International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 31, Issue 12, December 2025 ijppr.humanjournals.com ISSN: 2349-7203

Pharmacovigilance Plan in India with Its Clinical Risk and Benefits

Mr. Akash R. Salve[1], Mr. Saurabh Bondre [2], Dr. Sunil Jaybhaye[3], Ms. Sharda Devde[4]

Institute of pharmacy, Badnapur, Jalna 431202. India.
Dr. Babasaheb Ambedkar Technological University, Lonere, Raigad. India.

Received: 25 October 2025 Revised: 05 November 2025 Accepted: 26 November 2025

ABSTRACT

According to the World Health Organization, medicine safety, or pharmacovigilance, refers to the field of pharmacological science that involves the collection, identification, assessment, monitoring, and prevention of negative effects linked to pharmaceutical products. To safeguard the health of the Indian population, the Pharmacovigilance Program of India (PvPI) was established in 2010, aiming to ensure that the benefits of medications exceed their potential risks. Even if a drug has been approved in another country, conducting strict pharmacovigilance monitoring during clinical trials across diverse racial and ethnic groups is essential. This review article offers a brief overview of the development, functioning, current challenges, and future prospects of pharmacovigilance in India. Consider medications as a double-edged sword; they can provide healing benefits but may also lead to adverse effects. Pharmacovigilance acts as a national safeguard for all medications, involving ongoing drug monitoring, collecting feedback from patients and healthcare providers, and ensuring that the therapeutic advantages of a medicine significantly outweigh any adverse side effects. The Indian Pharmacopoeia Commission, which acts as the National Coordination Center (NCC) for the Pharmacovigilance Program of India (PvPI), emphasizes the promotion of safe medication use. Currently, the NCC receives reports of 179 adverse drug reactions (ADRs) from monitoring centers, contributing 3% to the global safety database with a completeness score of 0.93 out of 1. To enhance patient safety, the NCC collaborates with national health initiatives and various organizations to boost ADR reporting, improve monitoring and surveillance capabilities, and establish PvPI as a vital knowledge resource for Indian regulators. This year, the Central Drugs Standard Control Organization announced significant safety label updates for medications such as carbamazepine and piperacillin + tazobactam.

Keywords : Adverse drug reaction reporting, Pharmacovigilance Programme of India, patient safety.

