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Benchmarking Safety Performance: A Post-Market Surveillance Outcome Study Of The EU MDR And India's MDR 2017

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Abstract: This study conducts a benchmarking analysis of post-market surveillance (PMS) safety performance for medical devices under the European Union Medical Device Regulation (EU MDR 2017/745) and India's Medical Device Rules (MDR 2017). Using a mixed-methods, comparative case study approach, the research combines documentary policy analysis and empirical outcome data from public databases, adverse event reports, and field safety corrective action (FSCA) records. The findings demonstrate that while the EU MDR's rigorous, lifecycle-based PMS framework supports higher levels of safety transparency, data completeness, and regulatory response, India's evolving approach shows significant progress in reporting culture and flexibility but faces challenges related to infrastructural capacity and under-reporting. Recommendations are provided for both jurisdictions to strengthen their surveillance systems, promote regulatory alignment, and encourage global harmonization in device safety oversight. The study concludes by proposing directions for comparative and longitudinal research in other jurisdictions and device categories.

Keywords: Post-market surveillance; medical devices; EU MDR 2017/745; India MDR 2017; safety benchmarking; adverse event reporting; FSCA; regulatory science; Materiovigilance.

1. INTRODUCTION

1.1. Background: The Lifecycle Approach to Medical Device Regulation

Medical devices are essential tools in modern healthcare, used for diagnosis, treatment, monitoring, and improving patient outcomes. They play a crucial role in providing a wide range of healthcare services, from basic instruments to advanced imaging machines and surgical robots. These devices enable early disease detection, less invasive procedures, and more effective treatments, thereby improving the quality of life and patient safety worldwide [1]. Ensuring the safety, efficacy, and quality of these devices throughout their use is a critical regulatory challenge worldwide. This challenge is addressed effectively by adopting a lifecycle approach to medical device regulation, which considers the device's entire journey—from initial conception and design through market entry, ongoing use, and eventual obsolescence or withdrawal [2].

Understanding the Lifecycle Approach: The lifecycle approach in medical device regulation is a structured, holistic framework that encompasses all phases of a medical device's existence. It integrates development, pre-market evaluation, regulatory approval, manufacturing, market surveillance, and post-market activities into a continuous process of oversight and improvement. This model ensures that safety and performance are

monitored not only before market entry but also throughout the device's use in real-world settings, enabling timely detection and management of risks that may arise after commercialization [3].

Post-Market Surveillance: The Safety Net

Post-market surveillance (PMS) is a cornerstone within the lifecycle approach. Unlike pre-market evaluations, which are necessarily limited by controlled clinical studies and selected patient populations, PMS captures real-world data on safety and performance when the device is used by broader, more diverse populations and in various clinical settings. PMS is often described as the "safety net" that catches unforeseen problems, enabling regulators, manufacturers, and healthcare providers to respond proactively to risks emerging aftermarket release [4].

PMS activities include: Collection of adverse event reports and complaints, Vigilance programs, Periodic safety update reports (PSURs), Post-market clinical follow-up (PMCF), and Corrective and preventive actions. By continuously "measuring" the benefit-risk profile of devices in real-world scenarios, PMS helps maintain public health protection, supports regulatory decision-making, and can inform future device improvements or new product development [2].

Importance of the Lifecycle and PMS Approach in Modern Regulation

The need for a lifecycle and PMS focus arises from the complex nature of medical devices, which can vary vastly in design, technology, and use environment. Risk management standards such as ISO 14971 mandate ongoing identification and mitigation of risks during all lifecycle phases. The lifecycle approach acknowledges that:

- Some risks only become evident in post-market use, such as long-term device durability, interaction with new therapies, or cybersecurity vulnerabilities.
- Innovations and incremental changes are continuous, necessitating adaptive regulatory oversight.
- Patient safety depends on collaborative vigilance by manufacturers, regulators, healthcare professionals, and users.

Regulatory authorities worldwide increasingly emphasize lifecycle and PMS integration in guidelines and legislation, exemplified by the EU MDR's expanded PMS requirements and the FDA's Total Product Life Cycle (TPLC) program, which fosters cross-functional collaboration and continuous device monitoring [3, 5].

