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A comparative study of pharmacovigilance systems in India and United States

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Abstract
Pharmacovigilance (PV) is an essential scientific discipline focused on the detection, assessment, understanding, and prevention of adverse drug reactions (ADRs) and other medicine-related problems. It ensures continuous post-marketing surveillance and contributes to the safe, rational, and effective use of medicines at the population level. Over the decades, both India and the United States (U.S.) have developed structured pharmacovigilance frameworks aligned with global regulatory expectations. However, notable differences exist in regulatory mechanisms, reporting infrastructure, and implementation efficiency. This review provides an updated, comprehensive, and comparative analysis of PV guidelines in India and the U.S., highlighting regulatory principles, reporting requirements, data-management systems, and quality frameworks.

Keywords: Pharmacovigilance, adverse drug reactions, post-marketing surveillance, safety, regulation

Introduction
Pharmacovigilance (PV) emerged as a distinct scientific field following the thalidomide disaster reported in 1961 by McBride in *The Lancet*, which led to widespread congenital abnormalities in infants exposed in utero to the drug [1]. This incident underscored the need for systematic safety monitoring post-drug approval.

The World Health Organization (WHO) defines pharmacovigilance as the science and activities concerned with the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems [2]. PV plays a vital role in real-world safety monitoring since pre-marketing clinical trials often involve limited sample sizes, short follow-up periods, and controlled conditions that may not capture rare or long-term adverse reactions [3].

Key Objectives of Pharmacovigilance
1. **Monitoring drug safety in real-world settings:** Pharmacovigilance continuously evaluates the safety of medicines as they are used in routine clinical practice, beyond controlled clinical trials. This helps capture safety data across diverse populations and long-term use.
2. **Identifying previously unrecognized ADRs:** It enables early detection of rare, delayed, or unexpected adverse drug reactions that may not have been identified during pre-approval studies. This is critical for preventing harm and improving patient safety.
3. **Assessing benefit-risk profiles throughout the drug lifecycle:** Pharmacovigilance ensures that the therapeutic benefits of a drug continue to outweigh its risks from development through post-marketing phases. Ongoing assessment supports informed clinical and regulatory decisions.
4. **Promoting safe and rational drug use:** By generating and communicating safety information, pharmacovigilance encourages appropriate prescribing, dispensing, and use of medicines [4]. This minimizes medication errors and adverse outcomes.
5. **Supporting regulatory decision-making, including label updates or withdrawals:** Pharmacovigilance data guide regulators in implementing risk-minimization measures such as safety warnings, label changes, restrictions, or market withdrawal when necessary to protect public health [5].

Core concepts in pharmacovigilance

- Adverse Drug Reaction (ADR): A noxious and unintended response occurring at normal therapeutic doses [6]. ADRs represent a major cause of patient morbidity and serve as a primary focus for ongoing drug-safety monitoring.
- Signal Detection: Identification of new, rare, or serious safety concerns from diverse data sources. This process enables early recognition of potential safety issues that warrant further evaluation and regulatory action.
- Risk Management Plan (RMP): A structured approach to identifying and mitigating known and potential risks. RMPs outline proactive strategies to minimize harm while maintaining the therapeutic benefits of a medicinal product.
- Individual Case Safety Reports (ICSRs): Standardized case reports submitted by healthcare professionals, marketing authorization holders (MAHs), or patients [7]. ICSRs form the foundational data set for safety signal generation and regulatory safety assessments.

Given growing global emphasis on patient safety, PV systems worldwide aim to strengthen data quality, reporting efficiency, and regulatory compliance. This review compares the pharmacovigilance frameworks of India and the U.S. with emphasis on regulatory guidelines, reporting mechanisms, and system maturity.

Pharmacovigilance Guidelines in India

India's structured pharmacovigilance framework is governed primarily by the Central Drugs Standard Control Organization (CDSCO) and supplemented by the Pharmacovigilance Programme of India (PvPI), launched in 2010 [8]. PvPI was introduced with the objective of monitoring and improving the safety of medicines used in the country. It is coordinated by the Indian Pharmacopoeia Commission (IPC) under the Ministry of Health and Family Welfare. PvPI facilitates the collection, analysis, and assessment of adverse drug reaction reports from healthcare professionals and patients across India. The program aims to promote a culture of spontaneous reporting and enhance awareness of medicine safety among stakeholders. Through systematic signal detection and regulatory communication, PvPI supports informed decision-making to protect public health.

India follows the International Council for Harmonization (ICH) standards for safety reporting, especially the ICH E2 series.

Key ICH-based safety guidelines adopted in India [9]

- **E1:** Clinical safety for drugs intended for long-term treatment.
- **E2A:** Clinical safety data management and expedited reporting criteria.
- **E2B (R2/R3):** Electronic transmission of ICSRs, focusing on standardized data elements for global harmonization.
- **E2C (R2):** Periodic Benefit-Risk Evaluation Report (PBRER).
- **E2D:** Post-approval safety data management.
- **E2E:** Pharmacovigilance planning and risk-management strategies.
- **E2F:** Development Safety Update Report (DSUR).