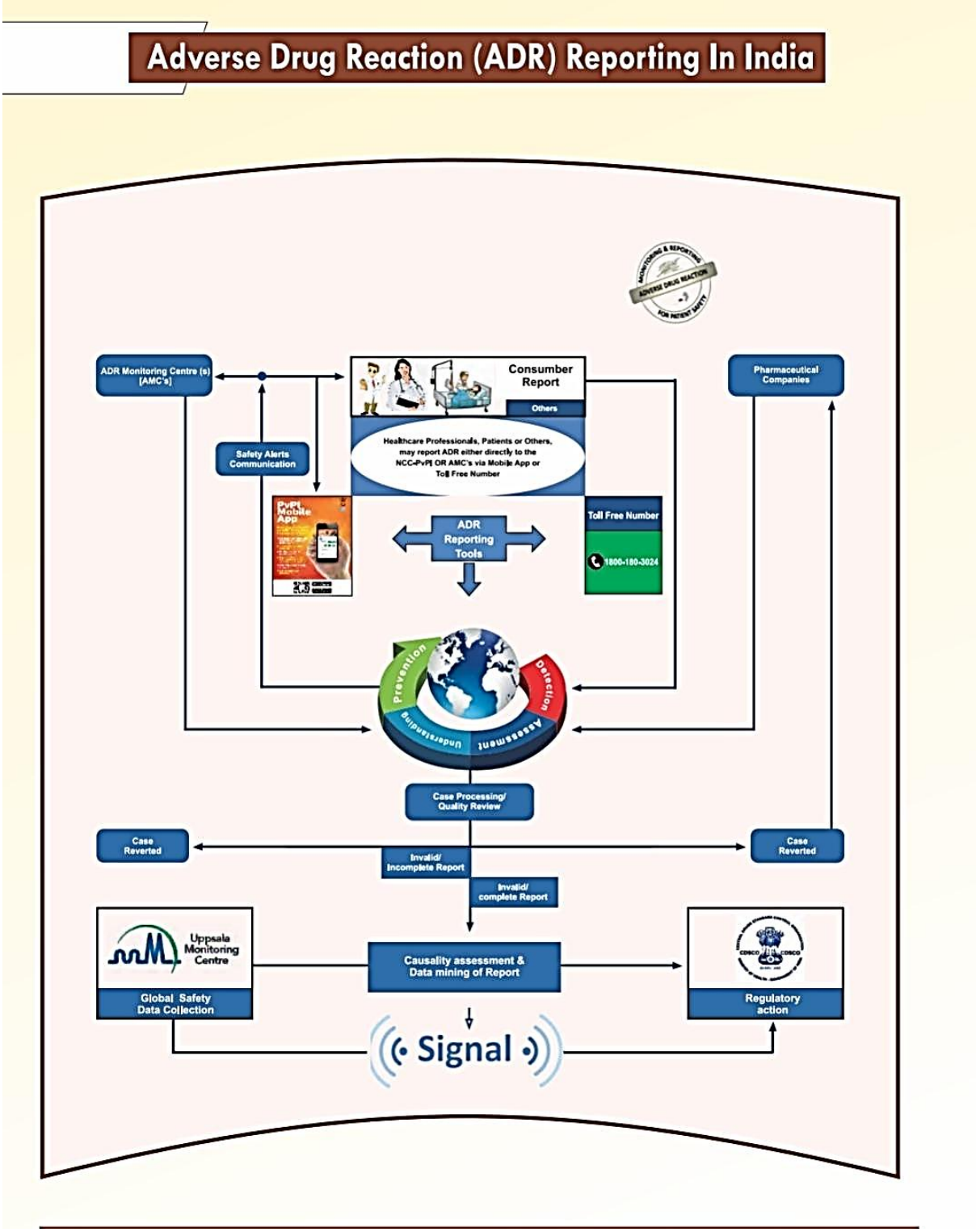
1. INTRODUCTION

Pharmacovigilance (PV) is crucial for monitoring the safety and effectiveness of medications throughout their lifecycle. This process involves identifying, assessing, understanding, and preventing adverse reactions and other drug-related issues. In India, the rapid expansion of the pharmaceutical sector and the growing number of new medications have created a need for a structured pharmacovigilance system. In response, the Government of India established the Pharmacovigilance Program of India (PvPI) in 2010, which operates under the oversight of the Central Drug Standards Control Organization (CDSCO) and is coordinated by the Indian Pharmacovigilance Commission (IPC) in Ghaziabad. [1]

The primary aim of the Pharmacovigilance Program of India (PvPI) is to track adverse drug reactions (ADRs), promote the safe use of medications, and safeguard public health. Over the years, PvPI has developed a network of more than 600 adverse drug reaction monitoring centers (AMC) across the nation, which gather and assess reports of adverse reactions from healthcare professionals, hospitals, and patients. These reports are analyzed for causality, severity, and frequency to identify new safety signals and to take prompt regulatory actions, such as changing labels, issuing safety alerts, or recalling products. From a clinical standpoint, pharmacovigilance provides significant advantages, such as enhancing the detection of previously unnoticed adverse reactions, improving drug safety profiles, and boosting public trust in healthcare systems. [3]

This also encourages rational prescribing and reduces drug-related morbidity and mortality. Nonetheless, various clinical risks and limitations remain in the Indian pharmacovigilance environment, including underreporting of adverse events, insufficient awareness among healthcare professionals, inconsistencies in reporting quality, and delays in regulatory responses. These issues may hinder the overall effectiveness of the system and impede the timely detection of drug-related risks. Despite these challenges, India's pharmacovigilance strategy is progressing through the implementation of electronic reporting systems, education for stakeholders,

and enhanced collaboration between healthcare providers and regulators. Given that India is one of the largest pharmaceutical markets globally, having a strong and transparent pharmacovigilance system is crucial to balance clinical risks with therapeutic benefits and ensure patient safety. [3]



2. AIM AND OBJECTIVES

- **AIM:**

The primary goal of the pharmacovigilance plan in India is to create a strong and dependable system for the ongoing surveillance of the safety of medications used by patients.

