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Research Article

Comparative Analysis of Integrated Pharmacovigilance Quality System Under EU-GVP Modules I-VII and Indian PvPI Version 2.0 Guidance for Pharmaceutical Products

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ABSTRACT

The significance of PV in assuring drug safety cannot be down played under any circumstances along the life cycle of a drug. The present study attempts to perform a comparative analysis between the Integrated Pharmacovigilance Quality Systems in European Union (EU-GVP Modules I–VII) & India (PvPI, v2.0). Qualitative document analysis method was utilized to analyze regulatory demands related to responsibilities, documents/records, trainings, audits, compliance monitoring and risk management in both pharmacovigilance quality systems. Regulatory sources used for data acquisition included EMA GVP modules and IPC-PvPI guidelines. The findings reveal that even though the EU-GVP offers a very well structured, legal and inspection-ready pharmacovigilance quality system, PvPI is a budding national program whose PVQS needs are yet emerging. However, certain key deficiencies found in PvPI were a non-QPPV kind of regulatory authority, shallow documentation and weak audit-compliance structures. But the end goals of patient safety and enhancing ADR reporting were common in both PV quality systems

INTRODUCTION

1.1 Background of Pharmacovigilance

Pharmacovigilance (PV) is the science and activities relating to the detection, assessment, understanding and prevention of adverse drug reactions (ADRs) and other drug related problems. It is an essential part of assuring that patients are protected and that medicines are used safely during the lifetime of a product. As therapies become more complex and international trade increases, the importance of effective PV systems has grown. National regulatory authorities across the world have established frameworks to support monitoring and minimize risk.

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1.2 Global Regulatory Perspective

At a global level, pharmacovigilance systems are governed by regulatory regimes that dictate how safety should be monitored and reported. A key example of such guidance is the European Union's Good Pharmacovigilance Practices (EU-GVP), which is an overarching and legally enforceable set of guidelines encompasses quality management systems, risk-based approaches, and ongoing safety assessment. This ensures harmonised pharmacovigilance across EU states with robust regulatory oversight and inspection capabilities.

1.3 Indian Pharmacovigilance System

India's program Monitors adverse effects of drugs and helps protect patients from harm from drugs. It is run via a national network of Adverse Drug Reaction Monitoring Centers with the Indian Pharmacopoeia Commission overseeing their operations as a part of the (CDSCO). (39) (40) The introduction of PvPI Version 2.0 strengthens this framework and re-emphasises India's commitment to international pharmacovigilance standards by providing an organized guide to pharmacovigilance operations, quality management systems, documentation training and safety reporting. (11)

1.4 Rationale of the Study

Although both EU-GVP and PvPI aim to ensure patient safety & effective drug monitoring, they differ significantly regarding the structure, quality system, documentations and compliance. A comparative analysis between two frameworks will help to bridge the gap, assess their maturity and also explore an opportunity to harmonize it with global pharmacovigilance standards.

2. AIM AND OBJECTIVES

Aim

To compare integrated pharmacovigilance quality systems under EU-GVP Modules I–VII and PvPI Version 2.0 guidelines.

Objectives

- To evaluate PV quality system requirements in EU-GVP and PvPI
- To compare organizational structure, documentation, and compliance systems
- To analyze risk management, audit, and training frameworks
- To identify regulatory gaps and implementation differences
- To propose harmonization improvements for PvPI systems

3. METHODOLOGY

3.1 Study Design

This study adopted a qualitative document analysis approach to systematically compare pharmacovigilance quality system requirements under the European Union Good Pharmacovigilance Practices (EU-GVP) framework and (PvPI) Version 2.0 guidelines. This design was selected because pharmacovigilance systems are primarily defined through regulatory guidelines and official documentation rather than experimental data.

The comparative analysis focused on identifying similarities, differences, and implementation gaps between the two regulatory frameworks, particularly in relation to quality system requirements.

3.2 Data Sources

Data were collected from officially published regulatory and guidance documents, including:

- (GVP Modules I–VII)
- Indian Pharmacopoeia Commission (IPC) PvPI Version 2.0 Guidelines
- Central Drugs Standard Control Organization (CDSCO) regulatory publications

These sources ensured authenticity, regulatory validity, and relevance for comparative analysis.

3.3 Data Collection

Relevant information was systematically extracted from pharmacovigilance guidelines using predefined comparison parameters. Key elements analyzed included organizational responsibilities, quality management systems, documentation practices, training requirements, record management, signal detection, risk management, audit systems, and compliance monitoring.

Data extraction was performed in a structured manner to ensure consistency across both EU and Indian frameworks. Multiple rounds of review were conducted to avoid omission and ensure accuracy of interpretation.

3.4 Analytical Framework

A structured comparative mapping approach was used to analyze pharmacovigilance quality system components. The EU-GVP and PvPI frameworks were compared using seven key quality system parameters:

- Governance and quality management principles
- Organizational structure and responsibilities
- Documentation and record management systems
- Training and competency management
- Risk management and signal detection
- Audit and inspection systems
- Corrective and preventive action (CAPA) systems

This framework enabled systematic evaluation of regulatory alignment, functional equivalence, and gaps between the two systems.

3.5 Data Analysis

The collected data were analyzed using qualitative content analysis and presented in a comparative tabular format. This approach facilitated clear interpretation of regulatory similarities and differences and enabled identification of gaps in implementation, compliance, and system maturity between EU-GVP and PvPI frameworks.

