Virtual Workshop on Pharmacovigilance (PV) for traditional medicine (TRM) products in the WHO South-East Asia Region

30 November – 2 December 2020
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**Acronyms**

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<td>ADR</td>
<td>Adverse Drug Reaction</td>
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<tr>
<td>AE</td>
<td>Adverse Event</td>
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<tr>
<td>ASEAN</td>
<td>Association of South-East Asian Nations</td>
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<td>ASU &amp; H Medicines</td>
<td>Ayurveda, Siddha, Unani &amp; Homoeopathy Medicines</td>
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<tr>
<td>CDSCO</td>
<td>Central Drugs Standard Control Organization</td>
</tr>
<tr>
<td>HATC</td>
<td>Herbal Anatomical Therapeutic Classification</td>
</tr>
<tr>
<td>HDI</td>
<td>Herb-Drug Interactions</td>
</tr>
<tr>
<td>IPC</td>
<td>Indian Pharmacopoeia Commission</td>
</tr>
<tr>
<td>NRA</td>
<td>National Regulatory Agency</td>
</tr>
<tr>
<td>PIDM</td>
<td>Programme for International Drug Monitoring</td>
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<td>PMS</td>
<td>Post-marketing Surveillance</td>
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<tr>
<td>PV</td>
<td>Pharmacovigilance</td>
</tr>
<tr>
<td>RC</td>
<td>Regional Committee (of WHO)</td>
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<tr>
<td>SEARN</td>
<td>South-East Asia Regulatory Network</td>
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<td>TRM</td>
<td>Traditional Medicine</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>WHO-CC</td>
<td>WHO Collaborating Centre</td>
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<td>WHO-UMC</td>
<td>WHO Uppsala Monitoring Centre</td>
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1. **Background**

Given the wide use of traditional medicine (TRM) in the public and private health sectors among the Member States of the WHO South-East Asia (SEA) Region, the safety of TRM products is of great importance for the health authorities and people at large. The WHO Regional Traditional Medicine Programme identified strengthening pharmacovigilance (PV) for TRM products as a regional priority area in 2015. This is aligned with the WHO Global Traditional Medicine Strategy 2014–2023. As per a survey carried out by the WHO Regional Office for South-East Asia (SEARO) in 2018, eight out of the 11 Member States had established pharmacovigilance systems to monitor allopathic medicine safety, but only four countries (Bhutan, India, Indonesia and Thailand) had included TRM products in their PV system.

During the Seventy-second session of the WHO Regional Committee for SEA Asia in New Delhi in September 2019, Member States had requested WHO to provide technical support in strengthening national regulatory systems to ensure safety and quality of TRM products, specifically through PV for TRM products. The proposed regional workshop will address this need and provide an opportunity for peer learning and identifying the region- and country-specific roadmap towards strengthened PV systems for TRM products.

The WHO Regional TRM Programme identified strengthening PV for TRM products as a key regional priority action point at the Regional workshop on appropriate integration of TRM into health-care delivery systems held in Pyongyang, DPR Korea in October 2015. In addition, an SEA Region Briefing Note on PV for TRM products was prepared in 2016 and a regional survey on PV for TRM products was also conducted in 2018. Two country case studies on PV for TRM products (India and Thailand) were also undertaken in 2017. Following this, Member States requested WHO to provide technical support to strengthen PV for TRM products at the Seventy-second Regional Committee session in September 2019.

In this context, this virtual Workshop on Pharmacovigilance for traditional medicine products in the WHO South-East Asia Region was organized on 30 November–2 December 2020. This workshop is expected to enable countries to update their knowledge on PV for TRM products, identify the regional and country priority action points, and evaluate technical areas for providing support to strengthen their PV systems to improve safety monitoring of TRM products.

This will also further contribute towards accelerating progress to achieve universal health coverage and the “Triple Billion” target of the WHO Thirteenth General Programme of Work (GPW13) through appropriate integration of safe and effective traditional medicines into national health-care delivery systems.

2. **Opening session**

The inaugural address of the Regional Director for WHO South-East Asia, Dr Poonam Khetrapal Singh, was delivered by Mr Manoj Jhalani, Director for the Department of Health Systems Development at SEARO. The Regional Director welcomed the participants to this regional event on pharmacovigilance for traditional medicine products.
Since 2014, achieving universal health coverage has been one of the Flagship Priority Programmes for the WHO South-East Asia Region. Traditional medicines have much to contribute in this regard, the Regional Director said. Not only do traditional medicines have great therapeutic potential, but they can also help integrate communities into health systems by providing positive and culturally familiar health-care experiences. It is with good reason that in recent years the popularity of traditional medicine has increased across the world as part of a move towards securing a more holistic approach to preventive and promotive health. One must ensure that all such products are safe and effective.

