The Use of
Herbal Medicines
in Primary Health Care

Report of the Regional Meeting
10–12 March 2009, Yangon, Myanmar

World Health Organization
Regional Office for South-East Asia

Names of medicinal plants in the cover of this report are as follows:

First row: **Morinda citrifolia* L., **Quisqualis indica* L., and **Senna alexandrina* Mill.

Second row: ⌘*Piper nepalense* Miq., ✦*Panax ginseng* L., and **Momordica charantia* L.

* Courtesy of Dr Nara Nakawattanukool
⌘ Courtesy of Mr Dorji Wangchuk
✦ Courtesy of Dr Xiaorui Zhang

SEA/HSD/322
Distribution: General

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Printed in India

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1 Introduction

1.1 Background

Herbal medicine (HM) and traditional medicine (TM) are widely used in countries of the South-East Asia (SEA) Region. Herbal medicine forms a substantial part of traditional medicine. According to WHO's definition, HM includes "herbs, herbal materials, herbal preparations and finished herbal products that contain as active ingredients, parts of plants, other plant materials or combination thereof". There is increasing demands for medicinal plants, both in the developing and developed countries.

Most of traditional medicines contain medicinal plants. Ayurveda, Chinese traditional medicine, homeopathy, naturopathy, Unani and TM systems in Africa and Latin America use herbal medicines. In the SEA Region, all Member States have medicinal plants in their traditional systems of medicine; *gSo-ba Rig-pa* in Bhutan, *Koryo* medicine in DPR Korea, *Jamu* in Indonesia, *Dhivehi bays* in Maldives, traditional or indigenous medicines in Myanmar, Sri Lanka and Thailand contain medicinal plants. Thus, herbal medicines form a significant component in traditional systems of medicine in countries of the Region.

There have been a number of important developments in the area of traditional medicine and herbal medicine over the years. The World Health Assembly (WHA) has passed nine resolutions since 1969 relating to traditional medicine; two of these resolutions are specifically on medicinal plants: WHA31.33 (1978) on Medicinal Plants and WHA41.19 (1988) on Traditional Medicine and Medicinal Plants.

In 2003, the health ministers of countries in South-East Asia Region, at their twenty-first meeting, agreed that traditional systems of medicine should be included as part of national health-care systems.

In 2004, the WHO Regional Committee for the South-East Asia Region at its Fifty-seventh Session recognized that traditional systems of medicine had played a vital role in contributing to health care. It urged interested governments of the Region to give adequate importance to developing traditional systems of medicine, not merely as an alternative to the modern system of medicine but in close conjunction with it so as to take advantage of the best from both systems.

In August 2007, the WHO Interregional Workshop on the Use of Traditional Medicine in Primary Health Care was held in Ulaanbaatar, Mongolia. It provided technical guidance to Member States, especially on the selection of traditional medicines in primary health care, with emphasis on ensuring efficacy, safety and quality.

In November 2008, the Beijing Declaration promulgated at the WHO Congress of Traditional Medicine expressed the need for action and cooperation by the international community, governments, and health professionals and workers to ensure proper use of traditional medicine as an important component contributing to the health of all people, in accordance with national capacities, priorities and relevant legislation.

In January 2009, the WHO Executive Board discussed a draft resolution on traditional medicine that would be tabled at the Sixty-second World Health Assembly (WHA) in May 2009. It urges Member States, in accordance with national capacities, priorities, relevant legislation and circumstances "to cooperate with each other to share knowledge and practices of traditional medicine and exchange training programmes on traditional medicine, consistent with national legislation and relevant international obligations". The World Health Assembly passed resolution WHA62.13 on Traditional medicine in May 2009.

This meeting aimed specifically to promote the potential of herbal medicines in national health systems in the Region.

1.2 Objectives

General Objective

To promote the use of herbal medicine in countries of the South-East Asia Region.

Specific Objectives

(1) To explain the role of WHO in promoting herbal medicine in primary health care (PHC).

(2) To share information on the use of herbal medicine among countries of the South-East Asia Region.

(3) To strengthen research in ensuring efficacy, safety and quality of herbal medicines.

(4) To discuss intercountry cooperation in herbal medicine.

(5) To prepare three generic frameworks; one for sharing information on the use of herbal medicine in PHC; one for research on efficacy, safety and quality of herbal medicine; and one for intercountry cooperation in the use of herbal medicine in PHC.

2 Opening session

The opening session consisted of a welcome address by Dr Tin Nyunt, Director-General, Department of Traditional Medicine, Ministry of Health, Myanmar, followed by inaugural address by Dr Samlee Plianbangchang, Regional Director, WHO South-East Asia.

Welcome Address by the Director-General, Department of Traditional Medicine, Ministry of Health, Myanmar

Dr Tin Nyunt welcomed everyone on behalf of the Department of Traditional Medicine, Ministry of Health, Myanmar. He said that it was an honour and a privilege to host the regional meeting. He described the scope of traditional medicine, emphasizing that herbal medicines were the main and sometimes only source of health care for millions of people living in the rural areas of developing countries. In Myanmar, traditional medicine has strong historical and cultural roots and practitioners command respect. A knowledge, attitude and practice (KAP) study on TM in Myanmar in 2008 revealed that the knowledge of TM among Myanmar people is more than 85%, the attitudes are positive (99.3%) and good practice was prevalent across the country (90%). Dr Tin Nyunt further went on to emphasize the need to bring herbal remedies into the existing framework of rational scientific use of medicines. Governments are increasingly supporting TM and the role of primary health care in improving health outcomes of the community is well known. It is against this background that this meeting gains importance. He said efforts to bring TM into the mainstream of health care must be encouraged by national policies that also stimulate research into the safety, efficacy and quality so

as to increase access and improve rational use of TM. He ended by summarizing the expected outcomes of the meeting and mentioning that health concerns were never confined by national or geographical boundaries, as was illustrated by the cooperative efforts during rehabilitation after cyclone Nargis hit the delta region of Myanmar in 2008.

Address by Dr Samlee Plianbangchang, Regional Director, WHO South-East Asia

The Regional Director first welcomed everyone to the meeting and thanked the Myanmar Ministry of Health, especially the Department of Traditional Medicine, for hosting the meeting. He said that in light of a widening gap between the "haves" and "have-nots" in health, and with the rapid increase in the cost of medical treatments worldwide, the theme of this meeting was timely and relevant, particularly for countries in the South-East Asia Region. TM continues to be a valuable source of remedies in the Region, and has developed through empirical experiences and the observations of people who use them. Because TM embodies age-old wisdom and forms an integral part of the social and cultural heritage of people (especially in rural areas), these systems are country- and locality-specific. However, today, herbal medicines have spread to neighbouring countries.

The Regional Director specified that it was important to distinguish between traditional medicines and modern medicines. Whereas traditional medicines rely on parts of medicinal plants as medicines, modern medicines are made from active ingredients that are purified into chemical forms. While modern medicines are developed through scientific research (which requires capital investment and is time-consuming), the active ingredients of most herbal raw materials used in TM are still unknown. Traditional herbal medicines are cheap when prepared in a traditional way, but if done using modern methods, they become expensive.

The Regional Director said that there had been resurgence in the use of herbal products since the 1990s and that this trend was likely to continue. Among the reasons was the desire of people to return to nature for their health care; the perception that herbal medicines derived from natural raw materials are safe and their availability and affordability, especially in rural areas.

WHO promotes the use of traditional medicines (particularly herbal medicines) in primary health care, helping to assure their quality, efficacy, and safety, as well as the availability of medicinal plants in the community. This meeting aimed to promote the sharing of information and experiences among institutions of countries in the Region on the use of herbal medicines in PHC and to further inter-institutional and inter-country cooperation.

The Regional Director mentioned that the time was right to meticulously examine the role of traditional and herbal medicines in assuring and promoting good health, especially in PHC, so that health-care coverage could improve, thereby reducing inequity in access to health-care services. The use of herbal medicines in PHC, he said, reflected the application of appropriate technology that was socially and culturally acceptable to people in a community; herbal medicines were meant for all strata of people in both the developing and developed world.

Countries in South-East Asia Region have vast resources of medicinal plants, and are custodians of a huge repository of knowledge in TM which needs protection. Otherwise, they would pay a high price for products made from their own medicinal plants by other countries with the capacity to invest in modern production methods. The Regional Director emphasized that herbal medicines could be developed by the countries in this Region through commercialization and modernization, and herbal medicines could contribute significantly to their economic and health gains. Protection of biodiversity for the sustainable use of medicinal plants was stressed; over-exploitation, especially by outsiders, could lead to depletion of these natural resources. The way forward was to protect the herbal heritage and promote production of herbal medicines for use by everyone, thus contributing to the self-reliance of the countries in the provision of "essential medicines". (For full text of Regional Director's address, see Annex 1.)

3 Plenary sessions

3.1 Introduction of participants and nomination of office bearers

Dr Kin Shein introduced the participants and presented the objectives and expected outcomes of the meeting. Dr Samlee Plianbangchang nominated Dr Tin Nyunt as Chairperson, Dr Budihardja M. Singgih as Co-chairperson and Dr S.D. Seth and Dr Urmila Thatte as rapporteurs.

3.2 Technical presentations

The Role of WHO in promoting the use of herbal medicines in primary health care

In her presentation, Dr Xiaorui Zhang said that traditional medicine was being used by both high- and low-income countries. Figures showed that 60-90% of the population in some developing countries depended on traditional medicine for their primary health care needs. About 70% of the population in Canada and 80% in Germany also used traditional medicine as complementary and alternative treatment. She described the situation in Member States in the SEA Region. In DPRK at the PHC level, coverage with traditional medicine accounted for more than 70%, while in India use of traditional medicine is widely accepted (in rural areas, 70% of the people use of traditional medicine). Interestingly, in India, among 2860 hospitals, more than 75% provided Ayurveda medicine in the year 2000. In

Myanmar, more than 85% of the population had used traditional medicines and more than 80% of people have used home remedies. Easy access was evident as more than 75% of households could reach traditional medicine services within one hour. Dr Zhang stated that there were 281 492 traditional healers in Indonesia, of which 96.2% used Indonesian indigenous medicine. Also, 40% (70% in rural areas) of Indonesia's population make use of traditional medicine. In regional/general hospitals of Thailand, 83.3% of patients used Thai traditional medicine, while at the community hospitals the figure was 67.8%.

Dr Zhang reminded participants that the Alma-Ata Declaration in 1978 specified that primary health care relies on traditional practitioners as needed to respond to the expressed health needs of the community. The SEA Region had a long history of use of traditional medicines, along with government support for the development and promotion of traditional medicine. In fact, governments in the Region are keen to further promote the use traditional medicine in primary health care. A WHO global survey published in 2005 showed that before 1986, 14 Member States had herbal medicines law or regulations, while in 2007 there were 110 with such regulations (i.e., 65% of respondents had established herbal medicines regulations). Additionally, 42 (49%) said regulations were in the process of being developed. The number of countries with a national research institute on TM or complementary and alternative medicine (CAM) or herbal medicines rose from a mere 12 in 1970 to 62 in 2007. Apart from Timor-Leste, all countries in the Region had a national policy, a traditional medicine department in the ministry of health, a national programme on TM and a national expert committee. When it came to regulation of TM, Bhutan, Maldives, Sri Lanka and Timor-Leste did not have a system in place; pharmacopeias or monographs did not exist in Bangladesh, Maldives, Nepal and Timor-Leste at the time of the survey. All countries except Maldives and Timor-Leste have TM Institutions for education, services (hospitals) and/or research.

More specifically, in relation to PHC, Dr Zhang said that Myanmar had a national programme on "Medicines in your garden" along with training for health workers in the use of traditional medicine for PHC. A *Manual of Myanmar Traditional Medicine for Primary Health Workers* has been published and 150 kits with herbal medicines for emergency use were formally distributed to representatives in 150 villages in three townships. In Thailand, traditional medicine services in public health facilities (PHF) are structured at three levels. Level 1 public health facilities are those that sell single herbal medicines or Thai traditional medicine preparations only. Level 2 PHF are those what sell herbal medicines and also provide Thai traditional medicine services, e.g. Thai massage, hot herbal compress, and herbal

steam bath. Level 3 PHF provide Level 2 services and also serve as training centre on Thai TM, e.g. training courses on Thai massage and *Ruesi Dud Ton* (traditional stretch exercises), while Level 4 PHF provide Level 3 services and also produce herbal medicines. Thailand has also brought out a *Manual for cultivation, production and utilization of herbal medicine in primary health care*.

