Review of Traditional Medicine in the South-East Asia Region

Report of the Regional Working Group Meeting
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1. INTRODUCTION

The South-East Asia (SEA) Region has a rich heritage of several systems of Traditional Medicine (TM), many of which are in popular use. WHO has been assisting countries to promote the use of TM so that this valuable resource is utilized safely and effectively. An intercountry meeting of a Regional Working Group was held on 16–17 August 2004 in New Delhi to help form a Regional Advisory Group for Traditional Medicine in the SEA Region. The Working Group was given the mandate of identifying the composition of the Advisory Group, defining its role and developing an agenda and Programme of Work for the proposed Regional Consultative Meeting to be held in early 2005. The meeting was attended by participants from Bhutan, India, Myanmar, Sri Lanka and Thailand (please see Annex 1 for list of participants).

2. INAUGURAL SESSION

2.1 Background

Dr Than Sein, Director, Health Systems Development, WHO SEARO, welcomed the participants and provided the background for the meeting.

In 1998, at the Health Ministers’ Meeting, the issue of TM was debated and it was agreed that a Regional Strategy on TM needed to be developed. A series of activities were initiated and a publication, Traditional Medicine in Asia – SEARO Regional Publication 39, 2002, brought out.

The issue of TM was relevant not just in the South-East Asia Region but in other Regions as well. In 2002, the World Health Assembly discussed the issue and adopted a resolution (WHA 56.31) on the WHO Traditional Medicine Strategy. The Strategy was then discussed at the Regional Committee Meeting held in Indonesia in 2002.

At the 21st Meeting of Health Ministers of the Region in 2003, progress during the past five years was reviewed. It was decided that an intercountry Working Group on TM should be established and potential areas to foster closer cooperation among SEAR countries be identified. Such areas could include sharing of pharmacopoeias and formularies, strategies and
experiences in quality control, standardization of drugs and scientific validation of TM. An exchange of experts/students/health professionals as well as collaborative research could be carried out. The countries of SEAR could collaborate in the development of new drugs.

At the 56th Session of the WHO Regional Committee for South-East Asia in 2003, Member States requested intercountry collaboration to develop and enhance health research efforts, human resources and exchange of information in TM. They decided that measures should be taken to protect, preserve and improve traditional knowledge and medicinal plant resources for sustainable development of TM, and that there was a need to promote the safety and efficacy of TM drugs.

The Regional Committee adopted a resolution (SEA/RC56/R6) requesting the Regional Director to (i) share information and country experiences on TM, (ii) assist Member States in developing and strengthening national policies and strategies related to TM, and (iii) establish a Regional Task Force on TM to regularly review the regional situation, and facilitate national and global alliances on TM.

In 2003, the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) was formed. This new Commission would among other things, examine the contribution of TM in improving health care.

At the 9th Meeting of Health Secretaries in July 2004, the focus was on Globalization, Trade, Intellectual Property Rights (IPR) and Health. Member States endorsed and appreciated the work of the CIPIH. It was recommended that SEARO facilitate the preparation of a common regional perspective focusing on the burden of disease and related health research and development, IPR and public health, other incentives for innovation, traditional systems of medicine and capacity building, to be presented to the CIPIH.

2.2 Objectives and Terms of Reference

The following were the specific objectives and terms of reference (TOR) for the Regional Working Group meeting:
Advise on the Terms of Reference (TOR) and composition of a Regional Advisory Group on TM;

Develop the agenda and Programme of Work for the Regional Consultative Meeting to be held in early 2005, with wider involvement and participation of all Member Countries;

Formulate a common regional perspective on IPR and other forms of protection in TM to be presented to the CIPIH.

2.3 Background Documents

Dr K. Weerasuriya, Regional Adviser, Essential Drugs and Medicines Policy, WHO SEARO, introduced the background documents for the meeting. Details of these documents are given in Annex 3.

He said that interest in strengthening TM in the Region spanned a period of over 30 years. The widespread use of TM, its accessibility and affordability particularly in rural areas, the need to enhance research and training facilities in the Region, as well as collaboration among countries was realized and noted in a resolution adopted by the WHO Regional Committee for South-East Asia in 1977 (SEA/RC30/R13).

The WHO Strategy for Traditional Medicine (2002–2005) acknowledges the widespread use of TM, not merely in the Region but globally. World Health Assembly resolution WHA 56.31 assigned specific roles/activities for countries and WHO, which form the basis of this Working Group.

