Meeting Report

MEETING ON STRENGTHENING QUALITY ASSURANCE OF TRADITIONAL MEDICINES

1–3 March 2017
Seoul, Republic of Korea

World Health Organization
Western Pacific Region

WORLD HEALTH ORGANIZATION

REGIONAL OFFICE FOR THE WESTERN PACIFIC

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NOTE

The views expressed in this report are those of the participants of the Meeting on Strengthening Quality Assurance of Traditional Medicines and do not necessarily reflect the policies of the conveners.

This report has been prepared by the World Health Organization Regional Office for the Western Pacific for Member States in the Region and for those who participated in the Meeting on Strengthening Quality Assurance of Traditional Medicines in Seoul, Republic of Korea from 1 to 3 March 2017.

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KEYWORDS: Medicine, Traditional – standards / Health policy / Health services

SUMMARY

Traditional medicines are extensively used in Member States of the Western Pacific Region. Thus, ensuring quality and safety of traditional medicines is critical to achieve universal health coverage in the Region. It is also one of the key objectives of *The Regional Strategy for Traditional Medicine in the Western Pacific Region (2011–2020)*.

Traditional medicines are produced by the manufacturing business or practitioners and dispensers. Furthermore, traditional medicines consist of various natural sources such as plants, minerals and animal-based materials. Thus, quality assurance of traditional medicines is very challenging even in Member States that have established regulatory systems for traditional medicines.

In order to address these challenges, WHO convened the Meeting on Strengthening Quality Assurance of Traditional Medicines in Seoul, Republic of Korea from 1–3 March 2017. Participants came from Cambodia, the Lao People's Democratic Republic, Mongolia, the Philippines and Viet Nam: one participant from each country who is responsible for the overall traditional medicine policy and another who is responsible for regulations for traditional medicines.

The objectives of the meeting were:

1) to share key components of quality assurance systems for traditional medicines with consideration of close linkages between traditional medicine products, practitioners and dispensers;
2) to analyse quality assurance systems in the countries and identify gaps and priority areas in the current system; and
3) to develop each participating country's implementation plan to strengthen quality assurance for traditional medicines.

The meeting participants identified gaps and substantial challenges in the current quality assurance systems in the countries as well as priorities to ensure quality of traditional medicines. In large-scale production of traditional medicines, registration, quality control and post-marketing surveillance were identified as common key focus areas for the regulatory authorities. For registration, the development of standards to measure effectiveness as well as clear registration requirements and processes are critical. Discussions emphasized the need for a risk-based approach to quality control and post-marketing surveillance.

In small-scale production of traditional medicines, regulation of traditional medicine practitioners through registration or licensing is essential to ensure quality and safety of traditional medicines produced by practitioners. Furthermore, development of standards of their practice including production of their own medicines, documentation of their practice to monitor their practice, and regulation on the facilities where they practice and produce traditional medicines were identified as key strategies to regulate practitioners.

Based on information shared among the participants and two panel discussions, the participants developed action plans to tackle key challenges in their respective countries. In addition, agreement was achieved on common key aspects for quality assurance system for traditional medicines: a) careful and sustained documentation of use; b) elimination of contamination and adulteration; and c) monitoring and pharmacovigilance.

Member States are encouraged to consider the following:

1) to collect information on current traditional medicine practice and use of traditional medicine and assess role of traditional medicine in the national health system;
2) to strengthen the quality assurance system including registration, laboratory capacity for quality control, documentation or development of pharmacopoeia and post-marketing surveillance for traditional medicines produced in large scale; and
3) to establish or strengthen regulatory system for traditional medicine practitioners and establish standards for their practice for traditional medicines produced in small scale.

WHO will:

1) facilitate information sharing on current regulatory practices for traditional medicine among Member States in the Region;
2) provide technical support in developing and implementing regulations on traditional medicines and traditional medicine practitioners;
3) provide support in strengthening the national laboratory experts' capacity for quality control of traditional medicines through hands-on laboratory training programmes; and
4) provide support in establishing or improving post-marketing surveillance and pharmacovigilance with medicines and vaccines.

1. INTRODUCTION

1.1 Meeting organization

Traditional medicines are widely used in the Western Pacific Region. It is often first-line therapy for a variety of health problems ranging from minor ailments to life-threatening diseases in countries and areas of the Region. To achieve universal health coverage[1], ensuring the safety, quality and effectiveness of traditional medicines is very critical.

Traditional medicines are often produced and prepared by individual practitioners and dispensers or produced by the manufacturing business. In the Western Pacific Region, many Member States have established regulatory system for traditional medicines and traditional medicine practitioners. Cambodia, the Lao People's Democratic Republic, Mongolia, the Philippines and Viet Nam are countries where traditional medicines are extensively used. They have established regulatory systems for traditional medicines, but are facing many challenges. These Member States have provided strong directions and commitment to regulate and ensure the quality and safety of traditional medicines. Furthermore, recognizing the role of traditional medicine practitioners in the health-care system and the importance of ensuring the safety and quality of their services, there are also ongoing efforts in these countries to establish or improve regulatory systems for traditional medicine practitioners. However, there are still quality and safety issues surrounding traditional medicines, such as unhygienic production by the practitioners and dispensers, misidentification, adulteration with pharmaceuticals, contamination with heavy metals or pesticide residues, and limited control of advertisement.

To tackle the major quality issues, the overall quality assurance system for traditional medicines produced by the manufacturing business and by the practitioners and dispensers needs to be strengthened. In consideration of these challenges and ongoing efforts, a meeting was held in Seoul, Republic of Korea on 1–3 March 2017 to discuss strategies and action plans to strengthen the quality assurance system for traditional medicines in the participating countries. Representatives from Cambodia, the Lao People's Democratic Republic, Mongolia, the Philippines and Viet Nam attended the meeting: one participant from each country who is responsible for the overall traditional medicine policy and another who is responsible for regulations for traditional medicines. The programme of activities and list of participants are available in Annexes 1 and 2, respectively.

