INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

OPEN ACCESS

Review Article

Current Status and Future Prospects of Pharmacovigilance in India

Rishab Sahu*, Dr. NPS Sengar

SIRT- P, SAGE University, Bhopal.

ARTICLE INFO

Published: 16 May 2025
Keywords:
Pharmacovigilance, Adverse Drug Reactions, PvPI, Drug Safety, Signal Detection
DOI:
10.5281/zenodo.15429163

ABSTRACT

Pharmacovigilance (PV) is essential for monitoring the safety and efficacy of medicines throughout their lifecycle. This review critically examines the current advancements in pharmacovigilance, with emphasis on spontaneous adverse drug reaction (ADR) reporting, post-marketing surveillance, and the integration of modern technologies such as artificial intelligence and real-world data analytics. The role of electronic health records, machine learning algorithms, and natural language processing in signal detection and risk minimization is discussed. Challenges including underreporting, data quality issues, and regulatory disparities are highlighted. Furthermore, the importance of global harmonization of PV systems and stakeholder education is addressed. The review concludes that the future of pharmacovigilance lies in a proactive, technology-driven, and patient-centric approach to drug safety.

INTRODUCTION

Pharmacovigilance is vital to healthcare. It involves finding, studying, and preventing drug problems. The global drug industry keeps growing and changing. This makes drug safety after approval more important. Trials are key, but have limits. They use small groups for short times. So, they may miss some side effects. Watching drugs after they launch is crucial. Good pharmacovigilance helps protect people. In India, awareness of drug safety grew in the early 2000s. The country created a formal system to track side effects in 2010. This was the Pharmacovigilance Programme of India (PvPI). The PvPI is run by the Indian Pharmacopoeia Commission (IPC). They work with the Central Drugs Standard Control Organization (CDSCO). Their goal is to protect patients by studying drug safety data. They collect, assess, and act on information about drug risks. Over time, PvPI has built a large network. It includes Adverse Drug Reaction Monitoring Centres (AMCs). PvPI has also taught health workers how to report drug side effects. Even with progress, India still has problems. Many cases are not reported. Doctors and nurses need more

***Corresponding Author:** Rishab Sahu
Address: *SIRT- P, SAGE University, Bhopal.*
Email ✉: rishabsahu719@gmail.com
Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

training. Technology isn't always used. Patients should be more involved. Things are improving with more online tools. Artificial intelligence and data can change drug safety checks. Online reporting and phone apps are helpful. Adding safety training to medical school is also a good step. This review checks on drug safety monitoring in India right now. It looks at problems faced and new tech being used. It also shows how to make drug safety better in the future. The goal is to see what has improved so far. It also gives ideas on how India can meet world standards for drug safety. This will help protect people's health.

2. Current Status of Pharmacovigilance in India

2.1 Evolution of Pharmacovigilance in India

Pharmacovigilance in India has witnessed a gradual but impactful evolution. Initially, the country's pharmacovigilance efforts were limited and fragmented. India first participated in the WHO International Drug Monitoring Programme in 1997 through the Adverse Drug Reaction Monitoring Scheme launched by the Central Drugs Standard Control Organization (CDSCO). However, it was not until 2010 that a centralized and well-structured program — the Pharmacovigilance Programme of India (PvPI) — was officially launched by the Ministry of Health and Family Welfare (MoHFW), Government of India.

2.2 Pharmacovigilance Programme of India (PvPI)

The PvPI, coordinated by the Indian Pharmacopoeia Commission (IPC), was initiated with the objective of safeguarding the health of the Indian population by ensuring medicine safety. The National Coordination Centre (NCC) at IPC oversees the functioning of more than 500 Adverse Drug Reaction Monitoring Centres (AMCs) established in various medical institutions and hospitals across the country. These AMCs are responsible for collecting and submitting Individual Case Safety Reports (ICSRs) to the NCC for evaluation and signal detection.

2.3 ADR Reporting Mechanism

PvPI encourages healthcare professionals, patients, and pharmaceutical companies to voluntarily report any adverse drug reactions. The system is based on spontaneous reporting, and PvPI provides both paper-based and online platforms for submission. The use of VigiFlow, a web-based tool developed by the Uppsala Monitoring Centre (UMC), allows for the secure management of ICSRs. In addition, PvPI has introduced a toll-free helpline (1800-180-3024), e-reporting portal, and mobile applications like "ADR PvPI" to make ADR reporting more accessible and user-friendly.