It emphasizes the early identification, assessment, and prevention of adverse drug reactions (ADR) to guarantee that drugs remain safe and effective throughout their duration. Additionally, the plan seeks to foster public trust in the health system by encouraging the responsible and safe use of medications in line with the guidelines provided by the Central Drug Standard Control Organization (CDSCO) and the Pharmacovigilance Program of India (PvPI). [4]

- **OBJECTIVES:**

1. Developing a robust pharmacovigilance framework: The primary objective is to create an efficient drug safety system that adheres to both national and international guidelines, making sure that all efforts concerning adverse drug reactions are effectively managed. [4]

2. Gathering and reporting of adverse drug reactions: The strategy emphasizes the organized detection, recording, and reporting of suspected adverse drug reactions, whether serious or not, to regulatory bodies within defined deadlines.[5]

3. Evaluate and handle the risks associated with the medication: the goal is to examine the gathered data, determine the potential connection between the drug and any adverse events, and continuously assess the overall benefit-risk ratio to guarantee patient safety. [5]

4. Fostering awareness and education: A key objective is to educate healthcare professionals, pharmacists, and others to identify, document, and properly communicate adverse reactions, which will help minimize under-reporting and enhance patient outcomes.

5. Implementation of strategies to minimize risks: Informed by pharmacovigilance findings, the plan seeks to establish measures like updated prescription information, patient counseling, and safety notifications to lower the potential hazards linked to drug usage.[5]

6. Ensuring consistent safety reporting: The system promotes the creation and submission of Periodic Safety Update Reports (PSUR) and Risk Management Plans (RMP) to national agencies such as CDSCO and PvPI as part of the continuous assessment of drug safety.

7. Enhancing public health protection: Ultimately, the Pharmacovigilance Plan strives to promote transparency, accountability, and ongoing improvement in the drug safety monitoring system in India to safeguard public health.[6]

3. LITERATURE REVIEW

Over the past twenty years, pharmacovigilance (PV) in India has become increasingly significant owing to the growing utilization of new medications, vaccines, and herbal products among different populations. Research highlights that pharmacovigilance is essential for identifying, assessing, and preventing adverse drug reactions (ADRs), thereby enhancing drug safety and public health results.[7]

Launched in 2010 by the Ministry of Health and Family Welfare under the Central Drug Standards Control Organization (CDSCO), the Pharmacovigilance Program of India (PvPI) serves as the foundation for post-marketing surveillance in the nation. It operates through over 600 Adverse Drug Reaction Monitoring Centers (AMCs) spread across India, gathering data from healthcare professionals, hospitals, and pharmaceutical companies. The Indian Pharmacopoeia Commission (IPC) coordinates the program, collaborating with the World Health Organization Monitoring Center in Uppsala (WHO-UMC) for international data sharing. Research indicates that the establishment of PvPI has notably enhanced awareness among healthcare professionals and increased the reporting of adverse reactions. For instance, data from several tertiary care hospitals has shown a rise in the rates of adverse event reporting after the roll-out of awareness initiatives and mobile reporting apps.

