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COMPARATIVE ANALYSIS OF THE EUROPEAN UNION'S PHARMACOVIGILANCE FRAMEWORK WITH INDIA'S DRUG SAFETY REGULATIONS

Parveen, Manju Kharb*

B.D.M. College of Pharmacy, Chhuchhakwas, Jhajjar, Haryana, India.

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***Corresponding Author: Parveen, Manju Kharb**
B.D.M. College of Pharmacy, Chhuchhakwas, Jhajjar, Haryana, India.
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ABSTRACT

Pharmacovigilance (PV) is the science and set of activities concerned with detecting, assessing, understanding and preventing adverse drug reactions (ADRs) and other medicine-related problems throughout a product's life cycle. The European Union (EU) operates one of the most comprehensive and integrated PV systems in the world, built on common legislation, Good Pharmacovigilance Practices (GVP), the EudraVigilance database and the Pharmacovigilance Risk Assessment Committee (PRAC). India's Pharmacovigilance Programme of India (PvPI), launched in 2010 and coordinated by the Indian Pharmacopoeia Commission (IPC) under the Central Drugs Standard Control Organisation (CDSCO), is a younger system that has expanded rapidly through a network of ADR Monitoring Centres (AMCs). This article reviews the historical and conceptual background of PV, describes the EU and Indian frameworks, and compares them across seven domains: legal and institutional structure, ADR/individual case safety report (ICSR) reporting, signal detection and management, risk management planning, post-authorisation safety surveillance, stakeholder and patient engagement, and regulatory capacity and workforce. Both systems share the same fundamental principles; the main differences lie in institutional integration, reporting volume and completeness, the use of active surveillance, stakeholder participation and the link between safety signals and regulatory action. Practical, resource-sensitive areas for strengthening the Indian system are proposed.

KEYWORDS: pharmacovigilance; European Union; India; PvPI; EudraVigilance; Good Pharmacovigilance Practices; signal detection; risk management plan; adverse drug reaction reporting.

1. INTRODUCTION

Medicines and vaccines have transformed the prevention and treatment of disease. Alongside their benefits, however, medicinal products may cause side effects, some of which are undesirable or unexpected.[1] Pharmacovigilance is the discipline that addresses this problem, and it has become an essential component of healthcare systems in many countries. It is regulated through national drug laws. In the EU, the laws of member states must conform to drug policy made at the regional level, and although definitions can vary slightly with differences in national law, most countries follow the key terms compiled by the World Health Organization (WHO) in collaboration with the Council for International Organizations of Medical Sciences (CIOMS) and the International Council for Harmonisation (ICH).[2]

Pharmacovigilance is not simply the science of ADRs. It is one of the main sciences dealing with patient safety and covers any drug-related problem that results in adverse events. This includes ineffectiveness: a drug is expected to reduce the burden of disease, and if it fails to do so, harm arises from treatment failure, which is itself a drug-related problem.[3] Consistent with this broader view, PV centre reports in countries with well-established systems now cover unexpected lack of efficacy, quality defects, drug abuse, medication errors, interactions with traditional and herbal medicines, and poisoning events.[4] In the EU and European Economic Area, a series of directives obliges marketing authorisation holders (MAHs) and regulators to set up PV systems that collect, collate and evaluate information on suspected adverse reactions and share relevant information so that all parties can meet their responsibilities.[4]

The main goal of PV is to promote the safe and effective use of health products, in particular by providing timely information on their safety to patients, healthcare professionals and the public, and thereby to protect patients and maintain public health.[5,6] The need for post-marketing vigilance arises because, by the time a drug is authorised, it has usually been assessed for efficacy and safety over a relatively short period and in a limited number of carefully selected patients.[6,7] Once available to the general public, the drug leaves this controlled environment, and its safety and efficacy must be monitored under real conditions of use.

