicity, interactions and contraindications, depending on the specific TM/CAM medication therapy used (*17*). Consumer information on safety is not intended to be alarmist; instead the aim is to minimize possible risks for the consumer.

4.4.4 Adverse events

TM/CAM-related adverse events are any unintended or undesirable events following the use of TM/CAM (see glossary). Consumers need to be informed about known adverse events and their causality. Consumers with allergies should be particularly observant when using TM/CAM medication therapies in case of an allergic reaction. Furthermore, consumers need to know what to do in case of adverse events or an overdose as well as whom to contact (see section 3.2.2). Examples of consumer information on adverse events are given in the leaflet material prepared by the Department of Health, Hong Kong SAR, China (see Annex I).

It is advisable to use a standard reporting form and to make these widely available. It should, however, be acceptable to re-

A case report of a suspected adverse event or overdose may contain some of the following information:

- Where it is permitted by the country health information privacy code, and with appropriate confidentiality, there should be some form of identification of the consumer/patient in order to avoid duplications and facilitate follow-up.
- Age, sex, and brief medical history (when relevant). In some countries ethnicity may need to be specified.
- Details of suspected TM/CAM therapy if known. For herbal medicines: species name and/or brand or ingredient name(s) including Latin binomial and common name, part of plant used, preparation methods; manufacturer, country of origin, batch number, expiry date and provider.
- Administration details: dose and quantity supplied, dosage form, route, start/stop dates.
- Indication or reason for use.
- Adverse events: date of onset (or duration from first administration to onset of event), description with symptoms and signs, severity and seriousness, results of clinical investigations and tests, course and outcome; and, if appropriate, consider dechallenge/rechallenge with the same product.
- All other medicines used (including self-medication) with administration details.
- Risk factors (e.g. age, impaired renal function, previous exposure to the therapy, previous allergies, drug misuse or abuse, recreational use of drugs).
- Name and address of reporter (to be considered confidential and to be used only for data verification, completion and case follow-up).

ceive reports by telephone, letter or e-mail. For health care providers already included in a national pharmacovigilance programme, the reporting form can be the same as the one already in use. A familiar form will facilitate reporting and the introduction of a second type of reporting form may cause confusion. Although the reporting system might coincide with the pharmacovigilance programme, the reports about adverse events following TM/CAM use need to be verified by TM/CAM experts.

Reporting forms should be provided to those involved in the provision of TM/CAM medication therapies, such as TM/CAM practitioners and TM/CAM retailers, who are not part of an existing national pharmacovigilance system. It may be necessary to design a special reporting form for those not familiar with the reporting of suspect reactions to medicines. Educational material regarding adverse events can be developed by TM/CAM professional organizations, for example, in collaboration with relevant authorities, in order to inform other professionals as well as consumers about adverse events and how to write a report about suspected adverse events.

4.4.5 Potent and/or toxic TM/CAM medication therapies

A number of TM/CAM medication therapies are very potent and sometimes toxic. Such medicines are often processed before use in order to decrease the toxicity. If incorrectly processed or used, these medicines can be very harmful and cause poisoning. In countries where such medicines are available, consumers need to be aware that they should not be used without a prescription and detailed instructions from a registered TM/CAM practitioner or a conventional health care provider knowledgeable in TM/CAM.

Often only certain TM/CAM practitioners have the legal right to prescribe potent and/or toxic medication therapies. Where this is the case, this is also something the consumer needs to be aware of (see section 4.6). A list of all toxic TM/CAM medication therapies can also be helpful for the consumer. In addition, consumers should pay particular attention to the prescriptions and dosage recommendations for these medications. Common symptoms of poisoning and possible pathways for reporting such suspected poisoning need to be described in accompanying information material (see section 3.2.2).

4.4.6 Interactions and contraindications

In many countries, TM/CAM medication therapies are commonly used in combination with conventional medicine, generally with satisfactory results. However, it is important to be aware of the possibility of interactions that may result from the concurrent use of several TM/CAM medication therapies and/or conventional drugs. The combination of several TM/CAM medication therapies and/or the concurrent use of conventional drugs may magnify or oppose the effect of the treatments (*24*). Consumers need to be informed about any potential interactions involved in their therapy and they also need to understand the importance of informing health care providers and TM/CAM providers about any parallel use of therapies and/or medicines. Because of the limited knowledge about interactions between conventional medicines and herbal medicines, this is an area that needs further study and it is important that professionals as well as consumers pay careful attention to this area and report any suspected interactions.

4.4.7 Posology

In order to get the desired effect of TM/CAM medication therapies it is essential to take them at the correct time, in the right dosage and for the appropriate length of time. Instructions on *when* to take the medicine (in the morning, mid-day, evening, before, with or after meals etc.), *how* to take it (with hot or cold drinks, with or without certain foods etc.) and for *how long* should be provided by the TM/CAM practitioner, and wherever possible clearly displayed on the label/leaflet attached to the medication. It is important to inform consumers about these issues so that they can be properly informed, and if necessary, they can ask their provider for such information (see Annex I).

4.4.8 Methods of administration

When using TM/CAM medication therapies, it is important to adhere to the recommended method of administration. Consumers need to be informed about different methods of administration for various dosage forms such as tablets, tinctures, decoctions, teas, capsules and salves. It is important that instructions for consumers on how to administer their medicines are clear-cut and that these are clearly displayed on the label. Both the advantages and disadvantages of each method of administration may also need to be discussed. For example, it may be more appropriate for children to take medicine in the form of syrups or tinctures rather than tablets. The most appropriate method of administration can be discussed with the TM/CAM practitioner or retailer.