Cambodia, Laos and Vietnam have also run programmes on "Your medicine in your garden". A Mongolian project in 2004-2006 involved family medical kits filled with traditional medicines based on the principle of "Use first and pay later". The project covered 10 000 families for a total of 50 000 family members and the total cost for one medical kit amounted to US$ 8 per year per family. In China, a new cooperative medical scheme is being funded with contributions of 40% by central government, 40% from the local government and family contributions of 20%. This scheme covers the medicines in the list of essential medicines which includes western medicines and traditional medicines, as well as acupuncture and Chinese tuina (Chinese massage therapy).

Dr. Zhang then discussed common challenges in the field of traditional medicine. She said that although TM has been used for ages, there is a lack of clinical evidence to prove efficacy and safety. This has been hindered by a lack of appropriate methodology and approaches to evaluate and conduct research on TM. Quality control and safety of herbal medicines remain complex, and the concept that "natural means safe" often leads to misuse of TM by the public for self-care. Additionally there are frequent reports of accidents due to unqualified practitioners.

In 2003, WHO organized a regional working group meeting for national drug regulatory authorities to develop regional guidelines for classification of traditional medicines; minimum requirements for safety, efficacy and quality assurance; and minimum requirements for safety monitoring and control of advertisements of traditional medicinal products. She also mentioned that "Indigenous herbal medicines guidelines" had been produced by WHO's SEA Region and traditional herbal medicines and new herbal medicines guidelines by the Eastern Mediterranean Region. Dr Zhang also pointed out that the SEA guidelines defined safety as "no known or potential harm to the people" and that three classes of safety were considered in these guidelines, which would dictate the nature of the necessary safety requirements. Class 1 included herbal medicines whose safety was established by long-time use. Class 2 were medicines that were safe under specific conditions of use (such as traditional medicines covered by well-established documentation such as monographs), while Class 3 were traditional medicines of uncertain safety

and would require safety data. Dr Zhang also provided an interesting summary of the efficacy data requirements for three categories of diseases. For acute conditions, pre-clinical and clinical data would be needed before it should be used. On the other hand, for chronic diseases, pre-clinical and clinical data may be required (but may not be needed, depending on the formulation), although other data indicating long-time use and supported by well- established documents such national pharmacopoeia and monographs also may be needed. If a medicine is to be used as health promoter, although pre-clinical and clinical data may not be required, the claim would have to be supported by well established documents such as national pharmacopoeia and monographs.

Dr Zhang referred to a number of relevant WHO manuals including *WHO quality control methods for medicinal plants and materials* (2000), *Guidelines for good agricultural practice and good collection practice for medicinal plants (GACP)* (2003), *WHO guidelines on assessing safety and quality of herbal medicines with reference to contaminants and residues* (2007), *WHO monograph on good agricultural practice and good collection practice (GACP) for Artemisia annua* (2006), and updated *WHO good manufacturing practice guidelines for herbal products* (2006).

Dr Zhang then highlighted the importance of intercountry cooperation by discussing the objectives of the Association of South-East Asian Nations' Traditional Medicines and Health Supplements Scientific Committee (ATSC), which include provision of scientific risk assessment based on accepted principles and recommendations to the Product Working Group. She explained that the ATSC has short-term, medium-term and long-term programmes in seven areas including negative list of ingredients, maximum levels of vitamins and minerals, limits of contaminants, bovine-derived substances, list of restricted additives/excipients, claims requirements and classification of products at the interface. Another example of intercountry cooperation cited was related to monographs developed in the Newly Independent States (NIS). She said that these activities help national authorities and experts to learn how to develop monographs on medicinal plants and build capacity to establish national standards for quality assurance and control measures for herbal medicines. Further, such cooperation also promotes research on herbal medicines and networking of researchers on herbal medicines within and outside the NIS and CCEE (countries of Central and Eastern Europe). It also establishes a network among these countries to facilitate sharing of information and experience in regulation, research, and use of herbal medicines.

Dr Zhang then went on to describe the International Regulatory Cooperation for Herbal Medicines (IRCH), which is a network to create, protect and promote public health and safety through improved regulation for herbal medicines. The two main activities of the IRCH are information-sharing on technical matters related to regulatory information of herbal medicines via electronic communication as the main tool, on a daily basis, through an information focal point nominated by the herbal medicine regulatory bodies, and through annual meetings. Currently there were 17 countries in the IRCH network and 5 subregional forums including the Forum on Harmonization of Herbal Medicines (FHH), the Pan American National Drug Regulatory Authorities Harmonization (PANDRH), the European Herbal Medicines Committee, the ASEAN Product Working Group on Traditional Medicines and Health Supplements (TMHSPWG), and the Latin American Parliament (PARLATINO). The IRCH shares information through dialogues on safety, quality, research and regulation, and this has been steadily increasing over the years. A number of working groups have been set up which look into various aspects like identification of adulteration of products, laboratory testing and quality of herbal materials and products (including reference standards), evidence for health-based claims, monographs, herb interactions, vigilance of herbal medicines, linkages to and promotion of research, consumer/practitioner awareness and education, and information sharing or communications.

Dr Zhang then described some of the recommendations from Thirteenth International Conference for Drug Regulatory Authorities (2008) that coincerned herbal medicines. These included requests to Member States to promote and improve the use of traditional medicine as an important therapeutic tool within health-care systems; provide well-balanced prescribing information concerning TM, including potential interactions with conventional medicines; promote research and use of TM as an important therapeutic tool; and raise awareness of cases of adulteration of TM with undeclared plants, conventional medicines, or synthetic substances. It was also recommended that countries with resources should support developing countries to achieve access to better technological tools for evaluation of the therapeutic potential of plants.

Dr Zhang discussed the WHO Executive Board Resolution on Traditional Medicine (Resolution EB124.R9), adopted in January 2009, which urges Member States to preserve and communicate knowledge of traditional medicine; formulate national policies, regulations and standards of traditional medicine; integrate traditional medicine into national health systems; develop research and innovation; establish qualifications and license practices; and strengthen communication

between conventional and traditional medicine providers. Finally, she suggested areas for future cooperation among SEA Region countries, including sharing national regulatory information in assessing safety, efficacy and quality of herbal medicines (countries could be encouraged to join International Regulatory Cooperation for Herbal Medicines). Another important area for cooperation is to share research information related to safety, efficacy and quality of traditional medicines through compiling monographs of commonly used medicinal plants in SEA Region based on existing national monographs and pharmacopoeias. Others include expanding national programmes on "medicine in your garden" to facilitate use of herbal medicines in PHC, encouraging countries to include herbal medicines in the list of national essential medicines, developing training materials for health workers in PHC for use of traditional medicine, and developing a self-care manual on the proper use of traditional medicines for PHC for the public and people in communities. In conclusion, Dr Zhang quoted from the address of Dr Margaret Chan, Director-General of WHO, at the WHO Congress on Traditional Medicine held in Beijing, China in November 2008: "The two systems of traditional and Western medicine need not clash. Within the context of primary health care, they can blend together in a beneficial harmony, using the best features of each system, and compensating for certain weaknesses in each."

Research strategy to ensure efficacy, safety and quality of herbal remedies

Dr Ranjit Roy Chaudhury presented a technical paper and said that traditionally, herbal remedies were prepared fresh from plants growing in the vicinity and used immediately, therefore not presenting problems in identification or preparation of the extract for administration to a patient. But today, freshly prepared formulations are rarely dispensed. The medicines are instead dispensed as packaged tablets or liquids whose shelf life is increased with preservatives. Naturally, issues of quality, which could impact effectiveness and safety of the plants, are raised; these challenges have to be addressed if herbal remedies are to be used in practice today.

After years of experience, standardized, validated research methods have been developed to assess efficacy, safety and quality of synthetic compounds. However, these methods are not appropriate for evaluating herbal medicines. In fact, use of these well-established research methods to evaluate herbal remedies could endanger and actually curb the discovery of new herbal remedies and could prevent development of herbal medicine. It is necessary to develop innovative research methods for assessing efficacy, safety and quality of herbal remedies for

use in PHC. Dr Roy Chaudhury further emphasized that it is challenging to evaluate herbal remedies within the rigourous framework of clinical pharmacological principles without contesting the concepts of traditional medicine.

Efficacy studies

The challenges for research on efficacy of herbal remedies begin with the quality of the final formulation to be tested. Dr Roy Chaudhury described the four phases through which synthetic drugs undergo development. Phase I studies assess safety and tolerance, usually in normal subjects, and are followed by Phase II exploratory studies, which are performed to determine efficacy in a small number of patients. Phase III studies are confirmatory efficacy studies conducted on a larger number of patients, usually in multiple centres, and Phase IV studies are conducted in the post-marketing stage. In all these phases, the gold standard for assessment of a synthetic drug is the randomized double blind controlled clinical trial (RCT). Such RCTs also have been performed with herbal remedies.

The most appropriate strategy for determining efficacy of a herbal remedy for use at the PHC level would be the "observational herbo-epidemiological method". In this type of study, the TM practitioner would continue to practice his medicine with no special intervention. The effect of the herbal remedies would be observed on a large number of patients and recorded. There could be a control group, so that one group is being given the herbal remedy while another group does not receive any herbal remedy. The findings will need to be carefully documented and the efficacy of the herbal remedy could be seen by noting whether the group receiving the herbal remedy improves more than the control group. Dr Roy Chaudhury mentioned that as a start, even if a control group is not available, simple but meticulous observation and recording of findings in the test group would yield very useful data. However, to make this type of study meaningful, several aspects must be addressed. The remedies to be evaluated must be identified and the diseases for which they would be administered identified. The sample size has to be adequate and observers must be thoroughly trained to assess and record the effects of the herbal remedy. This type of study would be appropriate for chronic diseases like hypertension, bronchial asthma, skin diseases and diabetes.

In addition to observational studies, Dr Roy Chaudhury recommended other designs including single case studies, add-on designs and qualitative research. Quality of life should be one of the variables studied with herbal medicines. The influence of the patients' constitution should also be considered, as this may influence the response to drugs. For example, it has been shown that obese patients

with *pitta prakriti* (Ayurvedic term for individual who sweat a lot and having higher than normal temperature) body responded better to sibutramine while most of the non-responders were of *kapha prakriti* (Ayurvedic term for individuals having soft limbs, slow gait and slow to understand). It has also been shown that fresh juice of *Momordica charantia* produced better effects in diabetic patients with *pitta prakrita* or *kapha prakriti* than those with *vata prakriti* (Ayurvedic term for individuals having dry skin, lightly built with quick mental process and initiation of action).

Safety studies

A number of factors can render a herbal remedy unsafe. These include wrong identification of the plant, lack of standardization, contamination with pesticide residues, microorganisms, heavy metals, substitution, adulteration, incorrect preparation or dosage. Dr Roy Chaudhury illustrated these issues with various examples. There could be problems in collection when a plant has multiple names. For example, the Chinese medicinal plant *Angelica polymorpha* is also known by many other names like Dong Quai, Dong Guai, Dang Gui or Tang Kuie; the Indian plant *Aegle marmelos* is known as Abiviagam, Lyalbudi, Kuvilam, Mavilangi, Villivassin and Vilvan in different parts of the country. Problems in standardization were illustrated by the study that investigated the quantity of ginsenoside in 50 commercial brands of ginseng sold in 11 countries. It was found that in 44 products, the concentration varied from 1.9% to 9.0% and 6 products contained no ginseng at all. The problem of contamination is more serious as illustrated by the fact that patients suffered from lead poisoning after taking herbal medicines and there were 6% to 60% weight for weight lead in these preparations. Dr Roy Chaudhury gave another example of introduction of *Aristolochia fangchi* containing aristolochic acid in place of *Stephania tetrandra,* which led to development of progressive interstitial nephritis.