1.2 Meeting objectives

The objectives of the meeting were:

1) to share key components of quality assurance systems for traditional medicines with consideration of close linkages between traditional medicine products, practitioners and dispensers;
2) to analyse quality assurance systems in the countries and identify gaps and priority areas in the current system; and
3) to develop each participating country's implementation plan to strengthen quality assurance for traditional medicines.

[1] Universal health coverage (UHC) is defined "as all people having access to quality health services without suffering the financial hardship associated with paying for care" (WHO. Universal health coverage: moving towards better health. Manila: WHO Regional Office for the Western Pacific; 2016).

2. PROCEEDINGS

2.1 Intercountry workshop

Dr Yu Lee Park introduced the objectives of the intercountry workshop: to understand key challenges and issues and analyse their root causes for large-scale and small-scale production of traditional medicines in each country through a mapping exercise, which served as the basis for discussion. She briefly explained that large-scale production referred to production by manufacturing factories such as pharmaceuticals and small-scale production meant production by individual practitioners or dispensers.

Based on group work and discussions during the workshop, each country shared information on their current situation and issues as follows:

Cambodia

Traditional medicines in Cambodia can be categorized into two categories: a) traditional medicines imported mainly from China, Malaysia and Viet Nam, and b) traditional medicines produced at home-based facilities or in homes.

The country has a national policy and a strategic plan on traditional medicine. Legislation for traditional medicines is also in place. Current regulations cover production, import, export, selling, registration and advertisements of traditional medicines. Three government agencies implement these regulations. The National Center of Traditional Medicine is in charge of overall policy and regulation of traditional medicine and training for the practitioners. The Department of Drugs and Food is responsible for regulation of traditional medicines, and the National Health Products Quality Control Center is responsible for laboratory testing for traditional medicines.

One critical issue that the regulatory authorities are facing is regulation of traditional medicines produced by individual practitioners and dispensers at home-based facilities or in homes. Thus, there are ongoing efforts to develop a subdecree on traditional medicine practitioners to improve the quality and safety of traditional medicines produced by them.

Laboratory testing for traditional medicines is another key issue in Cambodia. Importers should provide evidence of laboratory testing for the products, and the National Health Products Quality Control Center is requested to verify it. However, due to limited technical capacity and lack of testing equipment, laboratory testing is limited to identification and microbial testing. Lack of information on standards for quality control is also an important cause of this issue.

Lao People's Democratic Republic

The Ministry of Health issued a national policy on the promotion of traditional medicines in 1996, and the Lao National Strategy for Traditional Medicine 2012–2015 is in the process of revision based on national consultations. Furthermore, there are regulations on traditional medicines covering manufacturing, import, export, registration, selling and biodiversity management.

Traditional medicine services are provided at traditional medicine departments in 3 central hospitals, the Institute of Traditional Medicine, and 12 traditional medicine stations or units located in 12 provinces. However, there is no regulatory system for traditional medicine practitioners. Recognizing the importance of regulating the practitioners, the Government is trying to establish a regulatory

system for the practitioners. Academic training on traditional medicine at the university level started in the Faculty of Pharmacy, University of Health Sciences in 2017.

In charge of traditional medicines at the Ministry are the Traditional Medicine Division in the Food and Drug Department for regulation of traditional medicines, the Traditional Medicine Management Division in the Health Care Department, and the Institute of Traditional Medicine for research on medicinal plants and Lao traditional medicine.

According to current regulations, registration requirements and processes are the same for both pharmaceuticals and traditional medicines. As of 2015, 135 imported traditional medicines and 89 local traditional medicines have been registered. However, the implementation of the regulations on locally produced traditional medicines is challenging. There are two manufacturing facilities that produce traditional medicines, but their capacity is too limited to meet good manufacturing practice (GMP) standards and register their products. Since the ASEAN Guidelines on Claims and Claims Substantiation for Traditional Medicines and Health Supplements were adopted, the Food and Drug Department has tried to adopt the guidelines for the registration of locally produced traditional medicines. Improving the technical capacity of regulators to evaluate evidence will be important in implementing the guidelines.

In regard to quality control, the national laboratories are facing challenges including limited technical capacity and lack of testing standards. Continued support to improve the technical capacity of laboratory experts will be critical.

Post-marketing surveillance is conducted based on complaints reported by consumers and regular monitoring by the Food and Drug Department twice a year. However, it depends on budget. Regular quality and safety monitoring is also an important issue.

Mongolia

The first national policy on traditional medicines, approved by the Mongolian Parliament in 1999, provides the legal basis for developing traditional medicines in Mongolia. The Government has also developed the National Traditional Medicine Development Programme (2010–2018) and strategies (2016–2020) for implementation of the policy. The Law on Medicines and Medical Devices covers traditional medicines. According to the Law, both imported and locally produced traditional medicines should be registered. The imported products are mostly from China and India. The registration requirements were revised in January 2015. There are seven manufacturing factories producing traditional medicines, but none of them meet GMP standards.

According to the Medicines Law, the health workforce is composed of western medical doctors, traditional medicine doctors, dentists, nurses, and midwives. The Ministry of Health and Sports provides licenses for traditional medicine doctors and traditional medicine nurses. To obtain a license, the traditional medicine doctors need to complete six years of medical education at the university level and pass the licensing examination.

Within the Ministry of Health and Sports, the Department of Health Policy Implementation is responsible for overall policy implementation for traditional medicines, and the Department of Medicines Policy is in charge of regulation of traditional medicines. The Ministry of Education, Culture and Science is responsible for education of traditional medicines at universities and colleges.

Challenges in implementing the policy include lack of budget, limited standards of traditional medicine practice, lack of postgraduate training and absence of post-marketing surveillance.

Philippines

There are regulations on traditional and complementary medicines that cover production, advertisement and adverse event reporting. The Traditional and Alternative Medicine Act of 1997 also provides a legal basis to regulate traditional and complementary practices and practitioners.