Across the SEA Region, progress in this field has been discernible, the Regional Director said. A few countries have framed national policies on traditional medicine. Further, safety monitoring has also gathered pace. The Regional Office has identified the development of pharmacovigilance as one of the Region’s priority areas in traditional medicine. In 2018, a baseline survey on pharmacovigilance for traditional medicine products was conducted. There is a need to develop systems to share information on adverse events with other countries through mechanisms such as the South-East Asia Regulatory Network (SEARN).

Dr Poonam Singh further stated that the efforts to be made during the three-day workshop will build momentum in the field of PV and reiterated WHO’s full support in achieving health and well-being for all people at all ages (see Annexure 1 for full text of the address).

This was followed by an Introductory/Briefing Session focussing on the objectives and expected outcomes of the workshop that was coordinated by Dr Kim Sung Chol, Regional Adviser for Traditional Medicine at the WHO Regional Office in New Delhi. Dr Kim mentioned that, given the wide use of TRM in the Region, monitoring TRM product safety assumes significance. He further reiterated the request from Member States to WHO to provide technical support in strengthening safety monitoring of TRM products through PV. This strengthening of PV will further improve TRM product safety, he said, adding that the Member States need to be provided with technical guidance on the principles of good PV practices for monitoring safety of TRM products.

Dr Kim welcomed the Member States’ collaboration and suggested that the robust cooperation at regional and international levels be continued for information exchange on PV and active participation in the existing international network. The session concluded with the hope that the deliberations of the three-day workshop will update technical guidance on the principles of good PV practices for monitoring the safety of TRM products, and help identify best practices on PV for product safety and the ways forward for enhanced regional and global collaboration on PV for TRM products.

Dr Kim proposed the names of the moderator and rapporteur for the workshop and they were accepted by the members unanimously. Professor Urmila Thatte, Emeritus Professor, Department of Clinical Pharmacology at the Seth GS Medical College and KEM Hospital, Mumbai, was nominated as the moderator, and Dr Galib, Associate Professor, All India Institute of Ayurveda in New Delhi, was appointed the rapporteur.

3. Objectives

3.1 General objectives

The general objective of the workshop was to strengthen the pharmacovigilance system for improving the safety and quality of TRM products.
3.2 Specific objectives

The specific objectives of the workshop were to:

1. Provide technical guidance and updates on the principles of good PV practices for monitoring the safety of TRM products;
2. Identify region- and country-specific action points for strengthening TRM product safety monitoring in line with international standards and country contexts;
3. Promote safe use of TRM products through internationally coordinated information exchange on PV by encouraging more Member States to participate in the existing international network; and
4. Strengthen regional collaboration and cooperation in monitoring TRM product safety.

The agenda for the workshop is available in Annexure 2.

4. Proceedings

The first session on updating the sequence of activities undertaken in the past with regard to TRM product safety monitoring was covered by Professor Wimon Suwankesawong, former in-charge of Pharmacovigilance with the Food and Drug Administration of Thailand, who steered the discussions on Pharmacovigilance for traditional medicine in SEA Region Member countries.

The objectives of this presentation were to elaborate on:

1. Why PV for TRM is needed in SEA Region countries?
2. Objectives and methods
3. Results and conclusions

TRM products are widely used globally, but they have not been thoroughly reviewed in the context of their pharmacology and toxicology in the pre-marketing phase. Due to lack of pre-marketing clinical studies, there is inadequate data available on the adverse events of TRM products. Incidences ranging from hepatotoxicity to renal failure to allergic reactions have been reported to be caused by TRM products and this is often because of poor quality of the herbal material, adulteration, inappropriate dosage, etc.

To describe the current situation of PV for TRM in SEA Region countries and identify its challenges, a survey of pharmacovigilance focused on TRM in the WHO Member States of the Region was conducted in July–November 2018. This survey focused on determining the feasibility of including TRM in existing national pharmacovigilance systems or, in countries where such systems have not yet been developed, on the establishment of comprehensive systems with coverage of TRM. In addition, literature search using PubMed and Google Scholar was also performed to identify PV activities and other related issues and the number of individual case safety reports (ICSRs) submitted to the Uppsala Monitoring Centre during 2016–2017 was seen to reflect the contribution to the WHO global database.

All the countries in the region except Timor-Leste returned the completed questionnaire. The Democratic People’s Republic of Korea and Myanmar indicated that they had no clearly designated pharmacovigilance system in place. The other eight countries had established a national pharmacovigilance system separately from a post-marketing surveillance system and were members of the WHO Programme for International
Drug Monitoring (PIDM) The first pharmacovigilance system established in the Region was that of Thailand in 1984, followed by Indonesia (1990) and India (1997). The remaining countries developed their systems after 2000. The latest member, Maldives, joined in 2016.