The Role for WHO was identified as follows:

(1) Facilitate the efforts of interested Member States in formulating national policies and regulations on traditional and complementary and alternative medicine, and promoting the exchange of information and collaboration on national policy and regulation of TM among Member States;

(2) Provide technical support for the development of methodologies to monitor or ensure product quality, efficacy and safety, preparation of guidelines, and promotion of exchange of information; and

(3) Provide technical support to Member States in defining indications for the treatment of diseases and conditions by means of TM.
In 2003, the WHO Regional Committee for South-East Asia adopted a resolution (SEA/RC56/R6) urging the establishment of a Regional Task Force on Traditional Medicine to regularly review the regional situation and facilitate the development of national and regional strategies and policies on traditional systems of medicine.

The 9th Meeting of Health Secretaries of the Countries of WHO South-East Asia Region held at SEARO, New Delhi in July 2004 agreed that:

‘...WHO should facilitate preparation of a common regional perspective focusing on the burden of diseases and related health research and development, IPR and public health, other incentives for innovation, traditional systems of medicine and capacity building to be presented to the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) to support its work....’

3. COUNTRY AND REGIONAL ISSUES IN TRADITIONAL MEDICINE

Professor Ranjit Roy Chaudhury, Emeritus Scientist, National Institute of Immunology, New Delhi asked the representatives of various countries to present their country profile on TM under the following headings:

- Policy
- Safety, efficacy and quality
- Access
- Rational use

The following were the country presentations:

3.1 Bhutan

Mr Dorji Wangchuk, Director, Institute of Traditional Medicine, Department of Health Sciences, Ministry of Health, presented Bhutan’s country profile.

The kingdom of Bhutan is a small, landlocked country situated in the eastern Himalayas with a population of 698,000. It is known as Menjong
Gyalkhab, meaning the ‘land of medicinal plants’. To date, more than 600 medicinal plants have been identified and at least 300 of these are commonly used by practitioners.

The Bhutanese traditional medicine system is known as Sowa Rigpa, which was established in the 16th century after the arrival of Shabdrung Rinpoche from Tibet.

**Policy**

The national policy is to preserve and promote TM through capacity building and establishing an effective system within the framework of the national health care delivery system. TM was formally recognized and institutionalized as an integral part of the national health care delivery system in 1967.

The main objectives are (i) to preserve the unique culture and tradition related to medical practices; (ii) to promote and strengthen TM in the country; (iii) to provide an alternative system complementary to the allopathic system; (iv) to produce traditional medicines; (v) to conduct research and quality control of drugs; (vi) to develop human resources for TM; and (vii) to achieve excellence in TM services.

**Traditional medical services in Bhutan**

From a single indigenous dispensary in 1967, the TM service now covers the entire country. By the end of the Eighth Five-Year Plan (2001), TM units were established in all 20 districts. They are attached to district hospitals and are manned by one physician and one clinical assistant. Patients are at liberty to choose either system of medicine and substantial cross-referrals take place between the two systems. There is no individual (private) practice and all physicians are government employees. Services are also available beyond the districts, in blocks, which constitute the outreach services.

Training is imparted within the country through diploma and certificate courses.

**Safety**

There are 98 formulations and compounds. All are manufactured according to Good Manufacturing Practices (GMP), and quality control (QC) is maintained
for both raw materials as well as finished products. All drugs are centrally manufactured and distributed. The Pharmaceutical and Research Unit is responsible for the production of medicines and QC.

**Efficacy**

The general perception is that TM is very good for chronic ailments such as arthritis, asthma, rheumatism, liver problems and diseases related to the digestive and nervous systems. The rural population prefers TM, but the choice is left to the patient, unless the treating physician thinks that the other system may be more beneficial.

**Rational use**

Prescribing is done by qualified persons only. Other forms of therapy are also used; these include blood-letting, herbal therapy, steam and spa therapy. The only preparations that are available over-the-counter are herbal teas.

Mr Wangchuk concluded by saying that he hoped for an exchange of experiences with India, especially the northern states, where the practice of TM (Amchi) closely resembles Sowa Rigpa.

### 3.2 India

Dr S.K. Sharma, Adviser (Ayurveda), Ministry of Health and Family Welfare, Government of India; Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH), New Delhi, emphasized that India has a long tradition of TM.

The first National Health Policy of 1983 mentions that use should be made of India’s rich tradition of health care in national programmes. The National Population Policy states that TM experts and medicines should be used to stabilize the population. The Department of AYUSH, which started in 1995, regulates TM programmes. There are separate directorates of Indian Systems of Medicine and Homeopathy in 21 State Governments. The Government of India has an explicit and separate policy for Indian (Traditional) Medicine since 2002.
Education and research

There are four apex research councils in India carrying out research on TM. The Central Council for Indian Medicine (CCIM) is constituted under the Indian Medicine Central Council Act of 1970. It regulates the standards of teaching and registration for clinical practice. Both degree and short- to mid-term courses on TM are available. There are separate universities for Ayurveda as well. Bachelor’s, postgraduate and PhD degrees are offered.

