WAR Journal of Multidisciplinary Bulletin
(WARJMB)

ISSN (Online): 1595-6709
ISSN (Print): 1595-6636

Received: 02-03-2026 Revised: 26-03-2026 Accepted: 05-04-2026 Published: 18-04-2026

Research Article

Pharmacovigilance: Ensuring Drug Safety in Healthcare

Dr. Dewesh kumar dewanshu[1*], Prof. Dr Rinku Bishwas, Prof. Dr.Ruchi Wadhwa(Biswas)[2] ,Dr. Chandramani Singh[4], Dr.Renu Yadav[5], Dr.Peeyush Kumar Gupta[6]

[1]B.H.M.S., M.D.(Hom.), Ph.D (Homoeo.)-Assistant professor, Department of Homoeopathic pharmacy, State Lal Bahadur Shastri Homoeopathic medical College and Hospital, Shantipuram, Prayagraj,Uttar Pradesh
[2]B.H.M.S., M.D.(Hom), ,Ph.D(Hom.)(Sc.),H.O.D. and Professor-Department of Pathology & Microbiology, State Lalbahadur shastri Homoeopathic Medical College and Hospital, Shantipuram, Prayagraj,Uttar Pradesh
[3]B.H.M.S., M.D.(Hom), Ph.D (Hom.) (Sch.), Professor & H.O.D. –Dept. of Forensic Medicine & Toxicology -State National Homoeopathic Medical College & Hospital, Gomti Nagar ,Lucknow, Uttar Pradesh
[4]B.H.M.S.,M.D.(Hom.),Assistant Professor- Department of Practice of Medicine-State Lalbahadur shastri Homoeopathic Medical College and Hospital, Shantipuram, Prayagraj,Uttar Pradesh
[5]B.H.M.S., M.D.(Hom),Assistant professor- Department of Homoeopathic Materia Medica-Maharshi Menhi Homoeopathic medical college and hospital, katihar-Bihar Uttar Pradesh
[6]B.H.M.S., M.D.(Hom), Assistant Professor-Department of Homoeopathic Materia Medica, State Lalbahadur shastri Homoeopathic Medical College and Hospital, Shantipuram, Prayagraj,Uttar Pradesh

OPEN ACCESS

Published in
VOI- 2 Issue: 2

DOI: 10.5281/zenodo.20756351

PP: 47-52

Correspondence:

Dr. Dewesh kumar dewanshu

B.H.M.S., M.D.(Hom.), Ph.D (Homoeo.)-Assistant professor, Department of Homoeopathic pharmacy, State Lal Bahadur Shastri Homoeopathic medical College and Hospital, Shantipuram, Prayagraj,Uttar Pradesh Email: drrkbiswas77@gmail.com

Abstract

Pharmacovigilance is a vital discipline in modern healthcare that focuses on monitoring the safety of medicines and preventing adverse drug reactions (ADRs). It encompasses the detection, assessment, understanding, and prevention of adverse effects or any other problems related to drugs, including interactions, misuse, and quality-related issues. With the rising use of pharmaceuticals and complementary systems of medicine such as homoeopathy, pharmacovigilance plays a crucial role in protecting public health and ensuring rational therapeutics. This article discusses the concept, objectives, methods, global and national pharmacovigilance systems, and the special relevance of pharmacovigilance in homoeopathy.

Keywords*: Pharmacovigilance, Adverse Drug Reaction, Drug Safety, Drug Monitoring, Homoeopathy.*

Introduction

Pharmacovigilance is the science concerned with monitoring the safety of medicines and detecting adverse effects associated with their use throughout the lifecycle of a drug, from pre-clinical research to post-marketing surveillance. According to the World Health Organization (WHO), pharmacovigilance is defined as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.”

WAR Journal of Multidisciplinary Bulletin
(WARJMB)
ISSN (Online): 1595-6709
ISSN (Print): 1595-6636
Received: 02-03-2026 Revised: 26-03-2026 Accepted: 05-04-2026 Published: 18-04-2026

The importance of pharmacovigilance became evident after the Thalidomide tragedy in the early 1960s, when thousands of children worldwide were born with severe limb deformities due to maternal use of thalidomide for morning sickness. This disaster exposed the dangers of inadequate safety monitoring and triggered the development of international drug-monitoring systems and much stricter drug-safety regulations worldwide.

2. Objectives of Pharmacovigilance

The main objectives of pharmacovigilance include:

Detection and reporting of adverse drug reactions (ADRs) from healthcare settings and community use.

Assessment of the risk–benefit ratio of medicines, including both new and established drugs, to guide prescribing and regulatory decisions.

Improvement of patient safety and public health by minimizing harm from medicines while preserving their therapeutic benefits.

Promotion of rational and safe use of medicines through education, guidelines, and feedback to prescribers and patients.

Identification of drug interactions, long-term adverse effects, and misuse patterns that may not be evident in pre-marketing trials.

Provision of timely information to healthcare professionals, regulatory authorities, and the public regarding emerging safety signals and label changes.

