STM JOURNALS

Research & Reviews: A Journal of
Pharmacology

https://journals.stmjournals.com/rrjop

ISSN: 2230-9861 (Online)
ISSN: 2349-1299 (Print)
Volume 16, Issue 1, 2026
January–April
DOI (Journal): 10.37591/RRJoP

Review RRJOP

Pharmacovigilance: The Silent Guardian of Patient Safety

Kirti[1], Chandan Kumar[2,*], Ritika Saini[2], Kashish[3]

Abstract

Pharmacovigilance is critical in protecting the populace health by monitoring, detecting and preventing adverse drug reaction (ADR) post drug approval. Although there is technological advancement and national initiatives such as the Pharmacovigilance Programme of India (PvPI), there is still a great problem of underreporting. Many benefits of effective pharmacovigilance include identification of risks early, better prescriptions and patient confidence. There are historical examples of drugs being withdrawn due to thalidomide, rofecoxib, and ranitidine, which indicate the significance of post-marketing monitoring during the lifecycle of a drug. Pharmacists play a major role in the detection of ADR and patient counselling and rational drug use. The development of artificial intelligence and big data and patient-centered reporting systems in the future offers a revolutionary breakthrough in the field of safety monitoring. Nevertheless, it is important to fill the knowledge, educational, and infrastructural gaps. Its ability to be the silent watchdog of patient safety will continue to be reinforced by enhancing international cooperation and incorporating patient safety, through pharmacovigilance, into routine healthcare delivery.

Keywords: Pharmacovigilance, Adverse Drug Reactions (ADRs), Patient Safety, Drug Monitoring, Post-Marketing Surveillance, Pharmacovigilance Programme of India (PvPI), Artificial Intelligence, Healthcare Systems

INTRODUCTION

Pharmacovigilance, or the science and actions concerning the detection, evaluation, cognition, and prevention of adverse effects or any other drug-related issues, is a pillar of patient safety, ensuring that once a medication is put on the market, it still maintains a good balance of benefiting and causing harm [1]. Pharmacovigilance helps in the protection of patients as it helps in the early identification of risks, alerting regulators, and guiding healthcare providers on the right way to prescribe drugs [2]. This creates trust in the patient and enhances the outcome of health of the population in the context of modern healthcare, where quick innovation, polypharmacy, and broad use of biological and over-the-counter products are becoming more common [3]. The need to have pharmacovigilance has been underscored by the increasing cases of adverse drug reactions (ADRs), which remain among the ten most common causes of morbidity and mortality worldwide and lead to increased hospitalizations, increased medical expenses, and reduced compliance with treatment [4].

***Author for Correspondence**
Chandan Kumar
E-mail: chandanpandit853@gmail.com

[1]Assistant Professor, Department of Pharmacy, Adesh Institute of Pharmacy and Biomedical Sciences, Bathinda, Punjab, India
[2]Assistant Professor, Department of Pharmacy, Amritsar Group of Colleges, Amritsar, Punjab, India
[3]Research Scholar, Department of Pharmacognosy, Guru Nanak Dev University, Amritsar, Punjab, India

Received Date: November 05, 2025
Accepted Date: November 10, 2025
Published Date: November 15, 2025

Citation: Kirti, Chandan Kumar, Ritika Saini, Kashish. Pharmacovigilance: The Silent Guardian of Patient Safety. Research & Reviews: A Journal of Pharmacology. 2026; 16(1): 1–5p.

HISTORICAL PERSPECTIVE AND EVOLUTION

The underreporting issue in India is even present following the initiation of the Pharmacovigilance Programme of India (PvPI) in 2010, hence the pressing need to enhance the culture of awareness, training, and reporting to achieve international safety standards [5]. Strong reporting and

monitoring mechanisms have been established by the developed countries because preclinical research and clinical trials are incapable of identifying rare, delayed, and population-specific adverse effects in the process. Lessons learned over the years about drug withdrawals have reinforced the need for continuous monitoring once the drug has been approved [6]. To take a well-known instance, the thalidomide disaster of 1961 brought forth horrifying teratogenic effects, and the withdrawals of rofecoxib (Vioxx) in 2004 and ranitidine in 2019-2020 show that even advanced regulatory regimes are prone to oversight [7]. Table 1 (Major Drug Withdrawals due to Safety Concerns, 1961-2025) lists in brief unsafe drugs belonging to nearly all classes of therapeutic agents, including cardiovascular, metabolic, and gastrointestinal drugs, as well as analgesics and anti-obesity drugs [8]. This brings out the reality that no type of drug is risk-free and that post-marketing surveillance is crucial in the entire life cycle of the drug. The pharmacovigilance framework has three major pillars, including national programs, international organizations, and regulatory bodies. Regular collection, analysis, and safety of ADR is overseen by the authorities (such as the FDA, EMA, and the CDSCO in India) [8]. To streamline global collaboration, signal identification, and cross-border safety alerts, all of which are particularly useful to smaller or poorer countries with limited resources, the WHO-Uppsala Monitoring Centre (UMC) manages the largest ADR database ever seen. AMCs collect and evaluate, and send ADR data to the National Coordination Centre on behalf of national programs such as PvPI in India; however, the problem of underreporting, lack of awareness, and poor digital infrastructure is still present [9].