There are Pharmacopoeia Committees and laboratories for Ayurveda, Siddha and Unani medicines. In all, there are 424 single-drug monographs published in four volumes of the Ayurvedic Pharmacopoeia of India. The Ayurvedic Formulary of India has 636 formulations of multi-ingredient drugs. The National Siddha Formulary of India contains 240 formulations. Thirteen universities and various laboratories collaborate in pharmacopoeial work. As the physical characters of the ingredients may vary, standard operating procedures (SOPs) are being developed. At present, compound formulations are being standardized.

Regulation

Traditional medicine is also governed by the Drugs and Cosmetics Act, 1940. Licensing of manufacturers and the provisions of the Drugs Act are implemented by the State Governments. GMPs are mandatory since 2002, though not exactly those recommended by WHO, they are based on them. Kerala has 900 manufacturing units and only 300 follow GMPs. In some states, there is only 10%-20% compliance with GMPs. Central and state governments are impressing upon manufacturing units to comply with GMP norms and to ensure quality standards.

Safety and efficacy

Some of the multidrug formulations also contain food items, such as yoghurt, ghee, honey, milk, turmeric, etc. Such formulations are safe.

Schedule ‘E’ drugs contain toxic ingredients and are strictly regulated. Their safety profile should be available on request. Traditionally, no preservatives are used in Ayurvedic medicines, but the government is now permitting these so that these preparations have a reasonable shelf-life.
Access and availability

The Central Government allocates only 2% of the entire health budget for TM. In the state government sector, there are about 25,000 dispensaries, and 3000 hospitals with a bed capacity of 65,000. These are, by and large, functioning in parallel with allopathy institutions. Only about 30,000–40,000 doctors are in government service; the rest are private practitioners. India has about 500,000 practitioners of Ayurveda, Siddha and Unani, of whom about 70% are institutionally qualified.

In the national Reproductive and Child Health Programme (RCH), seven Ayurvedic and five Unani drugs have been introduced for distribution through the primary health care network.

TM drugs are available at chemist shops without a sale licence; it is now being proposed that drugs with some toxic ingredients should be sold under prescription. Regarding pharmacovigilance, toxic formulations are a matter for concern and need to be regulated.

Dr Sharma emphasized that distinct recognition should be given to Ayurveda, in keeping with its long tradition and the availability of standard texts such as the Charaka Samhita and Sushruta Samhita. Ayurveda and similar medical systems can, in no way, be equated with herbal medicine. Sharing of formularies, pharmacopoeias, and services of practitioners and teachers among countries would enhance the utilization of ayurveda in the Region.

3.3 Myanmar

Dr Thein Swe, Director-General, Department of Traditional Medicine, Ministry of Health, Yangon described the present status of TM in Myanmar.

Traditional Medicine has existed since time immemorial in Myanmar. The TM promotion office was established in 1953. In 1972, TM was included as one of the branches of the health care services in the National Health System. In 1989, the Unit was upgraded to a separate department under the Ministry of Health and, in 1997, it was upgraded again as the Department of Health. The TM Promulgation Law came into being in 1996, and gave the prerequisites for the practice of TM.
Myanmar has four TM systems: (i) Dessana, based on natural phenomena such as hot and cold. Its concept is largely based on Buddhist philosophy; (ii) Bethitza, based on Ayurvedic concepts with extensive use of herbal and mineral compounds; (iii) Vessadara, which is linked to meditation and the practice of alchemy; and (iv) Netkhata (astrology), based on calculations of the stars and planets, and the time of birth and age.

Training and education
Myanmar now gives priority to TM, as it is a part of its cultural heritage. Earlier, TM practitioners had no licence, and underwent a three-month training programme. At present, there is a one-year certification programme. A Diploma in Traditional Medicine (DipTM) was started in 1976.

A university of TM was established in 2001, which gives a five-year degree with one-year of internship. This is a Bachelor’s degree known as the Bachelor of Myanmar Traditional Medicine (BMTM). Since 2000, 36 hours of lectures in TM have been introduced in the third-year course of pharmacology for MBBS students. For health assistants, 12–20 hours of training is given.

Regulation
There are two laws for the regulation of TM. The TM Council Law controls the ethical aspects and the Traditional Drugs Law concerns applications for registration of drugs. These include pre-registration pharmacognosy tests, acute toxicity tests and tests for heavy metals. Registration is given only after the approval of registered laboratories.

