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PHARMACOVIGILANCE (PV): THE BACKBONE OF POST-MARKETING SURVEILLANCE (PMS) IN INDIA

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ABSTRACT

Pharmacovigilance (PV) plays a mission-critical role in ensuring drug safety beyond the controlled environment of clinical trials, making it the backbone of Post-Marketing Surveillance (PMS). In a diverse and populous country like India, where medicines are used across varied genetic, socio- economic, and healthcare settings, PMS becomes indispensable for the early detection, assessment, and prevention of adverse drug reactions (ADRs). This review highlights the growing need for robust post-marketing surveillance in India, emphasizing the limitations of pre-approval clinical trials in identifying rare, long-term, and population-specific safety concerns. The article provides an overview of the Pharmacovigilance Programme of India (PvPI), its organizational structure, reporting mechanisms, and its role in strengthening the national drug safety ecosystem. Despite significant progress, pharmacovigilance in India continues to face multiple challenges, including under-reporting of ADRs, lack of awareness among healthcare professionals and patients, inadequate infrastructure, and limited integration of digital health technologies. Furthermore, the review discusses future prospects of PMS in India, focusing on the adoption of electronic reporting systems, artificial intelligence-based signal detection, real-world evidence generation, patient-centric reporting, and stronger regulatory frameworks. To contextualize theoretical concepts, the article concludes with post-marketing safety examples of commonly used drugs, illustrating how pharmacovigilance interventions have contributed to risk identification and safer therapeutic outcomes. Strengthening pharmacovigilance and post-marketing surveillance is essential to enhance patient safety, regulatory decision-making, and public trust in the Indian healthcare system.

KEYWORDS: Pharmacovigilance; Post-Marketing Surveillance; Pharmacovigilance Programme of India (PvPI); Adverse Drug Reactions; Drug Safety; Real-World Evidence; Regulatory Framework; India.

INTRODUCTION

Pharmacovigilance is an essential and integral component of clinical research and public health, playing a critical role throughout the entire lifecycle of a medicinal product. Drug safety evaluation does not end with the completion of clinical trials; rather, it extends into the post-marketing phase, where medicines are exposed to a much larger, more diverse population. Both pre-marketing clinical trial safety assessment and post-marketing pharmacovigilance are therefore indispensable for ensuring the safe and effective use of medicines. Limitations of clinical trials such as restricted sample sizes, controlled study conditions, and short duration often prevent the detection of rare, long-term, or population-specific adverse effects, highlighting the necessity of robust post- marketing surveillance (PMS).

Pharmacovigilance is defined as the pharmacological science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. The discipline focuses on systematically evaluating the benefits and risks of medicines, identifying short-term and long-term adverse effects, and supporting regulatory decision-making to safeguard patient health. In the context of medicines regulation, pharmacovigilance plays a pivotal role by generating safety data that guide regulatory authorities, healthcare professionals, pharmaceutical

companies, and other stakeholders involved in drug development and use.

In India, pharmacovigilance remains a developing discipline, and awareness and understanding among healthcare professionals and the general population are still limited. While significant advancements in pharmacovigilance systems have been achieved in Western countries, progress in India has been comparatively slower. Nevertheless, pharmacovigilance is not a new concept in the Indian healthcare system. India formally initiated structured adverse event monitoring in 1998 when it joined the WHO Programme for International Drug Monitoring through the Uppsala Monitoring Centre. Since then, efforts have been made to strengthen drug safety monitoring frameworks and align national practices with global standards.

The growing importance of pharmacovigilance is evident as regulatory agencies, healthcare providers, the pharmaceutical industry, media, and consumers have become increasingly aware of the benefits and risks associated with medicinal products. An adverse event is defined as any untoward medical occurrence that may present during treatment with a drug but does not necessarily have a causal relationship with its use. In contrast, an adverse drug reaction (ADR) is defined as any noxious, unintended, and undesired effect of a drug that occurs at doses normally used in humans for prophylaxis, diagnosis, therapy, or modification of physiological functions. The distinction between adverse events and ADRs is fundamental to pharmacovigilance activities and safety data interpretation.

Spontaneous reporting of adverse drug reactions and adverse events remains one of the most important and cost-effective tools for post-marketing surveillance, enabling early signal detection and timely risk mitigation. In recent years, the Indian pharmaceutical industry has significantly increased investments in research and development, enhancing its capacity to develop, manufacture, and market new drugs based on indigenous research efforts. This expansion further reinforces the need for a strong pharmacovigilance system to monitor the safety of newly introduced medicines in real-world settings.