There are two government agencies in charge of traditional and complementary medicine in the Philippines: the Food and Drug Administration for regulation of the products and the Philippine Institute of Traditional and Alternative Health Care (PITAHC) for regulation of the practitioners and research.

Registration requirements for traditional and complementary medicine products are different for herbal medicines and traditionally used herbal products. For herbal medicines, scientific evidence including clinical trials is required for registration. On the other hand, historical evidence such as documentation on historical use for five or more decades or three generations can be used for registration of traditionally used herbal products. There are also ongoing efforts to implement ASEAN Guidelines on Claims and Claims Substantiation for Traditional Medicines. Control of advertisement is a challenging issue.

Regulatory systems for traditional and complementary medicine practitioners are in the process of development. There is currently only a certificate system for the practitioners, and PITAHC is trying to develop standards for each practice and qualifications for the certificate. Lack of legal authority of PITAHC is a key barrier in the implementation.

Viet Nam

In principle, the Pharmaceutical Law covers both pharmaceuticals and traditional medicines. There are also guidelines on GMPs, good agricultural and collection practices (GACP), good laboratory practices (GLP), good clinical practices (GCP), and good supply/distribution practices (GSP/ GDP) for traditional medicines.

The Traditional Medicine and Pharmacy Administration Department in the Ministry of Health is responsible for the development of legal documents, traditional medicine policy and strategy, and regulation of professionals. Traditional medicine divisions in the provinces, traditional medicine units in the districts and pharmaceutical councils of hospitals are in charge of regulation of traditional medicines. The National Institute of Drug Quality Control is responsible for laboratory testing.

One key issue is that the registration process for traditional medicines is not clear. Furthermore, there are no clear standards in the current regulations to differentiate traditional medicines from food supplements. Local manufacturing factories produce both pharmaceuticals and traditional medicines, and adulteration of traditional medicines with pharmaceuticals often occurs.

Viet Nam has established a regulatory system and six-year education system at the university level for traditional medicine practitioners. However, the qualifications of traditional medicine practitioners need to be reviewed and improved. The Government has recently developed a policy to integrate up to 40% of traditional medicine services into national health-care services by 2020. Prerequisites for implementation of this policy will be qualified traditional medicine practitioners, standards for integrated service delivery and clearly defined scope of practice of practitioners.

Based on country situation, there were discussions on the following key issues:

- Imported traditional medicines: recognition of registration categories in country of origin

In regard to imported traditional medicines, whether the regulatory authorities follow registration categories such as food supplements or medicines is one of the key issues discussed. Dr Alice Wong explained that the Department of Health, Hong Kong SAR (China), evaluates the products and claims based on their own standards, regardless of whether the products were registered as food supplements or medicines in the countries of origin. Representatives from Cambodia, the Lao People's Democratic Republic and the Philippines also mentioned that they evaluate evidence documents submitted by importers and follow their own regulations for registration of imported products rather than accept the registration status of the products in the country of origin. Viet Nam has an agreement with China to recognize the registration of selected traditional medicines produced and registered in China.

For this, the extent to which information for registration of the products can be shared with other countries became a subsequent subject of discussion. Dr Wong mentioned that Hong Kong SAR (China) can provide only publicly accessible and available documents since other supporting documents are often regarded as trade secrets. The Forum for the Harmonization of Herbal Medicines is currently trying to exchange information on their own pharmacopoeia, share new laboratory testing methodologies and develop reference materials that can be shared among members. At the end of the discussion, the importance of collaboration among countries to improve the quality and safety of imported products was highlighted. Furthermore, it was emphasized that regulatory convergence and information sharing do not intrude on a country's sovereignty.

- Laboratory testing and safety monitoring

The parameters for laboratory testing of traditional medicines depend on the national laboratory capacities in countries. For instance, Cambodia conducts microbial tests, the Lao People's Democratic Republic tests for pesticide residues and heavy metals, and the Philippines conducts microbial, pesticide residues and heavy metals tests. According to Dr Wong, approximately 605 selected herbal medicines and proprietary Chinese medicines are tested for post-marketing surveillance in Hong Kong SAR (China). For herbal medicines, the products are randomly sampled from retailers or wholesalers, and tests are required for identification, pesticide residues, heavy metals and microbials. For proprietary Chinese medicines, tests for adulteration with pharmaceuticals, pesticides, heavy metals and microbials are mandatory.

The participants agreed on two important aspects for the regulatory authorities to consider for safety monitoring and laboratory testing. In terms of safety monitoring, regulators need clarity about what they should regulate, what capacity they need, what the potential adverse events may be and what they should monitor. In terms of laboratory testing, it would be more important to place stronger focus on testing parameters for product safety in resource-poor environments.

2.2 Opening session

Dr Socorro Escalante welcomed the participants to the meeting and delivered the opening address on behalf of Dr Shin Young-soo, WHO Regional Director for the Western Pacific (Annex 3). In the opening address, Dr Shin highlighted the significant role of traditional medicine in primary health care in the Region and the importance of strengthening quality assurance systems for traditional medicines to achieve universal health coverage. He acknowledged the efforts to establish and improve regulatory systems for traditional medicines and traditional medicine practitioners in Cambodia, the

Lao People's Democratic Republic, Mongolia, the Philippines and Viet Nam. To achieve this common goal, Member States were encouraged to exchange information and cooperate for development of evidence-based policy.

2.3 Session 1: Key components of the quality assurance system for traditional medicines

Dr Socorro Escalante gave a presentation on quality assurance of medicines. She introduced the framework and ultimate goals of access to medicines. She clarified the definitions of quality assurance and quality control: quality assurance is a broader and systematic process to ensure the quality and safety of medicines, while quality control is the part of the quality assurance process that specifically focuses on testing. She explained the importance of quality assurance, its critical elements, and how it can be implemented and by whom. Quality assurance can cumulatively result in significant benefits at the point when patients take the medicines. All the elements and tools for quality assurance of medicines can be applied to traditional medicines too: registration, manufacturing, product quality, distribution and supply, information and advertisement, post-marketing, and pharmacovigilance. In traditional medicines, control of labelling and advertisements is important to ensure their appropriate use by practitioners and consumers.