The implementation of digital reporting tools and national training workshops has enhanced systematic monitoring and improved data quality. The clinical advantages of pharmacovigilance (PV) are well established in the literature. Effective PV practices have been instrumental in discovering previously unidentified adverse reactions, prompting label modifications, and influencing

regulatory decisions about drug withdrawals or use restrictions. For instance, the safety of certain antiretrovirals and antituberculosis medications has been reassessed using data from the Pharmacovigilance Programme of India (PvPI). Furthermore, pharmacovigilance was vital during the COVID-19 vaccination campaign, where safety data gathered through the Adverse Events after Immunization (AEFI) system was crucial in maintaining public trust and ensuring safe vaccination protocols. Nonetheless, some studies highlight persistent challenges, such as under-reporting, lack of awareness, and inadequate integration of pharmacovigilance into clinical practice.[8]

According to a systematic review by Garashi et al. (2022), a minimal percentage of adverse drug reactions (ADRs) are reported in developing countries like India, primarily due to inadequate training and infrastructure. Additionally, a significant challenge is the absence of active surveillance in rural regions, where healthcare access and reporting systems are restricted. To address these issues, the literature suggests enhancing healthcare professionals' training, encouraging patient-centered reporting, setting up monitoring through electronic health records (EHR), and ensuring that pharmaceutical companies adhere to mandatory pharmacovigilance requirements. [9]

4. METHODOLOGY

1. Establish the objectives and duties: The pharmacovigilance plan starts by identifying the medication, its intended use, and the target demographic. The Marketing Authorization Holder (MAH) designates a Qualified Pharmacovigilance Person (QPPV) to manage the gathering, documentation, and reporting of safety information. The organization, roles, and timelines are outlined in alignment with the guidelines set forth by CDSCO and PvPI.[11]

2. Data collection and sources: Data are collected from multiple sources, including Individual Safety Reports (ICSRs), clinical trials, post-marketing surveillance, literature, registries, and electronic health records. Reports from Adverse Drug Reaction Monitoring Centers (AMCs) under PvPI are a key source for national signal detection.[11]

3. Signal detection and analysis: Qualitative and quantitative approaches are applied. Quantitative signal detection uses statistical tools such as proportional ratio (PRR), odds ratio (OR) and Bayesian belief propagation neural network (BCPNN). Qualitative methods include expert clinical review and case evaluation. Signals are prioritized based on their severity, frequency and impact on public health.

4. Assessment of causality Reported adverse reactions are assessed for causality using standard algorithms, such as the WHO-UMC Causality Categories or Naranjo Scale. This step determines if the adverse event is related to the suspected drug based on parameters such as temporality, questionability, reattribution and alternative explanations.

5. Risk quantification: The absolute and relative risk of adverse events is estimated using exposure data from sales or prescription drug records. For rare events, “Observed vs. The "expected" (O/E) analysis is performed relative to baseline incidence rates.[13]

6. Benefits Assessment: Benefits are assessed using clinical trial results and real-world data to determine effectiveness, efficiency and improved patient outcomes. Measures such as absolute risk reduction (ARR), number needed to treat (NNT) and hospitalization prevention rates are used.

7. Risk-benefit assessment: A structured framework such as the Risk-Benefit Action Team (BRAT) model or the PrOACT-URL approach is used to compare the therapeutic benefits and identified risks. Each risk and benefit is evaluated based on its magnitude, severity and uncertainty to guide decision making.

8. Risk minimization and communication: Appropriate measures such as updating safety labels, issuing Distinguished Healthcare Professional (DHCP) letters or conducting additional safety studies are implemented when risks are confirmed. Communication with CDSCO and PvPI is essential for transparency and patient safety.[12]

9. Monitoring and evaluation of effectiveness: After the risk minimization actions have been implemented, monitoring is carried out to evaluate their effectiveness. Indicators include a reduced reporting of adverse events, better prescribing habits or better adherence to safety recommendations.

10. Regulatory Reporting and Documentation: All results, actions and results are documented in Periodic Safety Update Reports (PSUR) and Periodic Benefit and Risk Assessment Reports (PBRER), in accordance with CDSCO conditions. Continuous improvement is maintained through PvPI audits and feedback.[11]

5. CLINICAL RISK ASSESSMENT

Clinical risk assessment (short version) Clinical risk assessment in pharmacovigilance is the process of identifying and evaluating the adverse effects of drugs to ensure their safety and minimize harm to patients.

