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Regional workshop to share experience and evidence on appropriate integration of traditional medicine into national health-care systems

Report of the Regional Workshop
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Acronyms and abbreviations

AYUSH	Ayurveda, Yoga, Unani, Siddha, Homoeopathy
ASU	Ayurveda, Siddha, Unani
DoA	Department of Ayurveda (Nepal)
GACP	Good agriculture and collection practice
GMP	Good manufacturing practice
ICD-11	International Classification of Disease, 11th revision
ICT	Information and Communication Technologies
IPGT&RA	Institute for Post Graduate Teaching and Research in Ayurveda (India)
MoH	Ministry of Health
MoH&FW	Ministry of Health and Family Welfare (Bangladesh)
MoPH	Ministry of Public Health
NAMC	Nepal Ayurveda Medical Council
PV	Pharmacovigilance
SEAR	South-East Asia Region
T&CM	Traditional and complementary medicine
TRM	Traditional medicine
TTM	Thai Traditional Medicine
TT&CM	Thai traditional and complementary medicine
WHO-SEARO	World Health Organization, South-East Asia Regional Office

The regional meeting inaugurated by Dr Poonam Khetrapal Singh, Regional Director, WHO South-East Asia Region together with Dr Kang Ha Guk, Hon., Health Minister of Democratic People's Republic of Korea

1. Background

Traditional medicine has long been a popular source of care in the maintenance of health, and the prevention and treatment of disease – especially chronic disease – in countries in South-East Asia (SEA). World Health Organization (WHO) Member States have formally recognized that traditional and complementary medicine contribute to people's health and well-being, with the *Delhi Declaration on Traditional Medicine in 2013,* and the new global *WHO Traditional Medicine Strategy 2014–2023*. The goal of this strategy is "promoting the safe and effective use of traditional and complementary medicine through the regulation, research and integration of the products, practices and practitioners into the health system, as appropriate."

Health services are organized in many ways. In some countries, traditional and modern health services are practiced together at every level of the health system, governed by the same legislation and funded from similar sources of funds. In others, they are more separate. It means that traditional medicine (in SEA Region, the acronym TRM is used) has been integrated into national health-care systems in varying degrees. However, these different arrangements are not well documented, and the systematic monitoring and evaluation of traditional health services is limited. Questions such as who goes where for care, what health problems are being treated, what traditional medicines are provided, what are the results, how much do people spend, and how safe are TRM products and practices can be hard if not impossible to answer. This information is needed to formulate national policies, and appropriately finance, organize and manage TRM services.

This Regional workshop was designed to discuss practical ways to take this agenda further. The workshop brought together senior officials from both traditional and modern medicine with experts and researchers in the field. For the purpose of the workshop, **integration** of TRM with national health-care systems was defined as: *The organization and management of*

health services so that TRM and biomedical health-care services are offered so that people get the care they want and need in ways that achieve the desired results, are safe, sustainable and provide value for money.

2. Workshop objectives

The overall objective was to strengthen national capacity for appropriate integration of TRM with national health systems in SEA, and improve the knowledge base for TRM Specific objectives were:

- To share experience and knowledge about the integration of TRM into national health systems;
- To discuss current monitoring of TRM services availability, use, quality and safety;
- To agree on ways forward to improve monitoring and evaluation of TRM services as part of national health systems.

3. Workshop outcome: An action plan for the South-East Asia Region

The following five areas for action in the SEA Region were agreed upon. Consistent with the objectives of the WHO TRM strategy, these are to be implemented over the next five years.

3.1 TRM systems monitoring

WHO Member States to:

- Improve performance monitoring of TRM systems at all levels.

WHO to:

- Convene a task group to develop a minimum set of indicators, and associated definition.

3.2 TRM research

WHO Member States to:

- Encourage research on new developments in TRM, with a special focus on:
  - Noncommunicable disease management and the effectiveness and cost-effectiveness of combined modern and traditional therapy;
  - The impact of the modernization of TRM product processing, formulation and use; and
  - Combining modern diagnostics with TRM.
- Improve communication between policy-makers and researchers on the evidence base needed and available for TRM policy development.

WHO to:

- Support documentation of new developments in TRM, with a special focus on noncommunicable disease management, and on the impact of the modernization of TRM.
- Facilitate identification and dissemination of emerging research issues.
- Advocate for better communication between policy-makers and researchers.
- Develop policy briefs on emerging TRM issues.

3.3 TRM practitioners/TRM workforce

WHO Member States to:

- Foster greater understanding and mutual respect between traditional and modern practitioners through actions including: teaching on TRM during the basic training of modern medicine

practitioners, and vice versa; joint training facilities; and creating opportunities for joint policy discussion.

- Support the professional development of TRM practitioners by introducing mechanisms for career development and continuing professional development.
- Develop approaches to better identify the scale and practices of informal TRM practitioners, and use this information to develop policy.