Dr Yu Lee Park presented the WHO strategy for the quality assurance of traditional medicines. She noted that ensuring the quality, safety and effectiveness of traditional medicines and promoting their safe and effective use are essential to the integration traditional medicine in national health-care systems. She introduced various WHO guidelines on quality assurance of traditional medicines according to the quality assurance cycle. With regard to key quality and safety issues for the large-scale production of traditional medicines in the Region, she pointed out: defining the scope of traditional medicines to be regulated and categorization of traditional medicines for registration; risk-based approach depending on criteria such as ingredients, dosage form, claims and adverse reactions; and laboratory testing and post-marketing surveillance. In terms of small-scale production, key issues include limited baseline information on current practices, lack of documentation on traditional medicine practices and lack of regulations for the practitioners.

Dr Alice Wong spoke on the quality assurance system in Hong Kong SAR (China) with well-established regulatory systems for traditional Chinese medicine products and practitioners. She explained that the proportion of traditional medicine use in overall health service usage in Hong Kong SAR (China) is high. She also gave details of the legal basis and governance for regulation of traditional medicines as well as the overall quality assurance system for Chinese herbal medicines and proprietary Chinese medicines ranging from production (GMP), import and export control, registration, quality control, standards for testing, post-marketing surveillance, and emergency response to market exit. Furthermore, she provided an overview of the quality assurance system for the practitioners that includes registration, continuing education and a disciplinary system.

Dr Kyu Yeop Kim gave an explanation of the quality control of herbal medicines in the Republic of Korea by introducing the regulatory system and governance of herbal medicines. He described the application of Reference Medicinal Plant Materials for quality control of herbal medicines in the country and gave the example of *Angelica gigas*. He also shared a recent case of misidentification of a medicinal plant, associated safety issues and how the Ministry of Food and Drug Safety handled the issue. Based on his presentation, there were discussions on DNA barcoding and parameters tested for herbal medicines.

2.4 Session 2: Country presentation on current quality assurance system for traditional medicines

Participants made presentations on the respective current quality assurance system for traditional medicines in their countries, focusing on the regulatory system for products. All participating countries have regulations on traditional medicines, and they face common challenges in implementing them, especially in registration, laboratory testing and post-marketing surveillance. However, the levels of maturity of the regulatory systems for traditional medicine practitioners are diverse. Cambodia and the Lao People's Democratic Republic do not have regulations for practitioners, and there are ongoing efforts to establish some. On the other hand, Mongolia and Viet Nam have long had regulatory systems for practitioners and are trying to improve their systems. In the Philippines, PITAHC is trying to develop standards and certificates for practitioners, but the legal basis is quite limited.

A discussion on registration requirements followed the presentations. In the Lao People's Democratic Republic, a few traditional medicines are included in the current essential medicines list. The criteria for selection of traditional medicines include: frequent use by people, well-recognized effectiveness, and the acknowledged existence of historical evidence. Cambodia, the Lao People's Democratic Republic and the Philippines are currently trying to apply the ASEAN guidelines on claims and claims substantiation. Difficulties in evaluation of historical evidence were common across countries.

2.5 Session 3: Panel discussion on large-scale production of traditional medicines

2.5.1 GACP guidelines and enforcement

The participants acknowledged the importance of ensuring the quality of raw materials since the majority of traditional medicines in their countries are produced or prepared directly from the raw materials. However, due to lack of collaboration among the relevant ministries, information on the current regulatory status for GACP was quite limited.

2.5.2 Market entry

a) Registration

Appropriate categorization of traditional medicines is a critical issue in the registration of traditional medicines. The categories and scope of traditional medicines vary considerably across countries. Quality, safety and effectiveness standards for traditional medicines were also identified as critical in registration, especially where therapeutic claims are presented. In many countries, historical evidence and scientific evidence are used as registration requirements for traditional medicines. However, evaluation of the efficacy or effectiveness of traditional medicines is challenging since randomized controlled trials for traditional medicines or documentation on their historical use are lacking. In addition, modern scientific research methodologies have limitations when evaluating the effectiveness of traditional medicines, which often consist of several herbs, posing challenges even for identifying the active ingredient of a single herb. Although regulatory authorities require evidence from clinical trials, limited funding and the lack of capacity to conduct them are key barriers.

There was discussion on the regulatory convergence initiative for registration requirements depending on the level of therapeutic claims within ASEAN member states. Lessons from China, Hong Kong SAR (China), Japan and the Republic of Korea, which have developed registration systems over several decades, provide useful lessons to the participating countries on the use of historical evidence. Participants agreed that, although registration requirements may differ depending on claims, the safety

report on traditional medicines is the most critical factor for the regulatory authorities to evaluate. Furthermore, striking the right balance between good regulation and easy access to traditional medicines was emphasized as a consideration for regulators when developing registration requirements.

b) Licensing of manufacturing business

In the participating countries, manufacturers often produce both pharmaceuticals and traditional medicines. However, the capacity and size of the manufacturing business is quite limited, and there are only a few or sometimes no manufacturing businesses that meet the GMP guidelines.

2.5.3 Quality assurance in the market

a) Laboratory testing for quality control

Dr Hyo-Min Lee emphasized the importance of quality control of the raw materials of herbal medicines, especially their accurate identification, since many adverse events were caused by misidentification of raw materials. The Korean Government is currently trying to develop DNA barcoding and chemical profiling for accurate identification. She shared examples of current efforts by the Government, which include cross-validation between the national laboratory and provincial laboratories, training of inspection personnel, developing reference materials and sharing information through media and official websites.

Dr Alice Wong also mentioned that quality control is quite challenging since identification of active ingredients is difficult and herbal medicines can be easily contaminated through the collection, storage, processing and producing process.

