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REVIEW ARTICLE

A Review on the Evolution and Implementation Challenges of Pharmacovigilance in India

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Abstract: The escalation of pharmaceutical use and the emergence of India as a global leader in drug manufacturing and clinical research necessitate a robust pharmacovigilance (PV) system. This review discusses the trajectory of drug safety monitoring in India, from its nascent, fragmented beginnings to the establishment of the formal Pharmacovigilance Programme of India (PVPI). It analyzes the current operational structure coordinated by the Indian Pharmacopoeia Commission (IPC), which aims to collate and evaluate Adverse Drug Reaction (ADR) data from across the nation. Despite significant structural progress, the system's efficacy is impeded by critical challenges. Foremost among these is a pervasive culture of under-reporting by healthcare professionals, compounded by gaps in medical and pharmacy education where PV is often not integrated as a core clinical responsibility. Infrastructural deficits, particularly in rural healthcare settings, and a lack of standardized implementation across states further fragment the national data landscape. Patient reporting, a valuable data source in many Western nations, remains minimal. This analysis indicates the urgent need for a multi-pronged strategy focused on regulatory enforcement, educational reform, and the integration of clinical pharmacists into safety-monitoring protocols. Strengthening this system is a public health imperative to protect the population and ensure the benefits of therapeutic agents outweigh their risks.

Keywords: Pharmacovigilance; India; Adverse Drug Reaction (ADR); PVPI; Patient Safety

1. Introduction

Pharmacovigilance is the science and set of activities related to the detection, assessment, understanding, and prevention of adverse effects or any other medicine-related problem [1]. Its scope extends beyond spontaneously reported adverse drug reactions (ADRs) to encompass the surveillance of medication errors, lack of efficacy, suspected substandard or falsified medicines, and the misuse or abuse of drugs, all of which are critical to public health. The fundamental goal of any drug safety monitoring system is to safeguard the population by identifying and evaluating previously unrecognized hazards associated with pharmaceutical products. This process involves continuous benefit-risk assessment and, where necessary, the communication of these risks to healthcare providers and the public to mitigate harm. All therapeutic agents possess both beneficial and potential undesirable effects; ADRs remain a significant and often preventable cause of morbidity and mortality globally, contributing to a substantial number of hospitalizations in many countries [2].

The imperative for systematic, post-marketing drug surveillance was tragically solidified by the thalidomide disaster in the 1960s. The widespread use of this drug by pregnant women for morning sickness led to thousands of cases of severe congenital abnormalities, primarily phocomelia (limb malformation) [3]. This event revealed the catastrophic consequences of inadequate pre-market testing for teratogenicity and, critically, the absence of any system to detect and act upon post-approval safety signals. This global tragedy acted as a direct catalyst for the establishment of national regulatory bodies and international drug monitoring systems, including the WHO Programme for International Drug Monitoring in 1968 [4]. For India, this mandate is exceptionally critical. The nation's standing as a major consumer and one of the world's largest producers of pharmaceuticals, combined with its status as a burgeoning hub for global clinical trials, creates a complex risk environment [5]. This is further compounded by a vast and genetically diverse population, the concurrent use of traditional and modern medicines, and persistent challenges with substandard drugs. Therefore, an effective, responsive, and robust PV system is a non-negotiable component of India's national healthcare infrastructure. The main objectives of this review are to discuss the evolution of pharmacovigilance in India, explain the structure and functions of its current program, evaluate the persistent challenges impeding its success, and outline the strategic imperatives for its future development.

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2. The Evolution of Pharmacovigilance in India

2.1. Early Efforts

While the global focus on pharmacovigilance intensified in the latter half of the 20th century, formal ADR monitoring in India was slow to materialize. The concept was recognized, but translating it into a functional, national program proved difficult. The first concerted effort emerged in 1986, with a proposal for an ADR monitoring program involving 12 regional centers; however, this initiative failed to gain traction and became largely non-functional. Its failure is primarily attributed to a lack of sustainable funding and, just as importantly, insufficient awareness and engagement from prescribers who were not incentivized or trained to report [6].