The Democratic People’s Republic of Korea and Myanmar have no established national pharmacovigilance system for monitoring the safety of a medicine. Bangladesh, Maldives, Nepal and Sri Lanka have existing pharmacovigilance systems but TRM products are not integrated into these systems. The existing pharmacovigilance systems implemented in Bhutan, Indonesia and Thailand cover TRM products. India is the only country that has developed and applied a separate pharmacovigilance system focusing on TRM products since December 2017. All countries except Thailand are using VigiFlow for submitting ICSRs to WHO-UMC (WHO-Uppsala Monitoring Centre).

The 2018 regional survey has also demonstrated that marketing of TRM products is regulated in all countries (except Sri Lanka). In India, the marketing authorization for TRM products, both classical and proprietary products of the Ayurvedic, Siddha and Unani systems and homoeopathy, is granted by the state licensing authorities.

Limited resources, lack of trained manpower and limited expertise in causality assessment were highlighted to be some of the major challenges in the successful implementation of PV systems, especially in TRM products in the region. To enhance the system functions, it should improve capacity-building of human resources, and systems must operate alongside an effective national drug regulatory system so that the signal could be aligned with proper regulatory measures.

**Flowchart of pharmacovigilance system**

Some of the challenges identified in the study included:

- Limited resources:
  - Manpower constraints including TRM expert in PV centre.
  - No fixed annual budget to cover the operations.
➢ Lack of knowledge and expertise on causality assessment:
   - Insufficient information and difficulties to access reliable information support.
   - Quality testing of the suspected product.

Recommendations from the countries to take these activities forward in future included the following:

➢ Establishment of and strengthening the PV system for TRM products.
➢ Capacity-building on causality assessment.
➢ Sharing of information across WHO SEA Region countries.

This paper concluded that it is feasible to implement PV for TRM products in participating countries and PV for TRM could either be integrated into or separated from the existing national PV system. And the way forward depended on each country’s context, e.g. the legislation and regulations, the pattern of use and commercialization of TM products. However, it should be closely linked with the national PV system and operate alongside an effective national drug regulatory system.

The next address was from Dr Galib, Associate Professor, All India Institute of Ayurveda, New Delhi, who gave his views on the WHO guidelines on pharmacovigilance for herbal products (2004): key achievements and gaps. TRM can play a pivotal role in global health care, he said. Since the concept of “Health for All” through primary health care was launched at the Alma Ata Conference in 1978, there has been a global movement to realize universal health care coverage. It has been reported that 88% Member States have acknowledged the use of TRM. Traditional medicine continues to be a valuable source of remedies for people around the world to secure their health. It continues to expand rapidly across the world and many people now follow traditional systems of medicines for their health care and well-being.

Alongside this increasing demand and acceptance in various countries, concerns are growing on the safety of and adverse drug reactions from the use of TRM. Thus, safety, efficacy and quality control of TRM products has become essential to health authorities and a tangible need for developing PV in TRM has emerged. In this context, WHO produced guidelines for the Safety Monitoring of Herbal Medicines in PV Systems. In view of the unique characteristics of herbal medicines, the guidelines tried to identify certain challenges posed in monitoring the safety of herbal medicines effectively and proposed approaches to overcome such issues. Such PV systems are essential for developing reliable information on the safety of TRM practices.

As many TRM products on the market have not been thoroughly tested for their pharmacology and toxicology, PV has paramount importance in detecting unwanted reactions. This document is focused on measures to strengthen PV systems, particularly enhancing communication between the drug regulating authorities to ensure progress towards safety of TRM practices.

Though pharmacovigilance has been established in eight of the SEA Region’s Member countries, it is not fully functioning in all of them. Challenges in accomplishing safety surveillance of TRM products include:

(1) Unique therapeutic approaches: Health maintenance and disease management in TRM is unique and deals with empirical practices, including medication with natural elements focusing on overall wellness with varied methodologies and philosophies. Understanding an individual’s constitution forms the fundamental
basis in most TRM practices and the medicines are prescribed in a personalized manner after thorough examination of various factors. This suggests that every individual is unique with his constitution and treatment will be customized for every individual.

(2) Complexity of TRM products and preparation of a database: Unlike synthetic medicines, herbal medicines are typically chemically rich, complex products and not isolated single compounds. A number of factors can influence the qualitative and quantitative chemical profile of a product. Geographical origin (climate, soil, photoperiod), parts of the plant used (leaf, stem, root, etc.), time of harvesting (year, season, time of day), storage, processing, mode and chemical used for extraction, combinations of herbs and/or processing of the combined herbs as medicines all influence the final product and its actions and efficacy. These situations have a great impact on the chemo-profile of the TRM product. Thus, identifying and understanding such complexity is a difficult task in TRM therapeutics.

Besides herbal medicines, many TRM systems use processed metals, minerals and animal resources in therapeutics. All such resources also need to be considered under the PV systems.

(3) Herb-drug interactions: Often, consumers believe that TRM products are natural and safe and are increasingly being used as dietary supplements/nutraceuticals in the name of herbal products; and such supplements are available over the counter for self-medication. Unfortunately, evidence on herb-drug interactions (HDI) after their concomitant use with prescribed orthodox medicines is not available.