The conventional approach to safety studies for new chemical entities involves acute, subacute and chronic toxicology studies in two animal species. For herbal medications, a six week sub-acute study in two species is recommended with histopathological study of all organs at autopsy. Randomized controlled trials are also useful to assess safety. Here too, herbo-epidemiological studies in a large number of patients on a particular herbal preparation may be undertaken to assess safety.

Meticulous recording of side effects occurring in patients and careful record-keeping of all data collected are hallmarks of a good study. Futhermore, a sufficient number of patients taking a particular herbal remedy need to be observed, and it is necessary to train observers to look for and record side effects.

Quality

The factors that affect quality could compromise the safety of a herbal medicine. If a wrong plant is used, or if it has lost its efficacy due to inappropriate storage or is not well standardized, the quality is unacceptable. If an herbal medicine is to be used at a tertiary care hospital, performing standardization studies is necessary (although it is possible that appropriate quality control tests are not available for some plants as yet). Some basic quality tests are needed, e.g. site visit to the manufacturing unit, or testing of samples randomly collected after delivery against pre-defined quality criteria, or ensuring that good manufacturing practices have been followed.

If medicines are being centrally procured, quality can be assured at a central laboratory before being used at PHC level. If there is no functioning herbal medicine quality control laboratory, then it should be set up. If medicines are being locally produced or are being made fresh when they are being dispensed in the PHC centre, it may not be possible to perform quality control tests. No tests for quality may be required if the plant has been correctly identified and the fresh preparation is used soon after being made. Random samples may be sent to the central laboratory or simple tests for quality may be set up at PHC centres to ensure quality. The laboratory staff needs training and an appropriate system for random checks must be in place. Dr Roy Chaudhury concluded by saying that herbo-epidemiological studies for safety and efficacy were the need of the hour and that simple tests must be set up for quality.

Conservation of medicinal plants through sustainable harvesting practices

Dr G.G. Gangadharan gave a presentation on conservation of medicinal plants through sustainable harvesting practices. He explained that the primary focus of the Foundation for Revitalization of Local Health Traditions (FRLHT) since its inception in 1991 has been on conservation of medicinal plants both *in situ* and *ex situ*. His paper was highly influenced by experiences at FRLHT over the last two decades, he said.

Medicinal plants are distributed across various regions and are used in traditional medicine in unrefined or semi-processed form, often in mixtures with non-botanical components. Globally, it is estimated that as many as 35 000 to 70 000 species of plants have been used. In India, around 19 000 vascular plant species have been recorded (8% of total flowering species in the world), of which nearly 8000 species (40%) are described in scholarly literature and codified texts of

Indian System of Medicines (ISM). Around 70% of India's medicinal plant species are found in the tropical areas and out of 8000 species, over 1000 medicinal plant species are notified as threatened in India. More than 900 plant species are currently involved in the medicinal plant trade in India, in which 88 species are under commercial cultivation or plantations, 42 are imported and the remaining (about 85%) are primarily sourced from the wild. Millions of rural households use medicinal plants in a self-help mode. India itself has over one million traditional village-level healers and several million knowledgeable households. There are around 700 000 registered and licensed practitioners of the various codified Indian systems of medicine. According to a WHO estimate, the global demand for traditional medicine increased at an annual rate of 8% during the period 1994-2001, while in the United States and Europe, it has grown at an average of 10% per year and it is estimated that the global market would be worth US$ 5 trillion by the year 2050. A heavy demand for herbal products has created more pressure and commercial over-exploitation of medicinal plants which are currently plagued by destructive harvesting and over-harvesting. Current practices of unsustainable harvesting have ultimately led to the depletion of natural resources. At present, 95% of collection of medicinal plants is from the wild and more than 85% of the wild collections involve destructive harvesting. Although there are restrictions and prohibitions on extraction and procurement of certain medicinal plants from the wild, secretive and exploitative trade still persists.

The simplest definition of sustainable use may be "the use of plant resources at levels of harvesting and in such ways that the plants are able to continue to supply the products required indefinitely". This places an emphasis on maintenance of species populations in the wild, irrespective of high worldwide demand. It is important to conserve the plant populations of many commercially exploited species in the wild, which face the threat of extinction – culturally, ecologically and commercially. A decision-making matrix for sustainable management should emphasize optimization of quality as well as quantity of produce.

There is immense traditional and indigenous knowledge among local people about medicinal plant species, including medicinal uses, harvesting patterns and processing of medicinal plants, and a participatory approach involving local community in medicinal plants conservation is a positive approach. The integrated efforts of the forest department, voluntary sectors, industries and local community are essential to evolve a comprehensive planning and management system for medicinal plants.

Local communities can take more responsibility only if they are provided with suitable institutional arrangements, adequate income generation, control over

resources and the capacity to build the knowledge and skills required. Rural and tribal communities use medicinal plants for their health care and livelihood needs, and collect plants only whenever they need. Cutting down a tree to harvest the fruits has become common. Such short-sighted and wrong practices have a huge impact on the distribution and population of medicinal plant resources in the forest. Higher prices in the international and domestic market lure harvesters and local people to collect more material from the wild.

Several reasons can be found for destructive uses, including open access to medicinal plants in the wild; lack of sufficient data on wild plant populations; marketing and trading; inadequate regulations and legal protection; and poor access to appropriate technology for sound harvesting and plantation development. Unsustainable harvesting threatens not only the future of the plants, but also the livelihoods and health status of people throughout the world. The World Conservation Union's threat criteria placed significant numbers of medicinal plant species under threatened or endangered status. The dire consequences of unsustainable harvesting of some biological resources are evident today on a global scale.

There is immense traditional knowledge among local people on medicinal uses, harvesting patterns and processing of medicinal plants. They have complex relationships with their environment. It requires a paradigm shift for all the institutions and processes related to forest management. Integrated efforts of the forest department, voluntary sectors, industries and local communities are essential to evolve a comprehensive planning and management system for medicinal plants.

A participatory approach integrates people of different social status, and establishes a needs-based and objective-oriented local institution. Such an institution must recognize and provide for a continuous assimilation of intergenerational knowledge and wisdom available among the multiple stakeholders in the villages. This institution should facilitate coherent action and help the stakeholders contribute towards conservation and sustainable use of resources. It should help the resource managers to decentralize and broader conservation of valuable medicinal plants, which provide livelihood support for many people. In this context, the framework of participatory approach for sustainable management of medicinal plants should link with documentation and assimilation of traditional knowledge and involvement of local communities.

Some genuses like *Emblica, Embelia, Terminalia, Asparagus, Rauwolfia*, and *Tylophora* have shown rapid degradation within a decade. The factors responsible for the degradation of such species include increasing demand for these valuable

medicinal plants in the global market and availability of the vast forest resources in the Eastern Ghats of Orissa, India, hilly areas and national parks with rich and diversified medicinal plants encouraging massive collection from the wild rather than regeneration of plants. Availability of surplus and cheap labour in the forest belts and lack of alternative livelihood options for the forest dwellers results in engagement of human labour for collection of materials without appropriate eco-friendly management planning. Unorganized, uncontrolled and unfair trading involving different individuals at different levels in the trade channel, starting from primary gatherers to middlemen, private dealers and industries, is another reason for degradation. They neither have concern for plant sustenance nor possess knowledge regarding sustainable harvesting methods.

Interestingly, natural resources have been actively managed and utilized by indigenous healers. The healers use the plants for their own consumption and preparation of medicine only. They do not collect the materials in very large quantity at a time. The traditional practitioners strictly follow certain spiritual norms while collecting the medicinal plants. These norms act as a control mechanism for sustainable availability of plants. The plants are collected only during certain astronomical days like solar eclipse, lunar eclipse, full moon, *amavasya* (new moon day), *sankaranti* (Saturday and Sunday). According to their beliefs, the plants possess high medicinal quality during these events. Early morning is the most suitable time for collection. There are also norms regarding which plant should be collected during which particular event. These traditional beliefs and practices allow sufficient time for the plant's growth and bring back its normal status. For example, after collection of bark from an Arjuna *(Terminalia arjuna)* tree, six to nine months is required for regeneration of the tissues. The practitioners also follow certain restrictions in selecting the place for plant collection. They always prefer to collect plants grown in the dense forest region where human intervention is little or nil. The plants are not collected from graveyards or cremation fields, temples/sacred places, white ant hills, roadsides, just near a well, or dry and unhygienic places. These restrictions indirectly lead towards conservation of some species. The healers are very well aware of which plant is located in what type of forest and in which part of the forest. When roots of any plant are required, they are harvested without uprooting the plant, leaving some portions for its regeneration. When bark is required they cut from one portion. They follow certain methods during the harvesting of different parts of the plants in order to protect them from being destroyed and also preserve the plant for future use. For example, roots are collected from one side and in a northeast direction, the bark in an upward direction, and seeds in a matured form. The practitioners also follow certain seasonal norms in collecting different parts of different plants. For example, fruits are collected in the month of April, May and June. Bark is collected in autumn, while roots are harvested in winter.

Dr Gangadharan's recommendations included sensitizing multiple stakeholders such as manufacturers, pharmacies, primary collectors, or middlemen for conservation and sustainable harvesting. Establishment of a pressure group at district and state levels to advocate against unscrupulous and illegal trading, integration of planting of medicinal plants as intercropping in afforestation programmes and encouraging community forest management (which contributes not only towards sustainability of medicinal plants but also livelihood improvement for inhabitants residing in forest fringes) were other recommendations. Promoting cultivation of rare medicinal plants by the community and linkage with pharmaceuticals for buy-back arrangements will check massive collection from the wild. Wider promotion and conservation of species at household level through home herbal gardens and nurseries and establishment of a task team on sustainable conservation management and harvesting of medicinal plants were also recommended.

Finally, Dr Gangadharan recommended that a participatory approach involving various local stakeholders including the policy-makers would lead to development of an appropriate strategy for sustainable harvesting, and trace out suitable measures for protecting valuable knowledge and resources. It would be useful in realizing the twin goals of sustainable harvesting and conservation of dying resources, ultimately leading towards all-round community development.

3.3 Country presentations

The use of various medicinal plants are mentioned in country presentations. They are based on the tradition of the respective Member States.

Use of herbal medicines in Bangladesh

Dr A.H.M. Shafiquzzaman informed that Unani and Ayurvedic medicines were included in the primary health care programme in the Health and Population Sector Programme (HPSP) 1998 and Health, Nutrition and Population Sector Programme (HNPSP) 2003-2011. The Board of Unani and Ayurvedic System of Medicine (BUASM) was established in 1975. The process of legalization of indigenous system of medicine started after independence and Unani and Ayurvedic medicines were defined as drugs in The Drug (Control) Ordinance, 1982. The Bangladesh Unani and Ayurvedic Practitioners' Ordinance was adopted in 1983. There are several laws that directly or indirectly control and support the use of HM in health service system in Bangladesh, including The Drug Act,1940; The Drug Regulation, 1946, The Drug (Control) Ordinance, 1982; The Unani & Ayurvedic Practitioners'

Ordinance,1983; The Health and Nutrition Policy, 2005; The Population Policy of Bangladesh, 2005 and The Drug (Control) Amendment Act, 2006.

There is no separate national policy on traditional medicine in Bangladesh although TM is included in the national health policy. There is a treatment guideline on Unani and Ayurvedic medicine published by the Directorate General of Health Services. The Health and Nutrition Policy, 2005 emphasizes the best utilization of traditional medicine. Sharing of information with countries in the SEA Region is mainly through WHO support which coordinates these activities through technical training seminars, workshops, etc. There are, however, no Internet sites or network or electronic system yet in the country devoted to TM.

The Institute of medicinal and aromatic plant has done the pharmacological, phytochemical and biological screening of a good number of indigenous plants successfully. The establishment of another institute of HM to conduct research on Unani and Ayurvedic medicines and herbal products is underway. The Bangladesh Council of Science and Industrial Research (BCSIR) also supports research in TM.

There is a separate cell under the Drug Administration to monitor safety, efficacy and quality control of herbal medicines. The Ayurvedic Pharmacopoeia was published in 2006 while the Unani Pharmacopoeia is in preparation. Part 1 of the Ayurvedic Pharmacopoeia of Bangladesh comprises 52 monographs of Ayurvedic single drugs of plant origin.

