

Overview of WHO Publications on Traditional Medicine
Indigenous Knowledge Distance Learning Course
World Bank 2005

***Report of a WHO Informal Consultation on Traditional Medicine and AIDS:
In Vitro Screening of Traditional Medicines for Anti-HIV Activity, 1989***

A variety of plant products, traditional medicines, are currently being used to alleviate the symptoms of HIV/AIDS in many parts of the world. For example, the use of garlic (*Allium sativum*), shiitake mushrooms (*Lentinus edodes*), papaya (*Carica papaya*), ginseng (*Panax* species), Aloe vera, and Ukrain (*Chelidonium majus*) are a few examples of many plants products, that have not been tested in controlled laboratory settings, yet have showed positive results in HIV/AIDS patients.

Though efforts to scientifically validate these plants products has started with a few organizations, such as the National Institute of Cancer in the USA, further research can be conducted to ensure the safety and effective use of these medicines for HIV/AIDS patients. For example, the report outlines a methodology to detect antiviral screen, in this case for anti-HIV activity, in the plant products.

The following recommendations are made to research institutions to maximize research efforts in this area and include:

- Research in the area of traditional medicine should be considered within the framework of the national programs for the prevention and control of AIDS, and should result in the strengthening of the existing activities and institutions.
- The WHO should establish a mechanism for the definition of priorities, preparation of protocols and promotion and support of relevant research based on the approved strategies.
- National AIDS Commissions should collaborate with WHO in the identification of traditional medicinal remedies that would merit further scientific evaluation.
- The AIDS related remedies being practices by healers should be carefully monitored to detect any serious side effects associated with the treatment and to ensure that promising therapies are identified and subjected to further investigation.

***Report of a WHO Consultation on Traditional Medicine and AIDS: Clinical Evaluation of
Traditional Medicines and Natural Products, 1990***

Many countries are currently using traditional medicine to alleviate symptoms of HIV/AIDS. For example, in China, in vitro anti-HIV activity has been reported for the following locally grown plants: *Glycyrrhiza uralensis*, *Hypericum perforatum*, *Viola yedoensis*, *Alternanthera philoxeroides*, *Andrographis paniculata*, *Arctium lappa*, *Lithospermum erythrorhizon*, *Coptis chinensis*, *epimedium grandiflorum*, *Lonicera japonica* and *Prunella vulgaris*.

This report outlines preclinical and clinical considerations involved in assessing traditional plant products that have HIV anti-viral activities. In preclinical trials, botanical verification and pharmacological activity of the plant product must first be reported. Then safety must be tested

by first identifying any potential toxicity of the plant product and then recognizing any toxic events that may occur during the clinical trial. In this stage, clinical considerations and protocols should be written and approved before the study starts.

In clinical trials, the following experts should be part of the team: study coordinator, health care worker, nurse, clinical pharmacologist, pharmacist, statistician, traditional health practitioners, social worker, and others including botanists or a natural product chemist. A study sample and control group should be selected according to WHO guidelines. Treatment and data collection are followed after the approval of the above. All data is analyzed and referenced to WHO guidelines such as the Clinical staging system for HIV infection and disease.

Report of the WHO Consultation on AIDS and Traditional Medicine: Prospects for Involving Traditional Health Practitioners, 1990

This Report recommends effective collaboration between the traditional and modern health care sectors in WHO's member states. The guidelines established allow individual countries to decide which types of traditional practitioners they would want to involve in their national AIDS prevention, control, and care activities. While it is important to distinguish between different types of practitioners, it is understood that all types of traditional health practitioners recognized by their communities may well have important roles to play in AIDS prevention, counseling, and care and in community leadership.

Among other programs, research priorities, as defined by national AIDS programs in conjunction with the national body responsible and with the involvement of traditional practitioners, should be based on affordability, cost-effectiveness, and feasibility. Research results should be reported and disseminated, especially to health policy-makers and decisions makers at national level, as well as to the public, of information and education. All research must respect ethical principles.