WHO to:

- Encourage the documentation and exchange of country experience by addressing TRM practitioner/health workforce issues, through country case studies, intercountry exchanges and meetings.

3.4 Adverse events reporting

WHO Member States to:

- Share their experience in developing adverse event reporting systems, and share best practice within the Region.

WHO to:

- Support case studies that document how Member States developed their adverse events reporting systems.
- Prepare a briefing note on the WHO global adverse event reporting system based in the Uppsala Monitoring Centre, Sweden, and share with Member States.

3.5 Communication

WHO Member States to:

- Develop ways to better communicate the strengths and limitations of TRM to the general population, including the younger generation.
- Develop ways to improve communication between allopathic and traditional practitioners through joint activities.

WHO to:

- Facilitate the development of a regional TRM network, to exchange information and experience.

4. Summary of workshop proceedings

Inaugural session

In his welcome address, His Excellency Dr Kang Ha Guk, Minister of Public Health, Democratic People's Republic of Korea, said the workshop was an important forum to discuss further development of TRM in the South-East Asia Region. He noted achievements of TRM in Democratic People's Republic of Korea, particularly in Koryo medicine – for example, in research; standardization of Koryo medicine; and having TRM services available in all the health facilities. He emphasized the importance of integrated medical education for traditional and modern medicine. He highlighted the role and contribution of Information Communication Technology (ICT)in delivering TRM services. He said Democratic People's Republic of Korea was committed to intercountry cooperation on TRM, and hoped the regional workshop would be an opportunity to improve the efficacy, safety and quality of the TRM.

Dr Poonam Khetrapal Singh, WHO Regional Director, South-East Asia Region, spoke of the long and rich heritage of TRM in the Region, and its use by both rich and poor people. For example, Koryo TRM goes back more than 5 000 years. She mentioned that for some, TRM was still the

only source of health care. She noted the global commitment to strengthen traditional medicine as an integral part of health systems. She emphasized the importance of knowledge to help policy-makers frame sound national policies and regulations, and organize and manage TRM services. She hoped that the workshop would serve as an opportunity to share regional experiences about appropriate integration of TRM into national health-care systems, and ways to strengthen monitoring and evaluation. She reiterated WHO's commitment to support countries to strengthen the systems and services for TRM (see Annex 1 for full text).

4.1 Session 1: Setting the scene: Recent global and regional developments in traditional medicine

Dr Kim Sung Chol gave an overview of global and regional developments in TRM. He summarized information provided by workshop participants and results from the Second WHO Global Survey on TRM services, practitioners and resources. He noted that the number of governments working to integrate TRM with national health systems had increased between the first and second WHO Global Surveys on Traditional and Complementary Medicine. Issues and challenges identified during the session were as follows:

- Reliable information on number of users of TRM services remains limited, and it is often not well disseminated.
- Some degree of integration is common in many health systems in SEAR, but it is hard to judge actual levels of integration.
- Effective mechanisms to regulate quality and safety of TRM products remain a challenge. Regulating the education and training of TRM providers also continues to pose challenges.
- Relatively little attention has been paid to designing health services that facilitate the choice of the user between modern and TRM systems.
- Systems for monitoring and evaluation of TRM services with standard terminology commonly need strengthening.
- Government budgets for TRM services are reported to be small, while use by the public is reported to be high.

- More country-specific research is needed on TRM products, practices and service delivery models.

4.2 Session 2: What do we know about how TRM services are organized and managed in SEAR countries, and links with the modern health system?

The introduction by Dr Rachel Canaway noted that evidence shows there is no so-called one- size-fits-all model for TRM integration with national health systems in SEAR. Integration is also experienced at different levels: the consumer level, service level and system level. There are many barriers to integration, with a recurring one being trust between TRM providers and medical providers, which can prevent cross-referrals and cross-sector communication about patient treatment. Facilitators of integration include its cultural acceptance, strong leadership, advocacy, experience and political will, to ensure political and regulatory environments supportive of integration. Risks of integration were also discussed: treatment cost may increase (for example, when TRM practitioners are required to undertake further training and they subsequently increase costs for their services in keeping with their increased status); increasing modernization and standardization of products and practice can lead to loss of traditional knowledge and practice; and in some instances, marginalization of TRM practitioners when TRM knowledge or practices are co-opted by medical practitioners, or when practitioners of certain modalities of TRM are integrated into national health service delivery systems to the exclusion of others. Issues and challenges identified included:

- Terms and acronyms for traditional and complementary medicine, and its integration, are often used differently, which can be confusing. More consistent and comparable terminology and data collection between countries would be useful.
- Lack of research contributes to lack of understanding of TRM, its utilization, cost-effectiveness, outcomes and safety. This can lead to lack of understanding of why or how integration might or might not be beneficial.
- Although most Member States of the South-East Asia Region have infrastructure supporting integration of TRM with national

health systems (such as TRM regulation, government departments, offices, committees), it does not always follow that consumers can access or experience TRM within their local system of government-supported health service delivery.