Adverse drug reaction (ADR) data from sources such as ICSR, clinical trials and post-marketing surveillance under the Pharmacovigilance Program of India (PvPI)]. Hazards are categorized as expected/unforeseen and serious/not serious, which helps regulators prioritize safety signals.[14]

Quantative tools such as incidence rate and relative risk analysis are used to measure the frequency and severity of adverse events. Causality is assessed using standard methods such as the WHO-UMC system and the Naranjo algorithm, which help determine the likelihood that a drug will cause a reaction. Quantitative tools such as incidence rate and relative risk analysis are used to measure the frequency and severity of adverse events . Causality is assessed using standard methods such as the WHO-UMC system and the Naranjo algorithm, which help determine the probability that a drug will cause a reaction.

Finally, identified risks are communicated to CDSCO through Periodic Safety Reports (PSURs), which lead to actions such as label changes or withdrawal of unsafe medications to ensure patient safety.[15]

6. CLINICAL BENEFITS ASSESSMENT

Clinical benefit assessment in pharmacovigilance assesses the effectiveness with which a drug achieves the intended therapeutic results while ensuring patient safety. It focuses on measuring the positive effects of drugs, such as symptom improvement, disease control or increased survival, based on data from clinical trials, post-marketing studies and patient reports.[2]

Benefits are determined using metrics such as absolute risk reduction (ARR), relative risk reduction (RRR) and number of treatments needed (NNT) to show how effective the drug really is.

This evaluation also considers patient-reported outcomes, quality of life and long-term success of the treatment, ensuring that the benefits outweigh the potential risks.

The final assessment integrates benefit and risk data into a risk-benefit assessment framework, guiding CDSCO and PvPI regulatory decisions regarding approval or continued modification of drug use.[16]

7. RISK MINIMIZATION AND COMMUNICATION PLAN

Risk minimization and communication are essential elements of pharmacovigilance aimed at reducing the occurrence and impact of adverse drug reactions (ADRs) guaranteeing the safe and effective use of drugs.[17]

1. Risk Minimization Strategies

These strategies include routine and additional measures:

Routine strategies: updates to labeling, package inserts and description information.

Additional strategies: educational materials for health professionals, limited programs and patient monitoring systems.

In India, the Pharmacovigilance Program of India (PvPI) and CDSCO work together to implement and monitor these actions for marketed drugs.

2. Communication Plan

Effective communication ensures rapid sharing of drug safety information between healthcare professionals, manufacturers, regulators and the public.

This includes:

a.Issuimg drug safety alerts and adverse reaction information bulletins by PvPI.

b.Publication of security circulars and updates on the CDSCO website.

c.Engage in media awareness and health education programs to improve reporting of adverse reactions.

3. Evaluation and Follow-up

The success of risk minimization measures is evaluated through follow-up studies, health center feedback and trend analysis of adverse events to confirm whether risks have decreased over time.[18]

8. POST MARKETING SURVEILLANCE AND REPORTING

Once a drug is approved and released on the market, its safety continues to be monitored through a process called post-marketing surveillance (PMS). This step is essential because some side effects or safety issues may emerge only when the drug is used by a large and diverse population in real-world settings.[19]

1. Purpose and importance

The main aim of post-marketing surveillance is to keep track of how safe and effective a medicine remains once it's in use. It helps identify rare or long-term adverse drug reactions (ADRs) that may not have appeared during clinical trials and ensures that the overall benefit of the medicine still outweighs the risks.

2. PMS System in India

In India, post-marketing surveillance is managed by the Central Drug Standards Control Organization (CDSCO) and supported by the Pharmacovigilance Program of India (PvPI).

PvPI operates a large network of adverse drug reaction monitoring centers (ADCs) in hospitals and medical schools to collect safety data across the country (20).

Drug manufacturers are also required to submit Periodic Safety Update Reports (PSUR) and Periodic Risk-Benefit Evaluation Reports (PBRER) at regular intervals – every six months for the first two years after approval and once a year for the next two years. These reports help regulators determine whether the drug continues to be safe for public use.