4. RESULTS

COMPARATIVE PHARMACOVIGILANCE QUALITY SYSTEM FRAMEWORK: EU-GVP MODULES I -VII VS INDIAN PVPI GUIDANCE

EU-GVP Modules	Corresponding PvPI Chapters	EU-GVP Requirements	PvPI Requirements	Major Gap Identified
Module I – Pharmacovigilance Quality System	Chapter 4 – Quality Management System	EU-GVP requires a structured pharmacovigilance quality system with defined responsibilities,	PvPI requires maintenance of a pharmacovigilance quality system with trained personnel, ADR monitoring	PvPI lacks mandatory QPPV requirement and has variable implementation across centers,

		mandatory QPPV appointment, SOP implementation, staff training, compliance monitoring, CAPA management, audits, and continuous quality improvement to ensure patient safety and regulatory compliance.	procedures, documentation practices, compliance activities, and quality management processes to support safe use of medicines.	whereas EU-GVP is legally enforced and standardized.
Module II – Pharmacovigilance System Master File (PSMF)	Chapter 1 – PSMF	EU-GVP requires a detailed PSMF including organizational structure, responsibilities, PV procedures, outsourced activities, audit information, training systems, and complete documentation of PV operations.	PvPI requires maintenance of PSMF containing PV procedures, organizational details, ADR reporting systems, and safety documentation necessary for pharmacovigilance activities.	EU has fully standardized PSMF system, whereas India lacks a harmonized and comprehensive documentation structure.
Module III – Pharmacovigilance Inspections	Chapter 5 – Audits & Inspections	EU-GVP requires risk-based pharmacovigilance inspections by regulatory authorities to assess compliance, evaluate quality systems, and ensure corrective actions.	PvPI requires inspection of PV systems, ADR reporting activities, and safety records to assess compliance and identify corrective actions.	EU has standardized legally enforced inspection system; India shows gaps in uniform implementation and CAPA follow-up.
Module IV – Pharmacovigilance Audits	Chapter 5 – Audits & Inspections	EU-GVP requires strategic risk-based audits including planning, execution, documentation, CAPA implementation, root cause analysis, and continuous quality improvement.	PvPI requires internal/external audits, documentation of findings, implementation of corrective actions, and system performance monitoring.	EU has structured audit system with strong CAPA integration; India has limited audit uniformity and weaker CAPA enforcement.
Module V – Risk Management System	Chapter 6 – Risk Management Plan (RMP)	EU-GVP requires preparation and continuous updating of (RMPs) to identify, evaluate, prevent, and minimize risks throughout the product lifecycle.	PvPI requires monitoring of product safety, identification of risks, and implementation of pharmacovigilance activities for risk minimization.	EU has harmonized RMP system; India lacks fully standardized risk management implementation.
Module VI – Management &	Chapter 2 – ICSR Reporting	EU-GVP requires systematic collection, validation, coding,	PvPI requires collection, documentation,	EU has centralized electronic

Reporting of ICSRs		follow-up, and timely reporting of ICSRs using standardized systems (EudraVigilance).	evaluation, follow-up, and reporting of ADRs/ICSRs within defined timelines.	reporting with strict timelines; India faces underreporting and infrastructure limitations.
Module VII – Periodic Safety Update Reports (PSURs)	Chapter 3 – PSUR Submission	EU-GVP requires periodic PSUR submission with cumulative safety data, signal analysis, and benefit–risk evaluation after marketing authorization.	PvPI requires PSUR submission containing post-marketing safety data and benefit–risk evaluation for regulatory review.	EU has highly structured PSUR system; India shows variability in consistency and regulatory follow-up.

The comparison of Pharmacovigilance (Pv) quality systems under EU-GVP Modules I–VII and India's PvPI Version 2.0 showed their structural similarity and difference in regulations.

It can be inferred that both EU-GVP and PvPI frameworks have a common goal of ensuring drug safety via Pharmacovigilance activities such as ADRs documentation, registration, and regulatory reporting. But EU-GVP exhibits a more sophisticated, structured and legally implemented pharmacovigilance quality system with proper QPPV responsibility, PSMF standards, electronic reporting, and risk based regulatory control.

On the contrary, PvPI offers an immature pharmacovigilance structure focused mainly on ADR reporting and country wide coordination. Despite improving Pv awareness and reporting in India, it still lags behind in terms of uniform documentation, audit uniformity, CAPA, and regulatory enforcements

Overall, our findings underscore that EU-GVP is a mature pharmacovigilance model whereas PvPI is an evolving system with progressive improvements yet limited harmonisation with international regulatory standards. Our comparative results highlight the need to strengthen quality system components in PvPI to enhance global alignment and regulatory efficiency

5. DISCUSSION

This comparative study shows that the EU-GVP pharmacovigilance (PV) framework is an extremely well-structured, legalised framework with strong Quality Management Principles integrated across the entire PV spectrum. Key components such as QPPV, PSMF, risk-based inspections, structured audits & eCTD/ePMS driven reporting systems contribute towards a robust & harmonised PV system across EU.

On the other hand, India's Pharmacovigilance Programme of India (PvPI), despite having strengthened ADR reporting & awareness at national level, lags behind in terms of quality system documentation standardisation, uniformity in audit, CAPA implementation & advance regulatory enforcement.

6. CONCLUSION

The study concluded that the EU-GVP framework is a mature, well-structured, legally binding PV quality system; while PvPI is an evolving national program with considerable progress in ADR reporting but less structured incorporation of more

advanced quality system elements. We found key gaps in documentation control, audit systems, risk management, and regulatory enforcement. Strengthening PvPI according to EU-GVP principles would strengthen pharmacovigilance, harmonise regulation, and contribute towards global harmonisation of drug safety.

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