Following this introduction, there were presentations on the organization and management of TRM services in Democratic People's Republic of Korea by Dr Jo Tu Jin, and on TRM data and research in Democratic People's Republic of Korea by Dr Cheo Tuk Ryong. An issue of particular note related to integration is that all Koryo medical students are taught modern allopathic medicine and vice versa. The presentation on research development highlighted the development of the Koryo Medical Service Support System, which consists of the Koryo Medical Doctor Support System, Self-Health Assessment/Estimation System, Koryo Medical Data Searching System and Consultation System, as well as modernization and standardization of Koryo herbal products.

Following these presentations, countries worked in groups to share knowledge and experience about integration of TRM with their national health-care systems, and similarities and differences among countries, and opportunities and challenges for greater integration. Outcomes of the group work are found in Annex 4.

4.3 Session 3: Regulation of traditional medicine products, practices and practitioners: challenges, opportunities, progress

A range of regulatory issues were covered. A global perspective was provided by Professor David Briggs, who reiterated that integration of TRM into mainstream health care requires a strong evidence-base including quality, safety and efficacy. He noted that most TRMs have long histories of use (field-testing) in humans, and this should be included when considering the evidence base for use of TRM products – supplementing research data and adding weight to claims of efficacy related to traditional use. He outlined the key elements of medicines regulation: setting standards for quality, safety and efficacy; applying the standards, and post-market activities (laboratory testing, adverse event reporting, compliance and good manufacturing practice (GMP) audits, advertising controls, and enforcing sanctions when standards are not met). He noted that a risk-based

approach to regulation ensures public health and safety while not imposing unnecessary regulatory burden and costs. Evidence on cost-effectiveness of TRM products is useful for decision-makers. The following issues and challenges were identified:

- To meet expectations that all medicines will be of good quality, safe, effective; and that regulation will be commensurate with risk and consistent with international practice. Governments should set, implement and enforce appropriate regulations, standards and guidelines.
- Assurance of safety and efficacy cannot be provided without assurance of quality. Most adverse events are associated with inadequate plant identification, poor manufacturing, contamination, substandard or incorrect preparation or dosage.
- On herbal medicines, their chemical complexity is a major challenge to developing practical specifications to better reflect therapeutic activity and safety. Herbal medicines can be affected by environmental factors leading to inconsistency in products. Methods used to process some herbs have moved from traditional methods, the resulting products (such as tablets, capsules, in place of decoctions) might produce a different compositional profile. In such cases, it might not be appropriate to rely on evidence of historical use to support safety of so-called modernized TRM.
- Interaction of TRM products with other medicines or foods requires further investigation. Investigation of clinically relevant interactions should be included in safety and clinical protocols.

This introduction was followed by examples of country experience. Recent progress on pharmacovigilance (PV) in India was presented by Dr Anupam Srivastava. He noted that adverse events can occur with Ayurvedic, Siddha and Unani (ASU) medicines. In India, the National Pharmacovigilance Programme for ASU drugs was launched in 2008, administered through the Institute for Post Graduate Teaching and Research in Ayurveda (IPGT&RA), Gujarat Ayurved University, Jamnagar. There are now eight regional PV centres and 30 peripheral PV centres across the country that report to the national PV centre. The national PV

programme is promoted through brochures, continuing medical education programmes, lectures and advertisements in journals. The website for online reporting is: www.ayushsuraksha.com. A key challenge is how to further increase awareness and use of PV reporting systems. This can be done, in part, by promoting a culture of information and data sharing. He noted that it would be helpful if WHO or another organization set up an exclusive drug reaction monitoring centre for herbal drugs.

Strategies to ensure quality and safety of TRM services in Thailand were presented by Dr Anchalee Chuthaputti. Thailand has 74 herbal medicine items in the national list of essential medicines, and traditional Thai practices are also provided in many hospitals and clinics. Standards known as TIPhS (Traditional and Integrative medicine Promoting Hospital Standards) were developed in 2008 (updated 2013) by the Department of Thai Traditional and Complementary Medicine to assess the quality of Thai TRM service in public health service facilities. The standards are in five areas: facilities, tools, equipment and premises; personnel; operation; quality control; and management. The standards are set according to the three levels of service provider: regional/general hospitals; community hospitals; and subdistrict (Tambon) health promotion station. Standards for operation and quality control are the same for all levels of providers. There is a scoring system and assessment is performed every two years; and certificates are given to facilities meeting the standards. In 2013 (most recent results), the majority of hospitals passed their assessment, but only half of the assessed health promotion stations met the standards.