Against this backdrop, strengthening pharmacovigilance and post-marketing surveillance in India is essential to protect patient safety, improve regulatory oversight, and build public confidence in the healthcare system. This review examines the role of pharmacovigilance as the backbone of post-marketing surveillance in India, focusing on the need for PMS, the regulatory framework, existing challenges, future prospects, and real-world drug safety examples.

Need for Post-Marketing Surveillance in India

Post-marketing surveillance (PMS) is critically needed in India due to its highly diverse population, characterized by wide genetic heterogeneity, varied dietary habits, socio-cultural practices, and environmental exposures. These factors significantly influence pharmacokinetics, pharmacodynamics, and individual drug responses, often leading to variations in drug efficacy and safety that are not fully captured during pre-approval clinical trials. This need is reflected in real-world safety data, as the Pharmacovigilance Programme of India (PvPI) has accumulated **approximately 0.85 million Individual Case Safety Reports (ICSRs) as of mid-2024**, highlighting the magnitude of adverse drug reactions detected only after medicines are marketed and used across heterogeneous populations.

India's high disease burden further contributes to extensive and long-term exposure to medications among large patient populations, thereby increasing the likelihood of detecting **rare, serious, and delayed adverse drug reactions**. In recent reporting years, **around 20–28% of ADRs reported under PvPI have been classified as serious**, underscoring the clinical and public health significance of post-marketing safety monitoring in real-world settings.

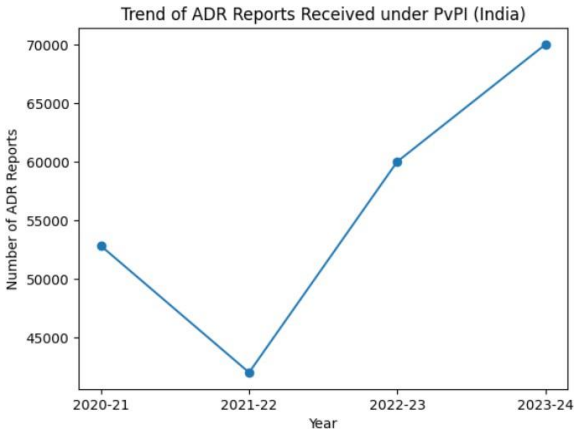

Fig. No. 1: ADR reports graph.

The increasing number of adverse drug reaction reports submitted to the Pharmacovigilance Programme of India in recent years (Figure 1) reflects the growing detection of drug-related safety issues during real-world use, reinforcing the critical need for an effective post-marketing surveillance system.

Furthermore, limited pre-marketing safety data remains a major concern, as clinical trials are typically conducted on relatively small, selective populations under controlled conditions and for shorter durations. Vulnerable groups such as pediatric and geriatric patients, pregnant women, and individuals with multiple comorbidities are often underrepresented in such studies. Consequently, crucial safety signals frequently emerge only after widespread drug use. The continuous rise in ADR reporting through **more than 300 ADR Monitoring Centres (AMCs)** across India further demonstrates the importance of PMS in generating real-world evidence and addressing gaps related to long-term

safety and drug interactions.

In addition, the widespread use of generic medicines manufactured by multiple pharmaceutical companies in India necessitates continuous post-marketing monitoring to ensure consistent quality, safety, and therapeutic effectiveness. The rapid introduction of new drugs and vaccines has further intensified ADR reporting trends, reinforcing the need for robust PMS mechanisms. Strengthening regulatory systems through effective PMS supports evidence-based decision- making by national authorities such as the **Central Drugs Standard Control Organization (CDSCO)** and **PvPI**, ultimately enhancing patient safety, regulatory vigilance, and public confidence in the healthcare system.

Role of Pharmacovigilance in Post-Marketing Surveillance

Because pre-marketing clinical trials cannot identify every possible risk, pharmacovigilance (PV) plays a vital role in post-marketing surveillance (PMS) once medicines are used by the general population. Clinical trials usually involve a limited number of patients and are carried out under controlled conditions, often excluding groups such as children, elderly individuals, pregnant women, and patients with multiple illnesses. When medicines are used in everyday clinical practice, rare, delayed, or unexpected adverse drug reactions may appear, and PV helps in identifying these safety issues early to protect patients.