4.4.9 Self-medication

When TM/CAM medication therapies are used as self-treatment, consumers need to be aware of the importance of following the proper recommendations. Consumers should always notify their conventional health care provider and TM/CAM practitioner if symptoms do not disappear, if there is no improvement in general (depending on the aim of the therapy), if symptoms get worse or adverse events are suspected. In addition, consumers using self-treatment need to pay special attention to all the issues outlined in the sections above as well as consult health providers, including those for traditional medicine, to ensure proper use of TM/CAM.

A list of TM/CAM medication therapies and conditions appropriate for self-medication can be helpful for the consumer who wishes to self-medicate. However, the suitability of self-medication is also dependant on the individual's own knowledge. When possible, consumers should be encouraged to discuss their self-medication with their TM/CAM provider, conventional health care provider or pharmacist.

4.4.10 Preparation of TM/CAM medication therapies

In some countries, it is common for consumers to prepare their own medicines from raw materials. In such cases, as for instance stated by the Department of Health in Hong Kong SAR, China (see Annex I), it is important that patients have some knowledge about the preparation of TM/CAM medication therapies. A recipe for the particular formula is always important. The consumer needs to be informed about how much material to use for a certain amount of water; in which order to put in

the ingredients; how long to boil/simmer/steep the ingredients; and for how long it can be used after preparation.

Ideally TM/CAM practitioners should provide this information. However, it is useful for public information initiatives to bring up these issues and to provide general directions in some form (e.g. through brochures) for the preparation of TM/CAM medication therapies.

4.4.11 Children, pregnant or lactating women and the elderly

Consumers need to be aware that decisions about medical care and treatment are best made in consultation with a health care provider. In particular, children, pregnant or lactating women or the elderly should always pay special attention and consult a health care provider and/or authorized TM/CAM practitioner before using any TM/CAM therapy. In the case of medication therapy, children and the elderly often require a different dosage than normally prescribed for adults. Meanwhile pregnant women may risk their own and/or their baby's health by using certain TM/CAM therapies, due to known or unknown side effects (*17*).

Information should emphasize that:

- Women who are pregnant or breastfeeding should consult an authorized TM/CAM practitioner before using any TM/CAM therapy.
- Where conventional health care is accessible, communication with the conventional health care provider about TM/CAM use needs to be particularly emphasized in the case of children, pregnant or lactating women and the elderly.

4.5 PROCEDURE-BASED TM/CAM THERAPIES

Procedure-based therapies use various techniques primarily without the use of medication therapies to provide health care. These include acupuncture and related techniques, manual therapies (e.g. massage, chiropractic, naprapathy and osteopathy, qi gong, tai ji quan, naturopathy), thermal medicine and other physical, mental, spiritual and mind-body based therapies.

4.5.1 Therapeutic claims

The effectiveness and benefits of procedure-based TM/CAM therapies usually depend on the individual practitioner's education and training level as well as clinical experience and the efficacy of the particular TM/CAM therapy.

In order to guide consumers in the selection of appropriate TM/CAM procedure-based therapies, national authorities and international or national/local professional organizations can develop national lists of widely used TM/CAM procedure-based therapies, together with the respective claims based on existing clinical evidence. Different levels of claims can be presented, such as suggested in section 4.4.1. The WHO document *Acupuncture: Review and Analysis of Reports on Controlled Clinical Trials* may serve as a good example (*30*).

The quality of a certain procedure-based TM/CAM therapy is largely dependent on the skills of the TM/CAM practitioner (see section 4.6).

4.5.2 Precautions

Although procedure-based therapies are usually safe, there are occasions when, because of the patient's particular condition (e.g. pregnancy), use of a particular therapeutic technique may be contraindicated. Organizations that regulate these therapies are mainly concerned with patient safety and can issue guidelines regarding contraindications.

4.6 PRACTITIONERS

In order to avoid treatment by non-qualified TM/CAM practitioners and malpractice, it is important that the consumer knows how to identify a qualified practitioner. In countries where the level of education and/or knowledge is controlled by statutory or voluntary regulations, a TM/CAM practitioner should generally have fulfilled these requirements in order to be considered qualified. One way of certifying a qualified TM/CAM practitioner's continuous 'good practice' is to register all qualified providers and to enforce a system where patients can report malpractice (*32*). Repeated or serious malpractice could lead to the withdrawal of the registration certificate. However, such a system of quality assurance relies on consumer awareness and responsibility since reports on incidents of malpractice come mainly from consumers themselves. Therefore, information must be available on where cases of malpractice can be reported (see section 3.2.2).

Qualified/registered TM/CAM practitioners can also be identified through a system of easily recognizable certificates displayed at the practice. Such certificates could be issued by the national authorities or by self-regulating pro-

fessional organizations and designed in a way so that they can be easily recognized. Moreover, lists of qualified/registered TM/CAM practitioners available to the public could be updated periodically and published in an easily accessible format in print or on the Internet and made available through a TM/CAM information centre, local authorities, consumer organizations and professional organizations, for example.

In the absence of adequate regulations, some TM/CAM practitioners may not adhere to adequate standards of clinical practice, with obvious implications for safety. One way to eliminate such concerns is to train, regulate and register all practitioners who employ TM/CAM and encourage consumers to seek treatment from competent practitioners who provide high quality services (*17*). Moreover, TM/CAM practitioners should preferably be educated in the general principles of conventional medicine in order to refer patients to conventional practitioners when appropriate. Another way to encourage good clinical practice is to help strengthen and increase the organization of TM/CAM practitioners. This helps facilitate the use of voluntary control mechanisms and contributes to increased professionalism among TM/CAM practitioners.