3. Reporting Mechanisms

Health professionals and patients play an important role in reporting adverse reactions.

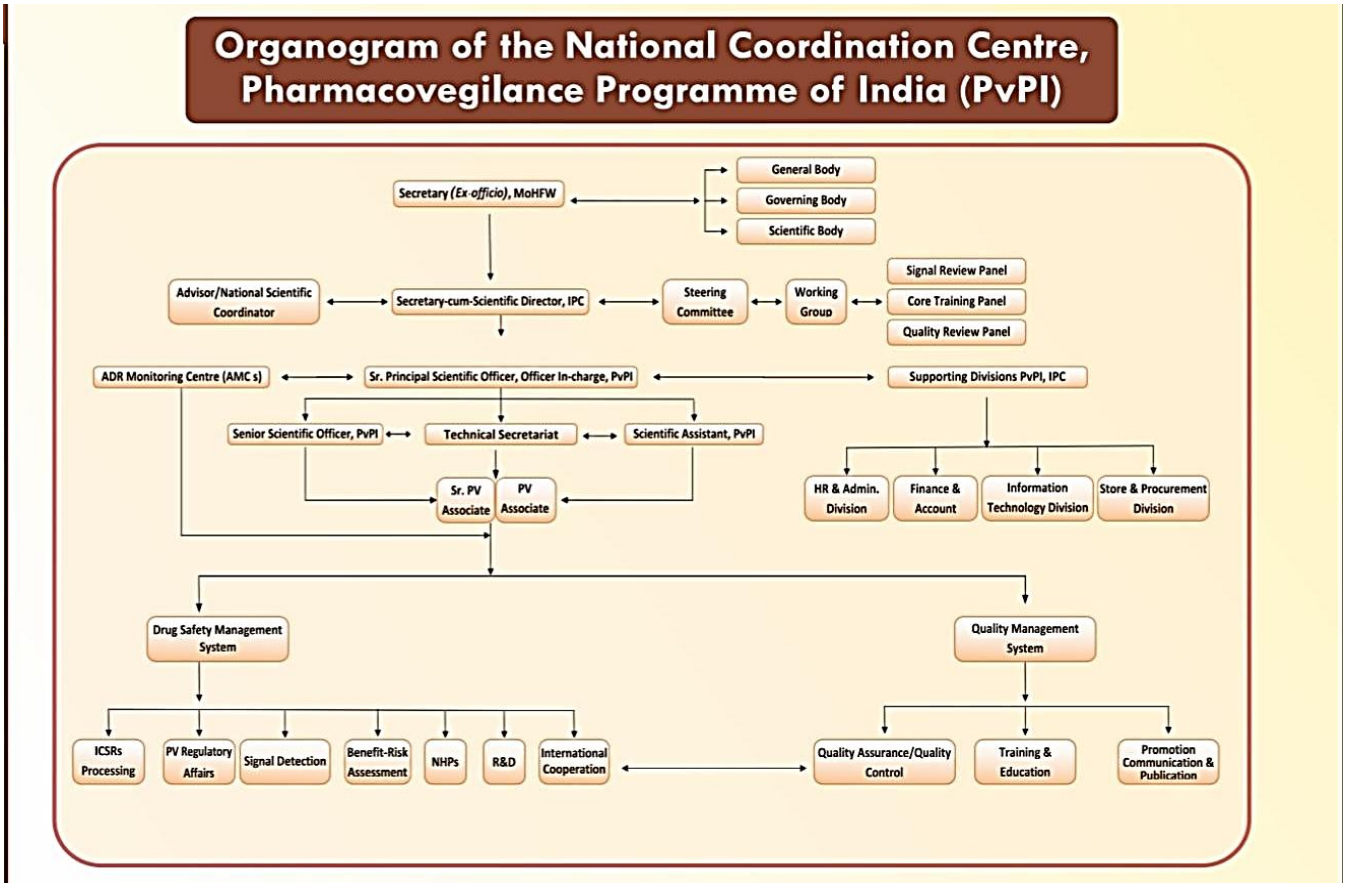
Doctors and pharmacists can report a suspected adverse reaction using the report form.