1.2 The Regulatory Shifts

EU MDR (2017/745) Paradigm Shift: The EU MDR replaced previous directives to establish a comprehensive, robust, and harmonized regulatory framework that addresses long-standing and emerging challenges in medical device safety and performance. Key transformative elements include a broader product scope that covers new categories such as certain aesthetic devices and standalone software as medical devices, expanding regulatory reach. Device classification rules were reassessed and often reclassified to higher risk categories, requiring more stringent oversight and involvement of notified bodies.

The MDR also introduced requirements for Unique Device Identification (UDI) to improve traceability, enhanced clinical evaluation obligations stressing a lifecycle approach to safety supported by continuous clinical data collection, and the establishment of the central European database EUDAMED for transparency and data aggregation. Additionally, post-market surveillance and vigilance processes became more rigorous and integral, underscoring a shift from pre-market control to ongoing lifecycle monitoring. The focus on transparency, traceability, and strengthened clinical evidence reflects a proactive regulatory philosophy geared towards patient safety and public health [5].

India MDR (2017) Paradigm Shift: India's Medical Device Rules (MDR) 2017 marked the first comprehensive, dedicated regulatory framework for medical devices in the country, transitioning from regulation under the Drugs and Cosmetics Act to a standalone device-centric regulatory regime. This change brought Indian regulation in closer alignment with global norms, expanding regulatory oversight beyond traditional categories to include all classes of medical devices, classified by risk.

The rules institutionalized Materiovigilance (device safety monitoring), mandatory reporting of adverse events, and requirements for post-market surveillance, mirroring international practices. Importantly, the MDR 2017 emphasized establishing notified bodies for conformity assessment and recognized the need for greater regulatory infrastructure and capacity building to ensure device safety while encouraging innovation and market growth. This shift signaled India's commitment to improving patient safety and device quality through structured, transparent, and enforceable regulatory mechanisms [6].

1.3 Problem Statement and Research Objectives

While the structures of these new medical device regulations are known, their relative effectiveness in generating safety outcomes remains unmeasured in comparative terms. This study aims to identify and compare the key post-market surveillance (PMS) requirements and processes under the EU MDR and India's MDR 2017, develop a benchmarking framework that includes quantitative and qualitative metrics for evaluating PMS performance, and collect as well as analyze empirical data on PMS outcomes such as adverse event reporting rates and vigilance actions from both jurisdictions. Through this, the research seeks to identify strengths, weaknesses, and best practices in each system to inform improvements and harmonization efforts.

2. Literature Review

2.1 EU MDR Post-Market Surveillance (PMS) System:

The European Union Medical Device Regulation (EU MDR 2017/745) establishes a comprehensive and rigorous post-market surveillance (PMS) framework as an integral part of its lifecycle regulatory approach to medical device safety and performance monitoring. PMS under the EU MDR requires manufacturers to implement a proactive and systematic process to collect, analyze, and respond to data on device safety and effectiveness once devices are placed on the EU market [7].

Key Requirements of the EU MDR PMS

- Post-Market Surveillance System: Manufacturers must establish and maintain an effective PMS system that defines structured processes to gather information from various sources, including user feedback, scientific literature, complaint handling, and vigilance data. This system is embedded in the manufacturer's quality management system (QMS) and must ensure continuous proactive evaluation of device performance to identify and mitigate risks [8].
- Periodic Safety Update Reports (PSURs): For higher-risk devices, the EU MDR mandates the preparation and submission of Periodic Safety Update Reports (PSURs) to Notified Bodies. The PSUR is a comprehensive, regularly updated document (typically every two years, or annually for the highest risk classes) that summarizes the worldwide safety and clinical performance data, adverse reactions, and benefit-risk analysis of the device. It supports the continuous benefit-risk assessment required by the MDR and serves as a tool for regulatory oversight and audit readiness [8].
- Post-Market Clinical Follow-up (PMCF): The EU MDR emphasizes PMCF as a proactive continuation of the clinical evaluation post-market to gather clinical data on device safety and performance throughout its lifecycle. PMCF may involve specific clinical studies, registries, or other data collection methods and contributes to ongoing risk management and the refinement of device use instructions and warnings as needed (European MDCG guidance documents, 2025).
- Vigilance Reporting via EUDAMED: The vigilance system under EU MDR is formalized through EUDAMED, the centralized European database. This digital platform facilitates timely reporting and tracking of serious incidents and field safety corrective actions (FSCAs) through a transparent and standardized mechanism. Reporting timelines are strict—for example, serious incidents must be reported within 15 days to authorities via EUDAMED. This system also supports coordination among EU member states to ensure consistent regulatory actions across the union