(4) Quality control: Quality control measures including standards for raw herbal material, good practices (including agricultural, cultivation, collection, storage, manufacturing, laboratory, and clinical, etc.) for TRM should be in place in all Member countries. Specified and uniform licensing schemes for manufacturing, import, export and marketing should be implemented that are pivotal to ensure safety and efficacy of TRM.

(5) Regulation: National regulation and registration of TRM practices differs from country to country. TRM products may be available as either prescription or non-prescription medicines and at times, they may also be available as health supplements, functional foods, dietary supplements, nutraceuticals, etc. There are subtleties in the legal differentiation between food supplement and herbal medicine. PV reporting may not be compulsory for such categories of non-medicine agents. Thus, the adverse reactions that may develop in such cases may not enter into the databases. Thus, it becomes mandatory to harmonize regulatory standards among all the Member States that can govern herbal supplements stringently.

(6) Objectionable advertisements: Misleading advertisements regarding TRM products are rampant in many countries and products that are so advertised are generally ineffective with potentially serious side-effects. It is pertinent to note that around 59% of Member States have reported a lack of appropriate mechanisms to control and regulate TRM product advertising. Except the PV programme for ASU&H medicines (Ayurveda, Siddha, Unani and Homeopathy) of India, none of the existing programmes considered reporting such rampant misleading advertisements in their PV programme. This aspect needs to be considered by national drug regulatory authorities.
(7) **Awareness and skilled manpower:** Despite global concerns about medication safety, there is a lack of awareness and knowledge of PV and ADR reporting among health-care professionals as yet. Early detection, management, and reporting of safety issues hold highest importance in this system; thus, the health-care professionals should be trained at regular intervals to improve skills related to the concepts of PV systems. These professionals particularly need to be trained in causality assessment.

(8) **Materiovigilance:** Any dysfunction or any change in the characteristics and/or performance of a device, which may lead to risk or serious relapse in the state of health of patients, is covered under this, and this needs to be reported. In TRM systems, it is common using various materials/instruments for different purposes. Except for classical literature, no systematic documented evidence is available on this aspect. It is important to consider this aspect in the national PV programme for TRM.

(9) **National inventories:** Though systematic documentation is seen in few Member countries, there is a need for preparing national inventories/catalogues on TRM resources.

Though WHO documents are available since more than a decade, PV for TRM is still in its infancy and its monitoring is experiencing unique challenges. To overcome these challenges, enabling methodologies, such as frequent training programmes, should be introduced.

Dr Manisha Shridhar, Technical Officer for IPR at the WHO Regional Office, expressed her views on the possible collaboration of the South-East Asian Regulatory Network (SEARN) for PV of TRM. She first elaborated on why SEARN is appropriate for this. She then described the complex and wide range of medical products in use, including medicines, vaccines, diagnostics and devices. She also described the need to leverage the expertise of the large pool of regulators for dynamic regulation, and to assist in science-based approaches to regulatory decision-making for assessing manufacturing quality, better allocation of resources to lower the regulatory burden on manufacturers and regulators, as well the complex influences on public health.

The five working groups of SEARN were for the following:

1. Quality assurance and standards of medical products, including laboratories.
2. Good regulatory practices (GRP), including GMP, GDP, etc.
3. Vigilance for medical products.
4. Information sharing platform.
5. Medical devices and diagnostics.

These can discuss about the challenges being faced in the PV of TRM and information can be shared among the Member States for further strengthening of the systems.

Professor Rachida Soulaymani, Director, WHO CC for PV, Morocco, discussed the WHO programme for International Drug Monitoring (PIDM) including the Uppsala Monitoring Centre and role of the WHO collaborating centre and said that the WHO PIDM started with the thalidomide tragedy which caused more than 12,000 cases of phocomelia in children born to mothers taking the drug in the 1950s and 1960s. The objective of PIDM is to promote the safe use of medicines and other health products around the world by maintaining and working on the World Database (VigiBase) of adverse effects of these health products.
The Safety and Vigilance Department at WHO headquarters, Geneva, is responsible for the development of policies, standards and guidelines for PV. This department is assisted by three WHO collaborating centres for pharmacovigilance that are appointed to promote WHO normative functions, to develop PV expertise, extend the scope of PV, and be a source of training and support for countries.

By 2020, 170 Member States participated in the PIDM to share the vision of safer and more effective use of medicines, to work nationally and collaborate internationally, and to monitor and identify the harm caused by medicines. These are engaged to report data collected on ADRs to the international Database (VigiBase) and to share their national experiences. The programme supports national PV centres by providing information exchange, guidelines, specific and targeted support, and building partnerships within the WHO public programme.

The best way to manage the widened scope of PV is to build an integrated system which will lead to sharing tasks and tools and to reduce human and financial needs. This integrated system will allow having a one stop shop for reporters to reduce the impact of underreporting and to develop a global database for robust and earlier signal detection and risk minimization, and finally an integrated vigilance system will reinforce sharing expertise and cross-learning between different types of vigilance processes.