4.7 PRICING AND HEALTH INSURANCE COVERAGE

In countries where TM/CAM is used in conjunction with conventional medicine, pricing and health insurance coverage is an important determinant for TM/CAM use (27, 36). Consumers in such countries need to be able to assess information about standard charges and health insurance coverage for certain TM/CAM therapies.

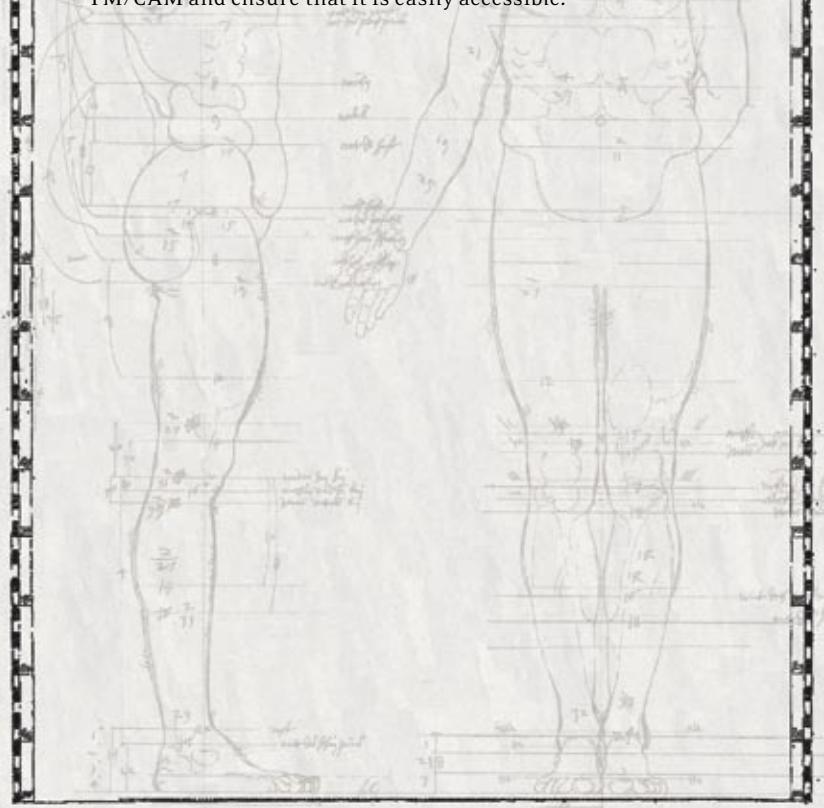
5 Use of this Publication

There are both benefits and risks associated with the use of TM/CAM, as highlighted by a number of recent reports. Therefore it is important to ensure that appropriate information is made available to consumers to enable them to maximize the benefits of TM/CAM while minimizing the risks.

A number of elements should be taken into account when developing consumer information. For example, TM/CAM therapies are often linked to the culture from which they have originated, and their use out of the original context can be a source of misunderstanding and/or improper use. In addition, each country has a different health care system and different pattern of utilization of TM/CAM by consumers. Therefore consumer information on TM/CAM needs to be

tailored to specific country needs.

This document provides important reference information that can be used by consumers and is intended to help guide them in their choice and use of TM/CAM therapies or products. The aim is to help protect consumers and reduce the risks involved in improper use of TM/CAM. Finally, as emphasized throughout this document, it is important that a number of key stakeholders work in collaboration with governments to develop much needed consumer information on TM/CAM and ensure that it is easily accessible.



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ANNEX I

Leaflets Promoting Proper Use of TM/CAM Published by the Department of Health, Hong Kong SAR, China

Example 1

General Knowledge of Toxic/Potent Chinese Herbal Medicines

Toxic / poison Chinese herbal medicines
Points to note when taking toxic / poison Chinese herbal medicines
• Safe is promised only with a prescription from a registered Chinese medicine practitioner
Chinese Medicines Shop
• Comply with the methods for decoction and administration as instructed by a Chinese medicine practitioner.
• Seek medical advice immediately if any symptoms of herbal poisoning are noticed.
Symptoms of herbal poisoning by Chinese herbal medicines
Symptoms of acute poisoning
• Symptoms of the digestive system, e.g. nausea, vomiting, burning abdominal pain, diarrhoea, or even vomiting blood, bloody stool, etc.
• Symptoms of the respiratory system, e.g. dyspnoea, loss of voice, bluish lip, etc.

Example 2

Points to note when purchasing Chinese Medicines


Understanding one's own body constitution
People with different body constitutions have different requirements for Chinese medicines. For example, people with cold constitution may have aversion to cold, loose stool and pale complexion. They may have discomfort after eating cold and raw food. In such a case, Chinese medicines of cold nature should be used with caution.
Aversion to cold
Pale complexion
Loose stool
Use them cautiously!
Understanding one's own illness and the causes
Different disease causations should be treated with different Chinese medicines. For example, there are many causes for flu-like illness. Flu-like illness caused by wind and cold should be treated with medicines for the wind-cold type, while that caused by wind and heat should be treated with medicines for the wind-heat type.
Read carefully the instructions on labeling on all prescriptions of Chinese medicines
Including ingredients, claims, indications, method of administration, dosage, method of preparation, precautions and contra-indications, etc.
Label
Ingredients
Claims
Indications
Dosage
Method of administration
Contra-indication
Proprietary Chinese Medicine
PRESCRIPTION
Method of preparation:
Method of administration:

Example 3

Registered and Listed Chinese Medicine Practitioners


Long-term arrangement
To be a registered Chinese medicine practitioner, one must obtain a degree in Chinese medicine recognized by the Chinese Medicine Practitioners Board of the Chinese Medicine Council of Hong Kong, or its equivalent, and pass the licensing examination organized by the Board.
Transitional arrangements
Chinese medicine practitioners who were practising Chinese medicine in Hong Kong on and before 3 January 2000 could apply to become a listed Chinese medicine practitioner. The Chinese Medicine Practitioners Board would assess their academic qualification and experience in Chinese medicine and make appropriate arrangements for their applications to become registered practitioners by three different ways.
During the transitional period, both registered and listed Chinese medicine practitioners can practise Chinese medicine lawfully. When the Secretary for Health, Welfare and Food promulgates that the transitional period comes to an end, only registered Chinese medicine practitioners can practise lawfully, and listed Chinese medicine practitioners can no longer practise.
During transition
After transition
Major differences between practices of registered and listed Chinese medicine practitioners
First, their titles are different.
Registered Chinese Medicine Practitioner
Listed Chinese Medicine Practitioner
Second, the certificates posted in their clinics are different.
Attention

Example 4

Adverse Effects of Misusing Herbal Tonics


Health and disease
• In Chinese medicine, health is preserved when a dynamic and harmonious billance is maintained among the interior parts of the body and between the body and the external environment, when the physiological and psychological functions are being normal. This is called "yin and yang in equilibrium" in Chinese medicine.
• When the human body is affected by pathogenic factors, the harmonious states among the interior parts of the body and between the body and the external environment will be disrupted. Diseases may then occur easily.
• As the pathogenic factors weaken the body's resistance, adaptability to the external environment and rehabilitation ability, symptoms of deficiency state may emerge.
Which kind of deficiency state does it belong to?
Replenishing
What Chinese herbs should be taken?
• Proper use of the right kind of herbal tonics can restore various deficiency states according to their natures and locations. However, wrong assessment of the deficiency state, or the nature and the location of the deficiency state, leading to inappropriate use of herbal tonics is hazardous to one's health.
Abusing herbal tonics is not beneficial but hazardous to your health!
Use of herbal tonics based on differentiation of syndrome
• In Chinese medicine, differentiation of syndrome based on professional assessment is emphasized when taking herbal tonics. One should first consult a Chinese medicine practitioner to determine the presence or otherwise of any deficiency state and for the location and nature of the deficiency before taking any herbal tonics.
No
Shall I take any herbal tonics, practitioner?
One should also know whether the herbal tonics selected are appropriate for one's own conditions. Use of herbal tonics without professional supervision is dangerous and should be avoided.
Taking herbal tonics based on differentiation of syndrome

ANNEX II

Things to Know about Evaluating Medical Resources on the Internet*

http://nccam.nih.gov/health/webresources/

The number of Web sites offering health-related resources grows every day. Many sites provide valuable information, while others may have information that is unreliable or misleading. This short guide contains important questions you should consider as you look for health information online. Answer-

* Information provided by National Center for Complementary and Alternative Medicine (NCCAM) at National Institute of Health, USA.

ing these questions when you visit a new site will help you evaluate the information you find.

1. Who runs this site?

Any good health-related Web site should make it easy for you to learn who is responsible for the site and its information. On this site, for example, the National Center for Complementary and Alternative Medicine (NCCAM) is clearly marked on every major page of the site, along with a link to the NCCAM homepage.

2. Who pays for the site?

It costs money to run a Web site. The source of a Web site's funding should be clearly stated or readily apparent. For example, Web addresses ending in ".gov" denote a Federal Government-sponsored site. You should know how the site pays for its existence. Does it sell advertising? Is it sponsored by a drug company? The source of funding can affect what content is presented, how the content is presented, and what the site owners want to accomplish on the site.

3. What is the purpose of the site?

This question is related to who runs and pays for the site. An "About This Site" link appears on many sites; if it's there, use it. The purpose of the site should be clearly stated and should help you evaluate the trustworthiness of the information.

4. Where does the information come from?

Many health/medical sites post information collected from other Web sites or sources. If the person or organization in charge of the site did not create the information, the original source should be clearly labeled.

5. What is the basis of the information?

In addition to identifying who wrote the material you are reading, the site should describe the evidence that the material is based on. Medical facts and figures should have references (such as to articles in medical journals). Also, opinions or advice should be clearly set apart from information that is "evidence-based" (that is, based on research results).

6. How is the information selected?

Is there an editorial board? Do people with excellent professional and scientific qualifications review the material before it is posted?

7. How current is the information?

Web sites should be reviewed and updated on a regular basis. It is particularly important that medical information be current. The most recent update or review date should be clearly posted. Even if the information has not changed, you want to know whether the site owners have reviewed it recently to ensure that it is still valid.

8. How does the site choose links to other sites?

Web sites usually have a policy about how they establish links to other sites. Some medical sites take a conservative approach and don't link to any other sites. Some link to any site that asks, or pays, for a link. Others only link to sites that have met certain criteria.

9. What information about you does the site collect, and why?

Web sites routinely track the paths visitors take through their sites to determine what pages are being used. However, many health Web sites ask for you to "subscribe" or "become a member." In some cases, this may be so that they can collect a user fee or select information for you that is relevant to your concerns. In all cases, this will give the site personal information about you.