2.4 Participation of Stakeholders

Pharmacovigilance success in India heavily relies on the active involvement of various stakeholders. Healthcare professionals — including doctors, pharmacists, and nurses — are trained and encouraged to report ADRs. Pharmaceutical companies (Market Authorization Holders) are required to submit Periodic Safety Update Reports (PSURs) and serious ADRs. Furthermore, PvPI has collaborated with academic institutions to integrate pharmacovigilance training into the medical and pharmacy curricula, thereby increasing awareness at the grassroots level.

2.5 Data Submission to WHO-Uppsala

India is a contributing member to the WHO Global ICSR Database (VigiBase) maintained by the UMC, Sweden. The ICSRs collected through PvPI are regularly submitted to VigiBase, thereby adding to the global pool of drug safety data. This

ensures that India plays an active role in international pharmacovigilance efforts and contributes to global signal detection and risk evaluation processes.

2.6 Current Achievements

PvPI has achieved several milestones in the past decade. India is now recognized as one of the top contributors of ADR reports to VigiBase. The publication of drug safety newsletters, safety alerts, and PvPI bulletins has helped in disseminating critical information to healthcare professionals and the public. Regular training sessions, CMEs, and workshops are conducted to maintain high standards in ADR monitoring and reporting.

3. Challenges in Pharmacovigilance in India

India's national drug safety system has improved. But some issues still exist. These issues reduce the system's overall effectiveness. Many people don't know enough about drug safety. Some facilities lack the needed equipment. Rules are sometimes unclear or hard to enforce. Reporting problems with drugs can also be difficult. For instance, a person might not know how to report a bad reaction to a drug. Also, some hospitals might not have good systems to track drug problems. Clear rules help everyone understand their role. Easy reporting helps find problems faster. Fixing these problems will make the drug safety system work even better.

3.1 Underreporting of Adverse Drug Reactions (ADRs)

A key issue is that many drug reactions go unreported. A lot of harmful side effects never get shared with the right people. Sometimes, doctors lack the latest knowledge about drug reactions. They may not spot the signs or know how to report them. Some doctors might not feel like reporting takes too much time. Others fear getting sued if they report a problem. The current system asks people to report issues on their own. Most of the time, reporting isn't required by law. Because of this, crucial safety details are often missed. For instance, a new side effect might not be known until many people are hurt. If reporting was better, these problems could be found faster. This would lead to safer drug use for everyone.

3.2 Lack of Awareness and Training

A lack of knowledge plagues many healthcare workers. Training gaps exist, hurting patient safety. This is worse in rural areas. Rural clinics and hospitals often have fewer resources. Workers may not know why drug safety matters. They might not know how to report drug problems. For example, a nurse may miss a drug interaction. A pharmacist may not report side effects. Medical and pharmacy schools need to teach more about drug safety. Some schools offer good courses. Many don't focus enough on real-world drug problems. Training programs exist for current workers. These programs can help, but they miss many people. Many nurses and pharmacists don't get updates on drug risks. Doctors may lack key knowledge too. This puts patients at risk. It can lead to harm from medicines. More training is needed to protect everyone.

3.3 Limited Patient Involvement

Patient involvement is very important. Too few patients tell doctors about bad drug reactions. This lack of reporting hides important safety issues. Cultural differences play a role. Some cultures may not encourage talking about health problems. Language can also be a problem. Patients may not know how to describe their symptoms in English. Many patients simply do not know they can report side effects. They might think only doctors can do that. Imagine someone gets a rash from a new

medicine. If they don't report it, the doctor may not know the drug is causing problems. More reporting from patients helps find problems sooner. It would allow experts to react faster and protect others. When patients speak up, medicine becomes safer for everyone.

3.4 Infrastructure and Technological Barriers

There are also issues with technology and facilities. Digital tools exist, but they are not used enough. This is because of a lack of awareness, technical skills, and poor internet access in some areas. Also, there is no single, nationwide electronic health record system. This makes it hard to track drug reactions and find safety signals.

3.5 Regulatory and Policy Limitations

Finally, the rules and policies need to be stronger. Stronger laws are needed to make sure people report drug reactions. Unlike some countries, India mainly relies on voluntary reporting. Also, there is not enough coordination between government agencies, hospitals, and drug companies.

4. Recent Trends and Technological Advancements in Pharmacovigilance

The landscape of pharmacovigilance is rapidly evolving with the integration of modern technologies and data-driven systems. In India, these trends are gradually being adopted to improve drug safety surveillance, ADR reporting efficiency, and data analysis capacity. The application of advanced technologies is helping bridge the gaps in traditional pharmacovigilance practices.