The National Formulary of Unani medicine was published in 1993 and the National Formulary on Ayurvedic medicine in 1992. A number of herbal preparations are used in their natural forms including, for example, *Phyllanthus emblica,* also called *Aamlokee,* which is indicated for heartburn, vitamin C deficiency, indigestion, diarrhoea, anorexia, dysentery, pyorrhea, palpitation, vomiting, insomnia, etc. Another popular medication is *Terminalia chebula* (*Hartaki*) which is recommended for heart burn, indigestion, constipation, hepatitis, piles, painful menstruation, diarrhoea and dysentery. *Centella asiatica* (*Thankuni Pata*) is used for diarrhoea, dysentery, weakness of memory and nerves, eczema, general weakness, etc. *Tinospora cordifolia* (*Gulancha*) is recommended for fever, hepatitis, rheumatism, diabetes, diarrhoea and dysentery, etc. *Momordica charantea* is used in diabetes, worm infestation, fever, hepatitis, itching, pustules, allergy, etc. *Azadirachta indica* (*Neem*) is indicated for itching, inflammatory skin conditions, worm infestation, fever, pustules, allergy, etc. Common turmeric (*Curcuma longa*) also known as *Holud*, is used in trauma induced pain, sprains, cough and cold, itching, joint pain, etc., and *Allium sativum* (*Rosun*) is indicated in hypertension, hypercholesterolemia, indigestion, worm infestation, fever, rheumatism, diabetes, cough and cold, etc.

Another food item used as herbal medicine is *Zingiber officinale* (*Ada*) in cough and cold, fever, indigestion, nausea, anorexia, heartburn, constipation, etc.

Ecological and biotic factors are conducive in Bangladesh to the cultivation of medicinal plants, and more than 800 medicinal plants are reported to be available in Bangladesh. These are mostly grown in forests, jungles and roadsides. There is some planned or systematic cultivation. However, methods for collection are so indiscriminate and extensive that there remains no scope for regeneration. There is little knowledge on post-harvest processing, and good practices for cleaning, drying and sorting plant are necessary. It is in these areas that intercountry cooperation is possible.

It is recommended that a traditional, complimentary and alternative medicine (TCAM) University be established. Other institutes such as a regional TCAM research institute and regional medicinal plant research institute could also be established. A policy on duty-free import of HM and regional TCAM herbarium and library are needed. It would also be useful to establish a regional TCAM forum.

Use of herbal medicines in Bhutan

Mr Dorji Wangchuk said that Bhutan has 455 outreach clinics, 178 basic health units, 30 district hospitals, 35 TM units, 2 training institutes, 3 regional referral hospitals and 1 national hospital (with a total of 1078 beds) to take care of the health of the people. Integrated health-care services are delivered through the same outlets. Health care is based on a PHC approach with efforts to assure equity and sustainability and cost-effective therapies. The primary level has 30 traditional medicines, the district hospitals have 50 medicines, regional hospital has 75 medicines and at the national level, there are 98 medicines. The top ten diseases seen in Bhutan in 2007 were common cold, skin infections, peptic ulcer syndrome, acute pharyngitis/tonsillitis, diarrhoea, other disorders of skin and subcutaneous tissue, other musculoskeletal disorders, other diseases of the digestive system, conjunctivitis and dysentery.

Bhutan is known as the southern land of medicinal plants and the traditional medicine in Bhutan is known as *gSo-ba Rig-pa*, which originated from Tibet in the Sixteenth century. It is based on Buddhist philosophy and was formally recognized in 1967. In 1968, one dispensary for indigenous medicine was established in Dechencholing and training programme of three years for Menpa (diploma holder in traditional medicine), was introduced in 1971. A course of five years for Bachelors of Science in Traditional Medicine for Drungtsho (Bhutanese traditional medical doctor) was introduced in 1978. In 1979, the dispensary was upgraded as the

National Indigenous Hospital and shifted to the present site in Kawang Jangsa. In 1988, the National Hospital was renamed as the National Institute of Traditional Medicine. In view of the increased functions, it was upgraded as the Institute of Traditional Medicine Services (ITMS) in 1998 with three functional units, namely, the National Traditional Medicine Hospital responsible for providing traditional medical services, the Pharmaceutical and Research Unit for the production of traditional medicines and for conducting research, and the National Institute of Traditional Medicine for development of human resources.

TM in Bhutan is one of the oldest medical traditions of the world. The clinical use is supported by four medical *tantras* known as *rGyud-zhi* (principles of an ancient Tibetan medical system). The Bhutanese Pharmacopoeia has been developed in 1983 with the help of WHO, and the current national formulary was developed in 2007. More than 600 medicinal plants have been identified in Bhutan and around 300 of them are currently being used for the production of medicines. The medicinal flora of Bhutan has been published in 1999 in Dzongkha, describing 74 plants, and monographs on 20 high-altitude medicinal plants were published in English in 2006. Monographs on 40 other high-altitude medicinal plants have been completed and are ready for publishing.

The quality control section of the Pharmaceutical and Research Unit of Institute of Traditional Medicine Services is responsible for developing test parameters, standards for raw materials, standards for finished products and carrying out routine quality assessments, using WHO guidelines for good manufacturing practices. The Drug Regulatory Authority and Quality Assurance and Standardization Division of the Ministry of Health are responsible for the quality inspection of products. A Pharmacovigilance Centre for traditional medicines was established in 2005 with the objectives of monitoring safety of traditional medicines, early detection of adverse drug reactions, identification of risk factors, promoting safe and rational use of TM, and conducting pharmacovigilance activities and research.

Bhutan has 98 traditional medicines which are all multi-ingredient, each containing about 5 to 35 raw materials (a total of 300 different ingredients are used in all) which are provided free, but under prescription, to the patients. The formulations are based on principles of *gSo-ba Rig-pa*. Guidelines for Appropriate use of traditional medicines were published in 2008 and standard treatment guidelines for traditional medicine are being drafted. More than 85% of raw materials are collected within Bhutan and the remaining are imported from India.

Community-based sustainable management of medicinal plants has been introduced and only local communities are registered as authorized collectors. A permit from the Department of Forestry, Ministry of Agriculture is required

for collection of medicinal plants. Cultivation of medicinal plants as cash crops has been introduced in some areas. A survey of medicinal plants for alternative sourcing is being carried out in different parts of Bhutan and training of farmers on sustainable collection methods and good collection practices are conducted regularly. Information on traditional medicines in Bhutan is available at www.health.gov.bt/traditional medicine and www.menjongpharma.com.bt. Small-scale research initiatives have been undertaken since 1990 on standardization and authentication of raw materials, including botanical and *gSo-ba Rig-pa* nomenclature; developing quality parameters for raw materials and finished products; standardization of the production processes; phytochemical screening of some medicinal plants; clinical studies of antidiabetic activities of the finished products; efficacy of gold needle therapy and herbal bath therapies; feasibility studies of alternative collection sites; and studies on local healing systems, hot springs and medicinal waters.

The national programme has identified preservation and promotion of traditional medicine and integration of the two systems (conventional medicine and *gSo-ba Rig-pa*) to complement each other is a priority. Other priorities are development of traditional medicine at par with modern medicine, conducting research in traditional medicine, and development of adequate infrastructure at the national level for improving the quality of services. The challenges identified include inadequate infrastructure especially at the national level, human resource development at Masters and Ph.D. levels in traditional medicine, inadequate budget provision for infrastructure development, and lack of appropriate institutes for possible linkages and collaboration.

Use of herbal medicines in DPR Korea

Dr So Yong Sun informed that historically, 10 700 medicinal herbs were used in 1433. As far back as in 1477, there are records to show the use of Moxa and garlic for treating diseases. In 1613, 3380 remedies were used. The Government promotes a combination of modern and traditional medicines, and herbal medicines constitute 60% of medicines used in PHC as there are vast resources and they have good therapeutic effects with few side-effects. There are more than 5000 units of PHC across the country. Medicines are manufactured in cities to meet demand. In the PHC units, medicines are also prepared based on the recipes and dispensed.

Some herbal medicines commonly used in PHC are – as antipyretic and anticonvulsive for children: Chongsim pill (*Insam, Cinnabaris*); as antitussive: Omisa syrup *(Schizandrae)* and Paekrihyang antitussive *(Herba Thymi)*; for common cold: Samhyanguhwangchongsim pill *(*containing 28 plants) and Paedok powder *(Radix Bupleuri* and 12 species of plants*)*; for indigestion: Ryongsin pill (containing

20 species of plants) and Dejung complex (*Rhyzoma et Radix Rhei*), for gastric protection: Insin-Changchul pill and Insin-Changchul granule *(Artemisia messer, Rhyzoma Atractylodis)* and Konwi powder (*Lignum Picrasmae*); for arthritis: Dokhaluj *(Radix Araliae)* and *Radix Paeoniae*; for hepatitis: a preparation from *Silimarin*; for tuberculosis: Kosam pill (*Radix Sophoa*); for constipation: Taehwang tablet (*Rhizoma et Radix Rhei*); for hypertension: Tuchung pill (*Cortex Eucommiae*); for parasitic infestation: Santonin pill (*Herba Artemisia maritima*); as analgesic: Atropine injection from *Rhizoma Scopoliae*; as antibiotic: Berberine injection (*Cortex Phellodendri)* and Bomsinga injection *(Radix Reynoutriae)*; and for gynecological diseases: Ikmo pill (*Herba Leonuri*).In 1956, the National Committee for National Pharmacopoeia was organized and the first edition of national pharmacopoeia was published in 1960. This has been re-edited and published for six times until now and the seventh edition is being prepared. There are approximately 500 species of medicinal herbs and 200 standardized preparations of herbal medicines in DPR Korea.

A national system to control, evaluate and standardize herbal drugs by batch production has been established. If new products are invented, the State Medical Drug Inspection Agency evaluates them and they are standardized by the General Bureau for Inspection of the Quality of Products. More than ten classical books have been edited and published, including *Tong Ui Bo Gam*, *Hyang Yank Zip Song Bang* and *Ui Bang Ryu Chi*. There are several scientific journals published including Korean Medicine, Korean Pharmacy, and Bulletin of Academy of Koryo Medical Sciences. A system to train the pharmacologists of traditional medicines has been established. There are *Koryo* traditional faculties in the medical universities, and *Koryo* pharmacology departments in the universities.

Current research focuses on extraction, standardization and scientific validation of traditional *Koryo* medicines, and antiseptic and dust free manufacturing process. In the area of conservation, a national exploration of medicinal herbs resources is carried out every five to six years to identify problems and take measures for protection. Wild herbs are collected by specific agencies and specialized farms produce more than 200 kinds of medicinal herbs according to the national plan, and health institutions, factories and schools grow several kinds of medicinal herbs if they have unused land. A national campaign to collect and cultivate medicinal herbs was launched in the "specific months for medicinal herbs" in every spring and autumn. The Ministry of Public Health is responsible for the creation and protection of medicinal plants in liaison with Ministry for Protection of Land and Environment. Joint research, study tours, fellowships and other types of scientific and technical exchange may be promoted among countries of the SEA Region.

Use of herbal medicines in India

Dr S.K. Sharma informed that India is divided into 12 agro-climatic zones having a wide range of medicinal plant species. There is a long history of use of medicinal plants and health practices in India (for example, Ayurveda which has existed since 5000 B.C.). Much of Ayurveda, Siddha, Unani and Yoga have been codified, organized, documented and are recognized officially.

Ayurveda, the Indian traditional medicinal system, uses holistic principles of nature. It is individualized, safe, and focuses on promotive, preventive and curative therapies mainly useful for management of chronic debilitating diseases. Eighteen specialities of Ayurveda are taught at the undergraduate and post-graduate levels. Along with Buddhism, Ayurveda spread to neighbouring countries and other parts of the world and was transformed into various traditional medical systems of these countries.

Siddha is the traditional system of medicine developed in southern India and is similar in philosophy to Ayurveda. It is specialized in iatro-chemistry and mercurial preparations. It is strong in treatment of psoriasis, arthritis and maternal health problems. Unani originated from the Greek physician Hippocrates (460–377 B.C.), and describes four humours and uses diagnosis through examination of *Nabz* (pulse), *Baul* (urine), and *Baraz* (stool). Unani uses Ilaj-Bid-Tadbeer (regimental therapy), Ilaj-Bid-Ghiza (dietotherapy), Ilaj-Bid-Dawa (pharmacotherapy) and Jarahat (surgery). Its strengths include treatment of skin disorders including vitiligo, digestive disorders, etc.