ROLE OF PHARMACISTS AND HEALTHCARE PROFESSIONALS IN DRUG SAFETY

In order to reduce medication errors and improve treatment outcomes, the clinical pharmacist in the hospital reviews the prescription, pays attention to the drug interactions, and provides counselling to patients. In community pharmacies where self-medication is the norm, pharmacists will be the first line of contact [10]. They identify adverse drug reactions (ADRs) on the fly, deter irrational use of drugs, and promote patient reporting. Moreover, pharmacists can assist patients and doctors in getting to know each other better by using fewer medical terms, simplifying instructions, and ensuring that prescribed courses are adhered to. This is to make pharmacovigilance become part of everyday life rather than a regulatory necessity [11].

CHALLENGES AND FUTURE DIRECTIONS IN PHARMACOVIGILANCE

This systematic approach notwithstanding, there exist significant challenges that still hinder pharmacovigilance from achieving its full potential. Underreporting has remained the most significant chronic barrier, and it is estimated that in even rich countries, fewer than one out of ten ADRs is documented; In India, the problem is worsened by such hurdles as a lack of motivation, fear of legal prosecution, and absence of feedback. Because pharmacovigilance is often overlooked in medical and pharmacy education, the lack of knowledge and insufficient training make healthcare workers less involved in ADR reporting. Technological and infrastructure limitations also impede the timely identification and sharing of safety signals, including discontinuous databases, paper-based reporting, insufficient digital integration, and the absence of funding [12]. There should be systemic changes and cultural changes that should be made to eliminate these barriers. The future directions of pharmacovigilance have indicated the future of change. Artificial intelligence (AI), machine learning, and big data analytics could lead to a revolution in pharmacovigilance. The technologies would allow detecting real-time safety signals, predictive modelling, and mining of patient-reported data on digital platforms and electronic health records. Although the issue of drug safety is cross-border, it remains essential to collaborate internationally. Enhancing systems interoperability, strengthening the VigiBase of the WHO, and increasing the level of openness can accelerate regulatory responses and safeguard populations in less-developed areas [13]. There is also an increasing popularity of patient-centric pharmacovigilance models. Those models enable patients to disclose adverse drug reactions (ADRs) via helplines, web portals, and mobile applications, enhance the level and quality of safety data, and make patients more confident in healthcare systems [14]. Pharmacovigilance is not only a legal requirement but also a moral and professional requirement that is mandatory in the safe usage of medicines. The safety of drugs is upheld as a collective responsibility because of its integration at all levels of healthcare, from regulators and pharmacists to the patients themselves [15]. The creation of a

strong and patient-focused system in the future will require the incorporation of pharmacovigilance into medical practice, the application of technology, awareness, and international collaboration. Through this, pharmacovigilance will continue to play the invisible safety guard of patients by ensuring that the innovation in drug development goes hand in hand with the protection of human health [16].

Table 1. Major Drug Withdrawals due to Safety Concerns (1961–2025).

Drug	Indication	Reason for Withdrawal	Year
Thalidomide	Morning sickness in pregnancy	Severe birth defects (phocomelia)	1961
Fenfluramine & Dexfenfluramine	Weight loss (anti-obesity)	Heart valve damage, pulmonary hypertension	1997
Cisapride	Gastroesophageal reflux (GERD)	Serious cardiac arrhythmias (QT prolongation)	2000
Phenylpropanolamine	Nasal decongestant, appetite suppressant	Risk of hemorrhagic stroke	2000
Cerivastatin	Hyperlipidemia (statin)	Fatal rhabdomyolysis	2001
Rofecoxib (Vioxx)	Pain & inflammation (NSAID)	Increased cardiovascular risk (MI, stroke)	2004
Valdecoxib	Pain & inflammation (NSAID)	Serious skin reactions, cardiovascular risks	2005
Tegaserod	Irritable bowel syndrome	Cardiovascular ischemic events	2007
Sibutramine	Weight loss (anti-obesity)	Cardiovascular risk (heart attack, stroke)	2010
Darvocet / Propoxyphene	Mild to moderate pain	Severe cardiac arrhythmias	2010
Dextropropoxyphene (India)	Analgesic	Cardiotoxicity, overdose risk	2013
Ranibizumab (some formulations)*	Eye disorders	Withdrawn in select markets for safety/efficacy gaps	2014–15*
Ranolazine (partial restrictions)	Angina	Safety concerns in certain regions	2016
Pioglitazone (temporarily in India)	Type 2 Diabetes	Risk of bladder cancer	2013, reinstated
NDMA-contaminated Ranitidine	Acid suppression (H2 blocker)	Probable human carcinogen (NDMA impurity)	2019–2020
Beloranib	Obesity, rare genetic obesity	Increased risk of thromboembolism	2016
Some COVID-19 drugs (e.g., Hydroxychloroquine use in COVID)	Off-label COVID treatment	Safety/ineffectiveness concerns	2020–2021
Lorcaserin	Weight loss	Increased cancer risk	2020
Umbralisib	Lymphoma treatment	Increased risk of death in clinical trials	2022
Fiasp® (fast-acting insulin aspart in some markets)	Diabetes	Safety and supply-related recalls	2023
Several NDMA-contaminated drugs (Valsartan, Losartan, Metformin)	Hypertension/Diabetes	Carcinogenic impurity detected	2018–2025