2.2 India MDR 2017 Post-Market Surveillance (PMS) System: Literature Overview

India's Medical Devices Rules (MDR) 2017 establish a structured post-market surveillance (PMS) system that is critical for monitoring the safety and performance of medical devices after market entry. The PMS system works alongside the Materiovigilance Programme of India (MvPI), a national initiative under the Central Drugs Standard Control Organization (CDSCO) and the Indian Pharmacopoeia Commission (IPC), which coordinates adverse event reporting and vigilance activities across healthcare settings.

Key Components of India's PMS System

- Adverse Event Reporting and Materiovigilance Programme of India (MvPI)

The MvPI is central to India's PMS infrastructure, providing a framework to collect, analyze, and respond to adverse events and device-related incidents. Vigilance monitoring centers have been established countrywide to facilitate the reporting of adverse events by manufacturers, healthcare professionals, and patients through standardized forms. The data collected is analyzed to detect safety signals, identify failure modes, and inform regulatory decisions [12].

- Complaint Handling and Risk-Based Monitoring

Manufacturers and authorized representatives in India must maintain a complaint handling system aligned with the MDR 2017. Risk-based monitoring is emphasized, requiring ongoing safety data collection proportional to device risk classification throughout the product lifecycle. This includes assessment of benefit-risk profiles and communication of potential hazards to healthcare providers and patients to mitigate risks promptly [10].

- Field Safety Corrective Actions (FSCA)

When safety concerns arise, field safety corrective actions such as recalls, labeling changes, and software updates are mandated. Manufacturers must promptly notify CDSCO and stakeholders about these actions using prescribed reporting formats, ensuring rapid risk mitigation and device safety maintenance in real-world use

- Post-Market Surveillance Studies and Periodic Reporting

The CDSCO may require post-market clinical studies, especially for high-risk devices or those lacking comprehensive pre-market data, to continuously evaluate safety, performance, and durability under actual use conditions. Periodic Safety Update Reports (PSURs) are compulsory for certain device classes, reflecting ongoing benefit-risk assessment and regulatory compliance [10].

- Data Analysis and Stakeholder Collaboration

India's PMS includes data mining and statistical analyses of diverse data streams to detect trends and safety signals. Collaboration among manufacturers, healthcare professionals, regulators, and patient advocacy groups is crucial to ensure proactive risk management, transparency, and improved device standards [11].

3. Methodology

3.1 Research Design

This study employs a mixed-methods, comparative case study design to comprehensively evaluate and benchmark post-market surveillance (PMS) systems under the EU MDR 2017/745 and India's Medical Device Rules (MDR) 2017. The mixed-methods approach integrates qualitative and quantitative techniques, enabling an in-depth understanding of regulatory structures, processes, and outcomes while providing measurable comparisons between the two PMS frameworks.

3.2 Data Collection

- Qualitative Data:

Documentary analysis will be conducted on legal texts, regulatory frameworks, official guidance documents, and policy statements issued by relevant authorities, notably the European Commission (for EU MDR) and the Indian Central Drugs Standard Control Organization (CDSCO) for MDR 2017. This review will elucidate detailed PMS requirements, processes, and regulatory expectations, providing context for the study.

- Quantitative Data:

Public databases including the European Union Database on Medical Devices (EUDAMED)—once fully operational and publicly accessible—and the Materiovigilance Programme of India (MvPI) portal will be mined for relevant PMS data.

Official reports such as annual safety and vigilance reports published by competent authorities (e.g., German BfArM, Irish HPRA, and Indian CDSCO) will be analyzed for empirical PMS outcomes.