A more structured, formal attempt commenced in 1997 when India became a member of the WHO Programme for International Drug Monitoring. This iteration established a National Pharmacovigilance Centre, based at the All India Institute of Medical Sciences (AIIMS) in New Delhi, and two WHO special centers in Mumbai (KEM Hospital) and Aligarh (JLN Hospital, Aligarh) [7]. Despite this improved framework and international linkage, this system also struggled to make a significant impact. It failed to generate a substantial volume of reports, remaining a largely academic exercise. The core problems persisted: a lack of sustainable funding, an absence of regulatory enforcement, and a deeply rooted, minimal reporting culture among healthcare professionals (HCPs), who did not yet view ADR reporting as a clinical or professional responsibility [8].

Table 1. Chronological Evolution of Pharmacovigilance Milestones in India

Year	Milestone	Significance
1986	First ADR Monitoring Program Proposed	An initial, albeit unsuccessful, attempt with 12 regional centers.
1997	India Joins WHO Programme	Formalized international collaboration; established a National Centre and two special centers.
2005	Launch of NPVP	National Pharmacovigilance Programme (NPVP) launched with World Bank support; implemented a zonal structure.
2010	Launch of PVPI	Pharmacovigilance Programme of India (PVPI) launched (July 14) to replace the NPVP, with AIIMS as the NCC.
2011	NCC Shifted to IPC	National Coordination Centre (NCC) moved from AIIMS to the Indian Pharmacopoeia Commission (IPC), Ghaziabad.
2016	Mandate for Industry Reporting	A formal mandate was established requiring pharmaceutical companies to report adverse effects for marketed drugs.

2.2. The National Pharmacovigilance Programme (NPVP)

Recognizing the critical gap and the public health implications, the Government of India, with significant financial and technical support from the World Bank, launched the National Pharmacovigilance Programme (NPVP) in January 2005 [9]. This program was a far more ambitious undertaking, designed with a defined hierarchical structure coordinated by the Central Drugs Standard Control Organization (CDSCO). It comprised two zonal centers (the South-West at KEM Hospital, Mumbai, and the North-East at AIIMS, New Delhi), which were to collect and collate data from regional centers, which in turn were fed by peripheral centers, often in medical colleges. The NPVP aimed to establish a functional, nationwide ADR monitoring system and, crucially, to begin the difficult task of fostering a national reporting culture. Despite its improved design and high-level support, the NPVP also faced significant operational hurdles. The top-down, hierarchical structure proved cumbersome, data flow was inefficient, and the program's visibility outside of the participating academic centers remained low. It failed to achieve its intended national impact, and the volume of reporting was still negligible compared to the size of the population and the volume of drugs consumed. The program's limitations made it clear that a new programmatic overhaul was necessary, one that was more centralized in its coordination and more integrated into the national regulatory framework [10].

3. Pharmacovigilance Programme of India (PVPI)

3.1. Establishment and Central Coordination

Learning from the limitations of its predecessors, the Government of India launched the Pharmacovigilance Programme of India (PVPI) in July 2010 [11]. A pivotal strategic decision was made on April 15, 2011, when the National Coordination Centre (NCC) for the program was shifted from the All India Institute of Medical Sciences (AIIMS), New Delhi, to the Indian Pharmacopoeia Commission (IPC) in Ghaziabad [12]. This move was intended to provide regulatory and administrative stability to the program, aligning it with the national body responsible for drug standards. The NCC-PVPI at IPC is tasked with coordinating all activities of

the program, including data collection, analysis, and stakeholder training, with the ultimate goal of creating an independent, robust drug safety database for the Indian population.

Table 2. Comparative Analysis of India's National PV Programs: NPVP vs. PVPI

Feature	National Pharmacovigilance Programme (NPVP)	Pharmacovigilance Programme of India (PVPI)
Operational Period	2005 - 2010	2010 - Present
National Coordinator	Central Drugs Standard Control Organization (CDSCO)	Indian Pharmacopoeia Commission (IPC) (since 2011)
Program Structure	Hierarchical: Zonal, Regional, and Peripheral Centres.	Networked: National Coordination Centre (NCC) and Adverse Drug Reaction Monitoring Centres (AMCs).
Data Management	Primarily manual/decentralized data collection.	Centralized database (VigiFlow); focus on electronic ICSR submission.
Primary Goal	Establish a basic ADR monitoring system.	Create a robust, independent national database for signal detection and regulatory action.
Funding	Primarily supported by the World Bank.	Funded by the Government of India, Ministry of Health & Family Welfare.