Information on drug safety comes from several sources: spontaneous ADR reporting schemes such as the UK Yellow Card scheme, clinical studies and investigations in wider populations, information from pharmaceutical companies and the medical literature, and data from regulatory authorities and morbidity and mortality databases.[7] MAHs are required to operate a system for monitoring and reporting on the safety of their products, and for new products the PV plan forms part of the risk planning information that accompanies the marketing authorisation application.[8] The objectives of PV programmes, as described by the WHO and other bodies, include improving the care and safety of patients and the public, assessing the effectiveness and risks of health products, promoting rational use, maintaining a robust monitoring system for new safety issues, implementing effective risk minimisation, enabling rapid decision-making when safety concerns arise, and promoting education, training and communication.[9] At the European level, the system also supports Europe-wide reviews of important safety and benefit-risk issues, including referral procedures in which the European Medicines Agency (EMA) is asked to carry out a scientific assessment of a safety concern for the whole EU.[10,11]

This review analysis the conceptual and historical background of PV, outlines the passive and active surveillance tools used in modern systems, describes the EU and Indian frameworks, and presents a domain-by-domain comparison. The intention is not to treat Europe as a benchmark against which India is judged, but to identify specific and achievable improvements while taking the different historical, institutional and economic contexts into account.

2. Historical Evolution of Pharmacovigilance

Pharmacovigilance began roughly 170 years ago, although it was not then called by that name. Its history runs from the first reports, which were essentially letters or warnings sent by clinicians to the editors of scientific journals, to today's highly structured electronic registries.[12] The scientific basis of the field has deep roots in early observations of temporally associated responses to mineral, plant and animal substances, and a widely accepted view holds that the thalidomide disaster was the pivotal event in the history of PV, because it changed the communication of drug safety information to include an institutional level of organisation.[13]

The thalidomide tragedy of the early 1960s exposed several critical problems: the reliability of animal tests, the conduct of the manufacturer and, above all, the importance of monitoring drugs after marketing. Thalidomide was identified as the common link in thousands of cases of congenital malformation.[14] Following the tragedy, spontaneous reporting of ADRs became systematic, organised and regulated. Earlier events such as the sulphanilamide disaster of 1937 had already prompted stricter drug regulation, and together these episodes led to the establishment of PV systems for the collection, detection, assessment, monitoring and prevention of adverse effects of pharmaceutical products.[15-17]

3. The Product Life Cycle and the Pharmacovigilance Cycle

A product's life cycle comprises discovery, preclinical studies, clinical trials, submission of product information to the regulator, the decision on whether to allow sale, distribution and sale, and finally monitoring, inspection and post-marketing investigation. PV plays a role throughout this sequence, from early development to post-marketing surveillance.[18]

Proactive pharmacovigilance is regarded as the future direction of drug safety. It demands a high level of expertise to detect risks early and to defend products against inappropriate withdrawal.[19] Regulatory documents such as the Periodic Safety Update Report (PSUR) and the Risk Management Plan (RMP) are used to manage the safety of a product across its life cycle, and the continuing optimisation of the benefit-risk profile draws on assessment strategies and frameworks developed by regulators and industry groups.[20] The PV cycle can be understood as a continuous loop of five steps: collect, manage and analyse data; review and assess; decide and act; communicate; and monitor the effect of the action taken.

4. Surveillance Tools in Pharmacovigilance

4.1 Passive surveillance: spontaneous reporting

A spontaneous report is an unsolicited communication from a healthcare professional or consumer to a manufacturer, regulatory authority or other organisation describing one or more adverse reactions in a patient who received a health product and who is not part of a clinical study or any organised data collection system.[21,22] Such reports are central to the identification of post-marketing safety signals. They can alert manufacturers and regulators to rare adverse effects that went undetected in clinical trials, and they may contain valuable information on risk groups, risk factors and the clinical features of known serious reactions.[23] Examples include the Yellow Card system operated by the UK Medicines and Healthcare products Regulatory Agency (MHRA), and the systems of the US Food and Drug Administration (FDA), which store drug-related reports in the Adverse Event Reporting System and vaccine-related reports in VAERS.[24]

4.2 Case series

Case series can provide evidence of a link between a drug and an adverse effect, but they are generally more useful for generating hypotheses about an association, which can then be tested using pharmacoepidemiological designs.[25] Certain events are known to be associated frequently with particular classes, for example autoimmune reactions, pure red cell aplasia, Stevens-Johnson syndrome and progressive multifocal leukoencephalopathy with some biological drugs. When such events are reported spontaneously, manufacturers should give priority to rapid and detailed follow-up.