Safety
Monitoring of herbal medicines is done through market surveys and investigations for adulteration. Some selected drugs are undergoing clinical trials, while newer drugs are being developed, especially for common diseases such as malaria, tuberculosis, dysentery and diarrhoea. There are two departments of medical research for the development of traditional drugs. There are 57 formularies and about 100 plants are routinely used.
Policy

There is no separate policy, but 17 elements of the National Health Policy emphasize the need for enhancing the use of TM and research in this area.

Myanmar is conducting research on the treatment of tuberculosis with herbal drugs, in the hope of reducing the duration of treatment for tuberculosis. About 85% of the country has been covered, either by private or TM practitioners.

Accessibility

There is increased access in rural areas. There are 14 separate TM hospitals in the country.

Rational use

Training programmes have been initiated, both for students as well as private practitioners of both systems of medicine. These focus on the uses of herbal drugs and management of uncommon diseases. TM is being introduced in rural areas through health centres; to this end, lady health visitors are being trained.

Country-specific issues

- There is a need to promote drug safety and research.
- Manpower development is required, particularly in the areas of herbal plants and clinical research.
- Development of fellowship programmes by means of short training courses (three months) need to be organized.
- Intercountry sharing of knowledge would help, especially as Myanmar’s TM systems are similar to those of other countries in the Region.
3.4 Sri Lanka

Dr Lakshmi Senaratne, Acting Director, Bandaranayake Memorial Ayurvedic Research Institute, Nawinna, Maharagama, explained that Sri Lanka has two systems of TM.

- The Ayurvedic system, which incorporates Ayurveda, Unani and Siddha; and
- The traditional system or Deshiya Chikitsa. This system is used for general disease conditions and in some specific areas such as snake bites, fractures and dislocations, eye diseases, boils and ulcers, skin diseases, hydrophobia, mental diseases, burns and diarrhoeal diseases. Acupuncture, although of a different origin, also comes under this system. Practitioners of this system obtain their training by the oral tradition.

Policy, education and training

Indigenous systems need to be improved in parallel with allopathic medicine. The Ministry of Indigenous Medicine has a Department of Ayurveda. There are three institutes for teaching and training. The Institute of Indigenous Medicine, University of Colombo, offers a Bachelor's degree and also has a postgraduate section; there are 16 Ayurveda colleges that run a diploma course, two teaching hospitals in Colombo, and an Ayurvedic Research Institute.

Access

There are 46 provincial hospitals, 122 central dispensaries and 231 local dispensaries. In addition, there are well-developed private hospitals. Among the population, about 45% seek indigenous medical treatment.

Safety and efficacy

An Act was gazetted in 2001, but the legal document is not yet ready. The Ayurvedic Drug Formulary Committee deals with the safety and efficacy of Ayurvedic drugs. All the drugs available in the market must have a report on their safety and clinical efficacy. Imported drugs also need to have these two reports.
The Ayurveda Act deals with education and research. Medicinal plants are identified before clinical research commences. There is a Pharmacognosy section in the Bandaranayake Institute for identification of plants; manufacture is according to the pharmacopoeia. There are three Ayurvedic, two Unani and one Siddha pharmacopoeias. For new drugs, clinical as well as safety studies are required.

There are 200 Ayurvedic drugs in the market, and about 174 herbs have been identified which are unique to Sri Lanka. There is a project to conserve these and promote their sustainable use funded by the World Bank. Commercial-scale cultivation has started.

3.5 Thailand

Dr Anchalee Chuthaputti, Institute of Thai Traditional Medicine, Department for Development of Thai Traditional and Alternative Medicine, Ministry of Public Health, Nonthaburi, Thailand, presented the country profile.

In Thailand, TM had been discontinued for about 70 years. It was encouraged by WHO following the Alma Ata declaration of 1978. In 2002, a new department for the development of Thai Traditional Medicine and Complementary and Alternative Systems of Medicine was established under the Ministry of Health. The 2002–2006 Ninth Five-Year Plan for National Economic and Social Development called for integration of TM into the primary health care system and significant progress has been made in this area.

The classical book of Thai TM uses language that is not easily understood. Many universities run BSc courses and are trying to understand the link with modern-day diseases.

Safety and efficacy

The Food and Drugs Administration (FDA) has put five medicinal plants in the Essential Drugs List. In addition, the FDA has also selected 60 plants to treat 25 minor diseases in primary health care. To manufacture these, recipes can be made into household remedies and sold anywhere.
Under the law, there is registration for modern medicines and TM. Herbal drugs are listed as herbal medicines. The manufacturer submits results of microbial limit tests, presence of contaminants such as pesticides, heavy metals, etc. according to permitted levels.

