Short Communication

Pharmacovigilance in AYUSH Systems of Medicine

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INTRODUCTION

The Sustainable Development Goals (SDGs), were adopted by all United Nations Member States in 2015 as a universal call to action to end poverty, protect the planet and ensure that all people enjoy peace and prosperity by 2030.[1] Traditional Medicine (TM) can play a pivotal role in meeting these SDGs particularly of the SDG 3 (*ensure healthy lives and promote wellbeing for all at all ages*). Across the world, TM is either the mainstay of healthcare delivery or serves as a complement to it. Traditional systems of medicines have a long history of use in the maintenance of health as well as in disease prevention and treatment. They are being used since centuries for healthcare by people in countries of South East Asia Region as well as in other parts of the world. Since the concept of Health for all through primary health care was launched at Alma-Ata in 1978; there has been a global movement to realize universal health-care coverage. The demand for traditional medicine is improving consistently at global levels. It has been reported that, 88% Member States have acknowledged the use of TM which corresponds to 170 Member States.[2] Traditional medicine continues to be a valuable source of remedies to the people around the world to secure their health,[3] and they continue to expand rapidly across the world and many people now follow traditional systems of medicines for their health care.

Parallel to this increasing demand and their acceptance in various countries; concerns are growing on safety and adverse drug reactions on the usage of TM. A few traditional formulations were said to have developed serious adverse events, including hepatotoxicity, renal failure, and allergic reactions.[4-11] Such adverse events can give a negative impression regarding the use of TM. Thus, Safety, Efficacy and Quality Control of TM related products became an important concern to health authorities and a need of developing pharmacovigilance systems in TM has been recommended. Subsequently, The World Health Organization (WHO) received requests from its Member States to assist Member States to strengthen national capacity in monitoring the safety of herbal medicines and in analysing the causes of adverse events, and to share safety information at various levels. In this sequence, WHO has produced guidelines for the *Safety Monitoring of Herbal Medicines in Pharmacovigilance System,* that has been developed as a joint project between the Traditional Medicine Team (TRM) and the Quality, Safety: Medicines Team (QSM) in the Department of Essential Drugs and Medicines Policy (EDM) at WHO headquarters.[12] The recommended approach is to include herbal medicines in existing national pharmacovigilance systems or, where such systems have not yet been developed and to establish comprehensive national pharmacovigilance systems which incorporate coverage of herbal medicines. In view of the unique characteristics of the herbal medicines; the guidelines tried to identify certain challenges posed in monitoring the safety of herbal medicines effectively and proposed approaches for overcoming such issues. Such Pharmacovigilance systems are essential for developing reliable information on the safety of TM practices.

As many TM products on the market have not been thoroughly tested for their pharmacology and toxicology, pharmacovigilance has paramount importance in detecting unwanted reactions. The WHO guidelines on *Safety*

Monitoring of Herbal Medicines in Pharmacovigilance System is thought to be a useful document for strengthening Pharmacovigilance system particularly enhancing communication in between the drug regulating authorities that is very much essential to ensure progress towards the common goal i.e. safety of TM practices.

In recent years, although several studies have been carried out to explore the structure, function and achievements of the pharmacovigilance landscape for Traditional & Complementary Medicine (T&CM) products in developed and developing countries, none of them have reported on the status of pharmacovigilance with a focus on T&CM in all the countries of the WHO South-East Asia Region.[13] Eight-member countries from SEARO had established national Pharmacovigilance programs. Thailand, Indonesia, and India have established centres before 2000, while in other countries the program was initiated after 2000. (Table-1)

Table-1: Situation of Pharmacovigilance for T&CM products

1	No established National Pharmacovigilance System	1. Democratic People's Republic of Korea 2. Myanmar
2	NOT having T&CM products integrated into the existing pharmacovigilance systems	1. Bangladesh, 2. Maldives, 3. Nepal, and 4. Sri Lanka
3	Existing pharmacovigilance systems covering T&CM products.	1. Bhutan, 2. Indonesia and 3. Thailand
4	Separate Pharmacovigilance system for T&CM products	1. India

Source: Pharmacovigilance and Traditional and Complementary Medicine in South-East Asia: A Situation Review (https://apps.who.int/iris/bitstream/handle/10665/325982/9789290227250-eng.pdf)

