Pharmacovigilance In Homoeopathy: A Review of Current Trends

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***Abstract*—Pharmacovigilance is an integral part of the healthcare system, focusing on the detection, evaluation, understanding, and prevention of adverse drug reactions and drug-related problems. However, due to the growing development of pharmaceuticals, vaccines, biologics, and Ayush systems of medicine, there has been a substantial increase in the role of pharmacovigilance. The recent trends in pharmacovigilance include focusing on patient-reported outcomes, international standardisation of drug databases, and pharmacovigilance in special populations. At the same time, systems like homoeopathy are finding greater importance in adopting the principles of pharmacovigilance to work towards drug safety and rational utilisation. This paper aims to discuss the current scenario of pharmacovigilance.**

***Index Terms*—Pharmacovigilance, Adverse Drug Reactions, Drug Safety, Current Trends**

I. INTRODUCTION

The word "pharmacovigilance" is derived from the Greek word "pharmakon," meaning "medicinal substances," and the Latin word "vigilare," meaning "to keep watch." It means to monitor how medications are working.[1]

The World Health Organisation (WHO) defines pharmacovigilance as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine/vaccine-related problem."[2]

II. EVOLUTION

A system to observe the effects of pharmaceuticals after they are cleared for mass usage was established due to several negative drug incidents in the past. Records indicate that the history of ADR began on January 29, 1848, when Hannah Greener, a young girl from northern England, passed away following the use of chloroform anaesthesia before the removal of an infected toenail.[3]

Over time, the entire world began to work to develop a pharmacovigilance system. As the WHO collaborating centre for international drug monitoring, the Uppsala Monitoring Centre (UMC) was established in Sweden in 1978. It runs the WHO's global pharmacovigilance network's scientific and technological components.[4]

In India, the India Pharmacovigilance Society began raising awareness of ADRs in October 1983 at Maulana Azad Medical College in New Delhi. In 1989, the ICMR sponsored the first ADR project in the pharmacology department of Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh. In 1999, the Society of Pharmacovigilance India (SoPI) was established and registered as a dedicated forum for future discussions. In 2010, the National Pharmacovigilance Programme (NPP) was introduced under the Central Drug Standard Control Organisation (CDSCO), Ministry of Health & Family Welfare, Government of India, New Delhi. In 2011, the National Coordinating Centre transferred from the All-India Institute of Medical Sciences (AIIMS) in New

Delhi to the Indian Pharmacopoeia Commission (IPC) in Ghaziabad, Uttar Pradesh.[5]

III. PHARMACOVIGILANCE IN HOMOEOPATHY

Worldwide, the use of homoeopathy as a therapeutic approach is becoming more and more popular every day. Pharmacovigilance is crucial in homoeopathy since it aids in determining the efficacy and safety of homoeopathic medications. Although homoeopathic medications are usually seen to be harmless, there have been some cases when they have had side effects. Thus, it is important to assess the effectiveness and safety of homoeopathic medications. The World Health Organisation (WHO) has created guidelines for pharmacovigilance in homoeopathy that address risk management, regulatory requirements, and pharmacovigilance concepts.[6]

The first work related to adverse drug reactions in the AYUSH sector occurred in 2005, when the Ibn Sina Academy of Medieval Medicine & Science (Aligarh) established the "Centre for Safety & Rational Use of Indian Systems of Medicine," in collaboration with WHO. In 2008, the Department of AYUSH, Ministry of Health and FW, Govt. of India, New Delhi, organised the first National Consultative Meet of the National Pharmacovigilance Programme. In March 2018, the Ministry of AYUSH signed an MoU with NCC-IPC; subsequently, the National Pharmacovigilance Program for Ayurveda, Siddha, Unani & Homoeopathy was launched as a Central sector scheme.[7]

IV. AYUSH PHARMACOVIGILANCE NETWORK [8,9]

To monitor the safety of AYUSH medications, the Ministry of AYUSH established a three-tiered network of pharmacovigilance centres, including Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homoeopathy. The goal of this system is to identify, evaluate, comprehend, and stop adverse drug events (ADEs) and other drug-related issues that are connected to various medical systems. The 3-tiered networks are:

1. A National Pharmacovigilance Coordination Centre (NPvCC): All India Institute of Ayurveda (AIIA), New Delhi, has been designated as NPvCC by the Ministry of AYUSH.
2. Intermediary Pharmacovigilance Centres (IPvCs): All the national institutes (AYUSH) are included. For homoeopathy, it is the National Institute of Homoeopathy, Kolkata, West Bengal.
3. Peripheral Pharmacovigilance Centres (PPvCs): There are 15 PPvCs in India.

i) National Homoeopathy Research Institute in Mental Health, under CCRH Kottayam, Kerala.
ii) D. P. Rastogi Central Research Institute for Homoeopathy, under CCRH, Noida, UP.
iii) Regional Research Institute for Homoeopathy, under CCRH Gudivada
iv) Regional Research Institute for Homoeopathy, under CCRH, Guwahati.
v) Regional Research Institute for Homoeopathy (Dr. Anjali Chatterjee RRI for Homoeopathy), under CCRH, Kolkata.
vi) Regional Research Institute for Homoeopathy, under CCRH, Mumbai.
vii) Regional Research Institute for Homoeopathy, under CCRH, Imphal.
viii) Regional Research Institute for Homoeopathy, under CCRH, Agartala.
ix) Government Homoeopathic Medical College and Hospital, Bhopal.
x) Mahesh Bhattacharya Homoeopathic Medical College & Hospital, Howrah, West Bengal.
xi) Sarada Krishna Homoeopathic Medical College, Kulasekharam, Kanyakumari, Tamil Nadu.
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Recently, on 30th May, 2025, the Ministry of Ayush has launched an online portal, the "Ayush Suraksha" Portal, to Address Issues of Misleading Advertisements and Adverse Drug reactions.

V. REPORTING [8]

Reporting of ADE (Adverse Drug Events)/ADR (Adverse Drug Reaction). There are a few criteria:

- Only a health care professional may report the ADR. If a patient develops ADR, he or she may report it through the physician under whom they have taken treatment.
- When reporting, the Adverse Drug Reaction Reporting Form, which is designed for AYUSH systems, must be used.

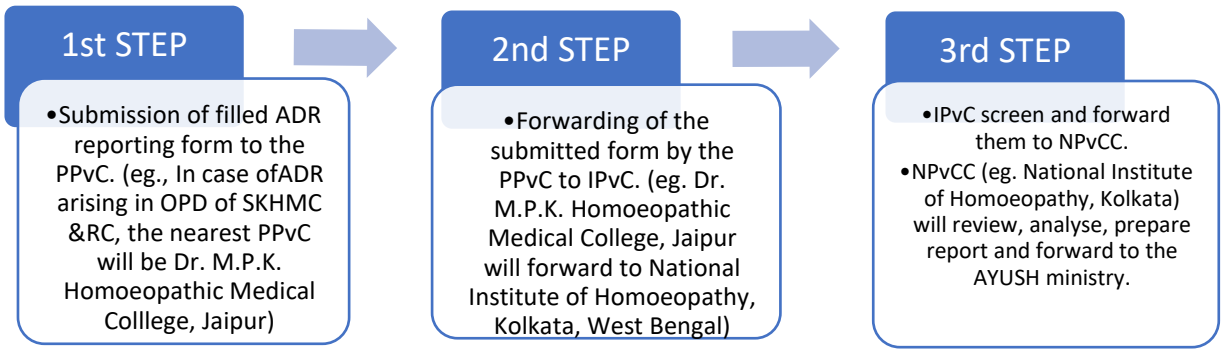

FIGURE 1: SEQUENCE OF REPORT OF ADR/ADE WITH EXAMPLE.

- Further, the compilation of data on ADRs and the safety profile of each drug is done.

VI. CONCLUSION

Pharmacovigilance in homoeopathy plays an essential role in ensuring patient safety, maintaining public trust, and gaining scientific research, but it faces several challenges and limitations. Some of these include the underreporting of adverse drug reactions (ADRs) due to misconceptions about the complete safety of homoeopathic remedies, a lack of training for practitioners on how to recognise ADRs, the absence of dedicated pharmacovigilance centres, poor integration with national reporting systems, and gaps in quality control. To create a reliable safety monitoring system in homoeopathy, we need to tackle these issues by enhancing reporting processes, launching comprehensive awareness campaigns, and strengthening the necessary infrastructure.

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