The Department of Medical Sciences has two volumes of the Thai herbal pharmacopoeia, which have 21 monographs. By 2007, monographs for 50 essential medicinal plants would be available. Pharmacological and toxicological studies are initially done on the crude drug, but they should have a fingerprint and QC. At present, assay of the active ingredient is not required. Preclinical data should be available and toxicological studies are submitted to the Ethics Committee for approval to conduct clinical studies.

Access

Under the universal coverage programme, TM is included. There is a law that protects national habitats, recipes and family traditions known as the sui generis law.

In 2003, 83.3% of regional general hospitals and 67.8% of community hospitals had at least one practitioner of TM. There are nearly 15,000 TM practitioners. Thai TM also includes massage therapy.

Rational use

The Department has developed a handbook of Thai TM that is widely distributed and is in great demand. There are plans to distribute it to the general population as well.

Discussion

The ensuing discussion highlighted some common issues.

- How can ancient knowledge be translated into modern concepts?
- How should TM drugs be standardized?
- How should clinical trials on TM drugs be carried out?
Should herbal drugs be included in the Essential Drugs List for allopathic drugs?

The policy of selecting certain diseases for treatment by traditional methods is an important aspect.

Should the Region concentrate on research in specific areas of interest, such as tuberculosis?

How best could TM knowledge be shared among countries?

Giving TM training to health workers: the public might find it easier to accept TM from practitioners of this system rather than allopaths.

How could pharmacopoeias developed in various countries be shared? What were the differences and similarities? Comparison of the lists of drugs by Member Countries would help in identifying commonalities. Unique plants, indigenous to various countries, also needed to be listed.

How can TM be integrated into the health care delivery system?

It was agreed that a background paper on the various types of integration in the countries of the Region would be helpful.

4. **INTERCOUNTRY COOPERATION IN TRADITIONAL MEDICINE**

Moderator: Dr Thein Swe

Several systems of TM prevailing in the Region were identified. These were Ayurveda, Siddha, Unani, Chinese, Sowa Rigpa, Mixed (indigenous), Alternative/Complementary. The Alternative/Complementary system includes Spiritual, Vedic, Alchemy, Chiropractic and other forms of Massage, and Naturopathy.

The country presentations highlighted that national policies differ from country to country. Some have national laws, others have national councils, some have national-level ministries, and others have national-level departments. In countries such as Bangladesh and Indonesia, there is a director in the Department of Health.
Training and research also differ from country to country. Some training institutes offer graduate and postgraduate courses (Thailand, India, Myanmar), while Sri Lanka has only Bachelor’s degree-level training. India, Sri Lanka, Thailand and Myanmar have TM research institutes.

The regulatory status of various preparations differs among countries – they may be prescription drugs, over-the-counter products, dietary supplements, health foods, functional foods, etc. Manufacturing requirements are different for various preparations.

In Bhutan, Myanmar, DPR Korea and China both the allopathic and TM systems are integrated with the health care delivery system. India has a parallel system, which is also the case with Thailand. Timor-Leste follows a system similar to that of Indonesia.

While, professional associations exist in India and Sri Lanka, some countries have laws to protect and preserve TM (Thailand, India), and others have no specific legislation. Countries allocate different proportions of their health budget for TM.

In some countries, there is a high level of political commitment, but the technical knowledge required is not available. The discussion concluded that this enormous diversity highlighted the need for intercountry collaboration. The following areas where collaboration would be the most useful were identified.

**Education**

There is a need for uniformity among countries in the curriculum at both graduate and postgraduate levels. Faculty exchange would then become possible. Consumer education in TM is also important for it to gain wider acceptability.

**Quality assurance**

Countries could compare their formularies and assess commonalities and differences in drugs, practices and traditions. Pharmacopoeias developed by one country could be used in others, to avoid duplication of effort. Best practices could be identified and shared. Fingerprinting of various raw ingredients would help all countries using that ingredient.
All countries of the Region should have standard measurements and manufacture drugs according to GMP as far as possible.

**Regulation**

All countries should establish TM Councils to regulate the practice of TM. IPR issues were also discussed, as Trade-Related Intellectual Property Rights (TRIPS) do not cover medicinal plants. For those countries with a large body of knowledge and the potential for export, there should be a way to do this. As many medicinal plants used are common, if these are used and protected jointly, they could also be exported. Alternatively, one country could grow the plant and another manufacture the drug. Inventories should be made and surplus availability of plants listed, so that countries could share raw materials.

Plant resources need to be protected by stringent laws. At present, Thailand and India are the only countries in the Region that have laws for the protection and conservation of medicinal plants.

**Documentation**

Documentation of knowledge is a vital issue. India has been documenting its Ayurvedic formulations by means of the Traditional Knowledge Digital Library. This electronic library can be translated into several languages, and it was suggested that countries seek India's help in developing such libraries. In addition, oral knowledge should be collected and documented.