There are 725 568 registered practitioners of traditional medicine in India, with 479 teaching institutions (105 postgraduate institutions and two universities with an annual admission capacity of 27 135 for undergraduates and 2252 for postgraduate courses). There are 2402 Ayurveda hospitals, with 43 751 beds and 13 913 dispensaries. Similarly, Siddha has 277 hospitals with 2569 beds and 488 dispensaries. Unani has 262 hospitals with 4671 beds and 1019 dispensaries. Homeopathy has 234 hospitals and 10 933 beds. Yoga has 12 hospitals and 495 beds and naturopathy has 171 hospitals and 5677 beds. The central government has a department of AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy) with state boards/councils for registration of practitioners, state drug licensing/drug control authorities, state colleges/institutions, state pharmacies, state drug testing laboratories and state medicinal plant boards.

An independent policy for AYUSH was promulgated in 2002, although the 1983 Health Policy envisaged an integrated role of AYUSH in health delivery, and the National Population Policy 2000 provided for utilization of AYUSH practitioners

in population stabilization programmes. The national policy is in conformity with the WHO strategy for traditional medicine. There are eight national institutes for AYUSH subjects and the Central Council for Research in Ayurveda & Siddha (CCRAS) runs 39 centres while the Central Council for Research in Unani Medicine (CCRUM) has 25 centres.

TM is taught at bachelor degree courses (BAMS/BUMS/BSMS/BHMS), postgraduate courses (M.D., Ph.D.), a membership course of National Ayurveda Academy, short- and mid-term courses and diplomas, and degrees and postgraduate courses for pharmacy education.

Ninety-five per cent of the raw materials in traditional medicines are of plant origin and about 1000 medicinal plants are commonly used. Fifty-eight different types of metals and minerals and 54 animal and marine products are used. The National Medicinal Plant Board and the state boards oversee cultivation and conservation of medicinal plants; supply of quality raw and plant materials; assessment of demand and supply position; standardization and quality control of medicinal plants; scientific, technological and economic research on medicinal plants; development of agro-technology and harvesting, semi-processing and value addition techniques; and trade and export of medicinal plant products. The area under cultivation is 40 000 hectares, and 15 000 hectares for forest species.

Several laws oversee TM issues including the Indian Medicine Central Council (IMCC) Act, 1970 for education and clinical practice, Drugs and Magic Remedies (Objectionable Advertisements) Act, Bio-diversity Act, Wildlife Protection Act and Indian Forests Act. A separate chapter and rules exist for Ayurveda, Siddha and Unani drugs in the Drugs & Cosmetics Act, 1940, and the Drug Technical Advisory Board is consulted for matters related to quality control and standardization. The Drugs Consultative Committee oversees uniform administration of legal provisions in different states. Licensing of manufacturing units is mandatory. The central government is empowered to prohibit manufacture and sale of certain drugs in the public interest. There are government drug analysts and several drug inspectors have been appointed. Schedule E lists poisonous materials, and misbranded, adulterated and spurious drugs have been defined for punitive action. Compulsory Good Manufacturing Practices (GMP), labeling/packing provisions, recognition of private and public drug testing laboratories for sample analysis, compulsory testing and certification for export ensure the quality of medicines.

The Ayurvedic Pharmacopoeia Committee (APC), Siddha Pharmacopoeia Committee (SPC) and Unani Pharmacopoeia Committee (UPC) notified by the Government approve the pharmacopoeial standards. Experts of Ayurveda, Unani,

Siddha, phytochemistry, pharmaceutical science, pharmacognosy, inorganic chemistry and medicinal plants are associated with scientific institutions/laboratories in undertaking basic work of standardization.

The Ayurvedic Pharmacopoeia has 540 monographs and 101 formulations covered in nine volumes. Besides this, India has an Ayurvedic Formulary in two volumes, containing 636 formulations. The Siddha Pharmacopoeia has 76 monographs and the Siddha Formulary describes 248 formulations. The Unani Pharmacopoeia is published in two volumes and the Unani Formulary has 812 formulations described in five volumes. An essential TM drug list has been published.

In an attempt to develop pharmacopoeial standards for multiple-ingredient Ayurvedic formulations, standard operating procedures (SOP) of the manufacturing process, standards of identity, purity and strength of ingredients and compound formulation and pharmacognostic and chemical standardization shelf-life studies have been used. Twenty laboratories and manufacturing companies are working on SOP. Pharmacopoeial standards of 101 formulations have been published. The annual target is 50 formulations per year to cover the 500 most widely used formulations.

The Pharmacopoeial Laboratory for Indian Medicine (PLIM) was established in 1970 and twenty other laboratories have been identified for evolving pharmacopoeial standards of Ayurvedic drugs. Universities, Council for Scientific and Industrial Research (CSIR) and other national laboratories are also associated with pharmacopoeial work, as are 26 state drug testing laboratories and 30 private laboratories approved by the government.

A National Pharmacovigilance Resource Centre has been established at Gujarat Ayurveda University, Jamnagar and state centres have been identified in 20 states. Regional training programmes have been conducted for reporting adverse drug reactions (ADR), undergraduate/postgraduate students are educated in areas such as pharmacovigilance and ADR.

The Traditional Knowledge Digital Library (TKDL) is a collaborative project between the Department of AYUSH and the Council for Scientific & Industrial Research, with the objective of protecting the ancient and traditional knowledge of the country from misappropriation. Formulations from classical Ayurveda, Unani, Siddha and Yoga practices from classical texts have been digitized in TKDL in five languages (English, French, German, Japanese and Spanish). The data are being shared with different international patent offices of the world.

Mainstreaming AYUSH is a policy commitment of the Government of India and received momentum when the National Rural Health Mission (NRHM) was launched in April 2005. The road map for mainstreaming of AYUSH has been sent to all the states of the country and all primary health centres (PHCs) will have an Ayurveda/Siddha/Unani/ Homoeopathy doctor. The Indian Public Health Standards (IPHS) have been finalized for community health centres (CHCs/primary health centres) envisaging AYUSH facilities. Training modules for Accredited Social Health Activist (ASHA) includes an AYUSH component and there is also an in-service training module for Auxiliary Nurse Midwife to incorporate information on AYUSH. The ASHA Drug Kit has been expanded to include Ayurveda, Siddha, and Unani drugs with proven efficacy. The central government is also providing infrastructure facilities for the creation of AYUSH units in public health-care facilities; 3933 AYUSH doctors and 831 AYUSH paramedical staff have been placed in allopathic public health facilities to fulfill the objectives of mainstreaming of AYUSH. An AYUSH representative has been included in the State Health Society, State Health Mission, and District Health Society under the National Rural Health Mission.

Some of the evidence-based therapies in Ayurveda include *ksharasootra* for fistula-in-ano, and *panchakarma* for neuromuscular diseases and arthritis. Exchange of experts and development of strategies on pharmaceutical technology, data-base and digitization, pharmacopoeias, formularies, regulatory mechanisms and standardization and quality control measures, scholarship programmes for students of TM desirous to undergo training at country institutions, and import and export of raw materials and finished TM products as per mutual agreement are examples of possible international cooperation between SEA Region countries. Other areas of cooperation are survey and documentation of traditionally used medicinal plants, remedies and practices; training programmes on agro-technology, manufacturing technology, quality control and standardization; research and development and collaborative scientific validation studies on TM; organization of bilateral and multilateral programmes on themes of common interest for development of TM; and the formulation of common strategy for protection of TM against misappropriation of patents and international market authorization of traditional herbal medicinal products.

Use of herbal medicines in Indonesia

Dr Bambang Sardjono informed that Indonesia has a huge biodiversity, with 30 000 plant species and 2000 medicinal plants. The traditional medicine of Indonesia is called Jamu (a term originating from the Javanese language) with each of the 336 tribes having their own formulae. Almost 70% to 80% of the population relies on

Jamu to maintain health, and it is used in parallel with formal health services. Jamu is believed to have several advantages; e.g. large source of plants in the forests and relative safety. A national survey on social economics conducted in 2001 showed that 57.7% of Indonesian society used self medication, 31.7% used herbal medicines and 9.8% seek help from traditional healers.

A total of 9737 herbal medicines have been registered in Indonesia (including 1039 imported products). Beside the registered products, Jamu Gendong (Jamu peddlers) and freshly compounded Jamu which do not have to register are also available. By the Health Law 23/1992, TM is a part of the health-care system and must be promoted to be effective, safe and of good quality in order to be used in community health care. By Ministerial Decree 1076/2003, traditional healers have been classified into physical healers (massage, bone setter, acupressure, acupuncture, etc.), herbalists (who use herbal and/or animal products, trace mineral, etc.), supranatural, spiritual power, inner power, mind manipulation, metaphysical power, etc. and those using religious approach.

Apart from Jamu formulae, Indonesia also uses standardized herbal and phytopharmaceutical formulations. The Indonesian Herbal Pharmacopoeia was first published in 2009. The Materia Medica Indonesia has 224 monographs and monographs of Indonesian medicinal plants extract (3 volumes, 2005-2008) have 95 monographs. The Herbal Preparation Reference has 4 volumes (2004-2008). Several guidelines have also been published including *Guidelines on traditional medicines GMP* (1994), *Standard parameter of medicinal plants extract* (2000), *Guidelines on preparing raw material for traditional medicines* (2005), and *Guidelines on Use of Herbal Products* (3 volumes, 2000-2007). To promote herbal medicine market authorization of TM products, GMP regulation for small-scale as well as large industries and product registration and certification have been introduced. The herbal garden located at the city of Citeureup, near Jakarta, oversees conservation and education facilities of Indonesia's herbal medicines and the taxonomy book of Citeureup Herbal Garden Plant Collection has been published in 2008.

The ASEAN Post Monitoring Alert System oversees safety monitoring of herbal medicines and the Herbal Preparation Reference ensures appropriate use of herbal medicines. The Centre for the Assessment of Herbs Cultivation is involved in ensuring provision of stocks of small-, medium- and large-scale stocks of herbs for internal use or export. The Centre for Testing of Pharmaceutical Bulks and Extract tests the quality of bulk pharmaceuticals and extracts based on certain standards. The Centre for the Development of Herbs and Natural Medicine (Diponegoro University) works toward safety, efficacy and quality through research. The Centre

of Agricultural Production Technology oversees cultivation of medicinal plants, especially for anti-cancer and degenerative diseases. The Centre of Pharmaceutical and Medical Technology develops pharmaceutical and processing technology and pre-clinical trials for anti-cancer and degenerative diseases. The Centre for Chemical Research (Indonesian Institute of Sciences) does phytochemical analysis, formulation technology, etc.

Indonesia promotes research to explore the original philosophy, recipes, and methods of diagnoses in TM. A Diploma Programme in Traditional Medicine (three years, part of Study Programme of Medical Faculty), complementary and alternative clinics (eight clinics in government hospitals) and private hospitals, and Model Community Health Care Centre for Complementary and Alternative Services have been established. TM is especially promoted at the household and village community health development levels and efforts have been made to promote the setting up of "family gardens".

In future, model community primary health care centres will be set up. The community's involvement in self-medication will be encouraged through medicinal plant gardens or collection. Efforts will be made to strengthen research in finding new herbs that could treat modern diseases (AIDS/HIV, TB control, degenerative disease, etc.), and to use the results of research for the TM industry. Jamu will be further developed more seriously for PHC, with the ultimate goal to create healthy Indonesian people.

Use of herbal medicines in Myanmar

Mr Win Myint informed that Myanmar's traditional medicine has been practiced since 600 B.C. and is an inherited profession. It is influenced by Buddhism, local traditions and customs, social values, geographical conditions and aquatic and terrestrial resources. A one-year course teaches basic principles of Myanmar TM. The University of Traditional Medicine was established in 2001 and confers a Bachelor's degree after four years of training and a one-year internship. TM is being integrated into the national health system and there are 2 50-bed TM hospitals, 12 16-bed TM hospitals, and 273 TM clinics. In an effort to integrate TM with western medicine, teaching of TM has been introduced into the curriculum of third year M.B.B.S. medical course since 2003. To provide easy access to common TM drugs for minor emergency illnesses for rural areas, a Household Traditional Medicine Kit has been provided to 1144 villages in five states and divisions.

