MATERIOVIGILANCE PROGRAMME OF INDIA: A GLOBAL PERSPECTIVE AND COMPARISON

Abstract

Despite the proposal to classify medical devices as drugs in the draft of the Drugs, Medical Devices and Cosmetics Bill, 2022 in India, the medical devices post-marketing vigilance system is currently less stringent than that for drugs and does not involve monitoring Adverse events (AEs) brought on by medical devices. The program focuses on identifying, collecting, reporting, and analyzing negative events associated with medical device usage to prevent recurrence and safeguard patient health. While many countries have initiated post-marketing surveillance (PMS) of medical devices, India's Materiovigilance program, launched in July 2015 by the Indian Pharmacopeia Commission (IPC), aims to monitor and record unfavorable incidents, produce safety-related information, enhance the understanding of all involved parties, and provides suggestions for optimal strategies and measures to enhance patient safety. Along with manufacturers, prescribers and users there is important role of regulators in patient safety related to medical devices. In this book chapter the current status of Materiovigilance Programme of India (MvPI) is examined, along with comparisons to developed nations, deficiencies are noted, and specific actions are suggested to strengthen the programme and also discuss steps to ensure a rigorous implementation of the current plan with a focus on how well they protect patient safety.

Keywords: Materiovigilance Programme, global, Perspective, Comparison

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I. INTRODUCTION

In India, the PMS system for medical devices is less strict than it is for medicines. Materiovigilance includes monitoring unfavourable outcomes brought on by medical devices after they have been marketed. Many nations, including India, have set up their own PMS systems in accordance with WHO guidelines. It is referred to as the MvPI in India. The MvPI current state is examined, along with comparisons to industrialized nations, deficiencies are noted, and specific actions are suggested to strengthen the programme. In modern times, medical devices have become a vital tool for diagnosing and treating a diverse range of illnesses in contemporary times. [1]. The global medical device industry has experienced substantial growth, with annual revenues surpassing USD 350 billion, while the fourth-largest medical device market in Asia is found in India, where the US$ 10 billion medical technology market is expected to grow to US$ 50 billion by 2025 [2]. High-profile product recalls [3] have shown that using medical gadgets poses serious hazards to patients. There are more than 5,000 different types of medical equipment, and there are innumerable vendors and healthcare organizations worldwide. Because of the risk of AEs occurring as a result of their use, which can have catastrophic consequences, including death, ensuring that medical devices are used safely and effectively after regulatory approval [4].

The year 2015 saw the inception of the Medical Devices Adverse Event Monitoring System, commonly referred to as MvPI. The primary goal of this system is to establish a robust mechanism that guarantees the safety of medical devices. It achieves this objective by systematically identifying AEs that occur as a result of using medical devices and then eliminating potential risks through a structured reporting process [5]. On January 31st, 2017, the Medical Devices Rules (MDR) was announced in India, and they came into effect on January 1st, 2018. The MDR provides a 15-day opportunity for the License Holder to notify the State Licensing Authority or Central Licensing Authority of any suspected unanticipated major adverse occurrences. They must also act responsibly, which may include recalling the affected medical devices (Table 1) [6].

Table 1: Mandatory Reporting Requirements [12]

Reporter	What to report?	Whom to report?	When to report?
Importers/ Manufacturers/Distributors / Marketing Authorization Holders (MAH)	Any suspected unanticipated serious adverse occurrence, such as deaths, serious injuries, or malfunction, as well as the response, including any recall	National coordination center which isIPC	Report event within 15 calendar days after becoming aware.
Healthcare providers	Death, catastrophic injury, malfunctions, and so on.	Marketing Authorization Holders (MAHs) - Indian Pharmacopoeia Commission	Serious events must be reported within 15 calendar days.Noted AEs which are non-serious must be reported within 30 calendar days.

A draft of the Drugs, Medical Devices, and Cosmetics Bill, 2022 was made available by the Ministry of Health and Family Welfare. In order to keep up with advancements in drug discovery and development, the Drugs and Cosmetics Act, 1940 will be reviewed, replaced, and modernized in July 2022. However, the Medical Devices Rules of 2017, the New Drugs and Clinical Trials Rules of 2019, and the Cosmetics Rules of 2020 are still in place until this takes effect.