Indian pharmacovigilance reporting structure

- Central Authority: CDSCO, with coordination through PvPI.
- National Centre: Indian Pharmacopoeia Commission (IPC) [10].
- Data Management System: VigiFlow, linked to WHO-UMC's global database (VigiBase).
- Reporting Types:
- Spontaneous ADR reporting by healthcare professionals and patients.
- PSUR submission as per Schedule Y requirements.
- Timelines: Serious unexpected ADRs are reported within 15 days of initial receipt.

India continues to improve ADR reporting culture, though challenges such as underreporting, infrastructural limitations, and inconsistent awareness persist.

Pharmacovigilance Guidelines in the United States

The U.S. has one of the world's most advanced pharmacovigilance systems, led by the Food and Drug Administration (FDA). Regulatory oversight is shared between:

- CDER (Center for Drug Evaluation and Research)
- CBER (Center for Biologics Evaluation and Research)

The U.S. pharmacovigilance framework emphasizes stringent reporting, risk-management strategies, and real-time safety surveillance.

Major U.S. pharmacovigilance regulations

- **21 CFR 314.80:** Post-marketing reporting of adverse drug experiences for approved drugs [11].
- **21 CFR 600.80:** Reporting requirements for biologics.
- **21 CFR 314.81:** Field alert reports and post-marketing study commitments.

FDA guidance documents

- Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment (2005).
- Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines.
- Risk Evaluation and Mitigation Strategies (REMS): Required for selected high-risk drugs [12].

Reporting mechanisms

Mandatory Reporting

- 15-day Alert Reports for serious, unexpected events.
- Periodic Adverse Drug Experience Reports (PADERs).
- Voluntary Reporting:
- MedWatch program (Forms 3500, 3500A, 3500B).
- Electronic Submissions:
- Mandatory use of FAERS with E2B (R3) standards.

Risk-management and surveillance systems

- **Sentinel Initiative:** A large-scale active surveillance program to monitor safety signals using linked electronic health data.
- **REMS:** Includes Medication Guides, ETASU, and communication plans.

The U.S. system is characterized by well-defined SOPs, routine inspections, and strong enforcement mechanisms.

Table 1: Comparative Analysis of Pharmacovigilance Systems in India and the U.S.

Parameter	India	U.S.
Regulatory Authority	CDSCO & PvPI	FDA (CDER/CBER)
Reporting Platform	VigiFlow	FAERS; Sentinel
Risk-Management Framework	PvPI-linked; partial RMP	REMS; advanced risk-mitigation tools
Electronic Reporting Standard	ICH-E2B (R3)	Mandatory E2B(R3) for ICSRs
Periodic Safety Updates	PSUR/PBRER as per ICH E2C	PADER; combination of periodic & real-time analysis
Public Reporting Tools	Available via PvPI	Robust MedWatch system
Inspection Framework	Developing	Well-established FDA PV inspections
ADR Reporting Culture	Moderate, improving	Strong, mature system

India's system is evolving towards global standards, whereas the U.S. has a long-established infrastructure for PV compliance, data analytics, and regulatory enforcement.

Conclusion

India and the U.S. share the common goal of improving drug safety through structured pharmacovigilance systems. While the U.S. operates a mature and technologically advanced PV framework with strong enforcement mechanisms, India continues to strengthen its regulatory structure through PvPI, ICH-aligned guidelines, and increased collaboration with global agencies. Despite challenges in awareness, reporting culture, and resource allocation, India is rapidly advancing its pharmacovigilance capacity. Continued harmonization, digitalization, and capacity building will enable India to develop a more comprehensive PV system comparable to international best practices.

References

1. McBride WG. Thalidomide and congenital abnormalities. Lancet. 1961;278:1358-1360.
2. World Health Organization. The importance of pharmacovigilance: safety monitoring of medicinal products. Geneva: WHO Press; 2002.
3. Hartmann K, *et al*. Post-marketing surveillance: limitations in clinical trials. Drug Saf. 2000;22:385-394.
4. Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis, and management. Lancet. 2000;356:1255-1259.
5. Uppsala Monitoring Centre. Safety monitoring of medicinal products: principles and practices. Uppsala: UMC; 2018.
6. Rawlins MD. Pharmacovigilance: origins and development. Br J Clin Pharmacol. 1995;40:581-586.
7. International Council for Harmonisation. ICH E2A guideline: clinical safety data management—definitions and standards for expedited reporting. Geneva: ICH; 1994.
8. Central Drugs Standard Control Organization. Pharmacovigilance Programme of India (PvPI). New Delhi: Ministry of Health and Family Welfare, Government of India; 2010.
9. International Council for Harmonisation. ICH harmonised guideline: integrated addendum to ICH E1-E2F pharmacovigilance and clinical safety guidelines. Geneva: ICH; 2017.
10. Indian Pharmacopoeia Commission. National Coordination Centre for Pharmacovigilance Programme of India (PvPI). Ghaziabad: IPC; 2017.
11. U.S. Food and Drug Administration. 21 CFR §314.80: postmarketing reporting of adverse drug experiences. Silver Spring (MD): FDA; 2020.
12. U.S. Food and Drug Administration. Risk Evaluation and Mitigation Strategies (REMS): guidance for industry. Silver Spring (MD): FDA; 2019.