Integrating TRM vigilance in the classical PV system is an efficient option but needs some new terminologies and coding development, a common reporting form including herbal specific items, an optimization of VigiFlow in order to report to VigiBase, and to retrieve information for signal detection from VigiBase by using VigiLyse. Methods and techniques should be developed in order to optimise causality assessment and data management.

The Safety and Vigilance Department in WHO Geneva and WHO collaborating centres can play a key role to support countries on this, particularly by developing and disseminating guidance on how to develop a phytovigilance system and an integrated vigilance system, by developing definitions, terminologies, coding tools and methodologies, and by assuring training and capacity-building.

Professor Liu Xinmin made a presentation on the important subject of Herb-drug interaction and pharmacovigilance for herbal medicine in the People’s Republic of China. Monitoring the safe use of herbal medicines is a big challenge, he said. Although there are many advisories and documents on this specific area, difficulties are still being faced. More and more people are using herbal medicines for preventive purposes and at times along with conventional medicines, but the legal status and definition of herbal medicine varies in different Member States.

Herb-drug interaction (HDI) is a big issue for PV programmes on herbal medicines, but the challenge remains with how to define herbal medicines and related products. Prof. Liu highlighted the importance of the need to define clearly all types of herbal medicines, and collect data on the legal status of herbal medicine in Member States. At the same time, evolving strategies to develop nationwide networking and systematic data collection is essential. Chinese experiences in safety monitoring of traditional medicines are useful and interesting and can be considered as an example.