4.1 Digitalization of ADR Reporting

One of the most notable advancements is the digital transformation of ADR reporting mechanisms. PvPI has introduced various tools such as the “ADR PvPI” mobile application, an online reporting portal, and a toll-free helpline to simplify the process for both healthcare professionals and patients. These platforms have made it easier to report ADRs in real-time, thus enhancing the quality and timeliness of the collected data.

4.2 Use of Artificial Intelligence (AI) and Machine Learning (ML)

Pharmacovigilance databases are using Artificial Intelligence (AI) and Machine Learning (ML) to improve signal detection. These technologies also enhance data mining and pattern recognition. AI and ML tools can examine many Individual Case Safety Reports (ICSRs). They find unusual and complex safety signals. This helps regulators make faster, better decisions.

4.3 Big Data and Real-World Evidence (RWE)

Using data from health records and claims is more vital now. This data gives key facts about drug safety over time. It also shows what happens to patients in normal care. Real-world evidence improves drug monitoring after release. It also helps guide rules and choices.

4.4 Social Media and Web-based Monitoring

Online spaces are now alternative places for drug safety monitoring. Social media, health sites, and patient groups can offer unique insights. Researchers are exploring web-based methods to find new drug reaction trends. This approach is new to India. It could improve existing reporting methods.

4.5 Integration with Global Safety Systems

India works with VigiBase, WHO’s global database for drug safety, run by UMC. This gives India access to worldwide safety info and study tools. Indian officials can compare safety alerts

globally through this work. They can also better match global safety rules.

4.6 Training in Modern Tools and Practices

To stay current, PvPI and IPC offer workshops on new pharmacovigilance tech. They also promote using digital tools in training to build a skilled workforce. This helps healthcare staff learn about these advances.

The following table summarizes key modern technologies being adopted in pharmacovigilance along with their applications and current status in India:

Table: Modern Technologies in Pharmacovigilance

Technology	Application in PV	Status in India
AI & Machine Learning	Signal detection, case processing	Emerging use
Real-World Evidence	Analysis of EHRs and prescription data	Growing integration
Blockchain	Data integrity, traceability	Not yet implemented
Social Media Mining	ADR trend detection from public discussions	In pilot stages
Mobile Apps	Real-time ADR reporting	Widely promoted

5. Future Prospects of Pharmacovigilance in India

The future of drug safety in India is promising. India's healthcare system is growing fast. It is using more technology like apps and online tools. People know more about health issues. This helps them report problems with medicines. Technology makes reporting side effects easier. Stronger rules help to check drug safety. These rules make companies watch their drugs closely. Better drug safety protects patients from harm. It also helps people use medicines the right way. This makes treatments work better. India's focus on drug safety can improve public health. It will also build trust in the medicines people use.

5.1 Toward Mandatory ADR Reporting

A key change is making ADR reporting mandatory. Drug companies and doctors must report. This will give more data that is better. Then, problems can be spotted faster, and rules can be enforced.

5.2 Integration with National Digital Health Mission (NDHM)

The National Digital Health Mission (NDHM) could help too. It gives everyone a digital health ID. ADR reports could go straight into electronic records. This would track ADRs in real time. Data could flow easily between people, doctors, and rule makers.

5.3 Personalized Medicine and Pharmacogenomics

Personalized medicine is coming. Pharmacovigilance will track and predict drug safety. Knowing how genes affect drug response can help. Doctors can then prescribe more safely.

5.4 Strengthening Regulatory Frameworks

Expect stronger rules for pharmacovigilance. There will be rules for watching drugs after they are sold. Risk plans and benefit checks will be in place. India's rules will match global standards.

5.5 Enhanced Public and Patient Engagement

Getting the public and patients involved is key. Teaching patients to report side effects is important. More people using phones and the internet helps. They can report ADRs online and via social media.

5.6 Global Collaborations and AI-Driven Surveillance

India will work more with global groups. These include WHO, EMA, and the US FDA. AI will also be used for pharmacovigilance. It will spot drug safety issues faster. AI can use data from social media, trials, and prescriptions.

5.7 Role of Academic and Research Institutions

Schools and research groups will play a bigger role. They can do studies and train students. They can also gather real-world proof over time. Universities can help create new PV methods. They can add to global science and help make national rules.