Any credible health site asking for this kind of information should tell you exactly what they will and will not do with it. Many commercial sites sell "aggregate" (collected) data about their users to other companies--information such as what percentage of their users are women with breast cancer, for example. In some cases they may collect and reuse information that is "personally identifiable," such as your ZIP code, gender, and birth date. Be certain that you read and understand any privacy policy or similar language on the site, and don't sign up for anything that you are not sure you fully understand.

10. How does the site manage interactions with visitors?

There should always be a way for you to contact the site owner if you run across problems or have questions or feedback. If the site hosts chat rooms or other online discussion areas, it should tell visitors what the terms of using this service are. Is it moderated? If so, by whom, and why? It is always a good idea to spend time reading the discussion without joining in, so that you feel comfortable with the environment before becoming a participant.

NCCAM has provided this material for your information. It is not intended to substitute for the medical expertise and advice of your primary health care provider. We encourage you to discuss any decisions about treatment or care with your health care provider. The mention of any product, service, or therapy in this information is not an endorsement by NCCAM.

This document is in the public domain. Duplication is encouraged.

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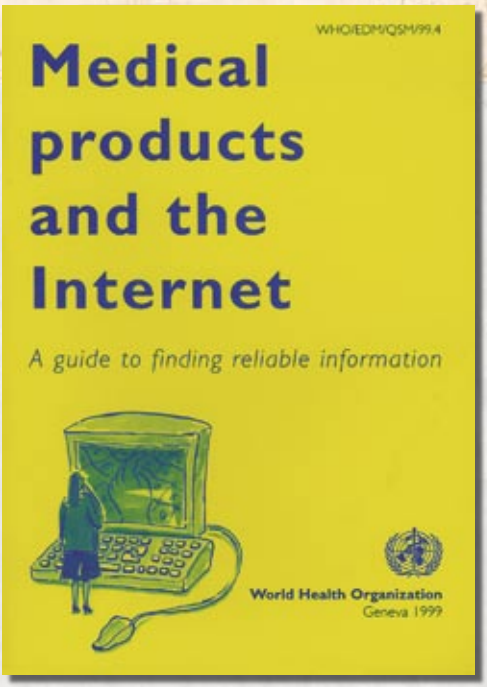
ANNEX III

Medical Products on the Internet: A Guide to Finding Reliable Information



WHO/EDM/QSM/99.1
Original: English
Distribution: General

Medical products and the Internet

A guide to finding reliable information

Regulatory Support Series, No. 8

World Health Organization
Geneva, 1999

Introduction

The Fifty-first World Health Assembly (Resolution WHA51.9, May 1998) requested the Director-General of WHO to develop a guide on medical products and the Internet. The guide was intended to serve as a model for Member States to adapt into locally meaningful advice for Internet users in order to help them to obtain reliable, independent and comparable information on medicinal products. The guide in this booklet has been prepared to meet the Health Assembly request. It has been developed in consultation with drug regulatory authorities, drug information experts, consumer organizations, and the pharmaceutical industry. It is a model guide, designed to be translated into national languages and modified as the local situation may require.

WHO would be grateful to receive any comments or experience gained from the practical use of the guide which would help in developing it further. Contact information appears below.

Department of Essential Drugs and Other Medicines (EDM)
World Health Organization
1211 Geneva 27, Switzerland
email: reggie@who.ch

Finally, national health authorities – such as drug regulatory agencies – and WHO are working together to address the illegal advertising and sale of medical products through the Internet. It is important that Internet users report suspected illegal activities and problem cases to their national health authorities.

Summary of key points

- **If used properly, the Internet allows quick and easy access to health information.** It provides useful information on such topics as diseases, conditions, therapies, medical products, and health and medical organizations and institutions (see Point 1).

- The information you obtain from the Internet can be helpful when you consult your doctor or other health care provider about your disease or condition. But **the guidance from the Internet should not replace consultation with your health care provider** (see Point 2).

- Although it is often difficult to determine, you still need to verify the **source of information** available on the Internet (see Point 2).

- Information that sounds too good to be true, in particular, requires verification and careful assessment (see Point 3).

- Be cautious about buying medical products via the Internet. In many countries, selling or buying medical products via the Internet may at present be an illegal activity. **You are strongly advised to obtain your medical products through legitimate distribution channels** such as pharmacies (see Point 4).

- **Consult your doctor** or other health care professional before you decide to treat yourself (see Point 5).

POINT 1

The Internet is a valuable source of information, but be sure you know and trust the source

The Internet is a valuable source of health information on topics such as diseases, conditions, therapies, medical products, and health and medical organizations. When used properly, it allows quick and easy access to such information from on-line medical libraries, universities, health associations and government agencies. However, the quality of health and medical product information on the Internet varies, and it is often difficult for the Internet user to identify the true source of the information and to determine whether it is reliable, complete and up to date.

POINT 2

Finding reliable health and medical information on the Internet

Reliable sources of health and medical information are available on the Internet. This information can be helpful when you consult your health care provider about your disease or condition, though it should not replace such consultation (see Point V). As you search for and evaluate information, however, keep these considerations in mind:

It may be difficult to determine the source of the information you find on a web site and to verify that source. If you are not familiar with the source of information, you may be able to find out more about it from health care professionals or reliable organizations with which you are familiar. Your own reliable sources may be able to give you help to evaluate the reliability and quality of the web site information.

Looking at a web site? Check the following:

- Is there clear indication of the name and current address of the web site owner?
- Is it clear which organization(s) contribute funding, services, or other support to the web site?
- If advertising or sponsorship is a source of funding, is this clearly stated?
- Is this a site for consumers, health professionals, or some other audience?
- When was the information displayed last updated?