Report of the WHO Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine, 2000

The workshop aimed to promote the development of traditional medicine taking into consideration intellectual property rights and their implications and identify gaps between those areas of traditional medicine and existing modern intellectual property law. Participants shared information on national patent laws and policies on intellectual property rights relating to traditional medicine and discussed strategies that could be used for protecting traditional medicine knowledge, resources and biodiversity in order to contribute to a fair and equitable sharing of benefits.

The Workshop delivered the following recommendations:

1. Countries should have a national policy on traditional medicine as part of the national health policy and countries should develop and utilize traditional medicine in a meaningful manner in the national health care system;
2. Organizational infrastructure of traditional medicine should be developed and/or strengthened and official recognition accorded to it;

3. National and regional strategies should be developed for protection of traditional medicine with the support of WHO and other international agencies;
4. Ways and means need to be devised and customary laws strengthened for the protection of traditional medicine knowledge of the community from biopiracy;
5. Efforts through technical cooperation among countries need to be made to add value through innovation for public health, indigenous and local communities should be involved in devising these models;
6. Traditional knowledge which is the public domain needs to be documented in the form of traditional knowledge digital libraries in the respective countries with the help of WHO and WIPO's work in this area;
7. Governments and Member States need to take initiative for capacity building, implementation and enforcing the legislation to protect and promote traditional medicine knowledge through training, seminars and workshops. International cooperation should be increased in this area;
8. Governments should develop and use all possible systems including the *sui generis* model for traditional medicine protection and equitable benefit sharing;
9. Countries should develop guidelines or laws and enforce them to ensure benefit sharing with the community for commercial use of traditional knowledge;
10. Traditional knowledge should be recognized in the form and concepts of the traditional medicine system of a particular country, and not necessarily on a western model;
11. Efforts should be made to utilize the flexibility provided under the TRIPS Agreement with a view to promoting easy access to traditional medicine for the health care needs of developing countries.

WHO Guidelines for Methodologies on Research and Evaluation of Traditional Medicine, 2000

The General guidelines for methodologies on research and evaluation of traditional medicine articulates a strategy to improve and promote the proper use and development of traditional medicine. The document defines herbal medicines as: "Finished, labeled medicinal products that contain as active ingredients aerial or underground parts of plants, or other plant material, or combinations thereof, whether in the crude state or as plant preparations. Plant materials include juices, gums, fatty oils, essential oils, and any other substances of this nature."

The guidelines for methodologies on research and evaluation of traditional medicine address the following needs: (1) To link and create a medical relationship between Western Medical terminology and practices to Traditional Medicine; (2) To provide an overview of laboratory research methodologies that can be used to evaluate the effectiveness of Traditional Medicines; (3) To improve the quality and value of laboratory research methodologies in Traditional Medicine; and (4) Points 2 and 3 will facilitate the development of the proper evaluation of Traditional Medicines to regulate and register them into mainstream medicine.

In detail three assessments are conducted to evaluate Traditional Medicines: (1) Assessment of quality: This involves a pharmaceutical assessment, crude plant assessment, and plant preparations; (2) Assessment of safety: This evaluation is according to medicinal product safety testing guidelines; (3) Assessment of efficacy: In this evaluation, pharmacological and clinical

effects of active ingredients and their constituents should be tested according to their therapeutic activity. In addition, combination of herbal medicine use (such as Ayurveda, TCM, Unani, and Siddha) should be reported.

The document also outlines guidelines for toxicity of herbal medicines. Suggestions include conducting acute and long-term toxicity tests. Short term testing lasts 2 week to a month and long term testing is 9 to 12 months.

Revised Draft WHO Guidelines for Assessing Safety and Quality of Herbal Medicines with reference to Contaminants and Residues, May 2004

The safety and quality of medicinal plant materials and finished herbal medicinal products are a major concern for health authorities, pharmaceutical industries and the public due to the increase use of Traditional Medicines by consumers in the global market. These Guidelines provide guiding principles for assessing safety of herbal medicines and the use of good agricultural and collection practices (GACP) certification for medicinal plants.