A national pharmacopoeia on herbal medicine is under preparation. The Myanmar Traditional Medicine Formulary (MTMF) has 57 Myanmar TM formulations. Eleven volumes, each containing monographs on 20 medicinal plants, have been published in the language of Myanmar. Two volumes have been published in English, each containing 60 monographs on medicinal plants. Standardization, pharmacological and toxicological evaluation on 57 MTMF have been carried out from 1984 to 1989 under a UNDP-WHO project. A Manual of Myanmar Traditional Medicine for Primary Health Workers has been published in both the Myanmar and English languages.

The National Health Policy of 1993 had 15 components. Number 14 emphasized the need "To reinforce the service and research activities of indigenous medicine to international level and to involve in community health care activities". Prior to 1996, TM medicine production was small. The Traditional Medicine Drug Law was promulgated in 1996 to ensure that the public can consume genuine, safe and efficacious traditional drugs of good quality. Manufacturers now must have a product license and advertising is controlled. The herbal preparations available include single- or multi-herb formulations, herbal ingredients with mineral salts, and animal products and marine products. The safety of TM formulations is ensured through various mechanisms. During registration of a product, labeling, background documentation, and laboratory reports for authenticity of ingredients, adulteration with western drugs or heavy metals or microbial contamination are tested. Post-marketing surveys are done to check labeling and quality.

Research in TM is encouraged through the Department of Medical Research (Lower Myanmar, Central Myanmar, Upper Myanmar) and Department of Traditional Medicine. Research projects regarding quality, safety and efficacy of traditional and herbal medicines are conducted.

In the area of intercountry cooperation, the ASEAN harmonization on standards and quality of TM, ACCSQ (ASEAN Consultative Committee for Standard and Quality), TMHS-PWG (Traditional Medicine and Health Supplement–Product Working Group) and ATSC (ASEAN Technical and Scientific Committee) are examples.

The Ministry of Health has nine herbal gardens with the aim to produce enough raw materials for the state-owned drug manufacturing factories, and to preserve the endangered species of Myanmar medicinal plants. The National Herbal Park at Nay Pyi Taw, the new capital of Myanmar, was opened in January 2007. It is 196.4 acres and has about 500 different species of medicinal plants collected

and cultivated from 14 states and divisions of Myanmar. Medicinal plants useful for six major diseases such as diabetes, hypertension, tuberculosis, malaria, diarrhoea and dysentery are cultivated.

Use of herbal medicines in Nepal

Dr Shyam Mani Adhikari informed that Ayurveda is the most reliable, easy to access, affordable and effective system practiced in Nepal, and more than 85% of people use it. It is well systemized, managed, and regulated and the government accepted Ayurveda as a national system of medicine in the existing National Ayurveda Health Plan (NAHP) of 1995. Unani, Naturopathy, Yoga, and Amchi (in the north) are also practiced. The number of traditional healers in Nepal is more than 400 000, including local Dhami, Jhankri, Sudeni (traditional birth attendants), Gurau, Amchi etc. Local communities have been using indigenous knowledge of herbal medicine for centuries under local laws, customs and traditions. Although raw materials for most herbal medicines are available locally, most Ayurvedic medicines used are imported.

The Department of Ayurveda is established under the Ministry of Health and Population. The Ayurveda and Alternative Medicine Service Unit, Ayurveda Units in five regional health directorates, the Nepal Ayurveda Medical Council and Nepal Health Professional Council regulate clinical practice. The Central Ayurveda Hospital at Kathmandu (100 beds and 18 cabins) has been functioning since 1974. The Regional Ayurvedic Hospital is located at Dang in midwest Nepal and has 30 beds and a pharmacy. There are 14 zonal Ayurveda Aushadhalayas (Ayurveda dispensaries), 61 district Ayurveda Health Centres and 214 Ayurveda Aushadhalayas. Medicine manufacturing is done at Singhadurbar Vaidyakhana which is more than 350 years old, but it came under the Development Committee in 1995. There are also four rural pharmacies in zonal and district Ayurveda Health Centres. An Ayurveda college is involved in teaching.

There are more than 4000 traditional manuscripts (ranging from 1 page to 2000 pages) written in several languages including Tadapatra, Bhojapatra and Nepali, on Ayurveda and herbal medicines in various languages (Sanskrit, Pali, Nepali, Newari, Tibetan and others). The *Chandra Nighantu,* published in 1909, has 1918 pages of special Nepali papers, in 10 volumes with hand-sketched colourful pictures and a description of more than 800 medicinal plants and about 200 minerals and animals. The number of plant species is more than 7000, of which more than 1600 are used as medicinal plants by different ethnic groups in different parts of the country.

Legal provisions regarding the quality assurance, safety and efficacy of Ayurvedic/herbal medicines in Nepal have been developed but are not followed consistently. Both the concerned departments (Department of Ayurveda and Department of Drug Administration) lack the facilities for quality tests, which have been felt to be urgently needed. Singhdurbar Vaidyakhana Development Committee (SDVKVS) has established a laboratory but can conduct only a few tests.

Development of a traditional/herbal medicine pharmacopoeia is prescribed in the National Ayurveda Health Policy (NAHP) 2052, but this is yet to be done. Ayurvedic/herbal medicines are produced mainly based on classical pharmacopoeias or available classical Ayurveda texts. SDVKVS (the state-owned manufacturing company of Ayurveda drugs) has developed a *Tarakiv* (its own pharmacopoeia) since the date of establishment and the Department of Ayurveda (DoAy) has published quality specifications of 50 formulations used in Ayurveda (2003).

Treatment protocols for 32 diseases have been developed for different levels of health care by DoAy. Orientation of stakeholders for rational use of herbal medicines is an urgently felt need of the country. The Essential Ayurvedic Drugs List (EADL) was developed and published by DoAy, and consists of a separate list of herbal medicines/Ayurvedic formulations for different levels of Ayurveda institutions. Most of the medicines of EADL are available or manufactured in the country. The basis for use of Ayurvedic drugs is still largely "on demand". Only about 30% of medicines are taken on prescription.

The Nepal Ayurveda Research and Training Centre is under construction. The Traditional Medicine Research Steering Committee under the Nepal Health Research Council (NHRC) has been formed, and studies on ethno-medicine in different districts/areas and efficacy of services provided by the government Ayurvedic institutions are being conducted. A study on the status of Ayurvedic/herbal medicines available in Nepalese markets has been conducted by NHRC (2008).

Several programmes have been proposed for conservation and promotion of medicinal plants, and protection of intellectual property rights related to indigenous traditional knowledge and technology regarding herbal medicine for the benefit of the people/ stakeholders. Efforts have been made to incorporate Ayurvedic treatments into primary health care. It is also proposed to distribute herbal medicine-based first-aid kits in villages; organize free Ayurveda general health camps and specialized camps for lumbar pain and ano-rectal diseases in all 75 districts; develop herbal gardens on the periphery of Ayurvedic institutions; collect data on locally available herbal medicines; and publish and distribute information, education and communication materials on Ayurveda and herbal medicines.

Intercountry coordination and cooperation are required for identification, cultivation and conservation of medicinal plants; protection of national heritage; understanding and preparing for implications of TRIPs (Trade Related Aspects of Intellectual Property Rights) and other international agreements; research and development of measures for standardization, quality assurance/control, safety and efficacy of herbal medicines; development of appropriate models and conduct of well-designed controlled clinical trials on herbal medicines; and promotion of the use of herbal medicines and practitioners by mainstreaming TM in the national system and programmes of primary health care.

Use of herbal medicines in Sri Lanka

Dr Hitlar Tennakoon informed that the traditional system of medicine in Sri Lanka is called Deshiya Chikithsa. There are about 1430 medicinal plants used in Sri Lanka, of which 208 are commonly used while 50 are most widely used.

Under the Ayurveda Act No. 31 of 1961 the Ministry of Indigenous Medicine was set up, under which the Department of Ayurveda was established. The Bandaranayke Memorial Ayurvedic Research Institute (BMARI), National Hospital for Ayurveda (teaching), National Institute of Traditional Medicine (NITM) and Ayurveda Medical Council are other institutions in the country involved in TM. The Ayurveda Pharmacopoeia has been published in three parts (Part 1, 1976; Part 2, 1979; and Part 3, 1985). Other books published include *Osuthuru Visithuru* (1994), Vol. I-IV, *Sri Lanka Deshiya Chikithsa Sangrahaya* (1984) and *A Compendium of Medicinal Plants (a Sri Lankan study)*, in 4 volumes (2001-2004).

Quality standards have been developed for 50 raw materials. Several formulations of herbal medicines are available in Sri Lanka including decoctions (e.g. *Yakshakshi adi* used to prevent worm infestations); *Swarasa* (juice of leaves) to prevent respiratory diseases; *Jeewananda* pills and tablets (used to prevent worm infestations and abdominal diseases); *Seetharama* (which increases immunity); *Kalka* and *Leha* (*Desadum kalka* or *Dathri rasayana,* to keep the body healthy and for longevity); *Churna* powder (*Seethopaladiya* to prevent respiratory diseases and communicable diseases); *Manibhadra* or *Sadikka churna* to remain healthy; *Wachadi churna* to increase immunity; oils (*Neelyadiya, Sidhdhartha, Vishaharana*), and Patthu (*Ketakela, Ettamuradi*) to cure fractures and dislocations.

Dr Tennakoon described several herbal preparations popular in Sri Lanka for PHC. They include Kolakenda preparations such as Gotukola, a brain tonic that keeps body in good health and improves immunity, Wel penela which improves body energy, prevents urinary diseases and also used as aphrodisiac; herbal teas made

from flowers of Ranawara (*Cassia auriculata*) and other herbal plants; herbal wines and beverages made from coriander, ginger, cumin and lemon; leafy vegetables for lactating mothers and to prevent malnutrition (*Wattakaka volubilis*) and to prevent anaemia (*Trianthema portulacastrum*). As food – nelli fruit (*Phyllanthus emblica*) for blood purification, healthy body and long life; beli (*Aegle marmelos*) which cures and prevents constipation; and delum fruit (*Punica granatum*) which improves vision and is used as brain tonic.

Nine publications in the area of herbal medicine, including an herbal pharmacopoeia and national formulary, are available. Herbal remedies can be made from plants grown in home gardens and used as household remedies for PHC. For intercountry cooperation, problems related to identification of controversial medicinal plants for use in PHC is an important area as clear-cut identification of medicinal plants still difficult because of confusion created by local names. Development of an awareness programme on the use of herbal medicines in PHC is another important area for intercountry cooperation.

Use of herbal medicines in Thailand

Dr Nara Nakwattananukool informed that introduction of western medicine in Thailand in the late nineteenth century and the establishment of the first western-style hospital in the early twentieth century led to the decline of Thai traditional medicine. Interest in Thai TM was revitalized after the 1978 Alma Ata Declaration on primary health care. In the Forth National Economic and Social Development Plan (1977-1981), 61 medicinal plants were recommended for use in PHC. The Fifth to Tenth National Economic and Social Development Plans (1981 to present) promote the use of medicinal plants and research and development of new drugs from medicinal plants. In 1993, the Institute of Thai Traditional Medicine (ITTM) was established under the Department of Medical Services. This served as a centre for collaboration and networking of Thai TM, centrally and regionally.

In 2002, the Department for Development of Thai Traditional and Alternative Medicine (DTAM) was established. Subsequently, activities relating to Thai TM and complementary and alternative medicine are placed under DTAM and include the following organizations: (1) Institute of Thai Traditional Medicine; (2) South Asian Institute of Thai-Chinese Medicine; (3) Division of Complementary and Alternative Medicine and (4) Office of Thai Indigenous Medicine. Thai TM services have been included in the Universal Coverage (UC) Programme in the national health security system. Treatment and rehabilitation are done using herbal medicines or therapeutic massage, herbal steam bath or hot herbal compress.

Dr Nara said that successful integration of Thai TM into the health-care system required government support and commitment, strengthening of the knowledge of Thai TM, human resource development and quality of Thai TM practice and products as well as good information systems, research and development, education and training, as well as national and international collaboration.