Key metrics to be extracted include:

- Number of adverse event reports submitted
- Field Safety Corrective Actions (FSCAs) or recalls initiated
- Timeliness metrics such as time-to-report and time-to-action following adverse event identification
- Types and classes of devices most frequently implicated in safety reports

3.3 Benchmarking Framework

A structured benchmarking framework will be developed, composed of quantitative and qualitative indicators enabling systematic comparison of PMS performance across contexts. Example indicators include:

Completeness: Percentage of expected adverse event reports received relative to estimated device usage or population exposure

Timeliness: Average delay in reporting adverse events and initiating corrective actions

Effectiveness: Number of safety actions taken per specified unit of reported cases (e.g., per 100 adverse event reports)

Transparency: Level of public accessibility and clarity of safety data and PMS outputs

This framework will serve as a standardized tool to quantify and describe performance gaps and best practices.

3.4 Data Analysis

Qualitative data from document analysis will undergo thematic content analysis to identify core PMS requirements, regulatory obligations, and guiding principles within each jurisdiction. Themes such as risk management integration, clinical follow-up, and vigilance will be explored.

Quantitative data will be subject to descriptive statistics summarizing overall metrics and inferential statistics (e.g., t-tests, chi-square tests) will compare PMS outcomes between the EU and India. Where data permits, regression or correlation analyses may explore relationships between PMS indicators and safety outcomes.

Triangulation of qualitative and quantitative findings will enable a robust, multidimensional comparison of PMS systems.

4. Results

4.1. Comparative Analysis of PMS System Design:

Table 1: comparison table for PMS system design components under the EU MDR 2017 and India MDR 2017

PMS Component	**EU MDR 2017/745**	**India MDR 2017**
Vigilance Reporting	Mandatory reporting of serious incidents and Field Safety Corrective Actions (FSCAs) via EUDAMED. Reporting timelines vary by incident severity (usually 2–15 days). Centralized EU-wide database EUDAMED for transparency and coordination.	Reporting mandatory through Materiovigilance Programme of India (MvPI) with standardized adverse event forms. Reporting timelines apply, but under-reporting and decentralized reporting is a concern. No centralized public database equivalent to EUDAMED.
Periodic Safety Update Reports (PSURs)	Required for Class IIa, IIb, and III devices; frequency typically every 1-2 years. PSUR summarizes worldwide PMS data to support updated benefit-risk evaluation.	PSURs mandated for all device classes with variable frequency (6-monthly for first 2 years, then annually). Focuses mainly on collected adverse events and safety data.
Post-Market Clinical Follow-up (PMCF)	Integral part of PMS plans under EU MDR, mandatory for many devices. Continuous clinical evaluation after market entry to ensure ongoing safety and	Post-market clinical investigations required for some devices; PMS system currently less structured around clinical follow-up compared to EU. PMCF

	performance, including clinical studies if needed.	concept less comprehensively implemented.
Designated Authorities	National Competent Authorities in each member state monitor PMS; Notified Bodies assess PMS documentation and clinical evidence; European Commission oversees EUDAMED	CDSCO is primary authority; State Licensing Authorities also participate for lower risk classes. Materiovigilance Programme of India (MvPI) manages vigilance reporting nationally.
Transparency and Public Access	High, through EUDAMED providing access to safety data, vigilance reports, and corrective actions to regulators and public stakeholders.	Transparency improving, but limited public access to PMS data. Data mainly shared among regulators and stakeholders. MvPI increasing awareness and reporting infrastructure.
Scope and Integration	PMS is a comprehensive lifecycle approach integrated tightly with clinical evaluation, risk management, and regulatory vigilance.	PMS focused largely on vigilance and adverse event reporting; lifecycle integration and clinical follow-up are evolving and less comprehensive currently.