There are many health and medical sites on the Internet which do provide good information that may not be easily available from other media. They may be designed for health professionals or for consumers. However, even information from reliable sources may require special training in order to evaluate it properly and to determine whether the information applies to your disease or condition. The information provided by these web sites covers such topics as:

- Research being conducted on a particular disease or a condition - including rare diseases - and related clinical trials;
- New product approvals by health authorities in your country for a specific disease or condition;
- General information about diseases or conditions, such as high blood pressure, arthritis or obesity;
- Support groups for people with certain diseases and conditions, such as HIV/AIDS or cancer;
- Lists of international, national and local organizations that provide support and information for a disease or condition.

Health authorities and organizations in each country can provide a list of sites with links to reliable sources of health and medical information. Additionally, several private organizations are actively searching for ways to ensure the quality of information on the Internet. Internet users may be interested in following or participating in these discussions and reading what others have to say on the topic. The following box lists two examples of organizations that are conducting such activities. National authorities should identify and list additional organizations and reliable web sites known to them.

Health on the Net Foundation: http://www.hon.ch
Internet Healthcare Coalition: http://www.ihc.com

POINT 3

Finding reliable medical product information on the Internet

The Internet also offers information on medical products. As you search for and evaluate product information, however, keep these considerations in mind:

● If information sounds too good to be true, it probably is. The following list some warning signs that medical product information may not be truthful: ● Advertisements or information that use phrases such as "scientific breakthrough", "miraculous cure", "exclusive product", "secret formula", "ancient ingredient", "without risk", "anti-ageing", "improve sexual performance", and "all natural"

● Case histories from "cured" customers claiming amazing results. When you see a testimonial, ask for proof of its "typical" nature.

● A list of symptoms and diseases it is claimed the product cures – for example, claims that one product can cure or treat HIV/AIDS, cancer, arthritis, Alzheimer's disease, wrinkles, weight problems, memory loss, and so on. ● Advertisements that issue the latest trendy ingredient in the news headlines. ● Claims that the product is available from only one source, for a limited time. ● Testimonials from "famous" medical experts. ● Claims of "no risk" or lack of any risk information – remember, no product or treatment is completely risk-free.

● Claims that a product is "scientifically proven" and "absolutely safe"

● Products with the same name may contain different ingredients in different countries. Therefore, when searching for information you should look at the International Nonproprietary Name (INN) of the active ingredients and not just the product name (brand name, trade name).

● Product information should be as complete as possible, and it should include at least the elements outlined in the following box:

Looking at product information!
A reliable web site will provide the following information:

- product name
- active ingredient(s)
- name of other ingredients known to cause problems in some people
- what to use the product for
- when not to use the product (for example, in pregnancy, allergies, interactions with other medicines or foods)
- how to use the product
- possible undesired effects
- how to store the product
- manufacturer's name and contact information
- last update of the information

POINT 4

Be cautious about buying medical products on the Internet

Medical products are often offered for sale on the Internet. Offering for sale and selling medical products or buying medical products from another country via the Internet may be illegal. Therefore, before buying a product, you should find out if it is legal to do so. If you are considering buying medical products through the Internet, be cautious, because you may risk your health and waste your money. Consult your health care professional before self-treatment.

There are many reasons why medical products bought through the Internet could represent a danger to you, or at the least cause inconvenience or loss of money. Six of these reasons are discussed here.

1 **Safety and efficacy assurance may be lacking** – In many countries, before medical products are approved, licensed or authorized for sale, the companies that develop and market them must conduct research and demonstrate to a drug regulatory authority that the products are safe, effective and of good quality for human use. Although these authorized medical products may be available through the Internet, there may also be products for sale that have not been studied and evaluated according to the laws and regulations of your country. There is no assurance of safety and effectiveness for such unauthorized products. As an Internet user you may find it difficult to distinguish between products that have met the requirements of your government and those that have not.

Information about medical products being developed and tested in humans is available on the Internet. If you have a disease or condition for which there is currently no treatment or cure, you may have searched for information about your disease or condition and read about these new products on the Internet. Although new products are often not available for prescription, sometimes a health care professional may prescribe a medication for you before approval, or discuss enrolling you in a clinical trial to study the product. It is important to understand that there may be additional risks to using such a product before approval, because the possible adverse effects (which may be serious or life-threatening) and the effectiveness and proper dosage schedule may not be known. In some cases, a prescription product may be unavailable in your country but approved for use in another. In such a case, your country may have special legal procedures allowing you to import prescribed medicines from abroad. This could be done with the help of your health care professional, through legitimate distribution channels.

2 **Instructions for use may be inadequate** – To be used properly and safely medical products need to be accompanied by precise instructions. There is no assurance that a product obtained via the Internet will have the correct instructions for use, dosage and precautions. In

children, instructions may be printed in a language that you do not know, or may they be unreliable, out of date, or otherwise unusable.

3 Quality may not be assured – When you buy a medical product through the appropriate channels, such as through your pharmacy, you can generally rely on the product meeting manufacturing requirements and you can count on its quality – in other words – the product contains the right active ingredients and has been manufactured, packaged, transported and properly stored before you buy it. By buying medical products through the Internet, you may forfeit the quality assurance offered by authorized channels of medical product manufacturing, distribution and sales in your country.

4 Products may circumvent regulatory protections – Medical products sold through the Internet may circumvent the regulatory protection provided by health authorities and your government. You may be unable to obtain compensation from the manufacturer or distributor for any damage resulting from the use of these products. The identities and locations of the sources of the products may be disguised. This is especially common in the case of fraudulent medical products.