4.3 Causality assessment

Causality assessment assigns a probability that a suspected ADR was caused by a health product. The central question is whether factor A (the health product) is the cause of event B (for example, anaemia), and for causality to hold the exposure must precede the event.[26] Causality can be examined at the individual level, asking whether the product caused the event in this patient, or at the population level, asking whether use of the product increases the risk of the event. A factor is described as having a specific relation if the event requires its presence, and a sufficient relation if its presence inevitably produces the event. Structured algorithms such as the Naranjo scale are widely used for individual case assessment.[27]

4.4 Periodic safety reports

The PSUR is a stand-alone document that provides a periodic and complete assessment of the safety data on a marketed product. It allows evaluation of the benefit-risk balance at defined time points after authorisation and serves as a safety summary of international data to facilitate communication between manufacturers and regulators.[28,29] The Periodic Benefit-Risk Evaluation Report (PBRER), described in ICH guideline E2C(R2), is the format on which the EU PSUR is based. It is prepared by the MAH at defined intervals and must summarise new evidence on safety, efficacy and effectiveness that may affect the balance of risks and benefits, identifying where risk management measures may be needed.[30,31]

4.5 Risk management plans

A risk management plan sets out activities for the detection, assessment, understanding, reporting and prevention of adverse effects of health products, and should be initiated early and revised as development proceeds.[32,33] Its overall objective is to ensure that benefits exceed risks by the greatest achievable margin for the individual patient and the target population, either by increasing benefits or by reducing risks. Risk management proceeds through three interrelated and iterative stages: characterising the safety profile, including what is known and unknown; planning PV activities to characterise risks and identify new ones; and planning, implementing and evaluating risk minimisation measures.[34] In the EU these elements are structured as the safety specification, the PV plan and the risk minimisation plan, and the system also provides for post-authorisation safety studies.[35] The ICH E2E guideline similarly sets out principles for PV planning, including the design of post-marketing pharmacoepidemiological studies.[36]

4.6 Active surveillance and patient registries

Unlike passive surveillance, active surveillance seeks to identify safety concerns through a continuous, pre-organised process of systematic data collection on patients who receive marketed drugs. Methods include sentinel sites, intensive monitoring protocols, follow-up of specific events, patient registries, observational studies and clinical trials.[37,38] A patient registry is a list of patients sharing a characteristic, either a disease or an exposure, from whom standardised

data are collected prospectively; registries can support signal detection, particularly for rare outcomes, and the growth of electronic health records and, in some countries, biobanks has extended their potential.[39] Their limitations are that they usually lack comparison groups, so they cannot answer questions on efficacy and cannot replace clinical trials, and their high operating costs make them most appropriate for highly specialised products.[40]

5. The European Union Pharmacovigilance Framework

5.1 Legislative basis and structure

Before the reforms of the early twenty-first century the European regulatory framework consisted of fragmented national systems, each with its own rules for monitoring ADRs. In response, European Directives and Regulations introduced between late 2010 and 2012, notably Directive 2010/84/EU and Regulation (EU) No 1235/2010, overhauled PV processes across the EU, producing harmonised decision-making, greater transparency with patient involvement, wider public access to information, patient ADR reporting, improved communication and closer cooperation between member states.[41] The 2012 legislation was described as the largest change to the regulation of human medicines in the EU since 1995.[42,43] Its main changes were a new definition of adverse reaction, EudraVigilance becoming the single receipt point for PV information, the creation of PRAC, strengthened post-authorisation safety and efficacy studies, and a requirement for risk management planning for all new medicines.[43,44] The Implementing Regulation (EU) No 520/2012 supports these provisions.[44]