**Conservation and sustainable production**

This could be achieved by the use of agro-technology and conservation of plant resources. All production should be according to WHO Good Agricultural and Collection Practices (GACP).

**Research and development**

This component was given much weightage during the session. Areas for concern were clinical trials, safety and efficacy of drugs, ethical issues, toxicology studies and standardization.
Information exchange

The areas in which information could be exchanged were identified as plants/plant products and other raw materials used in TM. Technical exchange in the above areas could also be sought by countries.

Integration

Countries could exchange information regarding what works and what does not in the areas of policy implementation and policy development.

5. PRESENTATION OF TRADITIONAL KNOWLEDGE DIGITAL LIBRARY

In his presentation on Traditional Knowledge Digital Library (TKDL), Dr V.K. Gupta said that the Government of India set up an interdisciplinary Task Force in 2000 to develop the TKDL so that traditional knowledge could be preserved and recorded. Ancient TM formulations were selected, with the software having the facility for translating the Sanskrit version into several languages such as French, German, English, etc. This exercise is of immense benefit, as much of the knowledge of TM has been lost. However, several countries that participated in the consultation said that they did not have the requisite expertise in IT, but would be interested in documenting their formularies in a similar manner. So far, 36,000 formulations have been documented. While this is not for the purpose of patenting, it helps to protect traditional knowledge.

Several participants felt that piracy of patents would also be prevented by the TKDL, as a country having such a system could easily prove that this knowledge was theirs. These formulations are given to patent offices on a non-disclosure basis. For others wanting them, the use to which it would be put has to be specified.

Documentation is also required to preserve oral traditions. However, those developing new knowledge with commercial applications can seek a patent, which has a cost attached to it. A patent should be sought only after a cost-benefit analysis.
Dr Gupta informed that there was a SAARC Documentation Centre, in which a SAARC TKDL had been created. Funds would be needed for other countries to use this. It was decided to refer this issue to the SAARC Secretariat.

6. COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH: FRAMEWORK AND OBJECTIVES

Dr K. Weerasuriya presented the framework paper. The background to this document was formed by the following: (i) TRIPS and Public Health; (ii) Doha Declaration of 2001; and (iii) WHO Public Health Objectives in Medicines.

Before 1995, patents for drugs (which are now a part of intellectual property) were decisions that countries made in their national interest. With the World Trade Organization (WTO) Agreement, which included a section on TRIPS, intellectual property became a part of the multilateral agreement. This severely limited the option for countries to obtain medicines that would improve the health of their people. Many countries were disturbed by this agreement and in a subsequent meeting in Doha (2001), agreed on a declaration where public health would be given priority. ‘We stress the importance we attach to the implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines ...’.

Because of the very complicated situation, the World Health Assembly recommended that WHO establish a Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) to assess which incentives would promote public health objectives. At present, the market potential appears to determine which medicines are developed. This is to the detriment of diseases found predominantly in the developing world, for which very few medicines have been developed. Less than 1% of new drugs developed in the past 25 years were for diseases of the developing world, which constitutes 80% of the world population.

CIPIH, while considering all possible mechanisms to provide some incentives for the development of medicines relevant to public health needs,
was also asked to consider whether TM could contribute to either discovering or delivering medicines for public health. It was noted that the most successful group of drugs available for malaria, the artemisinin derivatives, arose from TM; thus TM has potential. There is also an ongoing investigation into whether TM used in combination with standard antitubercular drugs decreases the adverse effects associated with this treatment. CIPIH was therefore requested to consider whether it was possible to use TM to develop medicines of public health importance.

7. **ROLE OF THE REGIONAL ADVISORY GROUP**

The working group identified the role of the Regional Advisory Group (RAG). This Group would initially (i) review the country situation; (ii) identify priorities for intercountry collaboration and formulate a Programme of Work; and (iii) exchange experiences. It was agreed that the RAG should identify areas where harmonization was possible.

**Programme of Work**

The Programme of Work was formulated as follows:

RAG should:

(1) Advise on policies and strategies

- Countries need assistance to develop national policies on TM. Technical support and guidance could be provided to those countries that do not have such policies in place.
- The Regional Strategic Framework for collaboration should be reviewed regularly. This calls for a periodic review of the situation in Member Countries.
- Global TM development: Apart from regional and intercountry collaboration, interregional collaboration could be encouraged so that the development of TM would be worldwide. As the SEA Region has a strong tradition of TM, it could set the stage for global promotion of TM.
(2) Identify priorities

- Harmonization: This covers the areas of curriculum development, pharmacopoeias and medicinal plants.
- Research and development: Collaboration in this area would cover clinical trials and the development of newer drugs.
- Safety measures: Countries could exchange knowledge on the safety and efficacy of various TM drugs.