Member States then shared their experiences with monitoring quality/safety of TRM products in their countries, especially focusing on best practices in PV. Some particular experiences are enumerated below:
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<tr>
<th></th>
<th>Country</th>
<th>Name and Position</th>
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</table>
|1 | Bangladesh | Dr Md Nuruzzaman Sarker  
Ayurvedic expert, Directorate General of Drug Administration (DGDA), Dhaka, Bangladesh |
|   | Bangladesh | There are three systems of TRM recognized by the Government of Bangladesh – Unani, Ayurveda and herbal medicine. National formularies and National Essential Medicines Lists (with 98 Ayurveda and 180 Unani products) are available for the respective systems. The Bangladesh National Ayurvedic formulary has about 300 formulations, while the Bangladesh National Unani formulary has 350 formulations. Though there is an existing PV system in the country, TRM products are not integrated into these systems. |
|2 | Bhutan | Mr Jigme Dorji,  
Regulatory Officer, Post-Marketing Control Division, Bhutan |
|   | Bhutan | Sowa Rigpa is the recognized TRM system in Bhutan. A total of 73 TRM products are registered in the country as of 2020, and no TRM products are listed in the National Essential Medicines List so far. The PV system for TRM is integrated under the National PV system since 2017. However, resources are minimal and trained manpower is lacking to identify and analyse ADRs. Awareness and frequent training are essential. |
|3 | India | Professor Tanuja Manoj Nesari,  
Director, National Pharmacovigilance Coordination Centre, All India Institute of Ayurveda, Ministry of AYUSH, New Delhi, India |
|   | India | Various TRM systems (Ayurveda, Yoga & naturopathy, Unani, Siddha, Sowa-Rigpa, Homoeopathy) are formally recognized in India and are being governed by the independent Ministry of AYUSH. The systems have been supported with policies and regulatory provisions. Pharmacopoeial committees and Essential Medicines Lists for individual systems are existing. A total of 1124 drugs (277 Ayurveda, 257 homoeopathy, 302 Siddha, 288 Unani) feature in the Essential Medicines List. India is the only country in the Region that has developed and applied a separate PV system focusing on TRM products. The system was initially established in 2008, however is revised in December 2017 with addition of Homoeopathy. The system has a three-tier hierarchy and about 80 centres are functioning throughout the country.  
The programme takes inputs from the Indian Pharmaceutical Commission (IPC) which houses the Pharmacovigilance Programme of India, the Central Drugs Standard Control Organization (CDSCO, a functional NRA), and the WHO Country Office (technical officer dealing with pharmacovigilance) at regular intervals. A separate website hosts information about this programme (https://www.ayushsuraksha.com/). A separate format for reporting suspected ADR is implemented. A unique feature of the programme is reporting misleading/objectionable advertisements along with reporting suspected ADRs. Although the system is well-established, it lacks trained/dedicated experts/manpower. |
|4 | Indonesia | Ms Lia Amalia,  
Section of Traditional Medicine and Health Supplements Safety Control, Jakarta, Indonesia |
<p>|   | Indonesia | Jamu, the standardized herbal medicine, and Phytopharmaca are the three officially recognized TRM systems in Indonesia. A total of 12 011 TRM products have been registered over the last five years in the country. However, no Essential Medicines List exists. The basic provisions for classifying and labelling TRM and PV system for TRM is integrated under the national PV system. However, coordination with health service facilities have not been established for PV of TM products. A total of 19 adverse events related to TRM products were reported in 2018, while 78 were reported in 2019. Under-reporting, minimal awareness, lack of association with conventional health service facilities are the challenges being faced. |</p>
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<thead>
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<th>Country</th>
<th>Name</th>
<th>Details</th>
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<tbody>
<tr>
<td>Maldives</td>
<td>Ms Bishara Ahmed, Pharmaceutical Officer, Male, Maldives</td>
<td>Dhivehi Beys and alternative medicine are the recognized TRM systems in the Maldives. The medicine regulations provide the regulatory framework to some extent. Till 2020, 468 products (42 Dhivehi Beys and 426 alternative medicine) were registered. The National Essential Medicines List exists, and 52 TRM products featured in the Essential Medicines List in 2018, while 5 more products were added in 2019. However, the legal framework for regulating TRM is not strong. PV of TRM products is not well established and ADR reporting is not mandatory. No trained and skilled manpower is available and there is a weak legal framework, inadequate resources and poor communication between other regulatory bodies in the Region are the challenges faced by the country.</td>
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<td>Myanmar</td>
<td>Dr Tun Myint Aye, Deputy Director, Department of Traditional Medicine, Ministry of Health and Sport, Nay Pyi Taw, Myanmar</td>
<td>Myanmar Traditional Medicine Systems include four “Nayas” (Desana, Bethizza, Netkhatta and Vezzadara). The product development assures safety protocols. The total number of registered TRM products in the country is 15 040 and 57 TRM products feature in the National Essential Medicines List as of 2020. One adverse event has been reported during 2019. Though a formal PV system is not established, PMS services are in force, functioning in association with the FDA, Department of Consumer Affairs, General Administration Department, and the Police. Unfamiliar PV systems, lack of the knowledge, and lack of trained persons are the challenges.</td>
</tr>
<tr>
<td>Nepal</td>
<td>Dr Santosh Kumar Thakur, Department of Drug Administration, Kathmandu, Nepal</td>
<td>Recognized TM systems in the country are Ayurveda, homeopathy, Unani and naturopathy. There are about 2000 registered TRM products and about 23 products feature in the National Essential Medicines List. PV system was established in 2004, however, no specific system exists for TM. Self-medication, concomitant use, and the general belief among the public that herbal medicines are safe are the major factors which welcome stringent product regulation and monitoring. Increasing awareness and improving skills through training programmes are required.</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>Dr S.G. Kisholorjan, Ayurveda Medical Officer, Bandaranaike Memorial Ayurvedic Research Institute &amp; Member, Formulary Committee, Colombo, Sri Lanka</td>
<td>Deshiya Chikitsa (indigenous TRM), Ayurveda, Siddha and Unani are the TRM systems in the country. Though 1193 TRM formulations are in national TRM pharmacopoeias, but there are no TRM products in the National Essential Medicines List. PV is operated by the National Medicines Regulatory Authority since 2015, but TRM is not incorporated into the National PV Programme. There is no organized formal mechanism for post-marketing assessment of TRM product safety. Insufficient integration with PV systems, non-availability of dedicated PV units, weak legal framework, poor awareness and lack of trained manpower are the challenges.</td>
</tr>
<tr>
<td>Thailand</td>
<td>Dr Pattreya Pokhagul, Head, Health Product Vigilance Centre, Thailand</td>
<td>TRM system is recognized by the consumer, health-care professional (HCP) and marketing authorization holder. About 18 823 herbal medicines and TRM products were registered till 2020 and about 74 herbal medicines and TRM products feature in the National Essential Medicines List. The PV system was established in 1983. Herbal medicines and TRM products are being monitored under PV since 2001.</td>
</tr>
</tbody>
</table>
Thailand has a well-established PV network and data management flow. Spontaneous reporting is the main method for collecting and reporting. Since 1984, PV is participating in the WHO PIDM and the number of Thai AE reports in the WHO VigiBase stand at 412,401. No ATC codes for Thai traditional medicines and less participation from Thai traditional health-care professionals to report are the challenges expressed.

10  Timor-Leste  
Dr Celeste Cham,  
Head, Pharmacovigilance and Medicines Control, MoH, Timor-Leste

The Department of PV and Medicine Control was established in 2016 under the National Directorate for Pharmacy and Medicines (equivalent to NRA). Only 20 TRM products were registered by 2020 and no product is enlisted in the National Essential Medicines List. The PV department has sent three pharmacists to undertake basic training in PV. This was followed by the conduct of a series of orientation workshops to disseminate the PV guidelines. However, there is no PV system for TRM products. TRM products are listed in the National Essential Medicines List. Weak legislation and lack of regulation for TRM products, limited staff, poor understanding and lack of manpower with expertise in PV are the challenges.