The following were identified as key issues in regard to quality control: limited technical capacity to conduct laboratory testing for traditional medicines including identification; contamination with microorganisms, heavy metals or pesticides, and adulteration with pharmaceuticals; lack of or no pharmacopoeia and/or monographs; and limited information on parameters and threshold values for the parameters. The importance of sharing information on parameters and thresholds for each parameter was highlighted. The participating countries requested support for the development of minimal standards on parameters and thresholds. Providing laboratory training to improve the technical capacity for quality control of traditional medicines and collaborating with existing resources such as WHO collaborating centres and the Forum for the Harmonization of Herbal Medicines will be further explored to support the development of standards.

b) Post-marketing surveillance and pharmacovigilance

Regular post-marketing surveillance is key to ensuring the quality and safety of products in the market. Random sampling along with a risk-based approach is important, to ensure the selection of products that have had safety and quality issues.

Pharmacovigilance is critical to monitor adverse events and ensure the safety of traditional medicines, especially when a robust registration system is not in place. In these countries, pharmacovigilance is weak for medicines and vaccines as well as traditional medicines. Thus, coordinated efforts are needed to strengthen pharmacovigilance across these different product streams.

2.6 Session 4: Panel discussion on small-scale production of traditional medicines

During the intercountry workshop, common challenges for small-scale production of traditional medicines were identified: unhygienic practices, lack of standards or evidence of their practice, and lack of regulations pertaining to the practitioners or dispensers and the facilities where they produce and prepare traditional medicines.

- Different approaches for the formal and informal sectors

Dr Socorro Escalante suggested different approaches for the formal and informal sectors. For producers in the formal sector of national health systems, such as licensed traditional medicine doctors or hospitals, key strategies to control this type of small-scale production are: developing standards and guidelines on their practice, monitoring by the regulatory authorities, requesting the practitioners to document their treatment and products in medical records, and regulating the facilities to maintain a hygienic environment. If the producers are in the informal sector, strategies for the regulatory authorities to consider are development of a regulatory system for them or at least development of guidelines on hygienic production and safety control and strong monitoring and pharmacovigilance.

Ms Sengphet Phongphachanh reiterated that regulations for facilities such as hospitals or health stations in the Lao People's Democratic Republic will have a great impact on the small-scale production of traditional medicines. She highlighted the importance of formalizing traditional medicine practice through integration of traditional medicine services into national health-care services.

- Top–down and bottom–up approaches

Dr Alice Wong shared how Hong Kong, SAR (China) ensures the quality and safety of small-scale production of traditional medicines and presented both top–down and bottom–up strategies employed in the formal sector. The top–down approach comprises regulating the practitioners, facilities and labelling; and the bottom–up strategy is empowering consumers through consumer education and providing relevant information on safety and quality issues of traditional medicines to the consumers. Strengthening pharmacovigilance and documentation of indigenous traditional medicines are other key strategies.

Overall, in regard to the small-scale production of traditional medicines, the panel concluded that regulation, such as through the licensing and/or registration of traditional medicine practitioners or dispensers, is critical. The importance of consumer education and pharmacovigilance was also highlighted.

Participants also discussed the difficulties in establishing and strengthening the regulatory system for traditional medicines due to lack of funding and political commitment. Ms Sengphet Phongphachanh emphasized the importance of demonstrating the potential benefits of investing in traditional medicines. Dr Socorro Escalante noted that every country faces funding challenges and weak political support. Analyzing how traditional medicines impact the safety of the population can be a practical starting point for regulatory authorities to gain political support.

2.7 Session 5: Country-specific strategies and action plans

Cambodia

Since there is no manufacturing facility to produce traditional medicines on a large scale, actions in Cambodia focus on the quality assurance system for traditional medicines produced by practitioners. Adoption of the ASEAN guidelines on claims and claims substantiation will be one of the priorities to regulate both imported and locally produced traditional medicines. In regard to laboratory testing, capacity-building to improve the technical capacity of laboratory experts and development of standards for testing are key planned actions.

The development of a draft subdecree on traditional medicine practitioners is an immediate action to improve the quality and safety of small-scale production of traditional medicines. The development of an education system for practitioners will be a critical mid- to long-term strategy.

Lao People's Democratic Republic

Immediate actions for large-scale production include the translation and adoption of the ASEAN guidelines and training for assessors, while mid- and long-term actions include efforts to implement the guidelines. Key short-term actions in regard to laboratory testing include capacity-building through in-country or overseas hands-on laboratory training. In the long term, the development of the Lao monograph and pharmacopoeia for selected medicinal plants will be essential.

The establishment of a regulatory system for traditional medicine practitioners, development of guidelines on hygienic production and consumer education on safety issues of traditional medicines are key immediate actions for the small-scale production of traditional medicines,. The development of a formal education system for the practitioners is a long-term strategy.

Mongolia

Immediate and midterm actions for large-scale production include a review of the current policy, laboratory training for the national experts for quality control of traditional medicines, the development of standards or pharmacopoeia for traditional medicines to provide a basis of laboratory training and future development of new traditional medicines, and the development and implementation of pharmacovigilance for traditional medicines.

The development of standards for traditional medicine practices and improvement of training for the practitioners are actions to ensure the quality and safety of small-scale production of traditional medicines.

Philippines

Short-term planned actions in regard to large-scale production of traditional medicines include: the development of national guidelines to adopt the ASEAN guidelines on claims and claims substantiation and training assessors on the guidelines and public consultation on the registration of homeopathic medicines. In the midterm, industries will be trained for adoption of the ASEAN guidelines. In the long term, guidelines on regulation of other complementary medicines will be developed with various stakeholders.

Short-term actions for the small-scale production of traditional medicines include: review of the Traditional and Alternative Medicine Act, creation of a task force, dialogue and collaboration with the

Food and Drug Administration and Department of Health, and continued documentation of traditional medicine practices Midterm priorities include possible amendment of the Traditional and Alternative Medicine Act to address gaps, and the development of guidelines for regulation. Creating a board of traditional and complementary medicine practitioners is one of the long-term priorities.