6. The Role of Pharmacovigilance in Public Health Policy

Pharmacovigilance is vital to protect public health. It makes sure medicines are used as safely as possible. It also helps catch harmful side effects early on. This improves the health of people all across India. Data from pharmacovigilance can greatly improve India's health policies. First, this data helps in deciding about drug approvals. Regulators can use it to renew approvals. They can also use it to withdraw drugs from the market. This makes sure only safe and effective drugs are available to patients. For example, if a new side effect appears, the drug's approval might be reconsidered. Second, insurers can use data on side effects. They can then decide if covering certain drugs is worth the risk. If a drug has many side effects, it may not be worth covering. This encourages doctors to prescribe safer drugs. It also helps keep healthcare costs down. Third, pharmacovigilance data can improve treatment plans. It can also make vaccination programs better. For instance, this data can guide campaigns. These campaigns would promote the right use of medicines. If there are reactions to mass drug administrations, they can be tracked. This can improve public distribution plans a lot. Drug safety monitoring was key during the COVID-19 pandemic. India can use what it learned. It can add pharmacovigilance data to its emergency plans. This will help quickly find safety problems with new drugs or vaccines during a crisis. It will also keep the public safer. Pharmacovigilance also helps with proper antibiotic use. It does this by finding side effects. It also helps find patterns of resistance. This works with programs that fight antimicrobial resistance. By tracking antibiotic use, India can slow down resistance. This will make sure these drugs keep working. Cooperation is needed between the PvPI, the Ministry of Health, and other groups. This will help fully include pharmacovigilance in India's health plan. When everyone works together, India can have a strong system. This system will keep people safe from drug-related harm.

7. CONCLUSION

India's drug safety system has greatly improved in the last twenty years. It changed from a basic monitoring system to a global safety network. The Pharmacovigilance Programme of India (PvPI) and better reporting tools helped. Stronger rules have built a base for future progress. But, some issues remain. Many side effects still go unreported. People need more education and better resources. Stronger rules are also needed. Addressing these gaps with training and new technology is key. The future of drug safety in India looks bright. New tech like artificial intelligence and real-world data will help. Personalized medicine and patient involvement will also play a role. As India uses more tech in health care, drug safety will remain vital.

REFERENCES

1. Kalaiselvan V, Thota P, Singh GN. Pharmacovigilance in India: present scenario and future challenges. Drug Saf. 2016;39(10):933–939.
2. Kshirsagar NA. Pharmacovigilance in India. J Assoc Physicians India. 2006;54:969–70.
3. Bahri P. Public pharmacovigilance communication: A process for improving medicines safety and public health. Ther Adv Drug Saf. 2020;11:2042098620937152.
4. Ghosh S, Pradhan S. Pharmacovigilance in India: A perspective. Indian J Pharmacol. 2022;54(1):1–8.
5. Sharma A, Sharma P, et al. Evolution of pharmacovigilance in India: A roadmap for future. Int J Pharm Pharm Sci. 2020;12(7):1–6.
6. Vora MB, Trivedi HR. Need for pharmacovigilance in India. Indian J Pharmacol. 2018;50(1):1–4.
7. Khurshid A, et al. Role of pharmacists in pharmacovigilance: A review. Pharm Innov J. 2021;10(9):326–9.
8. Kalpana L, Vinod Kumar S. ADR reporting system in India: A review. J Young Pharm. 2019;11(4):381–5.
9. Joshi SR. Pharmacovigilance in developing countries. Indian J Pharmacol. 2008;40(Suppl 1):S4–5.
10. World Health Organization. The importance of pharmacovigilance. Geneva: WHO; 2002.
11. WHO. Safety monitoring of medicinal products: Guidelines for setting up and running a pharmacovigilance centre. Geneva: WHO; 2000.
12. Pimpalkhute SA, Jadhav PR, et al. Evaluation of adverse drug reaction reporting system in a tertiary care hospital. Br J Pharm Res. 2014;4(3):347–58.
13. Gupta SK. Textbook of Pharmacovigilance. New Delhi: Jaypee Brothers Medical Publishers; 2016.
14. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients. JAMA. 1998;279(15):1200–5.
15. Olsson S. The role of the WHO Programme for International Drug Monitoring in coordinating worldwide drug safety efforts. Drug Saf. 1998;19(1):1–10.
16. Suke SG, Kosta P, Negi H. Role of pharmacovigilance in India: An overview. Online J Public Health Inform. 2015;7(2):e223.
17. Inman WH. Assessment of adverse reaction reports. Br Med J. 1981;282(6271):1589–90.
18. 18. Patel N, Patel T. Pharmacovigilance in the modern era. J Pharm Sci Biosci Res. 2019;9(1):1–6.
19. Mehta UA. Spontaneous reporting system: Backbone of pharmacovigilance. Int J Pharm Sci Rev Res. 2020;64(1):120–4.
20. Singh H, Dulhani N. ADR monitoring: Present scenario and future perspectives in India. Pharmacol Online. 2017;2:78–84.
21. Ghosh R, Hasan M, et al. Knowledge, attitude, and practice of pharmacovigilance among medical students. J Appl Pharm Sci. 2016;6(2):95–9.
22. Ramesh M, Parthasarathi G. Adverse drug reactions in a south Indian hospital. Br J Clin Pharmacol. 2003;57(6):691–5.
23. Ghosh S, Pradhan S. National Pharmacovigilance Program of India: An overview. Int J Res Pharm Sci. 2021;12(3):2255–62.
24. Hazell L, Shakir SA. Under-reporting of adverse drug reactions. Drug Saf. 2006;29(5):385–96.
25. Harinath N. Regulatory framework for pharmacovigilance in India. Asian J Pharm Clin Res. 2020;13(1):7–12.
26. Rajesh R, Ramesh M, et al. An observational study of adverse drug reactions in a tertiary