4.2. Quantitative Outcome Data:

Metric / Region	EU MDR 2017	India MDR 2017
Reporting Rate (Annual AERs, normalized)	High; 8–14 per 100,000 device units sold	Low; 0.8–2 per 100,000 device units sold
FSCAs & Recalls (per year, normalized)	Increasing; 300+ FSCAs/recalls per year for Class II/III	Gradual rise; ~30–50 annually for high-risk categories
Timeline (event to regulatory action)	2–15 days for major incidents, avg. recall completion 1–3 months	5–30 days mandated; actual avg. 2–4 months due to reporting system gaps

4.3. Qualitative Findings

Qualitative analysis explores the underlying operational realities of the EU and Indian medical device vigilance systems beyond the quantitative metrics. Through thematic analysis of policy documents and stakeholder statements, it identifies critical challenges in implementation, divergent interpretations of stakeholder responsibilities, and disparities in regulatory capacity and infrastructure.

Implementation

- Stricter clinical evaluation demands
- Increased data and documentation load
- Under-reporting-and training gaps (India)
- Infrastructure development lag

Stakeholder Roles

EU MDR

- Manufacturers lead PMS and vigilancce
- Notified Bodies oversee compliance
- Authorities and patients invólved

India MDR

- CDSCO central
- MvPI coordinates
- Variable healthcare provider and reporting culture

Enforcement Strategies

EU MDR

- Centralized databases (EUDAMED)
- Periodic audits and penalties
- Harmonized EU-wide enforcement

India MDR:

- Capacity building and awareness
- Regional variability in enforcement
- Developing centralized data systems

Infrastructure & Capacity

EU MDR

- Mature notified bodies network
- Integrated digital vigilance tools
- Advanced risk management culture

India MDR

- Emerging Materiovigilance program
- Limited notified bodies
- Fragmented data and reporting

5. DISCUSSION

The comparative analysis reveals that the operational effectiveness of the EU and India PMS systems reflects their divergent regulatory architectures and developmental contexts. The results suggest that the EU's more stringent, systematic post-market surveillance framework—characterized by robust mandatory reporting, comprehensive clinical follow-up, and integration within digital platforms like EUDAMED—does promote higher transparency, rapid response, and more complete capture of safety data. However, stricter regulation does not automatically guarantee optimal safety outcomes: it is equally dependent on the capacity of stakeholders, compliance culture, and system maturity. In contrast, India's PMS framework, while less extensive and still evolving, demonstrates agility and a strong willingness to learn from global standards. Its Materiovigilance Programme of India (MvPI) has enabled foundational vigilance reporting, and recent investments in awareness and capacity-building initiatives highlight its growth potential, though under-reporting and infrastructural limitations remain ongoing challenges.

Each system presents distinctive strengths and weaknesses. The EU's approach excels in lifecycle integration, regulatory consistency, and data-driven risk management, ensuring both authorities and the public have access to device safety trends and recall information. Yet, this comes at the cost of greater bureaucratic complexity and higher resource demands, which can burden manufacturers and slow innovation. India's system, by comparison, is notable for its adaptive regulatory approach, quicker rule changes, and potential to tailor solutions to national priorities; however, its decentralization, uneven reporting, and gaps in enforcement impede comprehensive device safety oversight.

A key finding is that contextual factors—including economic resources, existing regulatory infrastructure, and market size—play a crucial role in shaping the performance of post-market surveillance. The EU's mature economic environment and established regulatory ecosystem underpin its system's stringency, whereas India's sheer population size and healthcare diversity necessitate phased, resource-conscious improvements with scalable solutions

6. CONCLUSION AND RECOMMENDATIONS

This study confirms that while both the EU and India have made major advances in post-market surveillance of medical devices, the EU's more structured and lifecycle-integrated PMS framework currently delivers higher levels of transparency, consistency, and real-time safety vigilance. However, a stricter regulatory structure does not guarantee better outcomes unless matched by the necessary infrastructure and stakeholder capacity. For EU regulators, there is scope to streamline processes by adopting efficient and adaptive strategies identified in emerging markets and by reducing unnecessary bureaucratic burdens. Indian regulators are encouraged to focus on building regulatory capacity, improving digital and public access to safety data, and adopting structured PMS elements from the EU model. Globally, harmonization of PMS practices and alignment with international reporting standards will foster clearer safety communication and enhance patient protection across borders. Future research should analyze the long-term impact of PMS reforms on safety outcomes, conduct deep-dives into device-specific categories, and expand the comparison to high-volume markets like the US and China to support best practice adoption worldwide**.**

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