The EMA subsequently published the Guideline on Good Pharmacovigilance Practices (GVP) to give practical effect to the legislation. Compared with the earlier 2007 guidelines, GVP provides more comprehensive and systematic provisions on PV systems, quality systems, inspections and audits, and sets more specific requirements for risk management systems, management and reporting of adverse reactions, periodic safety reports, post-authorisation safety studies and signal management.[45] At the centre of the system, PRAC is responsible for assessing all aspects of the risk management of medicines. The approach is proactive, risk-proportionate and patient-centred, with a high level of transparency and engagement of civil society.[7]

5.2 EudraVigilance

EudraVigilance is the pillar of PV activity in the European Economic Area. Suspected adverse reactions reported by healthcare professionals, patients and MAHs are collected in a common platform that supports continuous monitoring and signal detection, and its operational plans aim to ensure sustainability and to engage stakeholders through training and communication.[46] Analysis of EudraVigilance data has shown that patient reporting makes a measurable contribution to the system.[47]

5.3 Signal detection and management

Signal management is a core PV activity because it rapidly delivers new information on the real-world safety of medicines. During the first six years of the EU signal management system, PRAC issued 453 recommendations, more than half of which concerned changes to product labelling, demonstrating the ability of the network to detect and evaluate new signals and convert them into warnings that guide safe use.[48] Quantitative methods are not infallible, however. A study of signal detection in EudraVigilance for orphan drugs raised the possibility of false negatives where the number of reports is small, a reminder that statistical tools must be complemented by clinical expertise.[49]

5.4 Risk management in practice

An analysis of EU-RMPs found that, of 197 safety concerns studied, 129 were removed and 19 were reclassified during the observation period. The implementation of GVP Module V in 2012 and its second revision in 2017 were associated with a noticeable decrease in the number of safety concerns, and dedicated post-authorisation studies led to the removal of 21 important risks and missing information items.[50] The finding suggests that RMPs in the EU are living documents that respond to accumulating knowledge, rather than static submissions.

5.5 Collaboration and communication

The SCOPE Joint Action, funded by the EU Health Programme, gathered information on how national regulators operate their PV systems and developed tools in areas such as collecting reports of suspected ADRs, managing signals, communicating risk and assessing risk minimisation, all supported by quality management.[51] For applicants, EU PV requirements are regarded as among the most comprehensive, complex and strict anywhere, and prospective MAHs must build an EU-compliant PV system and a product-specific RMP before and during the application process.[52] Regarding communication, a survey of 26 national competent authorities and 1766 general practitioners found that most authorities publish direct healthcare professional communications on their websites, and that over 90% of GPs were aware of them, although preferences for format varied between countries.[53] Patient engagement is also built into EMA structures,[54] and the EMA has been active in the safety monitoring of vaccines, including those for COVID-19.[10,55]

6. The Indian Pharmacovigilance Framework

6.1 Development of PvPI

India joined the WHO Programme for International Drug Monitoring in 1998, but the Pharmacovigilance Programme of India was formally launched in July 2010 under CDSCO. Coordination of the programme was transferred to the IPC, Ghaziabad, in 2011.[56] The national system for monitoring ADRs is therefore young, having developed over a decade and a half. The programme has expanded from a limited number of centres to several hundred AMCs in medical colleges and hospitals, and India contributes ICSRs to VigiBase, the WHO global database maintained by the Uppsala Monitoring Centre, through the VigiFlow reporting system.[57] An assessment of the programme's early years reported an approximately tenfold increase in India's ICSR contributions to VigiBase between launch and the mid-2010s.[58] Later reviews describe the progressive development of the system and the tools and regulatory measures that have emerged from PvPI outcomes, including mobile and electronic reporting tools.[59,60]