Pharmacovigilance supports informed decision-making by carefully collecting and reviewing reports of adverse drug reactions. By analyzing this real-world data, PV helps in recognizing patterns, identifying risk factors, and understanding how safe a medicine truly is over time. Based on these findings, regulatory authorities may take appropriate actions such as updating drug labels, adjusting doses, issuing safety warnings, or withdrawing medicines when necessary.

In addition, PV helps improve the overall use of medicines guiding healthcare professionals toward safer and more rational prescribing. It also strengthens communication between regulators, healthcare providers, and patients by sharing important drug safety information. Through continuous monitoring throughout a medicine's life cycle, pharmacovigilance ensures that medicines remain safe and effective, ultimately improving patient safety and maintaining public confidence in the healthcare system.

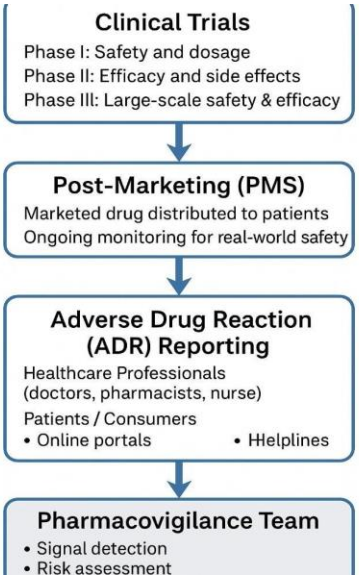

Fig. No. 2: flow chart of ADR Reporting.

Pharmacovigilance Programme in India (PvPI)

The **Pharmacovigilance Programme of India (PvPI)** was formally launched in 2010 by the Indian government under the aegis of the **Central Drugs Standard Control Organization (CDSCO)**. Its primary objective is to ensure patient safety by monitoring adverse drug reactions

(ADRs) associated with the use of medicines in the Indian population. PvPI provides a systematic framework for collecting, analyzing, and evaluating ADR reports from healthcare professionals, patients, and pharmaceutical companies across the country. This centralized system helps identify potential safety concerns and ensures timely regulatory interventions.

PvPI operates through a network of **Adverse Drug Reaction Monitoring Centres (AMCs)** located in medical colleges, hospitals, and other healthcare institutions. These centers collect detailed information on ADRs, which is then submitted to the **National Coordination Centre (NCC)**. The NCC evaluates the data and communicates findings to the CDSCO, which can take necessary regulatory actions such as updating drug labels, issuing safety alerts, or even withdrawing unsafe drugs from the market. This network ensures a comprehensive and continuous monitoring system covering diverse populations across India.

The program emphasizes collaboration and awareness among healthcare professionals, including doctors, pharmacists, and nurses, to encourage active reporting of ADRs. PvPI also promotes the use of **VigiFlow**, an online platform for ADR reporting that aligns with the **WHO's global pharmacovigilance database, VigiBase**. By integrating India's data with global safety information, PvPI contributes to international drug safety monitoring and helps identify rare or severe ADRs that may not be detected in clinical trials.

Over the years, PvPI has expanded its scope to include monitoring of **vaccines, herbal products, medical devices, and fixed-dose combinations**, reflecting the growing complexity of the Indian pharmaceutical market. Public awareness campaigns, training programs for healthcare professionals, and regular safety updates further strengthen the program's role in ensuring that medicines are safe, effective, and used rationally across the country.

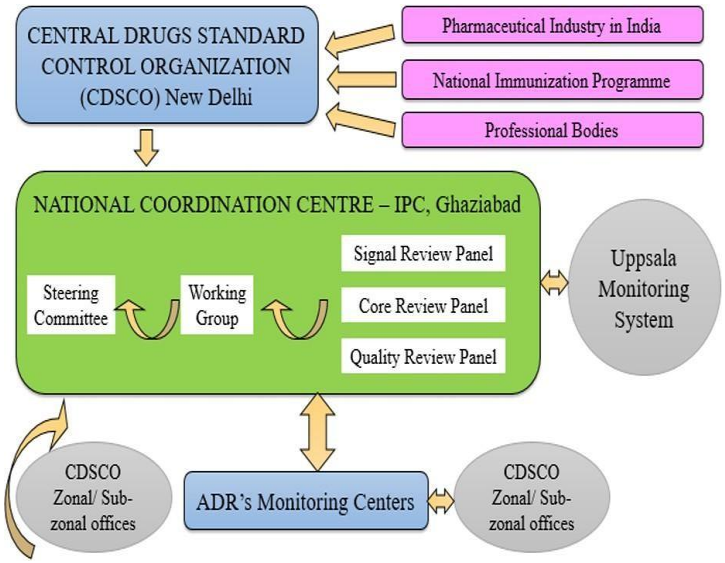

Fig. No. 3: Organisation Struture Of PVPI.