Dr Nara enumerated some examples of medicinal plants used commonly in Thailand, including common food items having medicinal value. Some examples of 61 medicinal plants recommended for PHC include the following: for treatment of peptic ulcer – turmeric and unripe banana; for flatulence and dyspepsia – ginger, clove and garlic; for constipation – tamarind, hairy basil and senna; for diarrhea – unripe banana, guava, mangosteen and pomegranate; for nausea and vomiting – ginger, noni, mahaat, pumpkin and Rangoon creeper; for toothache – *Spilanthes acmella, Murraya paniculata and Streblus asper*; for intestinal parasites – mahaat, pumpkin and Rangoon creeper. The scientific names of plants, family of the plant, part used and their use in PHC were also described.

4 Group work

4.1 Group A: Generic framework for sharing information on the use of herbal medicines in PHC

Member States shared their experiences in usage of traditional medicine in primary health care. The need for sharing information among Member States for effective use of TM in PHC was emphasized. The group also deliberated on basic minimum information that can be shared. The group discussion covered a generic framework for sharing information on the use of herbal medicines in PHC. The following are areas for sharing of information.

(1) For quality, efficacy and safety of herbal remedies:

- Develop national pharmacopoeia on herbal medicine
- Prepare monographs on medicinal plants
- Establish quality standards to assess/evaluate herbal remedies
- Monitor safety of herbal medicines
- Record appropriate use of herbal medicines

(2) For herbal preparations that are used in their natural forms such as roots, leaves, barks, flowers, etc.:

- Record preparations that are well accepted and used traditionally by the people in general

- List herbal preparations used for primary health care
- Develop herbal pharmacopoeia and National Formulary on herbal medicine
- Document preparation of herbal remedies – traditional methods and/or modern methods

(3) For sharing of information among institutions in the SEA Region:

- Share available publications on use of HM/TM in PHC
- Share Internet sites, information network, electronic interaction system, etc.

(4) For sharing information on research in use of herbal medicine in PHC:

- Exchange information on the present stage of development and future direction

4.2 Group B: Generic framework for research on efficacy, safety and quality of herbal medicines for use in PHC

After comprehensive discussions, the group arrived at the following generic framework to ensure efficacy, safety and quality of herbal medicines for use in PHC. This generic framework is applicable for **herbal remedies that are being used for a long time in the community.**

- A list of conditions most relevant to the topic should be made
- Herbal medicines being commonly used and widely accepted in the community (single plant or compound formulations) for treatment of common health problems should be identified
- If a *new herbal medicine* is to be tested, it needs to go through the entire preclinical and clinical evaluation as a new chemical entity

Quality

- Simple tests that are applicable at PHC level should be developed. For validation they must be compared to the existing test methods

- Set up (if it does not exist in the country) a quality control/testing laboratory

Safety

- Observational and epidemiological methods are preferable for safety evaluation
- Study of documentation of safety in traditional medicine/folk medicine literature is also recommended

Efficacy

- Observational studies should be performed and may be combined with safety studies
- Sample size should be calculated using appropriate statistical methods
- Multi-centred studies may be planned (e.g. to achieve the calculated sample size and have adequate representation of population diversity)
- Control arm for the study is recommended
- Adequately trained or experienced personnel (a multidisciplinary team if needed) is recommended for conducting research

4.3 Group C: Generic framework for intercountry cooperation in herbal medicine for use in PHC

The group discussed issues relating to a generic framework for intercountry cooperation (IC) in herbal medicine for use in PHC. The following are the areas for IC.

(1) For development of TM as part of the national health system:

- IC meeting on national TM policies, guidelines, programmes to develop or strengthen national TM policies and programmes based on national priorities
- IC meeting for sharing experiences and knowledge among countries and individual development of TM as part of each national health-care system

- Preparation of necessary laws and regulations concerning HM/TM
- Development of registration procedures for TM drugs and TM practitioners

(2) For safety, efficacy and/or quality of TM drugs:

- Harmonization of research methodology for developing an evidence base for traditional medicine therapies and products
- Development of national standard for ensuring safety, efficacy and quality control of traditional medicine therapies and products
- Development of herbal pharmacopoeias
- Training workshop on good manufacturing practices (GMP) and good agricultural and field collection practices (GACP)
- Sharing of knowledge and information to develop HM/TM database

(3) To increase access to HM/TM for primary health care:

- Development of monograph for use of TM at PHC level as well as other levels of health care
- Development of national traditional medicine formulary
- Promotion of sustainable use of herbal medicine in PHC
- Advocating and educating production of medicinal plants
- Promoting cooperation between traditional medicine providers and modern practitioners
- Official recognition of the role of traditional medicine practitioners in national health system

(4) To promote rational use of HM/TM:

- Development of basic guidelines for rational use of HM/TM
- Training workshop on the rational use of HM/TM for TM Practitioners as well as modern practitioners
- Promoting communication between traditional medicine and modern practitioners and between modern practitioners and TM consumers

- Promoting information/education of the public on the proper use of herbal and traditional medicine
- Intercountry fellowship training and study tour programme

4.4 Intercountry cooperation on use traditional medicine for PHC within SEA Regional countries

Dr Xiaorui Zhang presented a paper on Intercountry Cooperation on the Use of Traditional Medicine for Primary Health Care within SEA Regional Countries (ICTMPHC). She touched upon the following points.

Mission

To promote the use of traditional medicine for primary health care in SEA countries through sharing of information in the field of traditional medicine.

Objectives and scope

- To share national policy, regulation and administration information among the SEA countries to facilitate establishing/updating national policies and regulations for both herbal medicines and the practice of traditional medicine.
- To share the existing information of national pharmacopeia and formularies of herbal medicines for ensuring the safety, efficacy and quality of herbal medicines.
- To share research information and research methods to further improve and promote research and clinical studies of herbal medicines.
- To improve access to primary health care through the use of herbal medicine.

Expected outcomes of ICTMPHC

- Development of a process that addresses/resolves questions related to national policy and regulation related to traditional medicine as well as research and use of herbal medicines.

- Establishment of a communication network that fosters dialogue on two fields of national policy and regulation and technical issues particular related to safety, efficacy and quality of herbal medicines as well as research information and challenges and difficult issues.
- Development, through WHO, of efficient links between national health authorities and information focal points among the Member States of ICTMPHC.

Membership of ICTMPHC and admission process

Members must:

- Give active support to and participate in ICTMPHC objectives.
- Take responsibility and make contributions.
- Designate an information focal point.
- Conduct themselves in an ethical manner and display integrity, honesty and concern for the best interests of all.
- WHO SEA Regional Office would conduct administrative procedures for admission.
- WHO SEA Regional Office will then screen and review the application according to the admission criteria set out above, and inform the Members of the ICTMPHC on new focal points if the membership requested;
- TRM, WHO headquarters will respond to requests to share information with other countries outside of SEA Region.

5 Conclusions and recommendations

Theme: Sharing information on the use of herbal medicines in primary health care

Conclusions

(1) Countries lack focal points and mechanisms for information-sharing on the use of traditional medicine in primary health care.

(2) At present, there is no system for sharing information such as pharmacopoeia, publications on research, education and local traditional knowledge, etc.

Recommendations for Member States

(1) Countries should designate a focal point for traditional medicine, both for administrative and technical matters.

(2) Basic information should be shared among Member States such as pharmacopoeia, publications on research, education, local traditional knowledge and medicinal plant cultivation.

(3) Bilateral and multilateral agreements on sharing information between and among countries of the Region should be encouraged.

(4) Countries should create an independent website for traditional medicine.

Recommendations for WHO

(1) To support establishment of a mechanism for sharing information among Member States.

(2) To provide support for various information-sharing activities such as seminars and workshops.

Theme: Research on quality, safety and efficacy of herbal medicines for use in primary health care

Conclusions

(1) Herbal medicines continue to be a valuable source of remedies for PHC in countries of the SEA Region.

(2) There is a need to promote access to herbal medicines of assured quality, safety and efficacy, and their rational use.

(3) There is therefore a need for appropriate research to ensure quality, safety and efficacy of herbal medicines to be used at the PHC level.

Recommendations for Member States

(1) Every country should promote research in quality, safety and efficacy of herbal medicines for use in PHC.

(2) All research should be performed according to current national and international ethical guidelines.

(3) Countries should prioritize areas of research according to national needs.

(4) Appropriate training should be provided to researchers.

(5) As quality impacts both safety and efficacy, research in methods in quality assurance should be given weight.

(6) Community participation in research on quality, safety and efficacy of herbal medicines should be encouraged.

Recommendations for WHO

(1) Support should be provided for development and conduct of research at the PHC level.

(2) Training workshops on research methods, including preparation of training manuals, should be supported.

(3) Intercountry cooperation for sharing of results of research (e.g. publications and registry, etc.) and information exchange should be promoted.

Theme: Intercountry cooperation for use of herbal medicines in primary health care

Conclusions

(1) There is a need to recognize and harmonize pharmacopoeias of traditional/herbal medicine.

(2) Existing pharmacopoeias should be used to develop monographs by countries that do not have national pharmacopoeias.

(3) Member States need to prepare a formulary of traditional medicine based on the historically-used plants and their combinations. Formularies already available, such as those of Bhutan, the Ayurvedic formularies of India and Sri Lanka, etc. could be used as references.

(4) Regarding human resources, there is a need for all Member States to recognize the Bachelor's degree in traditional medicine (BTM). Moreover, the curriculum and duration of courses should be uniform – four to five years' duration in all Member States of the SEA Region. Traditional healers/clinical practitioners in respective countries should be registered and trained.

(5) Short-term training courses in Thai traditional massage, *panchakarma*, drug standardization, regimental therapy (venesection, cupping, sweating, diuresis, bath, massage, cauterization, purging, vomiting, exercise, and leeching, etc.) and use of common herbs for common ailments, and other areas need to be organized. Local communities should also be trained in the use of medicinal plants in health and hygiene practices. Courses leading to the Doctor of Medicine (MD) degree in *Ayurveda*/*Siddha*/*Unani* medicine are available in India and Sri Lanka for countries that may wish to sponsor candidates to these courses.

Recommendations for Member States

(1) Departments of traditional medicine in various countries should have their own websites on traditional medicine for sharing information.

(2) For the purpose of promoting trade, licensing for the manufacture of traditional medicine, good manufacturing practices (GMP) compliance certificates, single-drug or combination formulation should have references in official formulary/pharmacopoeia/ approved books of the country. Artificial or non-tariff trade barriers (e.g. duration or experience in the use of the product in importing country) should be removed for traditional products.

(3) Keeping in view the commonality of medicinal plants in the SEA Region, as well as the long history of their use as traditional medicine, a list of the most commonly used medicinal plants and formulations should be prepared for PHC. The list may contain up to 100 medicinal plants and up to 50 formulations/combinations, based on each country's needs. Trading in respect of such products may be promoted among countries of the SEA Region.

(4) Countries should take advantage of pharmacopoeias and formularies on traditional medicines that are already available in other countries when developing their own national pharmacopoeias and formularies.

(5) Countries may consider reciprocal recognition of degrees in traditional medicine and training to enhance academic activities that will promote the use of herbal medicine in PHC.

(6) Countries should promote training of local communities in the use of medicinal plants and traditional health and hygiene practices.

(7) Member States should set up medicinal plant gardens at community, district and national levels.

(8) Member States should set up advisory committees on traditional/herbal medicine.

(9) Mainstreaming of traditional/herbal medicine should be encouraged for PHC at all levels of national health-care delivery systems.

Recommendations for WHO

(1) Intercountry cooperation in the area of traditional/herbal medicine should be supported.

(2) WHO may consider compilation of a document on commonly used herbal medicines in PHC, based on their existing long tradition of use in countries of the SEA Region.

6 Closing session

Closing remarks of Dr Myint Htwe

Dr Myint Htwe made the closing remarks on behalf of the Regional Director. He said that discussion points made in this meeting are very important for promoting the use of herbal medicines in primary health care in the SEA Region, especially in the context of recommendations made at the Regional Conference on Revitalizing Primary Health Care in Jakarta, Indonesia in August 2008, as well as at the Regional Meeting on Self-Care conducted recently by the WHO Regional Office. He noted that the meeting had developed a generic framework for sharing of information on the use of herbal medicines. This is one way to promote use of herbal medicines in primary health care.