6.2 Regulatory framework

The regulatory basis of PV in India comprises the Drugs and Cosmetics Act, 1940 and Rules, 1945, the New Drugs and Clinical Trials (NDCT) Rules, 2019, and guidance documents issued by CDSCO and the IPC. The NDCT Rules introduced clearer requirements for reporting serious adverse events, including expedited timelines for suspected unexpected serious adverse reactions.[61,62] Efforts to align Indian requirements with international guidelines, including ICH E2A on clinical safety data management and E2B(R3) on electronic transmission of ICSRs, have contributed to the gradual evolution of the system.[63,64] The need to strengthen Indian regulatory requirements was stressed early. Khattri and colleagues argued that regulatory authorities and PV programmes must support each other, that the remit of the regulator must extend beyond approval to wider safety questions, and that Indian regulators were not yet insisting

on real-time updating of a drug's cumulative safety profile.[65] Since then, requirements for PSUR and PBRER submission and for MAH PV systems have been set out in IPC guidance.[8].

6.3 Challenges

Despite this progress, the literature identifies several persistent challenges. An early survey of physicians found that under-reporting was linked to lack of familiarity with what to report and how to report rather than lack of interest.[66] Later studies of nurses,[67] community pharmacists[68] and students[69] report similar findings. A common pattern emerges: many healthcare professionals have a positive attitude towards PV, but this does not always translate into actual ADR reporting,[70,71] so awareness and willingness alone are not enough. Electronic tools, including a mobile application for ADR reporting, have been introduced to reduce barriers.[72] Alongside the quantity of reports, quality matters: ICSRs from India have been reported to be less complete than those from many other countries, which limits their value for causality assessment and signal evaluation.

6.4 India's position in the global supply chain

India supplies a substantial proportion of the world's generic medicines and vaccine doses,[73] so the effectiveness of its post-marketing surveillance has implications beyond its borders. The nitrosamine contamination episodes involving valsartan in 2018 and ranitidine in 2019 showed how a manufacturing and quality problem can spread quickly through the international supply chain and demand coordinated regulatory responses.[74-76] India's association with the ICH since 2016 reflects a commitment to implementing internationally harmonised guidelines.[77] The reliability of Indian safety data can influence the confidence of regulators in Europe and elsewhere when they assess medicines made in India.

6.5 Under-reporting

Under-reporting of ADRs is a long-standing problem everywhere. A systematic review found substantial under-reporting across the spontaneous reporting systems examined,[78] and surveys of PV activities in low- and middle-income countries describe limited resources and infrastructure as common constraints.[79,80] In India, published estimates of reporting vary by population, centre, study design and period. The gap between reactions occurring in practice and those captured through spontaneous reporting restricts the information available for signal detection, so factors that drive under-reporting deserve attention.

7. Comparative Analysis Across Seven Domains

7.1 Context for comparison

Several authors have compared PV in India with that in other regions. Comparative reviews of India, the USA and the EU conclude that core PV functions broadly converge but that regulatory structure, documentation and oversight differ.[81-84] Studies across major authorities share ICH-based principles on seriousness criteria and expedited reporting of fatal or life-threatening suspected unexpected serious adverse reactions in clinical trials, but diverge in timelines, case thresholds and special obligations.[85] A qualitative document analysis of the EU GVP Modules I to VII against PvPI version 2.0 found that the EU offers a structured, legal and inspection-ready quality system, while PvPI is a developing programme whose quality system requirements are still emerging, with deficiencies including the absence of a qualified-person-type responsibility, limited documentation and weak audit and compliance structures.[86] Assessment tools such as the IPAT, WHO PV indicators and the WHO Global Benchmarking Tool vigilance module differ in scope, and relying on any one alone gives only a partial picture.[87] Dal Pan emphasised that differences in organisation and development mean a single approach is unsuitable for all regions, though best practice can be

shared.[88] Within India, the distributed nature of responsibilities among CDSCO, IPC, PvPI and AMCs requires effective coordination between data collection, analysis and regulatory action.[89] Comparisons have also been made between the EU and other regional regulators such as the Eurasian Economic Union.[90] The present comparison is organised around seven domains.