India is the only country in the South East Region of WHO that has developed and applied a separate Pharmacovigilance system focusing on TRM products. The system was initially established in 2008 at Gujarat Ayurved University, Jamnagar. In order to ensure effective implementation; the program has been restructured by the Ministry of AYUSH, Government of India, under the Central Sector Scheme including Homoeopathy component (i.e. ASU&H drugs) during 2017 in support and guidance of the Indian Pharmacopoeia Commission and concerned program officers of the WHO Country Office, India. The All India Institute of Ayurveda, New Delhi, has been recognized as National Pharmacovigilance Coordination Centre (NPvCC) for this program. The purpose of the initiative is to collect, collate and analyse data related to suspected adverse drug reactions (ADRs) and undertake surveillance of advertisements related to ASU&H drugs thus to establish evidence clinical safety of these drugs in a scientific manner.

The scheme mainly aims at

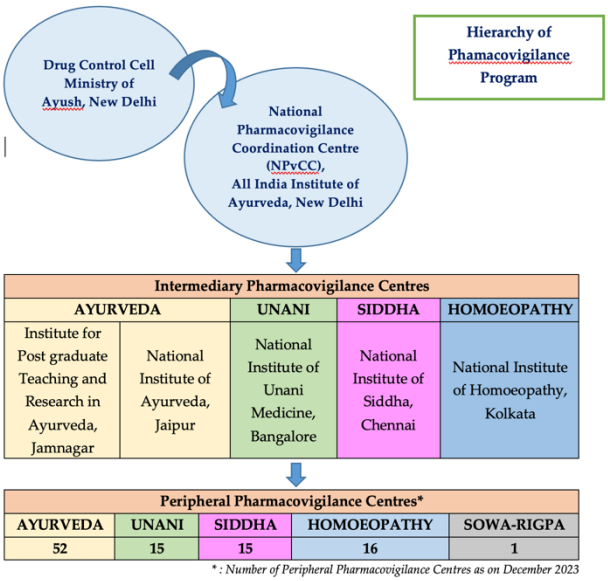
(i) inculcating reporting culture among ASU&H stakeholders to facilitate documentation of suspected ADRs ASU & H drugs;

(ii) inculcating reporting culture among ASU&H stakeholders to facilitate documentation of misleading advertisements for ASU & H drugs;

(iii) developing a system-wide database of ADRs associated with ASU&H drugs;

(iv) evolving evidence-based recommendations regarding the clinical safety and improper advertisements of ASU&H drugs for regulatory actions.

In order to monitor the implementation of the programme and measure its efficacy, the NPvCC established key indicators, such as (i) process (ii) outcome and (iii) impact of the program. The process indicators assess the number of ADR monitoring centres participating in the program and the surveillance of advertisements of ASU&H medicines, the number of personnel trained in ADR monitoring and surveillance of advertisements of ASU&H medicines and practices for effective implementation of the program. The outcome indicators evaluate the number of suspected ADR reports received and processed each year, and the number of misleading advertisements relating to ASU&H medicines and practices reported and processed each year.



During the past six years, the assessment of the data associated with the use of ASU&H medicines, inferred that most reports are attributable to improper use, and can be categorized under two headings i.e. patient-related and physician-related. Good dispensing practices ensure that an effective form of the correct medicine is delivered to the right patient, in the correct dosage and quantity, and with clear instructions. The efficacy of the drug also depends on its correct administration.

Disease management in ASU&H systems involves various practices, including medication with natural substances, with varied methodologies and philosophies, and in a personalized (individualised) manner after thorough examination of various factors. Unlike synthetic medicines, herbal medicines are complex products and not isolated single active molecules. Thus, evaluating ADR reports associated with use of medicines in ASU&H systems becomes a big challenge. The suspected ADR reports are often related to the gastro-intestinal system; the reported reactions include nausea, loss of appetite, hyperacidity, diarrhoea, constipation, abdominal bloating, are usually mild and non-serious in nature.

CONCLUSION

To Conclude: Traditional medicines are widely used in healthcare throughout the world. However, considering the safety concerns that may have a negative impact on the traditional practices and to increase recognition to these practices; safety monitoring mechanisms through pharmacovigilance systems is very much essential. Though WHO documents are available since more than a decade; the pharmacovigilance system for traditional systems is in infancy and its monitoring is experiencing unique challenges. To overcome these challenges; exclusive set-up equipped with dedicated, trained man-power is essential who can be enriched with frequent capacity building programs to enable the system.

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