3.2. Program Structure and Operational Goals

The PVPI operates through a nationwide network of Adverse Drug Reaction Monitoring Centres (AMCs), which are typically located in medical colleges, corporate hospitals, and public health programs. These AMCs are responsible for collecting, verifying, and entering individual case safety reports (ICSRs) into a centralized software, VigiFlow, which is provided by the WHO's collaborating centre in Uppsala, Sweden [13].

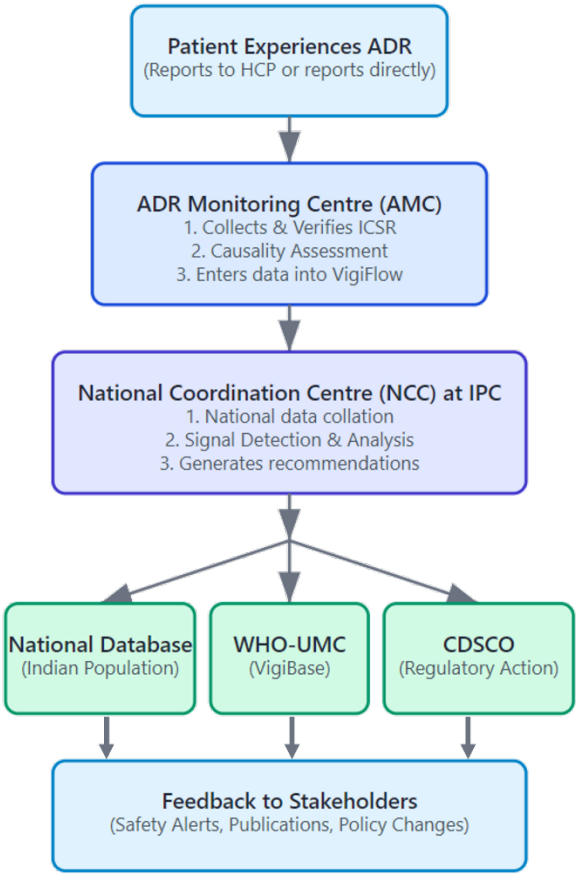

Figure 1. ADR Reporting and Data Processing in the PVPI

The program's development was structured in distinct phases. Initial targets focused on establishing the core infrastructure, enrolling the first wave of AMCs, and training personnel. Subsequent phases concentrated on expanding the network of AMCs across the country, enhancing the quality of reporting, initiating software development for a national database, and conducting workshops to promote drug safety awareness among HCPs and the public [14]. The long-term objective is to generate high-quality, indigenous data that can be used for signal detection, benefit-risk assessment, and informing regulatory interventions, such as changes to package inserts or, in rare cases, drug withdrawals specific to the Indian context [15].

4. Persistent Challenges in the Indian PV Landscape

Despite the establishment of the PVPI, its effectiveness and ability to protect public health are compromised by several deep-rooted and interconnected challenges.

4.1. The Culture of Under-reporting

The single greatest obstacle to effective pharmacovigilance in India is the gross under-reporting of ADRs [16]. This issue is systemic and stems from multiple factors. Many healthcare professionals, including physicians, pharmacists, and nurses, remain unaware of the PVPI's existence, its objectives, or the mechanisms for reporting. Among those who are aware, common deterrents include a lack of time, uncertainty about what to report (believing only "serious" or "novel" reactions are relevant), and a misperception that a single, unverified report is of little value [17]. This results in a database that captures only a small fraction of the ADRs occurring in the population, severely limiting its statistical power for signal detection.

4.2. Deficiencies in Healthcare Education

The problem of under-reporting is directly linked to foundational gaps in medical and pharmacy education. In many university curricula, pharmacovigilance is treated as a peripheral topic rather than an integral component of clinical practice and therapeutics [18]. Students may be required to complete a small number of ADR reports as a procedural hurdle for internship completion, rather than being trained to view safety monitoring as a lifelong professional and ethical responsibility. This lack of early and consistent integration fails to cultivate the necessary mindset and skills for vigilant post-marketing surveillance.