Viet Nam

The development of a clear registration process and registration requirements, enforcement of GMPs for manufacturing factories, strengthening laboratory capacity for quality control of traditional medicines, the development of quality and safety standards and the inclusion of selected traditional medicines in national health insurance coverage are critical short-term actions related to the large-production of traditional medicines.

Key priorities related to the small-scale production of traditional medicines include the development of guidelines on production of traditional medicines at the hospital level to ensure hygienic and safe practices, strengthening regulations and the development of guidelines on standardized practices for traditional medicine practitioners.

3. CONCLUSIONS AND RECOMMENDATIONS

3.1 Conclusions

Quality assurance of traditional medicines contributes to the achievement of universal health coverage in the Region. Ensuring the quality and safety of traditional medicines has a direct and great impact on public health in Member States where traditional medicines are extensively used.

The participating countries have established regulatory systems for traditional medicines, especially traditional medicines produced in large scale by manufacturing businesses. In the countries, laws and regulations on medicines cover traditional medicines as a part of medicines. However, the implementation of these regulations is challenging due to limited resources and capacities of regulatory authorities. Furthermore, there are unique and complex issues in regulating traditional medicines, such as the regulation of raw materials and difficulties in the development of common standards for the quality and safety of traditional medicines across the countries. Categories and registration requirements of traditional medicines also vary substantially across countries.

The key common issues include control of quality and safety of raw materials during cultivation, collection, storage and processing, identification of accurate raw materials, implementation of GMP guidelines, evaluation of effectiveness of traditional medicines for registration, and standards for laboratory testing. In particular, people value traditional medicines as a part of their culture, heritage and tradition, and thus, evaluation of the effectiveness of traditional medicines from the regulatory authorities' perspective is very challenging. Furthermore, even though randomized controlled trials on traditional medicines have greatly increased in many developed countries, there are still limited clinical studies in the participating countries due to lack of funding and human resources with adequate technical capacity.

The regulation of traditional medicines produced in small scale by practitioners or dispensers is more challenging. Traditional medicines produced in small scale to meet individual patients' needs cannot be regulated by general regulations on medicines. Thus, regulation of practitioners or dispensers is essential to ensure the quality and safety of these products. However, other than Mongolia and Viet

Nam, there are no regulatory systems for traditional medicine practitioners in place. In Cambodia, the Government is trying to develop a subdecree on regulation of traditional medicine practitioners. In the Lao People's Democratic Republic, the Government is also considering regulation of the practitioners as a priority. In the Philippines, PITAHC is trying to develop standards and registration requirements for the practitioners, but the Institute has no legal authority to regulate them. In Mongolia and Viet Nam, there is an education system for the practitioners at the university level and regulations, but implementation and improvement of competences of the practitioners are key issues.

Each country has their own specific issues; thus, there are no one-size-fits-all approaches. At the same time, there are common challenges mentioned above. Therefore, while the participants developed their own action plans, they could also reach agreement on key areas to be tackled and actions to strengthen the quality assurance of traditional medicines. In large-scale production of traditional medicines, registration, quality control and post-marketing surveillance were identified as common key areas for the regulatory authorities to focus on. To improve the registration process, the development of a clear registration process and requirements will be critical. Strengthening quality control requires great investment in improving the technical capacity of national laboratory experts and equipment. Within limited capacity, it is still important to test critical parameters to ensure the safety of traditional medicines. For this, sharing information on minimal and essential testing for safety of traditional medicines among Member States will be important. Finally, post-marketing surveillance should be strengthened based on a risk-based approach. If there is no strong safeguard in entry to market, post-marketing surveillance needs to be strengthened further and emphasized.

In small-scale production of traditional medicines, the regulation of traditional medicine practitioners through registration or licensing is essential to ensure the quality and safety of this category of traditional medicines. Furthermore, development of standards of their practice including production of their own medicines, documentation of their practice for record-keeping, and regulation on the facilities where they practice and produce traditional medicines are also key strategies to regulate the practitioners and their practice, including production of individualized traditional medicines.

Finally, there was also consensus on a few key considerations in improving the current regulatory system for traditional medicine in the countries. In the regulation of traditional medicines, the regulatory system for traditional medicines and that for practitioners are closely linked. Understanding this close link would be the first step for regulatory authorities to evaluate the current regulatory system and develop concrete action plans to improve the overall quality assurance system for traditional medicines.

Recent increases in importation and exportation of traditional medicines require regulatory authorities to share information and collaborate with each other to regulate traditional medicines more efficiently. The ultimate goal for the regulation of traditional medicines is ensuring access to qualified, safe and effective traditional medicines by consumers. Thus, the regulatory authorities need to consider a balance between regulation and access to medicines. In addition, current industry capacity is another critical factor to be considered when governments try to strengthen their regulatory standards.

3.2 Recommendations

3.2.1 Recommendations for Member States

In regard to large-scale production of traditional medicines, Member States are encouraged to consider the following actions:

1) to develop standards and benchmarks as a basis for the quality assurance system of traditional medicines;
2) to strengthen the quality assurance system including registration, laboratory capacity for quality control and post-marketing surveillance for traditional medicines; and
3) to take a risk-based approach to utilize limited resources more efficiently.

In regard to small-scale production of traditional medicines, Member States are encouraged to consider the following actions:

1) to collect information on current traditional medicine practices by practitioners and use of traditional medicines from consumers' point of view;
2) to assess the role of traditional medicines in the national health system, in particular in the primary health-care system; and
3) to establish or strengthen the regulatory system for traditional medicine practitioners and establish standards for their practice for traditional medicines produced in small-scale.