Experience with implementing Good Agriculture and Collection Practice (GACP) and Good Manufacturing Practice (GMP) in Bhutan was then presented by Mr Dorjee Tshering. The Drug Regulatory Authority of Bhutan has adopted the Pharmaceutical Inspection Cooperation/ Convention Scheme (PIC/S) – two international instruments to guide GMP for medicinal products. About 300 ingredients are used (~90% plant origin) in the manufacture of TRM products in Bhutan. About 85% of raw plant materials are collected within the country. WHO guidelines for GACP are used. Prior to collection expeditions, the annual requirements for the plant are calculated, collection permits gained and a collection team is compiled, including experts in plant identification and quality, and people to sort, clean, dry, store and transport the plants. Manufacturing personnel are registered with the Drug Regulatory Authority of Bhutan and provided with regular training on quality policy, hygiene and GMP requirements. Quality

control is undertaken of raw and finished products through self-inspections and site inspections by the Drug Regulatory Authority. Systems are in place for Corrective Actions and Preventive Actions (CAPA) towards continuous quality improvement. Complaint and product recall systems are also in place (linked to the CAPA system). Issues and challenges identified were as follows:

- Ensuring the sustainability of raw materials in the wild.
- Overcoming the hesitancy of farmers to domesticate herbs as new crops.
- Lack of updated technology for herbal product processing and low volume of TRM product production due to limited capacity.
- Limited know-how for processing raw material to enhance its market value and enable greater profit sharing to the producing community.
- Inadequate funding in TRM research and development and intellectual property protection.
- Overcoming the limited scope to share and learn lessons from similar industries.

4.4 Session 4: Monitoring and evaluation of TRM systems: recent developments

The principles of TRM monitoring and evaluation were introduced by Dr Rachel Canaway. She noted that monitoring can increase safety and quality and inform best practice with regard to TRM integration with national health systems. Principles include ensuring that collected data are useful and useable; that data are of good quality and appropriately interpreted, synthesized and communicated. Using a framework to guide monitoring or evaluation helps to increase the consistency and comparability of collected data within and between countries. A draft monitoring framework to evaluate process and performance of TRM sectors was presented, which has been adapted from an established WHO monitoring framework and could form the basis for improved TRM monitoring and evaluation in the Region.

Key findings from a literature review were highlighted: there is high variety and diversity in TRM monitoring and information gathering systems in SEAR. Points for discussion included:

- The benefits of more data consistency and comparability in and between countries;
- How to increase awareness of the benefits of data sharing and dissemination;
- How to ensure that data are of adequate quality and useful for decision-making;
- How to increase TRM sector capacity for data analysis and interpretation;
- How to use data and associated research to identify best practices for TRM; and
- How to monitor private and informal TRM services in addition to the public sector.

A range of country experience was then presented. Dr Taranath Poudel spoke about monitoring of TRM services in Nepal. He noted that monitoring of TRM is undertaken by several offices: there is one responsible for services and facilities (Department of Ayurveda [DoA]), one for education and human resources (Nepal Ayurveda Medical Council [NAMC]), and others for products (DoA, Department of Drug Administration, and producers/importers departments of food and quality). The DoA regularly monitors use of TRM in the public sector via the Ayurveda Reporting System, which has 24 different forms. All private facilities should be registered, and every facility is required to keep treatment records. NAMC sets standards, approves academic institutions and registers practitioners. He reported that although a number of products have failed quality tests, there have been no reports of adverse events. Collected data are used only within the public service sectors, mostly only by collectors. Compiled data are used by health planners within the DoA. There are no specified mechanisms for dissemination other than a small amount in the annual report of national health. Higher-level authorities are

reluctant to study, analyse and use TRM data and information. Monitoring issues and challenges identified in Nepal included:

- Formalizing monitoring of informal sectors;
- Lack of technology and training of the health workforce for undertaking monitoring;
- Exclusion of TRM from the national health management information system;
- Lack of a research environment and continuing medical education programme;

This was followed by a presentation on real-time data collection in Thailand by Dr Anchalee Chuthaputti. The Department of Thai Traditional and Complementary Medicine has developed the TTM Health Script programme, a real-time data collection system to obtain data on Thai Traditional and Complementary Medicine (TT&CM) services at the provincial level using the existing 43-standard folder system of the Ministry of Public Health (MoPH) as a tool for monitoring and evaluation. The 43 items of information are digitally captured by the health-care provider and reported upward to a province level central database where it is used to generate performance reports and other information about TT&CM services. The data are also uploaded to a national central database within the Health Data Centre of the MoPH. Web-based portals for the real-time data are available from http://203.157.81.35/mis/ and http://203.157.35/pandora/ These programmes can be accessed on smart phones for ease of data collection and access. Data can be viewed by health service delivery levels and include information on patient age, gender, diagnoses, treatment, prescriptions, inpatient/outpatient, financing scheme, percentage of patients receiving TT&CM compared with total number of health facility visits, etc. There is also a database for the Health Data Centre for mainstream health care. One particular challenge identified was that a way has not yet been found to combine the TT&CM and mainstream medicine databases despite a MoPH policy to have only a single database.