Table 3. Persistent Challenges Impeding Indian Pharmacovigilance

Challenge Category	Specific Challenge	Root Causes
Professional & Cultural	Gross Under-reporting	Lack of time; "lethargy"; fear of blame; uncertainty of what/how to report; belief that a single report is insignificant.
Educational	Deficiencies in Healthcare Curricula	PV is treated as a peripheral topic, not a core clinical competency; reporting is seen as a procedural task, not a professional duty.
Clinical Practice	Suboptimal Engagement of Pharmacists	Role of clinical pharmacists in ADR monitoring is not fully integrated or recognized in many hospital settings.
Infrastructural	Infrastructural & Regional Disparities	Lack of trained PV personnel and technical infrastructure in rural/district hospitals; inconsistent implementation across states.
Public & Industry	Low Stakeholder Contribution	Minimal direct reporting from patients due to low awareness; variable quality and consistency of industry reporting.

4.3. Suboptimal Engagement of Clinical Pharmacists

While clinical pharmacists are ideally positioned to lead ADR monitoring within hospitals, their role remains underutilized in many Indian healthcare settings [19]. Physicians are often overburdened with diagnostic and treatment responsibilities, making it difficult to recognize or document ADRs, which can mimic other clinical conditions. A trained clinical pharmacist, working collaboratively with the medical team, can focus on medication therapy management, patient counseling, and the identification and documentation of adverse events. However, the profession is still fighting for recognition and integration into the core clinical team in many institutions [20].

4.4. Infrastructural and Regional Disparities

India's vast and heterogeneous healthcare system presents significant logistical challenges. The safe and rational use of medicines in rural and remote areas, which are served primarily by district hospitals and primary health centers, is difficult to monitor [21]. These facilities often lack the trained personnel, technical infrastructure, or awareness to participate in the PVPI. This creates a substantial

data gap, as the ADR profile in rural populations may differ from that observed in urban tertiary care centers. Furthermore, the implementation of PV awareness and reporting systems is not uniform and depends heavily on the initiative of individual state governments, leading to a fragmented national safety net.

4.5. Low Patient and Industry Contribution

In many developed countries, such as the Netherlands and Sweden, direct reporting by consumers accounts for a significant percentage of spontaneous reports and has proven valuable for signal detection [22]. In India, patient contribution to the PVPI database remains minimal. This is largely due to a lack of public awareness that they can and should report suspected side effects directly. Concurrently, while reporting from pharmaceutical companies has improved since it was mandated, ensuring consistent, high-quality, and non-selective reporting from all segments of the industry remains a continuous regulatory task [23].

5. Imperatives for System Maturation

To transition from its current, developing state to a mature and effective national system, several strategic areas must be addressed.

5.1. Educational and Professional Development

The long-term solution to under-reporting lies in foundational educational reform. Pharmacovigilance must be woven into the core curricula of medical, pharmacy, and nursing programs, shifting its perception from a bureaucratic task to an essential clinical competency [24]. This must be supplemented by robust, continuous professional development (CPD) programs for practicing HCPs to ensure they are updated on reporting protocols and emerging safety issues. Furthermore, enhancing the capacity of the CDSCO by recruiting and training a larger cadre of scientific and medical assessors is crucial for managing the increasing volume of data from clinical trials and post-marketing surveillance [25].