3.2.2 Recommendations for WHO

In regard to large-scale production, WHO will:

1) support Member States in improving their quality assurance system for traditional medicines, in particular the registration system, standards on quality control of traditional medicines, laboratory capacity and post-marketing surveillance based on a risk-based approach;
2) provide technical support and a hands-on laboratory training programme for institutional development of the national laboratories through a twinning approach or use of existing resources such as WHO collaborating centres; and
3) provide support in establishing or improving post-marketing surveillance and pharmacovigilance with medicines and vaccines.

In regard to small-scale production, WHO will:

1) facilitate information-sharing on current regulatory practices for traditional medicine practitioners in the Region;
2) provide technical support in developing and implementing regulations on traditional medicine practitioners; and
3) provide technical support in developing standards on the practitioners' practices and improving the education system for the practitioners based on the standards.

ANNEX 1. Programme of activities

Time	Session	Moderator
Day 1 [1 March]		
8:30–9:00	Registration	
9:00-10:30	Introduction • Overview of the objectives for Day 1: Intercountry workshop • Introduction of participants Session 1 – Group work: Mapping exercise to identify gaps of quality assurance system (QAS) for traditional medicines • Mapping current quality assurance system for traditional medicines • Identification of gaps	Dr Yu Lee Park Technical Officer Traditional Medicine WHO/WPRO
10:30–11:00	Morning tea	
11:00–12:30	Session 2 – Poster presentation on group work: Information exchange • Poster presentation on group work by each country	
12:30–13:30	Lunch	
13:30–15:00	Session 3 – Group work: Key issues in large-scale and small-scale production of traditional medicines • Identification of key issues and priorities (up to 3) for large-scale and small-scale production • Root-cause analysis	
15:00–15:30	Afternoon tea	
15:30–17:00	Session 4 – Plenary: Feedback from group work • Presentation by each country • Discussion on key issues and challenges in quality assurance system	
Day 2 [2 March]		
9:00–10:00	Opening ceremony • Opening and welcome address • Overview of the meeting objectives • Nomination of chair and co-chair • Introduction of participants • Group photo	Dr Socorro Escalante Team Leader (Health Systems), WHO Viet Nam Dr Hyo-Min Lee, on behalf of Director General, National Institute of Food and Drug Safety Evaluation (NIFDS), Republic of Korea Dr Yu Lee Park
10:00–10:30	Morning tea	
10:30–12:00	Session 5 – Plenary: Key components of QAS for traditional medicines • Key components of QAS for medicines • WHO strategy on quality assurance of traditional medicines • QAS for traditional medicines in Hong Kong SAR (China) • Quality control of traditional medicines in the Republic of Korea	Dr Socorro Escalate Dr Yu Lee Park Dr Alice Wong, Hong Kong SAR (China) Dr Kyu Yeop Kim, NIFDS

	• Q&A, discussions	
12:00–13:00	Lunch	
13:00–15:00	Session 6 – Plenary: Country presentations on current QAS for traditional medicines • Cambodia • Lao People's Democratic Republic • Mongolia • Philippines • Viet Nam	
15:00–15:30	Afternoon tea	
15:30–17:00	Session 7 – Panel discussion: Large-scale production of traditional medicines • Brief presentation on common issues identified on Day 1 • Panel discussion: strengthening QAS for traditional medicines in large-scale production	Dr Socorro Escalante
Day 3 [3 March]		
8:50–9:00	Recap of Day 2	Ms Sengphet Phongphachanh National Professional Officer WHO Lao People's Democratic Republic
9:00–10:00	Session 8 – Panel discussion: Small-scale production of traditional medicines • Brief presentation on common issues identified on Day 1 • Panel topic: challenges and strategies for establishing/strengthening QAS for traditional medicines in small-scale production	Dr Yu Lee Park
10:00–10:30	Morning tea	
10:30–12:00	Session 9 – Group work: Strategies and action plan • Strategies to tackle the key issues identified through group work on Day 1 • Action plan	
12:00–13:00	Lunch	
13:00–15:00	Session 10 – Plenary: Feedback from group work and discussion • Presentation on action plan by each country	
15:00–15:30	Conclusions and recommendations • Meeting summary • Comments by the meeting participants • Closing remarks by the secretariat	

ANNEX 2. List of participants, temporary advisers, observers, secretariat and resource person

1. PARTICIPANTS

CAMBODIA	**Dr Huot THEANG,** Technical Officer, National Center for Traditional Medicine, #4 St, 118 Sangkat Mittapheap, Phnom Penh, Telephone: (855) 12 984 753, Email: theang.huot@yahoo.com
	Mr Sokchamroeun UY, Deputy Head, Technical and Development Research Section, National Health Product Quality, Control Center, Ministry of Health 245h, National Road 6A, Phnom Penh, Telephone: (855) 10 474 869, Email: uy.sokchamroeun9@gmail.com
LAO PEOPLE'S DEMOCRATIC REPUBLIC	**Mr Somthavy CHANGVISOMMID,** Director General, Food and Drug Department, Ministry of Health, Simuang Road, Vientiane, Telephone: (856) 21 21401314, Email: csomthavy_fdd@yahoo.com
	Mr Bounleuane DOUANGDEUANE, Head, Traditional Medicine Division, Food and Drug Department, Ministry of Health, Simuang Road, Vientiane, Telephone: (856) 21 222626, Email: bounleuane.dd@gmail.com
MONGOLIA	**Dr Dolgorsuren BALGANSUREN,** Officer, Department of Medical Services, Ministry of Health Olympic Street 2, Ulaanbaatar, Telephone: (976) 99182884, Email: dolgorsuren@moh.gov.mn
	Dr Munkh-Od Tseveenregzen, Officer-in-Charge, Registration of Medicines, Drug Regulation Unit Center for Health Development, Enkhtaivan street-13b, Sukhbaatar District, Ulaanbaatar, Telephone: (976) 70128804,Email: munkhod@hdc.gov.mn
PHILIPPINES	**Mr Willison John DE LUNA,** Officer III, Food-Drug Regulation, Food and Drug Administration, Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City, Telephone: (632) 857 1986, Email: wjedeluna@fda.gov.ph
	Ms Juris TRIUNFANTE Division Chief IV, Philippine Institute of Traditional and Alternative Health Care, Matapang Street, East Avenue Medical Center Compound, Quezon City, Telephone: (632) 976 3067, Email: juristriunfante@yahoo.com
VIET NAM	**Dr HOANG Thi Hoa Ly,** Main Specialist Traditional Medicine Administration