Patients can report directly through the PvPI mobile app or the toll-free helpline (1800-180-3024).

All the reports collected are sent to the National Coordination Center (NCC-PvPI), where experts analyze them for any new signals or security patterns.

4. Regulatory Actions

If a drug is found to pose serious risks, CDSCO and PvPI can take immediate regulatory action, such as updating the drug's safety label, issuing safety warnings, limiting use, or even withdrawing the product from the market.These measures ensure that only safe and effective medicines remain available to the public.[21]



9. CHALLENGES AND FUTURE PROSPECTS IN INDIAN PHARMACOVIGILANCE :

The Indian pharmacovigilance system has improved significantly since the launch of the Indian Pharmacovigilance Program (PvPI) in 2010. However, some challenges remain to make the system more efficient and patient-centered.[22]

1. Key Challenges

Under-reporting of adverse reactions: Many health professionals do not report adverse reactions to the drug due to lack of awareness or lack of time, limiting the data on the safety of the drug.

Low awareness and training: Pharmacovigilance is not yet widely included in medical or nursing training, which leads to a poor understanding of its importance.

Limited resources: Some adverse reaction monitoring centers do not have trained staff, funding or adequate technology to effectively process reports.

Data quality issues: An incomplete or unclear ADR report makes it difficult to detect new safety signals.[23]

2. Future Prospects

Use of Technology and AI: Digital tools and artificial intelligence can make the detection of adverse reactions faster and more accurate.

Global Collaboration: Closer ties with international agencies like WHO-WMC will help align India's safety standards with global systems.

Public Awareness: Education of healthcare workers and patients can improve the reporting of adverse reactions and create a culture of safety.

Better Regulation: CDSCO and PvPI are working on tighter post-trading rules and faster security responses.

Patient Engagement: Mobile apps and free helplines allow patients to directly report side effects, improving transparency.

3. Conclusion

India has made significant progress in drug safety monitoring, but improving awareness, data quality and the use of modern technology will be key to building a smarter, safer and more responsive pharmacovigilance system in the future.[24].

10. RESULT AND DISCUSSION

The Pharmacovigilance Program of India (PvPI) has led to a marked increase in the number of adverse drug reaction (ADR) reports and drug safety awareness. More than 600 adverse reaction monitoring centers collect and analyze safety data from hospitals and medical schools, helping to identify new risks from commonly used medications such as antibiotics and cancer drugs.[25]

Despite progress, underreporting remains a major challenge. Many health professionals do not know or are too busy to report side effects [3]. However, training programs, awareness campaigns and the PvPI mobile app have facilitated the sharing of safety information between professionals and patients.

Data collected through PvPI has already guided regulatory decisions such as updating drug labels and limiting unsafe drugs, demonstrating its growing importance in improving patient safety.

Overall, India's pharmacovigilance efforts are moving in a positive direction, but additional work in education, technology, and active participation is needed to make the system even stronger.[26]

11. CONCLUSION

In India, pharmacovigilance has emerged as a robust public health system aimed at ensuring the safe and effective use of drugs. Through the Pharmacovigilance Program of India (PvPI), adverse drug reactions (ADRs) are continuously monitored, reported and analyzed to protect patients from potential drug risks.

Although issues such as under-reporting, lack of awareness and limited infrastructure still exist, ongoing efforts such as digital reporting tools, global collaboration and stricter regulatory policies are making the system more effective.

The future of pharmacovigilance in India lies in the adoption of technology, improved training of healthcare professionals and increased patient engagement. These measures help maintain a healthy balance between clinical benefits and potential risks, ensuring safer medicines for every citizen.