It is also essential that network of institutions working on traditional medicines should be promoted, and to work very closely with all these institutions of excellence working on traditional medicines. The importance of traditional medicine or herbal medicine was highlighted by the fact that there are already approximately ten World Health Assembly resolutions on this subject and in the forthcoming World Health Assembly in May 2009, one resolution on traditional medicines will be adopted. (Update: WHA62.13 on Traditional medicine was adopted by the Sixty-second World Health Assembly on 22 May 2009).

Progress had also been made in the field of traditional medicine due to implementation of the WHO Traditional Medicine Strategy 2002-2005. At the WHO Executive Board meeting in January 2009, the Member States emphasized

that there is a need for action and coordination by the international community, governments, health professionals and workers to ensure proper use of traditional medicines as an important component contributing to the health of all people. It is also important to formulate national policies, regulations and standards as part of comprehensive national health systems to promote appropriate, safe and effective use of herbal medicines. In that context, proper recording of successful treatment of diseases and treatment failures using herbal medicines is essential. We need to share this information among our network institutions.

Development and promotion of herbal gardens in the respective Member States is one of the prerequisites if we are to promote the use of herbal medicines in primary health care. The importance of establishing sound systems for qualifications, accreditation and licensing of traditional medicine practitioners should be kept in mind. Ways and means to assist traditional medicine practitioners to upgrade their knowledge and skills through appropriate training programmes should be developed.

Dr Myint Htwe mentioned that in Africa, African Traditional Medicine Day is commemorated annually on 31 August in order to raise awareness of traditional medicine in the African region, as well as to promote its integration into national health system.

WHO would seriously consider the recommendations of this meeting in preparing its 2010-2011 biennial work plan in the 11 Member States of this Region. In conclusion, it is important that we should all work very closely and collaboratively to promote safe, efficacious and effective use of herbal medicines in the countries of the Region. WHO will do its best to support Member States in promoting the use of herbal medicine in primary health care.

Closing remarks of Dr Tin Nyunt

Dr Tin Nyunt expressed his appreciation for the tremendous efforts made by participants in country presentations, group work presentations, discussions and finally the recommendations. He agreed that these recommendations will be beneficial and will also harmonize with the western medicine in the context of PHC. The time is also right to view TM as a precious resource. There are increasing demands for medicinal plants, both in developing and developed countries.

Dr Tin Nyunt mentioned that the use of traditional medicines has become a multi-billion-dollar industry that is expected to continue to grow rapidly. This is

not the "poor man's alternative" to conventional care. According to the literature, many countries have brought the two systems together in highly effective ways. In several countries, where health systems are organized around PHC, traditional medicine is well integrated and provides a backbone of much preventive care and treatment of common ailments. Therefore, we need to keep abreast in sharing knowledge, information and current developments regarding the use of herbal medicine in primary health care.

Dr Tin Nyunt thanked the Ministry of Health and WHO for their kind support in conducting this important meeting. He also thanked the organizing committee, the secretariat group, the staff from the Department of Traditional Medicine, the WHO Representative's office in Myanmar, and the hotel staff for their assistance.

Dr Tin Nyunt said that there is more work to be done in the countries but he hoped this could be finished easily because of the good will and good ways and means of the participants. He also thanked them for their active participation and excellent contributions to the meeting.

Annex 1

Opening Address by Dr Samlee Plianbangchang Regional Director, WHO South-East Asia

Dr U Ko Ko, Honourable Regional Director Emeritus; Dr Tin Nyunt, Director-General, Department of Traditional Medicine, Myanmar; Honourable guests; Distinguished participants; Ladies and gentlemen:

It is my pleasure to warmly welcome you to this Regional Meeting on "the Use of Herbal Medicines in Primary Health Care". First of all, I would like to thank the Myanmar Ministry of Health, especially the Department of Traditional Medicine, for hosting the meeting. I also thank the honourable guests and distinguished participants for sparing their valuable time to attend this meeting.

Ladies and gentlemen,

In light of a wide gap between "haves" and "have-nots" in health and with the rapid increase in the cost of medical treatment worldwide, the theme of this meeting is timely and relevant indeed. This is particularly so for countries in the South-East Asia Region.

Traditional systems of medicine, including herbal medicines, have been used for several centuries by people in Asia, as well as in other parts of the world. Traditional medicine continues to be a valuable source of remedies that have been used by millions of people around the world to secure their health. As we know, traditional systems of medicine have been developed from empirical experiences and from observations by people who use them. It embodies age-old wisdom, and forms an integral part of the social and cultural heritage of peoples and countries. The system has been inherited and handed down from one generation to the next.

Therefore, to a large extent, traditional systems of medicine, including herbal medicines, are country- and locality-specific. These systems have long been a part of the life of people in communities, especially in rural areas. Herbal medicines are widely used by people as a primary source for their health care. Today, herbal medicines are embraced not only by people of the country where they originated

but by people of other countries as well. The traditional systems of medicine that have been practiced in countries of the SEA Region contain herbal remedies that can protect and promote health. These medicines can be used to cure common ailments of people, and are especially useful in rural communities.

Distinguished participants;

It is important to draw a line between traditional medicines and modern medicines. The domain of traditional medicines comprises preparations from parts of herbal plants, such as bark, leaves, roots, flowers, and so on. It involves direct use of parts of the herbal plants for medical purposes. Once the active ingredient is isolated from the herbal and natural raw materials and purified into chemical forms, we enter the domain of modern medicines.

Modern medicines are developed from scientific discovery and research. In the case of traditional medicines, the active ingredients of most herbal raw materials are still not known.

In this meeting, our attention is confined within the domain of traditional medicines, and our emphasis is on promotion of the use of herbal remedies in primary health care.

Isolation of active ingredients to find chemical forms of modern medicines entails research and development, which requires capital investment and is time-consuming. As we know, herbal medicines that are prepared by traditional methods are cheap. They are mainly used by people in rural areas. But when the preparation of these medicines is done through modern methods, they become expensive. Since the 1990s, there has been a resurgence in the use of herbal products. It is likely that this trend will continue in the future as well, for a number of reasons. I shall mention three of them. First, there is a desire of people to return to nature and to use natural products to take care of their own health. Second, there is a perception that herbal medicines are derived from natural raw materials, and that they are relatively safe. Third, herbal medicines are almost always available, and they are affordable in their traditional dosage forms, especially in rural areas.

WHO promotes the use of traditional medicines in primary health care, particularly the use of herbal products. As part of this promotion, WHO helps assure the quality, efficacy and safety of herbal remedies, as well as the availability of herbal plants, in the community.

This meeting aims to promote sharing of information and experiences among institutions of countries in the Region on the use of herbal medicines in PHC. The meeting is meant to initiate the networking of interested groups that can lead to inter-institutional and intercountry cooperation.

Ladies and gentlemen;

During recent years, there have been a number of important developments in the area of traditional and herbal medicines. In 2007, a WHO Interregional Workshop on the Use of Traditional Medicine in Primary Health Care was held in Mongolia. In 2008, a WHO Congress on traditional medicine was held in Beijing. In January this year, the WHO Executive Board passed a resolution on traditional medicine, which will be discussed at the upcoming World Health Assembly. All these developments put emphasis on promotion of the use of traditional medicines in primary health care. These efforts all aim to promote inter-institutional, intercountry and interagency coordination and cooperation in the area of traditional medicines.

The time has come to meticulously examine the role of traditional and herbal medicines in securing and promoting good health. The use of herbal medicines in PHC can help improve health-care coverage, and it can help reduce inequity in access to health-care services. It should be kept in mind that herbal medicines are for everyone, rich or poor, urban or rural, and the consumption of these preparations is equally relevant in both developed and developing countries.

The use of herbal medicines in PHC reflects the application of appropriate technology that is socially and culturally acceptable to people in a community. To reiterate, herbal medicines are affordable and people can get easy access to them.

Ladies and gentlemen;

Countries in South-East Asia Region have vast resources of medicinal plants, and thus these countries are custodians of a huge repository of knowledge in traditional medicines. They must be protected from exploitation or misuse. If not adequately protected, there is a possibility that the custodians of this knowledge would end up paying a high price for commercial products that are prepared from their own medicinal plants by other countries with the capacity to invest in modern production methods.

However, traditional and herbal medicines can certainly be developed and made commercially available by our own countries. Herbal medicines provide a sound basis for countries to embark on a long-term plan for ensuring better health for all their people. Through modernization of their production, and through commercialization, herbal medicines can contribute significantly to economic and health gains for our countries.

To achieve this goal, biodiversity needs to be promoted and protected for the sustainable use of medicinal plants in the Region. There is a lurking danger that overexploitation, especially by outsiders, may lead to the depletion of these fragile natural resources. Let us move forward together in protecting our herbal plants and promoting the production of herbal medicines for use by all population groups. This will contribute to the self-reliance of our countries in the provision of "essential medicines".

Let us advocate for herbal medicines to be on the national list of essential drugs. This meeting is an appropriate vehicle for creating opportunities for intercountry cooperation. This is the place where partnerships and networks among institutions can be initiated.

Networking is an efficient mechanism for addressing technical issues through combined wisdom and concerted action among institutions and countries. Networking is also an appropriate way to implement consensus-based activities aimed at achieving mutual objectives and mutual benefits. Furthermore, institutional capacity can be strengthened through this process.

Since traditional systems of medicine are to a large extent country- and locality-specific, the scope as well as limits of intercountry and inter-institutional cooperation need to be clearly defined. The feasibility of such cooperation depends mainly on the recognition and acceptance of ground realities and the uniqueness of traditional medicines in their social and cultural context.

With these words, I would like to wish you all every success in your deliberations during this meeting. I also wish you a very productive meeting, and an enjoyable stay in Yangon.

Thank you.

Annex 2

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Annex 3

Agenda

1. Opening session

   1.1 Welcome address by Director-General, Department of Traditional Medicine, Ministry of Health, Myanmar

   Inaugural address of the Regional Director, WHO South-East Asia

   1.2 Group photograph

2. Technical sessions

   2.1 Introduction of participants

   2.2 Nomination of Chairperson, Co-Chairperson and two Rapporteurs

   2.3 Objectives, expected outcomes of the meeting

   2.4 Paper presentations

   - The role of WHO in promoting herbal medicine in primary health care.
   - Research strategy to ensure efficacy, safety and quality of herbal medicine
   - Country papers on the use of herbal medicine in primary health care – Bangladesh, Bhutan, India, Indonesia, DPR Korea, Maldives, Myanmar, Nepal, Sri Lanka, and Thailand
   - Herbal gardens: Good agricultural and collection practices and conservation of medicinal plants

2.5 Group work and reporting of group work

- Generic framework for sharing of information on the use of herbal medicines in primary health care among Member States of South-East Asia Region
- Generic framework for research in efficacy, safety and quality of herbal medicines for primary health care
- Generic framework for intercountry cooperation in the use of herbal medicines in primary health care

2.6 Finalization of conclusions and recommendations

3. Closing session

3.1 Closing remarks by the Director, Programme Management, WHO South-East Asia

3.2 Chairperson's closing remarks and closure of meeting

Herbal medicines (HM) form an essential and major component of traditional medicines (TM). HM are commonly used in countries of the South-East Asia Region. This regional meeting was held to exchange information and to promote the development of herbal medicine for use in primary health care (PHC).

Technical presentations covered the role of WHO in promoting the use of herbal medicines in PHC; research strategy to ensure efficacy, safety and quality of herbal remedies; and conservation of medicinal plants through sustainable harvesting practices. Development of a generic framework on the sharing of information on the use of herbal medicines in PHC, a generic framework on quality, safety and efficacy of herbal remedies and a generic framework on intercountry cooperation in HM for use in PHC were developed through group work. Countries presented the use of herbal medicines in their respective countries, thereby providing the baseline status for development of HM in countries of the Region.

The meeting made a number of conclusions and recommendations on sharing of information on the use of HM/TM in PHC; research to improve quality, efficacy, and safety of herbal medicines; and for intercountry cooperation. Conservation and sustainable utilization of medicinal plants were also recommended, which would further facilitate the use of herbal medicines in countries of the SEA Region.

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SEA-HSD-322