3. Adverse Drug Reactions (ADRs)

An Adverse Drug Reaction (ADR) is defined by WHO as “a response to a drug which is noxious and unintended and occurs at doses normally used in humans for prophylaxis, diagnosis or therapy, or for the modification of physiological function.” ADRs can range from mild discomfort to life-threatening events and can significantly affect adherence, quality of life, and healthcare costs.

Classification of ADRs

ADRs are commonly classified into five types based on their mechanism and timing:

Type A (Augmented) reactions- Dose-dependent and predictable.

Related to the pharmacological action of the drug (e.g., bleeding with warfarin, hypoglycaemia with insulin).

Type B (Bizarre) reactions-

Unpredictable and not dose-dependent.

Often immune-mediated or idiosyncratic (e.g., anaphylaxis, Stevens-Johnson syndrome).

Type C (Chronic) reactions-

Occur due to prolonged drug use (e.g., tardive dyskinesia with long-term antipsychotics, osteoporosis with long-term steroids).

Type D (Delayed) reactions -

Apparatus or organ damage that appears after a long latent period (e.g., carcinogenic or teratogenic effects).

WAR Journal of Multidisciplinary Bulletin
(WARJMB)
ISSN (Online): 1595-6709
ISSN (Print): 1595-6636
Received: 02-03-2026 Revised: 26-03-2026 Accepted: 05-04-2026 Published: 18-04-2026

Type E (End-of-use) reactions- Occur after withdrawal of the drug (e.g., rebound hypertension after stopping clonidine, withdrawal seizures after abrupt benzodiazepine cessation).

4. Methods of Pharmacovigilance

Pharmacovigilance employs a range of methods to detect, analyse, and interpret drug-safety data. Key methods include both passive and active surveillance, as well as analytical epidemiological designs.

5. Passive Surveillance

Passive surveillance relies on spontaneous reporting of suspected ADRs by healthcare professionals, pharmacists, and sometimes patients to national or regional pharmacovigilance centres. It is simple, inexpensive, and widely used but is often limited by under-reporting and uneven data quality. Nevertheless, it remains a primary source of early safety signals for many medicines.

6. Active Surveillance

Active surveillance involves deliberate efforts to search for adverse events in defined populations, such as hospitals, clinics, or community cohorts. This may include structured follow-up, prospective data collection, or targeted monitoring of high-risk drugs and vulnerable patient groups (e.g., elderly, children, critically ill). Active surveillance improves completeness of data and helps detect rare or delayed ADRs that may be missed by passive reporting alone.

7. Cohort Event Monitoring

In cohort event monitoring, a group of patients receiving a specific medicine is monitored over time to record and analyse adverse events and their temporal relationship with drug exposure. This method is particularly useful for new drugs, biologicals, or medicines used in special populations, as it provides longitudinal safety information in real-world settings beyond clinical-trial conditions.

8. Case-Control Studies

Case-control studies compare patients who have experienced a specific adverse reaction with matched controls who have not, in order to identify potential risk factors and possible causal relationships with particular drugs. These studies are retrospective and statistically powerful for investigating rare events, but they require careful selection of cases and controls, clear exposure data, and control of confounding variables.

9. Global Pharmacovigilance Programme

The global pharmacovigilance system is coordinated by the World Health Organization (WHO) through the WHO Programme for International Drug Monitoring. The international database of adverse drug reactions is maintained by the Uppsala Monitoring Centre (UMC) in Sweden, which collects individual case safety reports from member countries.

Key functions of the global programme include:

Collection and analysis of ADR reports from more than 100 countries.

Detection of safety signals (new or emerging risks) using statistical and clinical methods.

Issuance of drug safety alerts and communications to regulatory authorities and healthcare professionals.
Supporting regulatory decisions, such as label changes, contraindications, restrictions, or withdrawal of medicines when risks outweigh benefits.

WAR Journal of Multidisciplinary Bulletin
(WARJMB)
ISSN (Online): 1595-6709
ISSN (Print): 1595-6636
Received: 02-03-2026 Revised: 26-03-2026 Accepted: 05-04-2026 Published: 18-04-2026

10. Pharmacovigilance Programme in India

In India, pharmacovigilance activities are coordinated through the Pharmacovigilance Programme of India (PvPI), launched in July 2010 by the Ministry of Health and Family Welfare. The programme is currently run by the Indian Pharmacopoeia Commission (IPC) in Ghaziabad, which serves as the National Coordination Centre for PvPI.

The programme operates a network of ADR Monitoring Centres (AMCs) across hospitals, medical colleges, and other healthcare institutions, where healthcare professionals report suspected ADRs.

Objectives of PvPI

Monitor ADRs in the Indian population, considering regional variations in drug use, comorbidities, and genetic factors.

Encourage ADR reporting among doctors, dentists, pharmacists, nurses, and other healthcare providers.
Ensure safer use of medicines by generating local evidence on drug safety.

Generate drug-safety data for regulatory authorities (e.g., Central Drugs Standard Control Organisation, CDSCO) to support policy and regulatory decisions.