The MvPI and MDR have greatly expanded healthcare professionals' post-market monitoring of medical devices. As a result, patients and users of medical equipment now have access to higher quality and safety standards [6]. The purpose of the MvPI is to collect, collate, and investigate voluntarily reported AEs related to medical devices. Through this procedure, useful, fact-based information is produced and disseminated to the public and regulatory body. (Figure1).

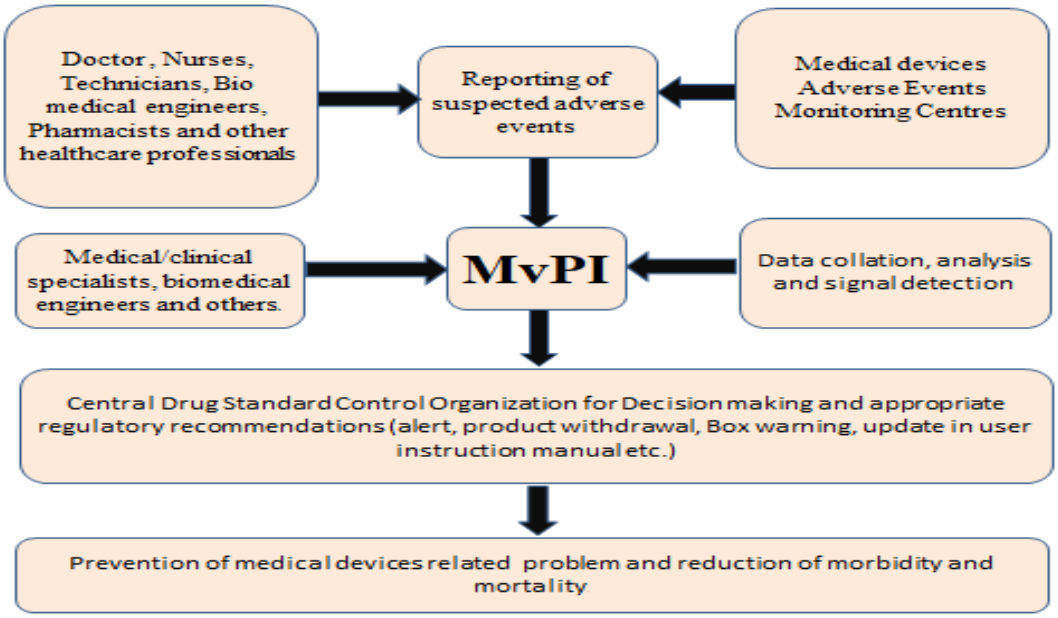

Figure 1: Process flow of Medical Device Adverse Event (MDAE) reporting system in MvPI.

While medical devices can offer substantial advantages to patients, it is crucial to acknowledge that they also pose significant potential risks. Medical devices have been subject to recalls due to defects or significant harm caused to users, as evidenced by various reported cases [7-9]. As a result, it is crucial to evaluate and weigh the benefits and drawbacks of using medical devices at each stage of their creation and application.

Implementing a strong monitoring mechanism is essential, but unfortunately, it is only practiced in a limited number of countries [10,11]. A monitoring system can effectively detect any problems or issues related to the utilization of medical devices and take appropriate measures to minimize potential risks and safeguard the well-being of patients. This way, we can optimize the benefits of medical devices while minimizing the potential harm they may cause.

II. MEDICAL DEVICE POST-MARKETING SURVEILLANCE PRACTICES IN DIFFERENT NATIONS

Medical device post-marketing surveillance (PMS) is a crucial part of assuring patient safety and reducing possible risk. The United States was a pioneer in this field, passing the Food and Drug Administration (FDA) Modernization Act in 1970, which included Section 522 for medical devices. Since that time, additional nations have passed legislation to strengthen the PMS of medical devices, including Australia, Canada, and the European Union [13,14].

The European Union, the United States, Japan, Australia, and Canada formed the Global Harmonization Task Force (GHTF) in 1993 to standardized the regulatory frameworks controlling the performance, quality, and safety of medical devices. [15]. The GHTF's work was expanded upon and the International Medical Device Regulators Forum (IMDRF) was established in 2011 to hasten regulatory convergence and harmonization of medical devices [16].

The Medical Devices Agency in the United Kingdom has established a vigilance reporting programme as well as an adverse event mechanism for PMS of medical devices. While the adverse event reporting scheme is optional for patients, hospital engineers, and health care professionals, the vigilance reporting programme is required for manufacturers. Manufacturers are obligated to report negative incidents within a certain timeframe; else, they risk fines. Health care providers are also required to report any negative outcomes and are anticipated to do so right away [16].