Besides this sharing of experiences, there was also a session of group work to identify country-specific priority action points in the field of PV. The countries were grouped into two as below:

Group 1: Countries with well-developed PV systems, including Bhutan, India, Indonesia and Thailand

Group 2: Countries with less-developed PV systems, including Bangladesh, Maldives, Myanmar, Nepal, Sri Lanka and Timor-Leste

The questions discussed in the group and priority action points expressed were:

**Question 1:** What would be the top priority areas to strengthen PV for TRM products, and specifically how to increase number of AEs reported?

1. Establishing PV systems with dedicated manpower in those Member States where no PV systems exist. Creating awareness regarding PV system among different stakeholders (MSs).
2. Improving voluntary participation of health-care professionals (MSs).
3. Developing linkages with national drug regulatory systems (MSs).
4. Creating AI-based mobile applications for easier reporting (MSs).
5. Strengthening the role of community pharmacists in reporting (MSs).
6. Uniform policies for pharmaceutical sectors of different systems (MSs).
7. Involving quality, safety-related aspects in public health programmes and PV related topics in TRM curriculum (MSs).
8. Developing skilled/trained manpower, particularly in causality assessment (MSs).
9. Appreciation of active involvement in the PV programme through incentives, and these incentives may be linked to continuum of licences, etc. (MSs).
10. Toll-free helpline on hospital cards (MSs).
11. Developing drug safety alert systems as in ASEAN countries (MSs).
12. Releasing E-newsletters at regular intervals (MSs).
Virtual Workshop on pharmacovigilance (PV) for traditional medicine (TRM) products in the WHO South-East Asia Region

Question 2: How to further strengthen collaboration with International / national programmes such as the WHO Programme for International Drug Monitoring (PIDM), the National Pharmacovigilance Center or National Regulatory Agency?

(1) Developing causality assessment scales suiting TRM therapeutics (WHO SEARO).
(2) A mechanism/common platform to exchange information related to PV between Member States (WHO SEARO).
(3) Communicate with the governments to facilitate harmony in PV systems of TRM and conventional medicine in respective countries (WHO SEARO).
(4) Organize frequent training programmes and encourage participation in them by Member States (WHO SEARO).
(5) Execute MoUs with the WHO collaborating centres (MSs).
(6) Initiate faculty exchange programmes (MSs).

Question 3: What kind of technical support do Member States expect from WHO?

(1) Skills of the PV personnel are to be strengthened through frequent training programmes, particularly in the field of signal detection processes, causality assessment, use of vigibase, vigilyze, systematic structuring of PV-related information, etc. (WHO).
(2) Training in the field of Herbal Anatomical Therapeutic Classification System (HATC) (WHO).
(3) Global consensus on the classification and definition of TRM practices (WHO).
(4) Consider the reporting of objectionable/misleading advertisements under the PV Programme (WHO).
(5) Consider aspects of Materiovigilance, Cosmetovigilance and Nutravigilance in PV of TRM systems (WHO).

5. Conclusions

The virtual workshop was concluded with below summarized recommendations:

(1) Establish an integrated PV system covering TRM products in all SEA Member States.
(2) Establish a mechanism or create a common platform to exchange information and sharing of experiences related to PV between Member States.
(3) Build capacity through frequent training programmes on PV with special emphasis on causality assessment and signal detection, use of VigiBase, VigiLyze, systematic structuring of PV related information, etc.
(4) Consider the reporting of objectionable/misleading advertisements under the PV Programme.
(5) Consider aspects of Materiovigilance, Cosmetovigilance and Nutravigilance in PV of TRM systems.
Annex 1

Message of the Regional Director, Dr Poonam Khetrapal Singh, at the virtual Workshop on pharmacovigilance for traditional medicine products in the South-East Asia Region

A warm welcome to this regional workshop on pharmacovigilance for traditional medicine products. Since 2014, achieving universal health coverage has been one of the WHO South-East Asia Region’s Flagship Priorities. To achieve that goal, traditional medicine has much to contribute. Not only do traditional medicines have great therapeutic potential, but they can also help integrate communities into health systems by providing positive, culturally familiar health-care experiences.

It is with good reason that in recent years the popularity of traditional medicine has increased across the world as part of a move towards a more holistic approach to preventive and promotive health. But as WHO’s Global Strategy on Traditional Medicine underscores, for us to leverage the full power of traditional medicine we must ensure that it is safe and effective – a message that is especially important in the current context as countries respond to the COVID-19 pandemic.

Across the Region, we are making real progress. Ten countries have national policies on traditional medicine. Nine have formal training and education systems for traditional medicine practitioners. Six countries have co-located traditional medicine services in their health systems at some or all levels. Five have an essential drug policy on traditional medicine products and include traditional medicine products in their national essential drug list.