Post-Marketing Strategies Adopted by Pharmaceutical Industries in India

After a drug is approved for marketing, pharmaceutical companies adopt various strategies to ensure its continued safety and efficacy. One key approach is the implementation of **Risk Management Plans (RMPs)**, which outline potential risks associated with the medicine and the measures to minimize them. Companies actively monitor adverse drug reactions (ADRs) reported by healthcare professionals, patients, and pharmacovigilance centers, and maintain **Periodic Safety Update Reports (PSURs)** to keep regulators informed about the drug's performance in the real world.

Pharmaceutical industries also conduct **post-marketing surveillance studies**, which may include observational studies, registries, and targeted safety studies to assess long-term effects or rare adverse events. These studies provide critical data that complement the findings from pre- marketing clinical trials, especially in populations that were underrepresented during the trials, such as elderly patients, children, or those with multiple health conditions.

To strengthen safety monitoring, companies frequently perform **pharmacovigilance audits** and signal detection analyses. These strategies help identify trends, patterns, or emerging risks associated with drug use. Additionally, pharmaceutical firms collaborate closely with the **Pharmacovigilance Programme of India (PvPI)** and regulatory authorities to ensure compliance with national safety standards and guidelines.

Awareness and education campaigns are another important strategy. Pharmaceutical companies train healthcare professionals on proper drug usage, reporting of adverse events, and safety precautions, while also providing information to patients about potential side effects and safe use of medicines. Together, these post-marketing strategies ensure that medicines remain safe, effective, and trusted by healthcare providers and the public throughout their lifecycle.

Table No. 1: Key Post-Marketing Strategies in India.

Strategy	Description	Effectiveness
Risk Management Plan (RMP)	Identify, monitor, and minimize drug risks	High
Periodic Safety Update Reports (PSURs)	Regular safety reporting to authorities	High
Patient Awareness Programs	Educate patients to report ADRs	Medium
Healthcare Professional Training	Train doctors, pharmacists, nurses on ADR reporting	High
Post-Approval Safety Studies (PASS)	Observational studies after drug approval	High
Electronic ADR Reporting Systems	Digital platforms for faster ADR reporting	High
Audits and Inspections	Internal checks to ensure PV compliance	Medium

Challenges in Post-Marketing Surveillance in India

One of the primary challenges in post-marketing surveillance (PMS) in India is the underreporting of adverse drug reactions (ADRs). Many healthcare professionals and patients either lack awareness of pharmacovigilance procedures or consider reporting ADRs time-consuming, resulting in incomplete data that can delay the detection of rare or serious drug-related issues.

Another significant challenge is the limited awareness and training among healthcare providers. While programs like PvPI aim to educate professionals, many doctors, pharmacists, and nurses in smaller towns and rural areas are not fully informed about ADR reporting protocols, leading to inconsistent reporting practices. Patients often do not recognize or report side effects, further limiting the flow of safety data.

Geographical and infrastructural challenges also impact effective PMS. India's vast and diverse population, combined with remote rural regions, makes it difficult to collect uniform and timely data. Limited access to digital reporting tools, poor internet connectivity in rural areas, and inadequate integration between hospitals, pharmaceutical companies, and PvPI slow down the monitoring process.

Variability in drug usage patterns adds another layer of complexity. Different patient populations may have different responses to the same medicine due to genetic, dietary, or environmental factors. This population diversity makes it challenging to detect rare or long-term adverse effects promptly.

Regulatory and resource constraints also pose challenges. Some pharmaceutical companies may lack dedicated pharmacovigilance teams, and regulatory bodies may face resource limitations in reviewing large volumes of ADR data. Additionally, the absence of standardized processes for monitoring newer products like herbal medicines, vaccines, and medical devices can create gaps in surveillance.