11. Pharmacovigilance in Homoeopathy

Homoeopathic medicines are generally considered safe due to their high dilution and low systemic bioavailability, but this does not eliminate the need for pharmacovigilance. The Ministry of AYUSH has implemented a National Pharmacovigilance Programme for Ayurveda, Siddha, Unani, and Homoeopathy (ASU&H) drugs to systematically monitor adverse events from these traditional systems.

The scheme, formally introduced in December 2017, has established a network comprising:

One National Pharmacovigilance Coordination Centre (hosted at All India Institute of Ayurveda, New Delhi).

Five Intermediary Pharmacovigilance Centres (one for each system: Ayurveda, Siddha, Unani, Homoeopathy).

Over seventy Peripheral Pharmacovigilance Centres across the country.

Aims of the ASU&H Pharmacovigilance Programme

Monitor suspected adverse drug events (ADEs) associated with homoeopathic medicines and other ASU&H drugs.

Ensure quality and safety of products by detecting adulteration, contamination, or improper preparation.
Surveillance of misleading advertisements and promotional claims for ASU&H medicines.
Improve public confidence in traditional medicine systems by providing evidence-based safety information and supporting regulatory action when needed.

12. Role of Healthcare Professionals

Healthcare professionals are the backbone of any pharmacovigilance system and play a central role in ensuring drug safety. Their responsibilities include:

- Identifying suspected adverse drug reactions by maintaining a high index of suspicion, especially for new drugs, polypharmacy, or high-risk patients.

WAR Journal of Multidisciplinary Bulletin
(WARJMB)
ISSN (Online): 1595-6709
ISSN (Print): 1595-6636
Received: 02-03-2026 Revised: 26-03-2026 Accepted: 05-04-2026 Published: 18-04-2026

- Reporting ADRs to the nearest ADR Monitoring Centre or online pharmacovigilance portals, even when the causal relationship is uncertain.
- Maintaining accurate, legible patient records that document drug-use history, doses, timing of events, and clinical outcomes, which are essential for causality assessment.
- Educating patients about possible side effects, interactions, and the importance of adherence and timely reporting of unusual symptoms.

13. Challenges in Pharmacovigilance

Despite its importance, pharmacovigilance faces several challenges, particularly in low- and middle-income countries like India:

- Under-reporting of ADRs due to lack of awareness, time constraints, fear of litigation, or perception that only serious events need to be reported.
- Lack of awareness and training among healthcare professionals regarding the principles and procedures of pharmacovigilance.
- Limited infrastructure for ADR monitoring, especially in rural and peripheral health facilities.
- Difficulty in detecting rare, delayed, or long-term adverse effects that require large datasets and long-term follow-up.
- Fragmented data systems and limited integration between electronic health records, regulatory databases, and pharmacovigilance networks.

14. Future Perspectives

Advances in digital health technology and data science are transforming pharmacovigilance. Emerging approaches include:

- Electronic health record (EHR)-based monitoring, where automated algorithms screen for potential ADRs in real-time.
- Artificial intelligence (AI) and machine-learning models for signal detection, pattern recognition, and prioritization of reports.
- Social media and mobile-based patient-reported outcome systems that allow direct reporting of adverse events by patients.Integration of pharmacogenomic data to understand genetic susceptibility to certain ADRs and personalize drug therapy. These innovations promise earlier detection of drug-related problems, more precise risk assessments, and improved patient safety, while also posing new challenges related to data privacy, standardization, and validation.

15. Conclusion

Pharmacovigilance is an essential component of modern healthcare systems aimed at ensuring the safety and rational use of medicines across both conventional and traditional systems. Effective pharmacovigilance systems help detect adverse drug reactions, evaluate the risk–benefit ratio of medicines, and support regulatory and clinical decisions that protect public health. With the increasing use of pharmaceuticals and homoeopathic (ASU&H) medicines, strengthening national and global pharmacovigilance programmes, including robust professional participation and digital infrastructure, is crucial for safeguarding patient safety in the 21st century.

References

1. World Health Organization. The Importance of Pharmacovigilance: Safety Monitoring of Medicinal Products. Geneva: WHO; 2002.
2. McBride WG. Thalidomide and congenital abnormalities. Lancet. 1961;2:1358.

WAR Journal of Multidisciplinary Bulletin
(WARJMB)
ISSN (Online): 1595-6709
ISSN (Print): 1595-6636
Received: 02-03-2026 Revised: 26-03-2026 Accepted: 05-04-2026 Published: 18-04-2026

3. Tripathi KD. Essentials of Medical Pharmacology. 8th ed. New Delhi: Jaypee Brothers; 2019.
4. Parthasarathi G, Nyfort-Hansen K, Nahata MC. A Textbook of Clinical Pharmacy Practice. Hyderabad: Universities Press; 2004.
5. Uppsala Monitoring Centre. WHO Programme for International Drug Monitoring. Sweden.
6. Indian Pharmacopoeia Commission. Pharmacovigilance Programme of India (PvPI). Ghaziabad; 2018.
7. Ministry of AYUSH. National Pharmacovigilance Programme for ASU&H Drugs. Government of India.