Two studies in India to evaluate TRM treatments were presented by Dr P. M. Varier. These were on the use and effect of *Kalavasti* (Ayurvedic)

treatment for (1) intervertebral disc prolapse and (2) osteoarthritis in knees. Subjective patient symptom data were correlated with objective data from modern technological investigations (such as MRI, x-ray) and quality of life measures, to evaluate treatment efficacy. Most patients reported high levels of palliation after Ayurvedic treatment. The objective data, however, often indicated no physiological change to the disease. The studies concluded that Ayurvedic treatment can functionally benefit patients and that research on the effectiveness of Ayurvedic treatment should include evaluation of functional status.

At the close of day one, a session on Yoga for management of stress-free life was held by Dr Ishwar Basavaraddi, National Institute of Yoga, India. A brief yoga practice was followed by a presentation on the traditions, philosophies, scientific and traditional bases of yoga.

4.5 Session 5: Strengthening routine monitoring systems for TRM

In this session, participants had a more in-depth discussion about their own country monitoring systems, and what practical steps could be taken to improve monitoring of TRM over the next two years. Outcomes of the work of the three groups are provided in Annex 4.

4.6 Session 6: Strengthening the evidence on integration of traditional medicine with national health systems, to improve access to health services and health outcomes

This session aimed to stimulate a discussion about the type of research that would be useful to policy-makers on TRM systems and services. The key issues and research areas identified were as follows:

- The type of evidence needed by policy-makers is often not available or known about.
- There is a perception that researchers study their own areas of interest rather than those of policy-makers. Researchers could usefully enter into dialogue with policy-makers to understand their research needs. It is difficult to identify researchers with specialized knowledge in TRM.

- Policy-makers could usefully release more data into the public domain so they are accessible to researchers – it would facilitate dialogue with policy-makers.
- Greater understanding is needed on what types of knowledge related to TRM is best disseminated via continuing medical education programmes.
- There is lack of funding for research.
- Suggested priority areas for TRM research included:
  - noncommunicable diseases (including diabetes and cancer treatment);
  - heavy metals in TRM products (toxicity, safety, bioavailability);
  - appropriate use of modern diagnostic equipment such as MRI, ultrasound, x-ray by TRM providers, and evaluation of integrative (combined modern and TRM) treatments for various disorders;
  - effects of modernization of TRM practices and products on their safety and efficacy;
  - context-specific evidence around best governance of TRM;
  - cost-effectiveness of TRMs, particularly compared with modern medical treatment;
  - qualitative research on consumer/patient treatment preferences.

There was some discussion about how to promote more research: for example, through the development of short- and long-term national research strategies – with relevant research and ethics committees in each country and lists of priority research areas. Thailand noted that a research strategy had been developed through an initial forum to explore ideas, which then led to a 5–10 year research strategy based on results from the forum.

4.7 Sessions 7 and 8: Strengthening TRM systems as part of national health systems in SEA Region: agreeing on practical next steps

These sessions discussed and made more explicit some of the major emerging themes from the meeting that require further action. The five themes identified were:

(1) Monitoring of TRM systems

(2) Research on traditional medicine

(3) Health workforce

(4) Adverse event reporting

(5) Communication and sharing of information

Monitoring of TRM systems

The discussion reinforced points made in earlier sessions that monitoring of TRM needs to occur at all levels – central, provincial and local. Monitoring and evaluation of TRM can be complicated because there are unresolved issues around terminology. Simplified, standardized terminology in the TRM sector is needed, consistent with terminology used within the mainstream (allopathic) medical sector. In terms of monitoring TRM products, practices and practitioners, there is need to determine the minimum dataset that should be collected. More consideration is also needed on whether and how information should or could be captured about the private sector and on folk/local healers. An example of monitoring and registering local healers in Thailand was provided.

Thailand's system for registering traditional folk healers: The Thai system for registering folk healers is aimed at capturing data on folk healers who work for the community, charging small fees, and are well respected within their community. A healer recognized by their community as someone worthy of registration is nominated by a community member or organization. A government official then visits their practice to evaluate them as per criteria so that they can become licensed. To accommodate this, change was made to the Thai law on TTM practice so that this group of practitioners could be recognized. Such folk healers are not equipped to

take a written examination, so the system has accommodated them in other ways to achieve licensing.

Research on TRM

Further elaboration of areas in need of research included:

- Clinical and case management research, particularly around TRM or combined TRM and modern medicine therapies for noncommunicable diseases (NCDs), and also use of modern diagnostic techniques (for example, the use of MRI in India alongside traditional Indian medicine therapies).
- Research to generate greater knowledge about TRM modernization, which leads to new pathways of care through new production processes, formulations and use. Reliance on safety and efficacy information, based on historical use, is not necessarily relevant to modernized TRM. There is a need to establish whether modern forms of production and use adversely effected safety, efficacy or therapeutic indication of TRM products.
- Research on cost-effectiveness of TRM alongside western medicine. If TRM is to be acknowledged within a national health system where money available for health is restricted, the TRM must be cost-effective. Modern production of some TRM products makes them as costly as modern pharmaceuticals.
- More research is needed to inform health policy-makers of decisions around TRM use and integration with national health systems.