Finally, public engagement and awareness remain low. Many patients are unaware of reporting channels for side effects, and cultural or literacy barriers can prevent effective communication about drug safety. Strengthening public education and creating simpler reporting mechanisms are essential to improving the reach and effectiveness of PMS in India.

Fig No. 4: Challenges in PMS.

Risk Evaluation and Mitigation Strategies (REMS)

Risk Evaluation and Mitigation Strategies (REMS) are systematic approaches adopted by pharmaceutical companies and regulatory authorities to ensure that the benefits of a drug outweigh its risks when used in the real world. While post-marketing surveillance identifies potential safety concerns, REMS takes a proactive approach to minimize those risks through planning, monitoring, and intervention.

REMS can include a variety of measures depending on the level of risk associated with a medicine. These may involve restricted distribution programs, patient and healthcare provider education, regular monitoring of specific laboratory parameters, or mandatory follow-up visits. For high-risk drugs, pharmaceutical companies may implement special prescribing programs where only trained or certified healthcare professionals can prescribe the medication, ensuring proper usage.

Additionally, REMS often involves the development of communication tools and educational materials to inform patients and healthcare providers about potential side effects, safe usage guidelines, and reporting procedures for adverse events. This not only improves patient safety but also encourages informed decision-making regarding therapy.

Furthermore, REMS emphasizes continuous assessment and improvement. Data collected from post-marketing surveillance, patient feedback, and healthcare provider reports are regularly analyzed to evaluate the effectiveness of the mitigation measures. If new risks are identified or if existing strategies are insufficient, the

REMS plan can be revised to include stricter monitoring, updated educational materials, or additional safety measures. This iterative approach ensures that the risk management process remains dynamic and responsive to real-world evidence, ultimately enhancing patient safety and supporting the responsible use of medicines across diverse populations.

In India, REMS is increasingly being recognized as a complementary strategy to traditional post- marketing surveillance. By combining real-world safety monitoring with preventive and corrective interventions, REMS ensures that high-risk medicines are used safely while maintaining therapeutic efficacy. It represents a shift from reactive to proactive pharmacovigilance, emphasizing both risk identification and mitigation for optimal patient outcomes.

Recent Developments and Regulatory Initiatives

India has made significant strides in strengthening pharmacovigilance and post-marketing surveillance through recent developments and regulatory initiatives. The Central Drugs Standard Control Organization (CDSCO), along with the Pharmacovigilance Programme of India (PvPI), has updated guidelines and regulations to improve drug safety monitoring and ensure compliance with international standards.

One major initiative is the enhancement of the PvPI network, which now includes more Adverse Drug Reaction Monitoring Centres (AMCs) across hospitals, medical colleges, and regional centers. This expansion allows for more comprehensive and timely data collection, covering diverse patient populations, including rural and underserved areas.

The Indian regulatory authorities have also introduced guidelines aligned with global standards, such as the International Council for Harmonisation (ICH) E2E guidelines on pharmacovigilance and risk management. These guidelines help standardize adverse event reporting, periodic safety update reports (PSURs), and signal detection practices, ensuring consistency and reliability in safety monitoring.

Digital initiatives have further strengthened regulatory oversight. Platforms like VigiFlow and electronic reporting systems make it easier for healthcare professionals to submit ADRs, while centralized databases allow for real-time analysis and risk evaluation. Additionally, regulatory authorities now encourage risk minimization plans and safety training for high-risk drugs, complementing traditional post-marketing surveillance measures.

Recent initiatives also include collaboration with international pharmacovigilance networks, integration of vaccine safety monitoring, and specific frameworks for monitoring herbal products, medical devices, and fixed-dose combinations. These efforts reflect India's commitment to proactive drug safety, aligning domestic practices with global pharmacovigilance standards and enhancing public confidence in healthcare.

Illustrative Case Studies in Pharmacovigilance and Post- Marketing Surveillanc

Illustrative case studies play a crucial role in demonstrating the real-world importance of pharmacovigilance (PV) and post-marketing surveillance (PMS). While regulatory frameworks and surveillance systems provide theoretical and structural guidance, historical and contemporary drug safety cases offer practical evidence of how inadequate monitoring can lead to serious public health consequences. These cases highlight the limitations of pre-marketing clinical trials and reinforce the need for continuous safety evaluation throughout a drug's lifecycle.