5 Products may be fraudulent and harmful to your health – Products promoted and offered for sale on the Internet may be fraudulent if they do not meet the standards required for approval in your country and are not sold by licensed or authorized health organizations. Using such products to treat yourself may be harmful to your health. The products may provide no benefit to your disease or condition and you may miss an opportunity to be properly treated by health care professionals. Ineffacy of a medical product is not only frustrating it can also be dangerous. Treatment with fraudulent products may actually be harmful to your health, not just without benefit.

6 Reimbursement may not be possible – In many countries health insurance programmes may not agree to reimburse you for medical products bought through the Internet. Before you purchase a medical product through this channel, even if the product seems legitimate to you, contact your insurance or other health coverage organization to find out if the purchase would be covered and if the Internet medical product provider is recognized by your health insurer or organization.

7 Products may waste your resources – By visiting medical treatment through the Internet instead of through health care professionals, you could be wasting valuable resources – your time and money – because the treatments may not help and, therefore, your money has been wasted. In addition, you may spend valuable time in treating yourself with an ineffective product when you could have been properly treated during that time by going to a health care professional.

8 Products bought across borders may not be allowed in your country – Countries have different laws about what medical products can be sold and shipped across national borders. This means that it is possible that products that are not approved for marketing in your country or products that have been identified as a hazard to public health may not be allowed into your country if they are identified at entry. If you have already paid for the product, you may not be able to receive it or have its cost reimbursed. In addition, the prescription status of medical products varies from country to country. For instance, products that are available only on prescription in one country may be sold without prescription, or may even be unregulated, in another.

9 Products with the same name may be different in different countries – Internet users need to be aware that products with the same name may contain different ingredients in different countries. Therefore, you may be taking the wrong product. In addition, countries may have different standards for the quality of medical products and their manufacturers. Products purchased across borders might not be exactly the same product or quality as in your own country.

10 Your personal information may not remain confidential – Many web sites require you to disclose personal medical data. Users must be aware that there is no assurance that this information will be kept confidential. Users who feel uncomfortable with the potential use of their personal data should purchase their medical products through conventional, legitimate distribution channels.

POINT 5

See your health care professional before you decide to treat yourself or change your medication

Even after finding reliable, truthful health or medical information on the Internet, it is important to go to your health care provider to discuss your disease or condition and the information you have found before you take steps to treat yourself. This is important for several reasons:

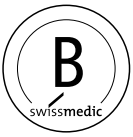
- Not all diseases and symptoms need medical treatment. You may be taking medicines or using medical products unnecessarily and exposing yourself to an unnecessary risk.
- Many medications or other medical products may cause harm if they are used improperly. It is important to be under the care of a health care professional when using such products.
- Appropriate medication or appropriate medical treatment for your disease or symptoms is important to your health. Not every medication is appropriate for everyone. For example, some individuals may be allergic to certain medications.

A health care professional can help you to determine the best medicine or treatment for your disease or condition.

● A health care professional can provide guidance on how best to take your medication safely. For example, the effectiveness of some medications may be influenced by other products, such as other medications, alcohol or certain foods. Mixing your medication with these other products could strengthen or weaken the effect of the medication or cause an adverse reaction. This could be dangerous to your health or, at the very least, interfere with your speedy recovery. ● Patients with particular characteristics , such as pregnant or breast-feeding women, the elderly and children, have special concerns, needs and considerations when taking medication or using medical products. In particular, a number of medications are specifically known to cause harm to unborn children. Pregnant women should therefore be sure to consult a health care professional before self-treatment. ● Any time you take medication or use a medical product it is important to inform your health care professional of any side-effects you may experience when using the product. By going through your health care professional for treatment, you can make sure that he or she will be better prepared to advise you or change the treatment if you do have an adverse reaction to a product. ● By ordering medical products through the Internet you may deprive yourself of the opportunity for personal, professional care and advice from your doctor, pharmacist or other health care professional.

ANNEX IV

Licence Symbol, Swissmedic[1]

Licence symbol A	Licence symbol B	Licence symbol C
		
Licence symbol D	**Licence symbol E**	
		

1 Swissmedic Internet communication 4 September, 2003 at http://www.swissmedic.ch/en/industrie/overall.asp?theme=0.00107.00004.00001&theme_id=916&news_id=1839&page=1

The licence symbol indicates that Swissmedic, the Swiss Agency for Therapeutic Products, has issued an authorization for a specific preparation. (It corresponds to the previous "IKS/OICM" including the (IKS/Uhu) logo in the corner with the distribution category.) Owing to the disbanding of Sanphar the previous "IKS Vignettes" may not be replaced with "Medwin Vignettes" and the old IKS logo will no longer be continued by Swissmedic. A new format for the licence symbol will therefore be made available to companies requiring it. It was decided that the all black version of the Swissmedic logo should appear in the circle indicating the distribution category. For reasons of space the authorization number had to be left out of this circle. On the packaging the authorization number is indicated under the EAN barcode. As this number is the only way of faultlessly classifying the package, the package indication in the form of a three-figure pharmaceutical code for IKS preparations or the two-figure pharmaceutical code for the former BAG preparations is printed in the EAN barcode next to the former five-figure IKS number or the former three-figure BAG number. However, as it is not legally compulsory to place a barcode on the package, in the absence of the EAN barcode the authorization number must be printed on the packaging, with the indication "Zulassungs-Nr." (abbreviated to: "Zul.-Nr."). The previous bilingual indication "IKS/OICM" or "BAG/OFSP" must of course be replaced by "SWISSMEDIC" (in capitals to make it easier to read). The time allowed for the change-over to the Swissmedic licence symbol is one year from the expiry of the existing IKS or BAG certificate and its replacement by a new Swissmedic authorization. The change-over to the Swissmedic authorization symbol may be made earlier but in this case Swissmedic must be informed that this aspect of the packaging has been modified.