CONCLUSION

Pharmacovigilance is an important protection mechanism in the safety and effectiveness of medicines in their lifetime. Regardless of high progress in regulating mechanisms, issues of underreporting, ignorance, and inadequate digital infrastructure still exist especially in developing countries such as India. To ensure drug monitoring is effective, it is necessary to strengthen Pharmacovigilance Programme of India (PvPI), introduce technology, and facilitate active involvement of healthcare professionals and patients. With medicine constantly advancing, pharmacovigilance should be an ongoing, multi-disciplinary and patient-focused endeavor - such that therapeutic innovation is never compromised in terms of patient safety and protection of the population.

Ethical Approval
No ethical approval in this study

Consent to Participate
Yes

Consent to Publish
Yes

Funding
No Source of Funding

Competing Interests
No Competing Interests

Availability of Data and Materials
All data is available in the manuscript file

Conflict of Interest
No conflict of interest

REFERENCES

1. Sulashvili N, Jadhav RD, Beglaryan M, Gorgaslidze N, Gabunia L, Alavidze N, et al. The scientific talks of comprehensive analysis of pharmacogenetic and patient-centered care approaches on medication-induced adverse effects and toxicities, pharmacovigilance challenges, implicated drugs, underlying determinants of risk, and strategic approaches to pharmacotherapeutic management. Georgian Scientists. 2025;7(3):217–262.
2. Anestina N, Obiageli C, Anthony O, Alade A, Mustapha A, Oluwaferanmi A. Ensuring drug safety: comprehensive pharmacovigilance strategies for public health. 2025.
3. Pandian S, Ragavan YV, Pandian AG, Kumaraguru AK, Subramanian KK. Enhancing public health with pharmacovigilance: tools, strategies, and impacts. Biomed Pharmacol J. 2025;18(2).
4. Religioni U, Barrios-Rodríguez R, Requena P, Borowska M, Ostrowski J. Enhancing therapy adherence: impact on clinical outcomes, healthcare costs, and patient quality of life. Medicina (Kaunas). 2025;61(1):153.
5. Khot A, Dakhale G. Monitoring (pharmacovigilance). In: Pharmacovigilance—Facts, Challenges, Limitations and Opportunities. 2025. p. 87.
6. Ganhao AM. Experiences of informal primary caregivers of adult patients with aggressive primary malignant brain tumors: a qualitative metasummary. JFK School of Psychology and Social Sciences at National University; 2025.
7. Power L. Understanding mental health: the use of narratives by those that have experienced state care. 2025.
8. Rehman W, Arfons LM, Lazarus HM. The rise, fall and subsequent triumph of thalidomide: lessons learned in drug development. Ther Adv Hematol. 2011;2(5):291–308.
9. Doomra R, Inder D, Kumar P. Way forward to pharmacovigilance and adverse drug reaction monitoring in India: a critical review. J Integr Med Res. 2025;3(2):91–96.
10. McNeilage AG, Browne E, Nielsen S, Ashton-James CE, Murnion B. Healthcare practitioner and other professionals' perspectives on gabapentinoid misuse and dependence: a systematic review of qualitative studies. Eur J Pain. 2025;29(9):e70116.
11. Mann NA, Khan ZA, Asghar S, Rani A, Hussain N, Akhtar SS, et al. Patterns of health services and medicine utilisation by first-generation Pakistani immigrants in New Zealand. Health Expect. 2025;28(1):e70169.

12. Amekpor F, Mwansa C, Benjamin DO, Adedokun DA, Aderonke TR, Kamfechukwu OG, et al. The prospects and challenges of telemedicine and digital health tools in enhancing the timely reporting and surveillance of malaria cases. J Health Sci Med Res. 2025:20251167.
13. Skupień ET. The maturity model as a tool for assessing transportation systems on the example of inland navigation. Sustainability. 2025;17(4):1577.
14. Abdel-Basset M, Mohamed R, Chang V. A multi-criteria decision-making framework to evaluate the impact of industry 5.0 technologies: case study, lessons learned, challenges and future directions. Inf Syst Front. 2025;27(2):791–821.
15. Ahmed R, Tamim TR. Enhancing medication safety: the role of community and hospital pharmacists in modern healthcare systems. Radinka J Health Sci. 2025;2(3):328–355.
16. Mayimele N. Leadership for Pharmacists: Moving Towards Strategic Roles in the Pharmaceutical Industry. Taylor & Francis; 2025.