Progress on safety monitoring has gathered pace. In 2015 the WHO Regional Office identified the development of pharmacovigilance systems as one of the Region’s priority areas in traditional medicine. In 2017 WHO developed a Briefing Note on Pharmacovigilance, which was followed in 2018 by the carrying out of a baseline survey on pharmacovigilance for traditional medicine products. Your efforts over the coming days will build on this momentum, and I wish you successful deliberations.

It is imperative that as a result of this workshop all countries establish or strengthen safety monitoring systems, ideally as part of nationwide integrated pharmacovigilance systems. Such systems must be able to rapidly identify adverse events and provide health authorities the chance to efficiently respond.

Moreover, all countries must develop systems to share information on adverse events with other countries through mechanisms such as the South-East Asia Regulatory Network. I am certain that the best practices identified and shared through this workshop, in addition to the experiences you will share with one another, will help achieve these outcomes.

WHO’s Global Traditional and Complementary Medicine Strategy has three strategic objectives. First, to build our knowledge base. Second, to strengthen quality assurance, safety and effectiveness. And third, to promote universal health coverage. This workshop will help us deliver on all three. I wish the workshop all success and reiterate WHO’s full support to you as together we strive to achieve health and well-being for all people, at all ages.
Annex 2

Agenda

The agenda for the meeting included:

1. Brief on overall situation of Pharmacovigilance for TRM products for the WHO South-East Asia Region.
2. Brief on overall situation of the WHO programme for International Drug Monitoring (PIDM) including Uppsala Monitoring Centre (UMC)'s role.
3. Key technical issues for herbal medicines with reference to interaction with other medicines.
4. Training and update on safety monitoring of herbal medicines in pharmacovigilance systems.
5. International experience in monitoring TRM products’ safety/quality (outside WHO SEA Region).
6. Update on SEARN.
7. Member States’ experiences in monitoring safety and quality of TRM products.
9. Group/plenary discussions on country and region-specific action points/roadmap towards enhanced safety monitoring for TRM products and international network.
10. Way forward/priority action points.
11. Conclusions and recommendations.
Annex 3

Example of Reporting form for suspected adverse reaction to herbal medicines

PLEASE NOTE: all consumer/patient and reporter information will remain confidential.

Patient/consumer identification (please complete or tick boxes below as appropriate)

<table>
<thead>
<tr>
<th>Patient initials</th>
<th>Patient/record number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethnicity</td>
<td>Date of birth</td>
</tr>
<tr>
<td>Address (place and region, or health facility may be used)</td>
<td>Sex □ M □ F Others</td>
</tr>
<tr>
<td></td>
<td>Constitution / Temperament</td>
</tr>
</tbody>
</table>

List of all medicines/vaccines/herbal medicines used by the patient during the past one month. Please indicate suspected medicines with an asterisk (*) (please complete boxes below)

<table>
<thead>
<tr>
<th>Medicine(s)</th>
<th>vaccine(s)</th>
<th>herbal medicine(s) + batch no.</th>
<th>Daily dose</th>
<th>Route of administration</th>
<th>Date started</th>
<th>Date stopped</th>
<th>Reason for use and specific instruction of herbal drug use were followed or not?</th>
</tr>
</thead>
</table>

Give detailed information on the product

Product name:

How was the product obtained?

How the products are being used? (Self-Medication / Under consultancy)

Concomitant Use?

List of product ingredients; attach product label if available:

Expiry date:

Name and address of the manufacturer:

Name and address of the distributor:

Other relevant information:

Description of the suspected adverse reaction (please complete boxes below)

Date of onset of reaction (dd/mm/yy):

Description of reaction (please include results of laboratory tests if available):

Outcome of the suspected adverse reaction (please tick boxes as appropriate)

<table>
<thead>
<tr>
<th>Recovered</th>
<th>Not yet recovered</th>
<th>Unknown</th>
<th>Fatal</th>
<th>Date of death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe? Yes □ No □</td>
<td>Rechallenge? Yes □ No □</td>
<td>Result:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Was the patient admitted to hospital?

If yes, give name and address of hospital:

Other factors (please tick box or describe as appropriate)

<table>
<thead>
<tr>
<th>Kidney disease</th>
<th>Liver disease</th>
<th>Allergy (please describe)</th>
<th>Malnutrition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other illnesses (please describe):</td>
<td>Malnutrition</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Report identification

Type (please circle): nurse/doctor/pharmacist/other health worker/manufacturer/distributor/supplier

Name: 

Address: 

Telephone: 

E-mail address: 

Signature of reporter: .......................................................... 

Date: ..........................................................

Please send completed form to: ..........................................................
## Annex 4

### List of participants

<table>
<thead>
<tr>
<th>Government Nominees</th>
<th>Maldives</th>
</tr>
</thead>
<tbody>
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<td>Ms Bishara Ahmed</td>
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Virtual Workshop on Pharmacovigilance (PV) for traditional medicine (TRM) products in the WHO South-East Asia Region

30 November – 2 December 2020