(3) Exchange experiences

- Progress: Member Countries could compare experiences in the areas of policy, safety, efficacy and quality of TM drugs, and access of their respective populations to TM.
- Knowledge management: Databases could be compared/shared, and networks such as HeLLIS help countries gain access to the work done by other countries.
- Centres of excellence: Intercountry and intercentre collaboration should be a priority of the RAG. WHO Coordinating Centres could be set up, though this was difficult.

(4) Develop a Work Plan

- The Work Plan would involve cooperation that was not just regional, but multicountry and interregional. The RAG should also contribute to global expertise.

(5) Membership

A group of experts was suggested, with subgroups for specific areas, as and when needed. Experts would be representatives from the following areas:

- Regulatory authority
- Education
- Research
- Standardization of medicines
- Clinical expertise in TM
- Pharmacology
8. CONCLUSIONS AND RECOMMENDATIONS

In this session, moderated by Dr Kin Shein, Programme Coordinator – TRM, WHO Kobe Centre, the following conclusions and recommendations were arrived at:

8.1 Conclusions: Provisional Agenda for the Regional Consultation, Early 2005

(1) Purpose: The main purpose of the Consultation would be to define the objectives and encourage wider participation.

- Objectives: These would include (i) review of country and regional developments in TM and identification of issues and challenges; (ii) review of the regional strategic framework for the development of TM in the Region; (iii) identifying priority areas for collaboration between countries; and (iv) formulating and agreeing on the Programme of Work.

- Participation by the following: (i) Governments should be involved, as budgetary allocations and policies would need to be worked out. High-level policy-makers and senior programme managers could represent the government; (ii) TM experts; (iii) members of scientific advisory groups (SAGs); (iv) manufacturers of TM drugs; (v) Intellectual Property Right experts of TM; (vi) economists; (vii) international agencies; (viii) WHO

(2) Regional Strategic Framework: This would include:

- formulating a 5–6-year medium-term work plan
- formulating strategies in specific areas such as policy, safety, access and rational use of TM
Ø developing a work plan to identify priority areas for collaboration
Ø mobilizing resources by allocating funds through country budgets as well as intercountry programmes. From the next biennium, there would be no intercountry budget, hence a part of the country budget should be reserved for intercountry activities. Countries such as India that have a budget for TM do not have a problem, but other countries would have to mobilize funds.

(3) Policy: Policies for TM differed among countries. The RAG could advise Member Countries on national legislation for TM, IPR and TM, and on developing a TM database.

(4) Safety/efficacy/quality of TM drugs: It was suggested that technical managers should work together, and arrive at a regional agreement on testing and clinical trials. This would help to raise the quality of research and methodology as, at present, only a small minority of clinical trials are acceptable for various reasons. Good Manufacturing Practices should be adhered to and standardization and regulation made uniform.

(5) Enhance access to TM, which would involve (i) collaboration and integration with the allopathic system; (ii) education, including curriculum development; (iii) sustainable production of medicinal plants and other raw materials for TM according to GACP, as well as access to such materials.

(6) Rational use: To encourage rational use, the following actions were thought to be necessary: (i) consider the inclusion of TM drugs in the Essential Drugs List; and (ii) consumer education in TM to increase awareness.

8.2 Recommendations

The Working Group made the following recommendations:

(1) Intercountry collaboration: Collaboration in the areas of education, including curriculum development and faculty exchange; information exchange on plant/plant products and raw materials; research and development; documentation; technical exchange and sustainable production would help countries of the Region to avoid duplication of effort and benefit from each other.
(2) Interregional collaboration: The RAG should promote collaboration among regions as well as worldwide. The RAG is ideally suited for this, as most of the TM systems in use are indigenous to the SEA Region.

(3) Integration with the health services: The Group should help countries formulate national policies to integrate TM with National Health Programmes, especially in the area of primary health care. This would ensure access and help promote the use of TM. Countries without a national policy for TM should be helped to develop one. The aim would be to introduce TM in treatment and service delivery at the community level.

(4) Develop evidence-based information regarding the safety, efficacy and quality of TM drugs: Pharmacovigilance and toxicology studies should be carried out, with countries pooling their resources.

(5) Research and development: The RAG should actively source funds for R&D. Countries should reserve a part of their budget for intercountry activities. New drug development should be carried out and ways to minimize the side-effects or enhance the action of allopathic drugs should be considered.