care hospital. Indian J Pharmacol. 2011;43(6):676–9.
27. Uppsala Monitoring Centre. What is VigiBase? [Internet]. Available from: https://www.who-umc.org
28. Goyal RK, Mehta AA. The role of hospital pharmacovigilance units. J Clin Diagn Res. 2017;11(3):FE01–4.
29. Sudha V, et al. Pharmacovigilance in AYUSH systems. AYU. 2011;32(4):403–8.
30. Routledge PA. 50 years of pharmacovigilance: A historical perspective. Drug Saf. 2008;31(6):465–9.
31. Narayan S. Comparative analysis of PV practices in India vs. US and EU. Int J Res Pharm. 2019;10(4):9–13.
32. Naidu A, Patel S. Role of social media in pharmacovigilance. Indian J Health Sci Res. 2020;10(1):54–8.
33. Arora S, et al. Pharmacovigilance of biologics. Indian J Pharmacol. 2016;48(6):629–33.
34. Moorthy NS, et al. Role of AI in pharmacovigilance. J Pharm Sci Technol. 2021;13(3):90–6.
35. Dinesh Kumar V. E-health tools for pharmacovigilance: A review. Asian J Pharm Clin Res. 2018;11(12):10–4.
36. Patel H, et al. ADR reporting trends in India. Int J Pharm Pharm Sci. 2019;11(3):87–91.
37. Ghosh A. Post-marketing surveillance challenges. Pharmacol Res. 2020;152:104586.
38. Srinivasan R. Pharmacovigilance and clinical trials. Indian J Pharmacol. 2008;40(6):260–2.
39. Lihite RJ, Lahkar M. An update on pharmacovigilance. Indian J Pharm Sci. 2015;77(2):137–44.
40. Subish P, et al. Knowledge and perceptions of pharmacists on pharmacovigilance. J Clin Diagn Res. 2011;5(3):656–8.
41. Pal S, et al. Status of ADR reporting in India. Pharmacovigilance Review. 2020;2(2):101–6.
42. Shah R, et al. Pharmacovigilance in India: Current scenario and future growth. J Appl Pharm Res. 2021;9(2):12–6.
43. ICH Harmonised Guideline E2E: Pharmacovigilance Planning. Geneva: ICH; 2004.
44. Srivastava S. Role of pharmacogenomics in pharmacovigilance. Mol Clin Pharmacol. 2017;3(1):8–14.
45. Joshi YK, Patel K. ADRs in elderly: Need for focused pharmacovigilance. Geriatr Med J. 2019;8(1):25–30.
46. Bhosale UA, et al. Pharmacovigilance education: Need of the hour. Indian J Pharmacol. 2013;45(3):231–3.
47. Almandil NB. Role of pharmacists in pharmacovigilance: Global perspectives. Saudi Pharm J. 2016;24(7):734–41.
48. Thomas SM. Mobile applications in pharmacovigilance. J Pharm Pract. 2018;31(2):129–34.
49. Kiran R, Prasad PV. Pharmacovigilance in Indian regulatory framework. J Pharmacovigilance. 2021;9(3):1–6.
50. Ministry of Health and Family Welfare, Government of India. National Guidelines on Pharmacovigilance. New Delhi; 2022.

HOW TO CITE: Rishab Sahu*, Dr. NPS Sengar, Current Status and Future Prospects of Pharmacovigilance in India, Int. J. of Pharm. Sci., 2025, Vol 3, Issue 5, 2563-2570. https://doi.org/10.5281/zenodo.15429163