7.2 Domain I: legal and institutional structure

The EU framework shows a highly structured division of responsibilities among the European Commission, EMA, PRAC, national competent authorities and MAHs, and common legislation with GVP gives a consistent framework across member states.[7] In India, responsibilities are distributed among the Ministry of Health, CDSCO, the IPC with PvPI, and the AMC network.[56,89] Table 1 summarises the main parameters.

Table 1: Comparative assessment of legal and institutional structure.

Parameter	European Union	India
Principal regulatory framework	EU PV legislation and GVP	Drugs and Cosmetics Act/Rules, NDCT Rules 2019 and CDSCO guidance
Central regulatory authority	EMA and European regulatory network	CDSCO
PV coordination	EMA/PRAC and national competent authorities	IPC/PvPI and CDSCO
Central safety database	EudraVigilance	PvPI/VigiFlow with WHO-UMC connectivity
Signal assessment	PRAC-led regulatory process	PvPI/CDSCO regulatory processes
MAH responsibilities	Defined under EU legislation and GVP	Defined through Indian regulatory requirements and guidance
Reporting network	National competent authorities in member states	ADR Monitoring Centres
Regulatory communication	EU and national safety communications	CDSCO/PvPI communications

The main finding is structural convergence in objectives and divergence in organisation. The EU system was built around a common framework covering multiple member states, whereas India's system has developed within a single national environment with large geographical and healthcare diversity. An additional difference concerns governance: India involves both central and state drug-control authorities, whereas the EU operates through a supranational arrangement among the European Commission, EMA, PRAC and national competent authorities. These differences should be borne in mind when interpreting performance gaps.

7.3 Domain II: ADR and ICSR reporting

Both systems provide routes for spontaneous reporting. The EU accepts reports through national competent authorities, healthcare professionals, patients and MAHs, all of which flow into EudraVigilance.[47] In India, suspected ADRs are collected through PvPI and its AMCs, with healthcare professionals the main contributors, and mechanisms for patient reporting have been developed.[60] Secondary data show a steady increase in ADR/ICSR reporting in India over the study period, indicating expansion of the network and growing participation. EU volumes are substantially larger, but absolute numbers cannot be compared directly because populations, market exposure, healthcare systems, reporting infrastructure, database coverage and active surveillance differ.

Completeness of reports is a more informative indicator. In the data compiled for this analysis (Table 2), completeness was higher in the EU than in India in all four categories, with differences of 20 to 25 percentage points.

Table 2: ICSR completeness: EU versus India (secondary data).

ICSR information category	EU (%)	India (%)	Difference (percentage points)
Patient information	85	65	20
Medicine information	90	70	20
Reaction information	80	60	20
Outcome information	85	60	25

These values describe different information categories, not successive years, so no temporal trend can be inferred from them. Higher-quality reports provide more useful information for causality assessment and signal evaluation, so improving completeness is an essential component of strengthening PV. Adaptation of the EU's integrated reporting infrastructure to India would need to build on the existing PvPI and CDSCO structure rather than copy the EU model.

7.4 Domain III: signal detection and management

In the EU, signal detection uses EudraVigilance and other sources, and potential signals go through validation and assessment, with PRAC evaluating signals and recommending regulatory action.[45,48] This links database-based signal identification with expert clinical and regulatory review. India has developed signal detection through PvPI using reports from the AMC network and connected databases, with signal review and communication to regulators where action is needed.[60] Table 3 compares the two pathways.

Table 3: Comparative assessment of signal detection and management.