ANNEX 5

Selected WHO Publications and Documents on Traditional Medicine

Publications and documents listed below are available in English. The following abbreviations are used to indicate the availability of language editions: Ar: Arabic; C: Chinese; F: French; R: Russian; S: Spanish. * Respective language version in preparation.

National policy and monitoring

WHO Traditional Medicines Strategy: 2002-2005. Geneva, World Health Organization, 2002 (document reference WHO/EDM/TRM/2002.1) (Ar/C/F/S/R).

Traditional Medicine - Growing Needs and Potential. Geneva, World Health Organization, 2002 (document reference WHO/TRM/2002.4) (Ar/C/F/S/R).

Legal Status of Traditional medicine and Complementary/Alternative Medicine: a Worldwide Review. Geneva, World Health Organization, 2001 (document reference WHO/EDM/TRM/2001.2) (F*/R/S*).

Report of the Inter-regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine. Geneva, World Health Organization, 2001 (document reference WHO/EDM/TRM/2001.1).

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

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

WHO Monographs on Selected Medicinal Plants. Vol. 3. Geneva, World Health Organization, in preparation.

WHO Guidelines on Safety Monitoring and Pharmacovigilance of Herbal Medicines. Geneva, World Health Organization, in preparation.

WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants. Geneva, World Health Organization, 2003 (Ar*/C*/F*/R*/S*).

WHO Monographs on Selected Medicinal Plants. Vol. 2. Geneva, World Health Organization, 2002.

WHO Monographs on Selected Medicinal Plants. Vol. 1. Geneva, World Health Organization, 1999.

Basic Tests for Drugs: Pharmaceutical Substances, Medicinal Plant Materials and Dosage Forms. Geneva, World Health Organization, 1998 (F/S).

Quality Control Methods for Medicinal Plant Materials. Geneva, World Health Organization, 1998.

Good Manufacturing Practices: Supplementary Guidelines for the Manufacture of Herbal Medicinal Products. Annex 8 of WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-fourth Report. Geneva, World Health Organization, 1996 (WHO Technical Report Series, No. 863) (F/S). (This supplementary guideline is also included in *Quality Assurance of Pharmaceuticals: A compendium of guidelines and related*

materials, Vol. 2: Good manufacturing practices and inspection. Geneva, World Health Organization, 1999 (F).)

Guidelines for the Assessment of Herbal Medicines. Annex 11 of WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-fourth Report. Geneva, World Health Organization, 1996 (WHO Technical Report Series, No. 863) (F/S). (This guideline is also included in *Quality Assurance of Pharmaceuticals: A compendium of guidelines and related materials, Vol. 1.* Geneva, World Health Organization, 1997 (F).)

Research

Report of the Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine, Bangkok, Thailand, 6-8 December 2000. Geneva, World Health Organization, 2001 (document reference WHO/EDM/TRM/2001.1).

General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine. Geneva, World Health Organization, 2000 (document reference WHO/EDM/TRM/2000.1) (F/S/R).

Clinical Evaluation of Traditional Medicines and Natural Products. Report of a WHO Consultation on Traditional Medicine and AIDS, Geneva, 26-28 September 1990. Geneva, World Health Organization, 1990 (document reference WHO/TM/GPA/90.2).

Rational use

Acupuncture nomenclature

A Proposed Standard International Acupuncture Nomenclature: Report of a WHO Scientific Group. Geneva, World Health Organization, 1991.

Report of the Working Group on Auricular Acupuncture Nomenclature. Lyon, France, 28-30 November 1990. Geneva, World Health Organization, 1991 (document reference WHO/TM/91.2).

Conservation of medicinal plants

WHO/IUCN/WWF Guidelines on the Conservation of Medicinal Plants. Gland, Switzerland, International Union for the Conservation of Nature, 1993 (F/S).

Training and good practice

Acupuncture: Review and Analysis of Reports on Controlled Clinical Trials. Geneva, World Health Organization, 2002.

Guidelines on Basic Training and Safety in Acupuncture. Geneva, World Health Organization, 1999 (document reference WHO/EDM/TM/99.1) (F/S).

Guidelines for Training Traditional Health Practitioners in Primary Health Care. Geneva, World Health Organization, 1995 (document reference WHO/SHS/DHS/TM/95.5).

Prospects for Involving Traditional Health Practitioners. Report of the Consultation on AIDS and Traditional Medicine, Francistown, Botswana, 23-27 July 1990. Geneva, World Health Organization, 1990 (document reference WHO/TM/GPA/90.1) (F).

ANNEX VI

List of Participants

WHO Consultation on Proper Use of Traditional Medicine and Complementary Medicine by Consumers, Milan, Italy, 1–3 December 2003

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Dr Layla Ashoor, Family Physician, Focal Point for CAM in Baharain, Ministry of Health, Karbabad, Kingdom of Bahrain

Mr Myat Kyaw U. Aung, Director, Department of Traditional Medicine, Yangon, Myanmar [Vice-Chairperson]

Dr Sassan Behjat, Coordinator, Complementary and Alternative Medicine Unit, Ministry of Health, Abu Dhabi, United Arab Emirates [Chairperson]

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Dr Gordon Brown, Head, Complementary Therapies Team, Department of Health, London, United Kingdom

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