138A Giang Vo Street, Ba Dinh District, Hanoi, Telephone: 84 0912081218, Email: hoaly1968@gmail.com

Dr NGUYEN Dieu Ngoc Tuyen, Managing Quantity of Medicine, Traditional Medicine Institute, 273 Nguyen van troi Street, Phu Nhuan District, Ho Chi Minh City, Telephone: 84 0908436728, Email: bsnguyendieungoctuyen@gmail.com

2. TEMPORARY ADVISERS

Dr LEE Hyo-Min, Director, Herbal Medicine Research Division, National Institute of Food and Drug Safety Evaluation, Ministry of Food and Drug Safety, 187 Osongsaengmyeong, Chungcheongbuk-do, Republic of Korea, Telephone: 82 43 719 2359, Email: hmlee0983@korea.kr

Dr Alice WONG, Principal Medical Officer, Traditional Chinese Medicine, Department of Health, 16F, AIA Kowloon Tower, Landmark East Kwun Tong, Hong Kong SAR (China), Telephone: 852 3904 9272, Email: alice_wong@dh.gov.hk

3. OBSERVERS

Dr LEE Soojin, Associate Professor, Dept. of Physiology, College of Korean Medicine, Sangji University, Seoul, Republic of Korea, Telephone: +82 33 730 0673, Email: jinlee@sangji.ac.kr

Dr LEE Rana Jongran, Researcher, Korea Institute of Oriental Medicine, WHO Collaborating Centre for Traditional Medicine, Seoul, Republic of Korea, Telephone: 042-869-2704, Email: ranalee@kiom.re.kr

Dr KANG Sohyeon, Clinical Researcher, Institute of Safety, Efficacy and Effectiveness Evaluation for Korean Medicine, Kyung Hee University, WHO Collaborating Centre for Traditional Medicine, Seoul, Republic of Korea, Telephone: 02-961-0114, Email: kangsohyeon@gmail.com

4. SECRETARIAT

Dr Yu Lee PARK (Responsible Officer), Technical Officer, Traditional Medicine, WHO Regional Office for the Western Pacific, 1000 Manila, Philippines, Telephone: (632) 528 9046, Email: parkyl@who.int

Dr Socorro ESCALANTE, Acting Coordinator, Essential Medicines and Technology Division of Health Systems, WHO Regional Office for Western Pacific, 1000 Manila, Philippines, Telephone: (632) 528 3828, Email: escalantes@who.int

Mrs Sengphet PHONGPHACHANH, Technical Officer, Essential Drugs and Medicines World Health Organization, 125 Saphanthong Road, Unit 5, Ban Saphangthongtai, Sisattanak District, Vientiane, Lao People's Democratic Republic, Telephone: (856) 21 353902, Email: phongphachanhs@who.int

5. RESOURCE PERSON

Dr Kyu Yeop Kim, Scientific Officer, Ministry of Food and Drug Safety, Chungcheongbuk-do, Republic of Korea, Telephone: +82-43-719-1564, Email: yeop007@korea.kr

ANNEX 3. Speech of Dr Shin Young-soo, WHO Regional Director for the Western Pacific at the Meeting on Strengthening Quality Assurance of Traditional Medicines

Distinguished Guests, Participants, Colleagues, Ladies and Gentlemen:

Welcome to the Meeting on Strengthening Quality Assurance of Traditional Medicines.

Dr Shin Young-soo, WHO Regional Director for the Western Pacific, regrets not being able to join us due to previous commitments. He has asked me to send his regards and deliver these words.

Traditional medicines are widely used in the region. It forms part of the basic primary health care intervention and the management and care for a variety of health problems from minor ailments to life-threatening diseases.

Ensuring safety, quality, and effectiveness of traditional medicines is critical for a well-functioning primary health care system and in achieving Universal Health Coverage.

Recognizing the importance of traditional medicines, the World Health Assembly Resolution on strengthening integrated, people-centred services in 2016 called for the integration of traditional medicines into health service provision.

Traditional medicines are produced from different sources and prepared by individual practitioners and dispensers or produced by the manufacturing business.

WHO has provided continuous support to Member States in developing policies and regulations on traditional medicine products, practitioners and dispensers and building national regulatory capacities.

It is commendable that Cambodia, Lao People's Democratic Republic, Mongolia, Philippines and Viet Nam have established regulatory system for traditional medicines. Encouragingly, the countries have made continuous efforts to improve regulatory system for traditional medicines.

In Lao People's Democratic Republic and Mongolia, the governments have initiated development of national standards for quality control of traditional medicines.

Cambodia is currently developing regulatory framework for traditional medicine practitioners. In Philippines, efforts are also underway to establish standards of practice and regulate the practitioners.

Viet Nam is in the initial stage of developing its traditional medicine law to strengthen regulatory system for traditional medicine. This comes after the high level government decision to integrate traditional medicine in their health service delivery system.

Despite these successes and efforts, there are still concerns over quality issues of traditional medicines. Unhygienic production of the products by the practitioners and dispensers, adulteration with active pharmaceutical substances, contamination with heavy metals or pesticide residues and misidentification are critical issues.

It is therefore important that overall quality assurance system for traditional medicines produced by practitioners and dispensers as well as the manufacturing business needs to be strengthened.

Exchange information and international cooperation among Member States will contribute to development of evidence-based policies for this.

We hope that this meeting provides such opportunity to share experiences, to identify priorities for strategic actions, and to develop concrete plans for strengthening quality assurance system of traditional medicines.

I wish you have fruitful discussion to improve access to quality traditional medicines.

Thank you all for participating in the meeting.

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