The guidelines for assessing potentially hazardous contaminants and residues in herbal medicines include, physicochemical and environmental contaminants and/or residues such as arsenic and toxic metals, radioactive substances, mycotoxins and other endotoxins, pesticide residues, processing residues and solvents, persistent organic pollutants (POPs) and other contaminants, and Microbial pathogens that may be present in herbal medicines such as microbial contaminants and parasites.

The guidelines also provide recommended analytical procedures to evaluate the safety and quality of Traditional Medicines. The recommendations include: (1) Determination of arsenic and toxic metals; (2) Limit test for cadmium and lead; (3) Limit tests for total toxic metals as lead; (4) Determination of Microorganisms; (5) Determination of Aflatoxins which test for the presence of aflatoxins B1, B2, G1, and G2, contaminants in material of plant origin; and (6) Determination of pesticide residues.

Draft WHO Guidelines on the Conservation of Medicinal Plants, December 2004

These guidelines recommend approaches and actions for the conservation of medicinal plants. In specific, the guidelines provide broad principles on the conservation of medicinal plants for those actors and stakeholders involved in the process. The content areas provided in the guidelines include issues of social equity, intellectual property rights, and responsible business practices. In addition, they provide technical guidance on the conservation, production, harvest and use of medicinal plants.

As an example, in situ and ex situ conservation methods are described. An example of ex situ conservation is to, “support, and when necessary, develop botanic gardens and local botanical reserves (e.g. community-level gene banks, university arboreta, home gardens) that maintain living collections of medicinal plants and act as repositories for medicinal plant germplasm, preferably in the country/region of origin.”

WHO Guidelines for Consumers on Proper Use of Traditional Medicine and Complementary/Alternative Medicine, December 2002

An important issue is to ensure public and consumer safety on the use of TM/CAM. These guidelines inform consumers on safety and quality issues, efficacy, access, and proper use of TM/CAM.

The guidelines advocate for the proper use of TM/CAM to: (1) Strengthen and increase the organization of TM/CAM providers to contribute towards the professionalism of TM/CAM providers; (2) Create standardized training and/or knowledge requirements for the consistency of TM/CAM use; (3) Establish regulatory systems for quality assurance and registration of TM/CAM to maintain high quality of products; (4) Conduct clinical studies on TM/CAM to prevent irrational treatments and increase consumer safety; (5) Improve the collaboration between TM/CAM providers and allopathic providers to create an integrative health care system; and (6) Improve the dialogue between TM/CAM consumers and their health care providers so consumers are aware of medical alternatives and can properly use TM/CAM with allopathic medical care.

In addition, this report describes two stages in assuring the quality of TM/CAM.

The first stage involves identifying the plant species involved in the use of TM/CAM. Botanical verification can help identify the species, minerals, and vitamins involved.

The second stage involves assuring the quality of the product. Such as by Good Manufacturing Practice, Good Agricultural Practice, and standards set in Pharmacopoeias.

Draft WHO Guidelines for the Consumers in Promoting Proper Use of Traditional and Complementary and Alternative Medicine, May 2002

According to these guidelines, the main areas of importance for the appropriate use of TM/CAM are: (1) To assure that reliable information for consumers on appropriate use of TM/CAM therapies and products are provided; (2) To improve the communication between allopathic medicine practitioners and their patients concerning the patients use of TM/CAM; (3) To develop training guidelines for most commonly used TM/CAM therapies; (4) To develop standard treatment guidelines that provide information about appropriate use of the most commonly used TM/CAM therapies; (5) To strengthen and increase the organization of TM/CAM providers; and (6) To strengthen the cooperation between TM/CAM providers and conventional providers.

There are six proposed activities to meet the above objectives: (1) Make available reliable information for consumers on appropriate use of TM/CAM; (2) Improve the communication between allopathic medicine practitioners and their patients concerning the use of TM/CAM; (3) Develop training guidelines for most commonly used TM/CAM therapies; (4) Develop standard treatment guidelines providing information about proper use of the most commonly used TM/CAM therapies; (5) Strengthen and increase the organization of TM/CAM providers; and (6) Increase cooperation between TM/CAM providers and conventional providers.