Health workforce

Given that mutual respect between modern and TRM workforces is essential to facilitate integration, ways of fostering mutual respect and integration were discussed. These included:

- constitutional or government recognition of equal status between TRM and modern medicine systems – for example, Bhutan and Democratic People's Republic of Korea;
- equal status between tertiary educational institutions for TRM and modern medicine;
- TRM practitioners undergoing a similar education process to practitioners of modern medicine;
- TRM workforces further professionalize to gain more equal status with modern medicine; and
- greater career development for TRM workforces, including greater opportunity for more TRM practitioners to work in policy and advocacy positions in government.

It was also suggested that if TRM personnel have good coordination and mutual understanding with the government, then better integration will occur. For example, in Bhutan, modern medicine personnel have greater career development due to their higher education and involvement in research, despite equality in the Constitution between TRM and medical systems. Concerns were voiced that modernization of TRM can mean it loses its authenticity, yet at the same time TRM should make use of advances in modern equipment for product production, diagnosis and treatment so that TRM professions can advance in terms of safety, efficacy and patient outcomes.

Adverse event reporting

Most countries have systems for adverse events reporting, but they are not necessarily well functioning or adequately followed up. Some countries with well-developed cultures and systems of adverse events reporting and monitoring would like greater protocols to share information between countries; particularly information on developing systems of pharmacovigilance and monitoring; what has worked and what has not. More sharing of information is needed between countries. There is no doubt that adverse events reporting should be done, the question is how it is best done. Training TRM students to recognize, document and report adverse events is essential to foster a culture of adverse events reporting.

India and Thailand agreed to do case studies on their systems of pharmacovigilance – including education of consumers to report suspected adverse events, and training of personnel to take quality case histories from consumers. Other case studies could be useful to help identify deficiencies in pharmacovigilance systems and how they might be overcome.

There are many aspects to consider around pharmacovigilance systems, including mandatory reporting, to where consumers should report data, how reported data are handled, what to do when an adverse event is confirmed, and on how the product is analysed. It was noted that most adverse events among TRM products are the result of contamination, adulteration, misidentification or nontraditional use. The establishment of a network for TRM adverse event reporting was discussed. It was considered that it would be prudent to first make better use of the WHO Programme for International Drug Monitoring in Uppsala, Sweden (the Uppsala Monitoring Centre, a WHO Collaborating Centre).

Communication and sharing of information

Communication and sharing of information is related to mutual respect within and between health-care sectors. Information production and sharing is needed on the following: for example, new models of delivering services; models and examples of integration of TRM into health systems; establishing well-functioning pharmacovigilance systems; research and policy-relevant information. It was suggested that a multi-purpose network – or forum for continuing exchange – for SEAR Member States should be established to facilitate the sharing of information on what has worked and what has not, relating to all aspects of TRM – as the above point expanded. It was also agreed that communication to and education of the general population is also essential to facilitate TRM integration with national health systems, and that communication is needed to improve relationships and standing between TRM and allopathic practitioners (to increase mutual respect).

The meeting closed with agreement on an action plan covering these five areas, with actions identified for Member States and WHO. This action plan can be found in Section 3 of this report.

Annex 1

Address by Dr Poonam Khetrapal Singh, Regional Director, WHO South-East Asia Region

Your Excellency, Dr Kang Ha Guk, Honorable Health Minister of Democratic People's Republic of Korea; Dr Pak Jong Min, Director of External Affairs Department, Ministry of Public Health; Dr Jo Tu Jin, Director, Koryo Traditional Medicine Guidance Department; Distinguished Participants,

Ladies and Gentlemen,

A very good morning!

It is always a great pleasure to be here in this country. Although I have been here before, this is my first visit since I was appointed the Regional Director for WHO's South-East Asia Region. I would like to thank the Government of Democratic People's Republic of Korea and the Ministry of Public Health for giving me the opportunity to be here today. More importantly I am very happy to be here today to open the Regional workshop on the appropriate integration of traditional medicine into national health-care systems.

This is an important meeting. The countries of South-East Asia have a long and rich heritage of traditional medicine. It is widely used by both rich and poor people alike. In many countries, about 45% to 85% of people use some form of traditional medicine to treat their health problems. And for some, this is their only source of health care. Dr Margaret Chan, WHO's Director General, noted at the International Forum on Traditional Medicine that "Modern medicine and traditional medicine make unique contributions to health". Strengthening traditional medicine in the countries of our Region is consistent with WHO's policy to promote integrated and balanced health-care systems in harmony with the country's socio-cultural environment and health needs.