(6) Review specific areas: One member from each country should regularly present an updated country status report in the areas defined by WHO, i.e. policy, safety and efficacy, access and rational use. A review of available pharmacopoeias and exchange of these should be done to facilitate better collaboration.

(7) Create awareness among the medical fraternity regarding TM by developing short training programmes, or during the MB,BS course. Health workers should also undergo training in TM.

(8) Ensure that TM practitioners are registered and qualified. Curriculum development should be made uniform throughout the Region to facilitate exchange of students and faculty.

(9) Highlight the benefits of TM: TM is a valuable resource in the Region, with few side-effects, low cost and high acceptability. The use of TM as an adjunct to allopathy should be stressed.

(10) Support incentives to develop TM by standardization of drugs, clinical trials, more effective training, etc.

(11) Write a prospective paper for the CIPIH, which would be a major component of the Commission’s Position Paper.
9. REGIONAL DIRECTOR’S ADDRESS

Dr Samlee Plianbangchang, Regional Director, WHO South-East Asia Region in his remarks at the closing session emphasized that TM has been a part of our lives for much longer than modern medicine. Another term for TM is holistic medicine. It is a cultural and historical aspect of our lives that is difficult to internationalize. There is a substantial component passed on from generation to generation by the oral tradition.

The challenge before us is huge. Much in the realm of TM is unknown, but it is certainly accepted and practised. Modern medicine is based on scientific discovery. However, TM needs to be tested according to methods appropriate for it, and not by the same methods used for testing modern medicine.

WHO’s policy is to encourage countries to use TM as they see fit, particularly in primary health care. WHO would assist countries in developing mechanisms for availability, strategy and information-sharing. There should be a framework to move forward, but interregional variations must be considered. Herbal medicine is a separate area, as are food supplements, acupuncture, etc. National mechanisms must be put in place to ensure the quality and availability of TM.

The sociocultural context should also be kept in mind. This is a heritage that we all share, Dr Samlee added.
Annex 1

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Annex 2

PROGRAMME

Monday, 16 August 2004

0900-0930 Registration

0930-1030
- Inauguration
- Opening Remarks by Director/HSD
- Introduction of Participants
- Background to the Working Group:
  Global & SEARO documents, WHO Traditional Medicine
  Strategy, Resolutions on Traditional Medicine, 9th Health
  Secretaries Meeting,
- Regional Guidelines for Regulation of Herbal Medicines (Draft) –
  An example of Regional Cooperation by RA/EDM
- Announcements by RA/EDM

1030-1100 Tea/Coffee

1100-1230 Country and Regional issues in Traditional Medicine
- Group discussion

1230-1330 Lunch

1330-1430 Intercountry cooperation in Traditional Medicine
  Multicountry, bilateral and other modalities
  Which is appropriate for what?

1430-1530 Regional Priorities in Traditional Medicine
- Group discussion

1530-1600 Tea/Coffee

1600-1645 Role of the Regional Advisory Group in Traditional Medicine
  Terms of reference and composition of the Regional Advisory Group
  for Traditional Medicine
- Group discussion
Tuesday, 17 August 2004

0900-1000 Development of an agenda and Programme of Work for the proposed regional Consultative Meeting on Traditional Medicine in 2005
   - Group discussion

1000-1030 Tea/coffee

   CIPIH and Traditional Medicine – by RA/EDM
   - Group discussion

1230-1330 Lunch

1330-1500 Drafting of recommendations

1500-1530 Tea/coffee

1530-1630 Closing Session:
   Remarks by Regional Director
   Presentation of Final Recommendations
Annex 3

BACKGROUND DOCUMENTS

(1) Resolutions and Reports from SEAR Regional Committee sessions SEA/RC29/R11 (1976); Traditional Systems of Medicine & Follow-up SEA/RC30/R13 (1977)

(2) Traditional Medicine – Growing Needs and Potential (WHO Policy Perspective 2002)

(3) SEAR Regional Committee Background Paper – SEA/RC55/13

(4) Report on Traditional Medicine to the Fifty-sixth World Health Assembly 2003 WHA56/18

(5) Resolution on Traditional Medicine adopted by World Health Assembly 2003 – WHA56.31

(6) Resolution on Traditional Medicine adopted by SEARO 2003 – SEA/RC56/R6

(7) Report of the Ninth Meeting of Health Secretaries of the Countries of WHO South-East Asia Region 2004 – SEA-HS Meet-9

(8) WHO South-East Asia Region Minimum Requirements for the Regulation of Traditional Medicines (Draft)

(9) Regulatory Situation of Herbal Medicines 2004

(10) WHO Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine

This MindManager was developed during a brainstorming session in the working group meeting to identify issues in traditional medicine in the South-East Asia Region.