Component	EU	India
Primary source of spontaneous data	EudraVigilance	PvPI/VigiFlow
Signal identification	Systematic database-based monitoring	PvPI-based signal monitoring
Signal validation	Established EU procedures	PvPI review procedures
Expert assessment	PRAC and regulatory network	PvPI/CDSCO mechanisms
Regulatory action	EU/national regulatory authorities	CDSCO
Safety communication	EMA and national authorities	CDSCO/PvPI

Both systems have therefore moved beyond passive collection towards systematic detection, but the EU pathway is more extensively integrated from identification to regulatory decision. Effectiveness depends on data quality, clinical expertise, access to complementary evidence and the ability of regulators to convert validated signals into action.[49]

7.5 Domain IV: risk management planning

EU risk management is built on the EU-RMP and GVP requirements, with a safety specification, PV activities and risk minimisation measures, and additional studies where important uncertainties remain.[35,50] India has incorporated risk management into its regulatory framework for new drugs and post-marketing monitoring, and uses PSUR/PBRER and other post-marketing information for ongoing assessment.[8,65] The two approaches are conceptually aligned. Both recognise that PV is more than collecting ADR reports and must include planned activities to characterise and minimise identified risks. The principal difference is the degree to which RMP activities are integrated into a full regulatory life cycle. The EU provides detailed guidance on the structure and implementation of risk management, while in India continued strengthening of implementation, monitoring and documentation could improve the practical contribution of RMPs to post-marketing safety.

7.6 Domain V: post-authorisation safety surveillance

Clinical trials are conducted in relatively controlled populations and cannot detect every safety issue that arises after wider use. Both the EU and India use periodic PSUR/PBRER evaluation, and both rely on spontaneous reporting as the

foundation of continuous monitoring.[28-31] The EU additionally has an established framework for post-authorisation safety studies and develops active surveillance through multiple data sources,[43] whereas in India active surveillance is still developing and expanding.[37,38] Spontaneous reporting is valuable for identifying unexpected signals, but it is affected by reporting behaviour and cannot provide full information on exposure or incidence. Active surveillance and observational approaches complement it by providing evidence for specific concerns.[39,40] For India, expansion should be selective and based on infrastructure, disease burden, medicine utilisation and regulatory priorities.

7.7 Domain VI: stakeholder and patient engagement

Healthcare professionals are an important source of ADR reports in both systems, and reporting forms, electronic mechanisms and PV training support their participation. In the EU, communication with healthcare professionals and the public is highly developed.[53,54] In India, the AMC network links healthcare institutions to the national programme and PvPI conducts training and awareness activities.[60] Patients can contribute reports on symptoms, quality-of-life effects and medicine experiences that clinicians may not capture.[47] However, the existence of reporting mechanisms does not guarantee high participation. Awareness, ease of reporting, feedback and confidence that reports lead to regulatory action all influence behaviour.[66-70] In India, raising awareness among healthcare professionals and patients, particularly outside major urban and tertiary-care centres, would improve representativeness and completeness of safety information.

7.8 Domain VII: regulatory ability and workforce

The EU system draws on EMA, PRAC, national competent authorities, specialised scientific committees and PV staff in marketing authorisation holders, which provides access to expertise in clinical medicine, epidemiology, statistics, pharmacology and regulatory science. India's system relies on CDSCO, IPC, PvPI and the AMC network, which has increased the geographical coverage of ADR monitoring and created institutional capacity. Building a future workforce, especially of PV physicians and scientists, needs targeted training because medical and pharmacy curricula may not emphasise the required skills, and collaboration among academia, industry and regulators to create hands-on training opportunities has been recommended.[91]

Table 4: Comparative assessment of regulatory ability.

Parameter	European Union	India
Central regulatory expertise	EMA/PRAC	CDSCO
PV coordination	EMA/national competent authorities	IPC/PvPI
Reporting centres	National competent authorities/healthcare systems	AMC network
Specialist scientific review	Established committees and experts	Regulatory and PV experts
Training	Established within regulatory network	PvPI/AMC training programmes
National coverage	EU member states	Nationwide AMC network

8. Gaps and Opportunities for Strengthening India's System

The comparative assessment points to six interrelated areas for attention, each related to the others through data quality, system integration, evidence generation, training and transparency.

Reporting quality and completeness: Although a nationwide reporting network exists, the lower completeness of ICSRs reduces their usefulness. Greater awareness among healthcare professionals and patients, simplified electronic reporting, structured forms that prompt for key data elements and feedback to reporters may help improve quality.

Expanding and strengthening the AMC network, including its capacity to follow up incomplete reports, supports the same aim.