Therefore, there is no place better suited to hold this meeting than here in Pyongyang. This country has a traditional medicine practice, the Koryo Traditional Medicine that goes back more than 5 000 years. And the country has set up universities, specialized training institutes, pharmaceutical establishments, and research facilities to build on their rich traditional heritage and to promote and strengthen the Koryo traditional medicine practices in the country.

Likewise I am happy that other countries are here too. All our countries have rich traditions and vast experiences in providing medical care, especially traditional medical care. There is an increasing global attention and commitment to strengthen traditional medicine as an integrated and holistic part of health systems in countries to deliver on the goal of Universal Health Coverage or UHC. UHC means all people getting the care they need, without suffering financial hardship. Frontline – or primary care – services are central to improved access to care. As I have said before, traditional medical practitioners remain the main primary health-care providers for millions of people in South-East Asia, especially in rural areas. Moreover, chronic diseases are increasingly common as our population age. Traditional medicine has a long history in the prevention and treatment of chronic disease. These developments are putting more attention on traditional medicine.

This workshop takes forward several recent political commitments. At our WHO South East Asia Regional Committee in Dhaka last year, ministers discussed the new WHO traditional medicine strategy, adopted by the World Health Assembly in May 2014. The ministers reiterated their support for the two important goals of the traditional medicine strategy, namely: harnessing the contribution of traditional medicine to health, wellness and people-centred care; and promoting safe and effective use of TRM by regulating, researching and integrating TRM products and practitioners into national health systems where appropriate.

In the resulting Regional Resolution of the 67th Regional Committee, countries committed to implement the new WHO global traditional medicine strategy, and to continue the regional cooperation enshrined in the Delhi Declaration on Traditional Medicine of 2013. This Region is far ahead in some aspects. For example, almost all countries now have national TRM policies, which is an important element of the new global strategy.

Policy-makers need timely and relevant knowledge to help them frame sound national policies and regulations, and organize and manage traditional medicine services. Moreover, all health care must be safe, effective and affordable. Traditional medicine services in our Region are organized in many ways. In some countries, traditional and modern health services are provided together at every level of health system. In others, they are more separate. There is much experiences to share among countries and there is also a lot of effort needed to document and disseminate best practices.

This means evidence is often not available to domestic decision-makers, and those in other countries. There remains a real need to better document who is using TRM services and for what health conditions; how services are organized, financed and regulated, and the costs and benefits. This meeting focuses specifically on exchanging information on different approaches to the organization, management and monitoring of TRM services, and what we know about how well they are working. The posters up around the room bear testament to your readiness for this.

We have invited both traditional and modern medicine professionals to this workshop, as each has much to offer to enrich the discussions in the next few days. I believe the workshop provides an excellent opportunity to share regional experience about appropriate integration of traditional medicine into national health-care systems, and ways to strengthen monitoring and evaluation. I hope you will be able to come out with some agreed concrete and practical action plans to be taken by governments and other key stakeholders. As WHO, I reiterate our commitment to support countries in whatever manner possible to promote the use of traditional medicine and to help strengthen the systems and services for traditional medicine.

I wish you all success in your deliberations, and a very pleasant stay here.

Annex 2

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Annex 3

Agenda

(1) Opening

(2) Recent global and regional developments in traditional medicine

(3) Organization and management of TRM services in SEAR countries, and links with the modern health system

(4) Regulation of traditional medicine products, practices and practitioners: challenges, opportunities, progress

(5) Monitoring and evaluation of TRM systems: recent developments

(6) Strengthening routine monitoring systems for TRM

(7) Strengthening the evidence on integration of traditional medicine with national health systems to improve access to health services and health outcomes

(8) Strengthening TRM systems as part of national health systems in the South-East Asia Region – agreeing on practical next steps

(9) Develop regional action plans for Member States and WHO

(10) Closing

Annex 4

Outcomes of group work in sessions 2 and 5

Session 2: What do we know about how TRM services are organized and managed in SEAR, and links with the modern health system?

Objectives of session 2 group work

- To better understand how TRM is managed and delivered within SEAR countries, and its place in relation to established systems of modern medicine.
- To share experience and knowledge about integration of TRM with national health-care systems.

Participants worked in three groups arranged by country to discuss their country's similarities and differences in TRM service organization and management. Tables 2 and 3 from the background document were provided to facilitate discussion. A group representative reported back on similarities and differences in terms of integration and supporting infrastructure, and opportunities and challenges of integration. The outcomes of the group work were as follows:

Group 1: India, Nepal and Indonesia

The process of integrating TRMs into national health-care delivery systems is well underway in India, Nepal and Indonesia, where there is a growing demand for TRM and also regulatory infrastructures are in place for monitoring safety, quality and effectiveness of TRM. Notable differences among these countries were in the degree of regulation and its implementation. It was considered that greater integration would enable: achieving Universal Health Coverage within a shorter period of time;

greater address of the problem of chronic and noncommunicable disease; and greater affordability of health care and TRM. Challenges for integration included integrating modern science to strengthen and upgrade TRM knowledge; increasing government expenditure on TRM; building TRM practitioner knowledge; and addressing problems where some systems of service delivery level integration lead to TRM practitioners having to practise modern medicine.