Classic examples such as thalidomide, sulfonamides, and chloroform underscore how the absence of effective post-marketing surveillance resulted in severe adverse outcomes, ultimately shaping modern drug safety regulations worldwide. These historical incidents laid the foundation for systematic pharmacovigilance practices by emphasizing early signal detection, risk assessment, and timely regulatory intervention.

1. Thalidomide(1950s–1960s)

The Thalidomide tragedy remains one of the most cited examples of the importance of post-marketing surveillance. Marketed as a sedative and anti-nausea drug for pregnant women, Thalidomide caused severe congenital malformations in thousands of newborns worldwide. The lack of adequate post-marketing monitoring highlighted the limitations of pre-approval clinical trials and led to the establishment of stricter pharmacovigilance regulations globally. This case underscores how PV systems are critical for early detection of rare but serious adverse drug reactions.

2. Sulfonamide Disaster (1937)

A formulation of sulfonamide with diethylene glycol resulted in over 100 deaths due to kidney failure. This incident exposed the dangers of inadequate toxicity testing and poor post-marketing oversight. The event prompted the development of drug safety laws and reinforced the necessity of systematic post-marketing surveillance to prevent mass harm from pharmaceuticals.

3. Chloroform as an Anesthetic

Although widely used in the 19th and early 20th centuries, chloroform caused fatal cardiac arrhythmias and liver toxicity in certain patients. The absence of structured monitoring during its widespread clinical use illustrated the need for pharmacovigilance to identify adverse outcomes, even with commonly used therapies.

Some Cases Reporting in India

1. Covid-19Vaccine(India)

post-marketing surveillance under the Pharmacovigilance

Programme of India enabled the detection of rare adverse events following COVID-19 vaccination, including thromboembolic and hypersensitivity reactions. These findings supported timely regulatory communication, updated clinical guidance, and reinforced risk–benefit assessment at the population level.

2. Anti-DiabeticDrugs

Pharmacovigilance reporting in India has identified adverse reactions such as hypoglycemia, gastrointestinal effects, and renal complications associated with anti-diabetic medicines. Continuous post-marketing monitoring has contributed to improved prescribing practices, dosage warnings, and enhanced patient safety in long-term diabetes management.

Future Directions in Pharmacovigilance and Post-Marketing Surveillance in India

The future of pharmacovigilance (PV) in India lies in digital transformation and integration of technology into safety monitoring. Electronic reporting systems, mobile applications, and online platforms can streamline adverse drug reaction (ADR) reporting, making it easier for healthcare professionals and patients to participate actively. Such systems allow real-time data collection and analysis, improving the timeliness and accuracy of post-marketing surveillance (PMS).

Artificial intelligence (AI) and advanced data analytics are expected to play a significant role in the coming years. AI-driven signal detection can identify potential ADR trends faster than traditional methods, while big data from hospitals, pharmacies, and electronic health records can be analyzed to predict high-risk scenarios. This approach will help detect rare or long-term adverse effects in diverse patient populations more efficiently.

Patient engagement will also be a key focus, with patient-centric reporting mechanisms enabling individuals to directly submit ADRs. Simplified reporting forms, awareness campaigns, and educational programs can empower patients to contribute to drug safety monitoring, complementing professional reporting and enhancing the overall pharmacovigilance ecosystem.

Furthermore, integration with real-world evidence (RWE) will strengthen PV by incorporating observational studies, registries, and post-marketing clinical data. This will allow continuous assessment of long-term safety and therapeutic effectiveness across diverse populations. Coupled with stronger regulatory frameworks, mandatory risk minimization plans, and global collaborations, these initiatives aim to create a proactive, robust, and responsive pharmacovigilance system in India.

CONCLUSION

Pharmacovigilance and post-marketing surveillance are essential for ensuring drug safety beyond the limitations of pre-marketing clinical trials, particularly in a diverse and populous country like India. Continuous monitoring enables early detection of rare, long-term, and population-specific adverse drug reactions, thereby improving patient safety and therapeutic outcomes.

The Pharmacovigilance Programme of India has significantly strengthened the national drug safety framework through systematic ADR reporting, signal detection, and regulatory interventions. Recent Indian examples, including COVID-19 vaccines and anti-diabetic medicines, demonstrate the practical value of PMS in guiding evidence-based decisions. Further strengthening of reporting systems, digital integration, and stakeholder participation will be crucial for advancing pharmacovigilance in India.

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