Signal detection and its link to regulation: Closer integration between PvPI signals and formal regulatory assessment by CDSCO would improve the use of safety data for timely risk management. Clear procedures for validating signals, documenting decisions and communicating outcomes, as in the EU where signals lead to labelling changes and other measures,[48] would help translate detection into protection.

Active surveillance: Spontaneous reporting should be complemented by active surveillance, observational studies and registries for selected medicines and safety concerns where passive data are insufficient. Because registries and active methods are costly and may lack comparison groups,[40] they should be targeted to high-priority products and conditions, and the use of electronic health records and other data sources can be explored as infrastructure develops.

Risk management: RMP implementation and monitoring of risk minimisation measures should be integrated into the post-authorisation regulatory process and tracked throughout the product's life rather than treated as isolated submissions. The EU experience of periodically revisiting safety concerns in RMPs illustrates how such plans can remain current.[50]

Stakeholder participation: Healthcare professionals and patients should continue to be encouraged to report. Accessible reporting channels, training embedded in undergraduate and continuing education,[69,70] and feedback on how reports are used help to sustain participation.

Regulatory integration and capacity: Better coordination and information sharing among CDSCO, IPC, PvPI, AMCs, state authorities and MAHs, and continued development of a specialist PV workforce, would enhance the practical value of the national system.[89,91] Quality systems for PV, including documentation and audit, are an area where EU practice offers useful reference points.[86]

The proposals above can be summarised as ten priority actions: improve ADR report quality and completeness; expand and strengthen the AMC network; promote electronic and patient-friendly reporting; strengthen systematic signal detection and validation; integrate PvPI more closely with regulatory decision-making; expand active surveillance and post-authorisation studies; improve monitoring of risk minimisation measures; increase participation by patients and healthcare professionals; develop the specialist PV workforce; and improve coordination and information sharing among relevant bodies. These actions are areas for system strengthening, not instructions to copy the EU framework.

10. CONCLUSION

Pharmacovigilance protects public health by identifying, assessing and preventing the adverse effects of medicines, many of which become apparent only after use in larger and more diverse populations than those studied before authorisation. This review has compared the EU's PV framework with India's drug safety system across seven domains. Both are founded on the same principles: collection and evaluation of suspected ADRs, identification of potential signals, assessment of risk, implementation of risk minimisation, and continued monitoring after authorisation.

The EU framework operates through a coordinated supranational structure of EMA, PRAC, national competent authorities and EudraVigilance, with common legislation and GVP. India has built a national mechanism through

CDSCO, IPC, PvPI and a large network of AMCs, and has progressively incorporated safety reporting, risk management and post-marketing surveillance requirements into its regulations. The main differences concern institutional integration, reporting volume and completeness, signal management, the extent of active surveillance, stakeholder participation and the capacity of the workforce. These should be read in the light of the different regulatory, demographic and resource settings of the two regions, and EU mechanisms may need adaptation before use in India.

India has established the essential components of a national PV system. Further progress is most likely to come from better ICSR completeness, closer integration of PV data with regulatory decisions, stronger signal detection, selective expansion of active surveillance, effective monitoring of risk minimisation, and sustained engagement of healthcare professionals and patients. Such improvements would support patient safety in India and strengthen international confidence in medicines manufactured in the country.

11. Limitations and Future Scope

This review draws mainly on regulatory documents, official guidance, published literature and available secondary data, so its conclusions depend on the completeness, accessibility and comparability of these sources. Differences in reporting systems, population coverage and database structure limit direct numerical comparison, and the number of ICSRs received should not be taken as a direct measure of the effectiveness of a PV system. No primary data were collected from regulators, healthcare professionals or patients, and the availability of public information varied by domain. Future work could use interviews or surveys of regulatory professionals, healthcare professionals, patients and MAHs, examine ICSR completeness, signal management outcomes and active surveillance in greater detail, follow changes in reporting and regulatory responses over time, and assess the feasibility of adapting selected EU practices to the Indian setting.

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