Group 2: Bhutan, Democratic People's Republic of Korea, Sri Lanka

Most elements of supporting infrastructure were similar between Bhutan, Democratic People's Republic of Korea and Sri Lanka, although Democratic People's Republic of Korea was more comprehensive in its TRM National Advisory Committee and TRM regulations. TRM treatment guidelines were considered an area for urgent attention. A notable difference in terms of integration was that in Sri Lanka and Bhutan, TRM practitioners cannot practice allopathic medicine and vice versa, whereas they can in Democratic People's Republic of Korea. Opportunities for further integration included: educating and creating awareness about both sectors within and between providers/stakeholders; having TRM and biomedicine under the same government ministry to facilitate conducting common reviews and using common monitoring mechanisms; and focusing on the increased demand for preventive and cosmetic aspects of TRM. Challenges for integration include: achieving regulatory compliance for providers and products; gaining mutual understanding and respect between stakeholders in both sectors; and the difficulty in developing common standards due to the diversity of TRM sectors between Member States.

Group 3: Myanmar, Thailand and Maldives

Notable similarities in supporting infrastructure were around policy and treatment guidelines. Notable difference were around pharmacopoeia (the Maldives does not have this), health insurance (Thailand has this, Myanmar is about to have this, but Maldives does not) and the essential medicine list (only Thailand has this). There are new developments in integration in that Thailand has new service plans and Myanmar provides combined TRM and allopathic therapy for diabetes mellitus and for drug resistant tuberculosis. Further opportunities for integration were considered to be integrating TRM knowledge into basic training of other health-care personnel, and

integrating TRM services into national service plans. The greatest challenges for TRM integration into national health systems were ensuring adequate number and quality of TRM practitioners, quality of TRM products, and overcoming beliefs within TRM profession, which reject greater TRM integration.

Session 5: Strengthening routine monitoring systems for TRM

Objective of session 5 group work

- To share experiences and knowledge with regard to current country mechanisms for monitoring and evaluation of TRM services

Participants worked in the same three groups as in Session 2 to discuss TRM data collection in their country. A group representative then reported back to everyone including on what practical steps could be taken to improve monitoring of TRM over the next two years. Figure 2 and Table 4 in the background document were used to facilitate the discussion. The outcomes of the group work were as follows:

Group 1: India, Nepal and Indonesia

Referring to the table, most data areas were monitored. The most important monitoring gaps were private sector information and healers who are outside of any official system of health service delivery. Practical steps to improve monitoring included: developing an integrated reporting system; increasing budgets for monitoring; including private sector monitoring; standardization of terms to enable shared understanding of the parameters and content of data collection (need to capture the right data); and specific to India, having the Central Drug Controller separated from AYUSH and the Central Council for Paramedics also separated.

Group 2: Bhutan, Democratic People's Republic of Korea, Sri Lanka

Between the three countries, TRM sector data was collected at different intervals. Bhutan and Democratic People's Republic of Korea undertook the same reporting for TRM as for modern medicine. Data were used by service providers as well as by government departments. A notable gap was that Democratic People's Republic of Korea and Sri Lanka do not publish a routine annual health report to more broadly disseminate collected data; such annual, routine publication would be beneficial. It was noted that TRM treatment for inpatients is not captured in Bhutan. To improve systems of monitoring and data collection, it was agreed that: better use should be made of information and computer technologies because currently, all three countries dealt in hard copies of collected data; better use could be made of data for planning (HR, budgeting, infrastructure, equipment, medicines); and it would be useful to establish a forum for learning – to share best practice information among Member States of South-East Asia Region with annual workshops, exchange personnel and study visits.

Group 3: Myanmar, Thailand, Maldives

Between the three countries, there was great variance in frequency and extensiveness of data reporting, how it was reported and to what authority. Commensurate with the little use of TRM in the Maldives and scarcity of TRM practitioners, there is no public TRM sector. The greatest gaps in data collection identified were that Myanmar and Thailand do not collect private sector data; little is collected or known about TRM product efficacy; and Thailand requires more information for monitoring and evaluation from the University Hospital from Bangkok (which is outside of the main data-capture region), and lacks a TRM specialist workforce. Suggestions for possible steps to remedy the gaps included the establishment of National Boards of TRM consisting of many stakeholders; negotiate with private service providers to facilitate monitoring and evaluation; and greater use of information and computer technologies for monitoring and evaluation of TRM sectors.