12. REFERANCES

1., Ministry of Health and Family Welfare. Pharmacovigilance Programme of India (PvPI): Guidance Document. Central Drugs Standard Control Organization (CDSCO); 2010.
2., Pal SN, Duncombe C, Falzon D, Olsson S. WHO Strategy for collecting safety data in public health programmes: Complementing pharmacovigilance. Drug Saf. 2013;36(2):75–81.
3., Gupta SK, Nayak RP. Pharmacovigilance in India: Current scenario and future challenges. Int J Pharm Sci Rev Res. 2021;68(1):45–50.
4., World Health Organization (WHO). Pharmacovigilance: Ensuring the Safe Use of Medicines. WHO, Geneva
5., Central Drugs Standard Control Organization (CDSCO). Guidance Document for Marketing Authorization Holders on Submission of Individual Case Safety Reports (ICSRs) and PSURs, Ministry of Health & Family Welfare, Government of India, 2018.
6., World Health Organization (WHO). Pharmacovigilance Indicators: A Practical Manual for the Assessment of Pharmacovigilance Systems, 2015.
7., WHO. The Importance of Pharmacovigilance: Safety Monitoring of Medicinal Products. World Health Organization; Geneva, 2002.1. WHO. The Importance of Pharmacovigilance: Safety Monitoring of Medicinal Products. World Health Organization; Geneva, 2002.

8., Jose J, Rao PG. Pattern of Adverse Drug Reactions and the Role of Pharmacovigilance in India. Pharm Pract. 2019;17(3):1541–1548
9., Gupta SK, et al. Strengthening Pharmacovigilance in India: A Way Forward. Indian J Pharm Sci. 2020;82(1):12–18
10., CDSCO. Guidelines for Pharmacovigilance Requirements of Marketed Drugs in India. Central Drugs Standard Control Organisation; 2024.13. CDSCO. Guidelines
for Pharmacovigilance Requirements of Marketed Drugs in India. Central Drugs Standard Control Organisation; 2024.
11., Central Drugs Standard Control Organization (CDSCO). Pharmacovigilance Guidance Document for Marketing Authorization Holders of Pharmaceutical Products, CDSCO–PvPI, 2023.
12., PvPI. Communication Plan for Risk Minimization Activities in India, IPC, 2020
13., van Puijenbroek E. et al. Signal Detection and Evaluation in Pharmacovigilance. Br J Clin Pharmacol, 2002;54(5):501–507.
14., Edwards I.R., Aronson J.K. Adverse Drug Reactions. Lancet. 2000;356(9237):1255–1259.
15., CDSCO. Pharmacovigilance Guidance for MAHs. 2023.
16., IPC. Pharmacovigilance Programme of India (PvPI) Operational Guidelines. 2021.
17., WHO. The Importance of Pharmacovigilance: Safety Monitoring of Medicinal Products. WHO, Geneva, 2002.
18., Arora D. Pharmacovigilance Obligations of the Pharmaceutical Companies in India. Indian J Pharmacol. 2008;40(Suppl 1):S13–S16.
19., World Health Organization. Pharmacovigilance: Ensuring the Safe Use of Medicines. WHO, Geneva, 2004.
20., Indian Pharmacopoeia Commission. Pharmacovigilance Programme of India (PvPI) Operational Guidelines. IPC, 2021.
21., EMA. Good Pharmacovigilance Practices (GVP) Module IX – Signal Management. European Medicines Agency, 2017.
22., Indian Pharmacopoeia Commission. PvPI Operational Guidelines. IPC, 2021.
23., Wadhwa T. et al. Pharmacovigilance Challenges and Future Prospects in India. Int J Pharm Sci Res. 2020.
24., WHO. Pharmacovigilance in Developing Countries: Future Prospects. 2020.
25., Suke S.G., et al. Role of Pharmacovigilance in India. Online J Public Health Inform. 2015.

How to cite this article:
Mr. Akash R. Salve et al. Ijppr.Human, 2025; Vol. 31 (12): 240-248.
Conflict of Interest Statement: All authors have nothing else to disclose.