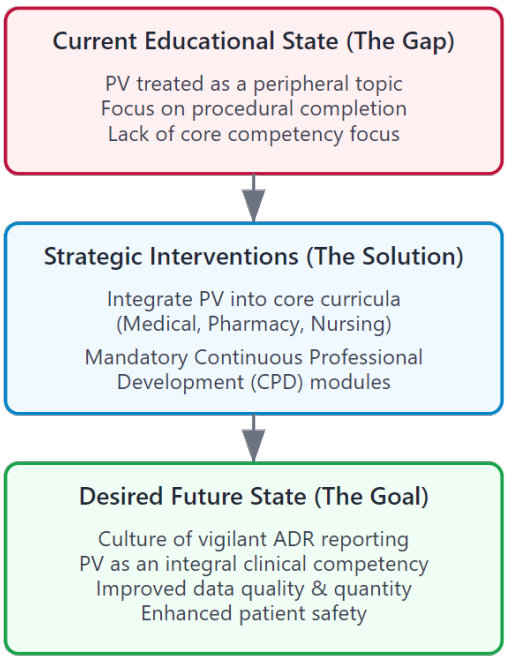

Figure 2. Educational Reforms to Improve PV Reporting

5.2. Regulatory and Policy Reinforcement

A culture of reporting can be significantly strengthened by regulatory action. This includes moving toward mandatory ADR reporting for all healthcare professionals, not just for the pharmaceutical industry. The implementation and enforcement of Good Pharmacovigilance Practices (GPP) through regular inspections of AMCs and industry stakeholders would standardize processes and ensure data quality [26]. Critically, this must be a federated effort, with state health regulatory authorities taking an active role in establishing and regularizing PV units within all government hospitals to ensure consistent, nationwide implementation, particularly extending into district-level and rural healthcare centers [27].

Table 4. Mapping Strategic Measures to Address Pharmacovigilance Challenges

Identified Challenge	Strategic Measures	Recommended Actions
Under-reporting & Educational Gaps	Educational & Professional Development	Integrate PV as a core subject in medical/pharmacy/nursing curricula. Implement mandatory Continuous Professional Development (CPD) modules on PV.
Inconsistent Reporting & Quality	Regulatory & Policy Reinforcement	Move toward mandatory ADR reporting for all HCPs. Enforce Good Pharmacovigilance Practices (GPP) via regular inspections.
Regional Disparities & Lack of Staff	Regulatory & Policy Reinforcement	Mandate and regularize PV units in all state-run government and district hospitals. Increase CDSCO capacity with more trained assessors.
Inefficient Data Analysis & Access	Infrastructural & Technological Integration	Develop unified database for clinical trial and post-marketing data. Implement AI/data mining for signal detection.
Low Patient Contribution	Infrastructural & Technological Integration	Create and promote user-friendly mobile/web platforms for direct patient reporting. Launch national public awareness campaigns

5.3. Infrastructural and Technological Integration

The utility of the national database depends on its comprehensiveness and the tools used to analyze it. There is a need to develop a unified national database that integrates safety data from both post-marketing surveillance (spontaneous reports) and clinical trials [28]. The adoption of advanced data mining and artificial intelligence (AI) algorithms for signal detection within this large dataset will be essential for identifying complex or masked safety signals more efficiently [29]. Technological advancements should also focus on simplifying the reporting process, for instance, through standardized, user-friendly digital reporting forms and mobile applications accessible to both HCPs and patients. Empowering patients as a source of information, a strategy proven effective elsewhere, requires dedicated platforms for consumer reporting and public awareness campaigns to build trust and encourage participation [30].

6. Conclusion

Pharmacovigilance in India has traversed a challenging path from fragmented, unsuccessful initiatives to the establishment of a formal, coordinated national program under the PVPI. This structural progress is significant, placing India in alignment with global drug safety monitoring standards. The program, coordinated by the IPC, has laid the essential groundwork for creating an indigenous safety database. However, the system's potential is far from realized. Its effectiveness is profoundly limited by a deep-seated culture of under-reporting, educational deficiencies that fail to instill PV as a core clinical duty, and significant infrastructural gaps, especially in non-urban healthcare settings. India's status as a global pharmaceutical powerhouse and a major clinical trial destination creates an urgent and non-negotiable public health responsibility. Meeting this responsibility requires moving beyond the current framework. The future of patient safety in India depends on a concerted, multi-pronged effort: integrating PV into the DNA of medical education, enforcing reporting as a regulatory and professional standard, leveraging technology to build a comprehensive and intelligent national database, and actively engaging patients in the safety monitoring process. Achieving this maturation is a collective responsibility, essential for ensuring that the therapeutic benefits of medicines decisively outweigh their inherent risks for the Indian population.

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