Similarly, in the United States, the FDA has put in place mandatory and voluntary reporting programmes for medical devices. The Medical Device Reporting Regulation (21 CFR 803) requires makers, importers, and user facilities to report certain AEs and concerns linked to the use of devices on the FDA MedWatch form 3500A or an electronic equivalent. Importers and producers of medical devices must report occurrences of serious injury, death or device failure within a certain amount of time. A suspected serious injury or death caused by a medical device must also be reported by device user facilities to the FDA and the manufacturer within the allotted time frames. Furthermore, these facilities must file an annual summary report of fatalities using form 3419 FDA [17].

The FDA advises medical professionals and device users to report any suspected device-related harm or negative effects using FDA form 3500 or the MedWatcher mobile app. [18]. This reporting is necessary for the prompt detection and management of potential risks associated with the use of medical devices.

III. INDIA'S MATERIOVIGILANCE PROGRAMME

In India, the regulation of medical devices is governed by the Drug and Cosmetic Acts of 1940 and the Rules of 1945. But up until recently, there was no efficient system in place to monitor adverse effects connected to the use of medical technology. The Medical Devices Rules, 2017 were introduced by the Government of India to solve this issue, and they went into effect on January 1, 2018 [19].

Materiovigilance, which comprises the detection, gathering, assessment and reporting of adverse events (AEs) connected to the medical devices use, is an essential part of monitoring medical device safety [20][21]. The DCGI established the MvPI at the IPC in 2015 to document AEs related with medical devices, educate healthcare professionals about the necessity of reporting AEs, and produce independent safety statistics for medical devices [22]. The MvPI scheme is monitored by both the CDSCO and the IPC. The program's primary purpose was to encourage voluntary reporting of adverse occurrences by recruiting 10 medical institutions from four distinct locations of India. The programme does, however, seek to broaden its coverage to both private and public healthcare delivery systems, create an electronic reporting system, and mandate that both device manufacturers and healthcare providers record AEs.

1. Objectives of MvPI

The MvPI was formed with the following objectives in mind:

- Establishing a national strategy for observing patient safety
- Examining the medical device's benefit-risk ratio
- Generating evidence-based information for medical equipment linked to unfavourable incidents
- Supporting the Central Drugs Standard Control Organization (CDSCO) make choices about the nation's regulation related to medical device
- Sharing safety-related information with diverse industry stakeholders.
- Working together with international organizations and other healthcare organizations to handle data and exchange information.

The MvPI works with makers, importers, authorized representatives, healthcare facilities, and individual consumers to report adverse occurrences linked to medical devices through its reporting system in order to improve the safety and efficacy of medical devices in India (23). In order to share knowledge and best practices on Materiovigilance, the MvPI collaborates with various national and international regulatory agencies like FDA MAUDE, PMDA, MHRA, TGA, EMEA and CDSCO (24). By achieving these goals, the MvPI hopes to offer consumers and healthcare professionals safe and reliable medical equipment.

2. **Documenting and Reporting Adverse Events:** To ensure patient safety and raise the standard of healthcare services in India, it is crucial to record and report adverse occurrences related to medical devices. A two-page Medical Device Adverse Event Reporting Form was developed by the Pharmacovigilance Programme of India (PvPI) and is easily accessible on the IPC website [25].

This form makes it easier to report any and all adverse events (AEs) involving medical devices, regardless of how serious, common, or unusual they may be. It can be sent via email after being scanned and sent to the email sctismt.ac.in with a copy to email mvpi.ipcindia@gmail.com, directly to the National Collaborating Centre (NCC), or to the nearest Medical Device Monitoring Centre (MDMC). The patient, the adverse event, the device, the regulator, and the reporter are all given in great detail. Reporters can also call the NCC-PvPI helpline number (1800-180-3024) to report an unfavourable event.

Various stakeholders are involved in documenting and reporting adverse occurrences related to medical devices. Medical device adverse events may be reported by a clinician, biomedical and clinical engineers, hospital technology management, chemists, nurses and technicians, Importers, producers, and traders of medical devices may also report adverse occurrences unique to their product to the National Collaboration Centre (NCC), or SCTIMST, in Thiruvananthapuram. [22]

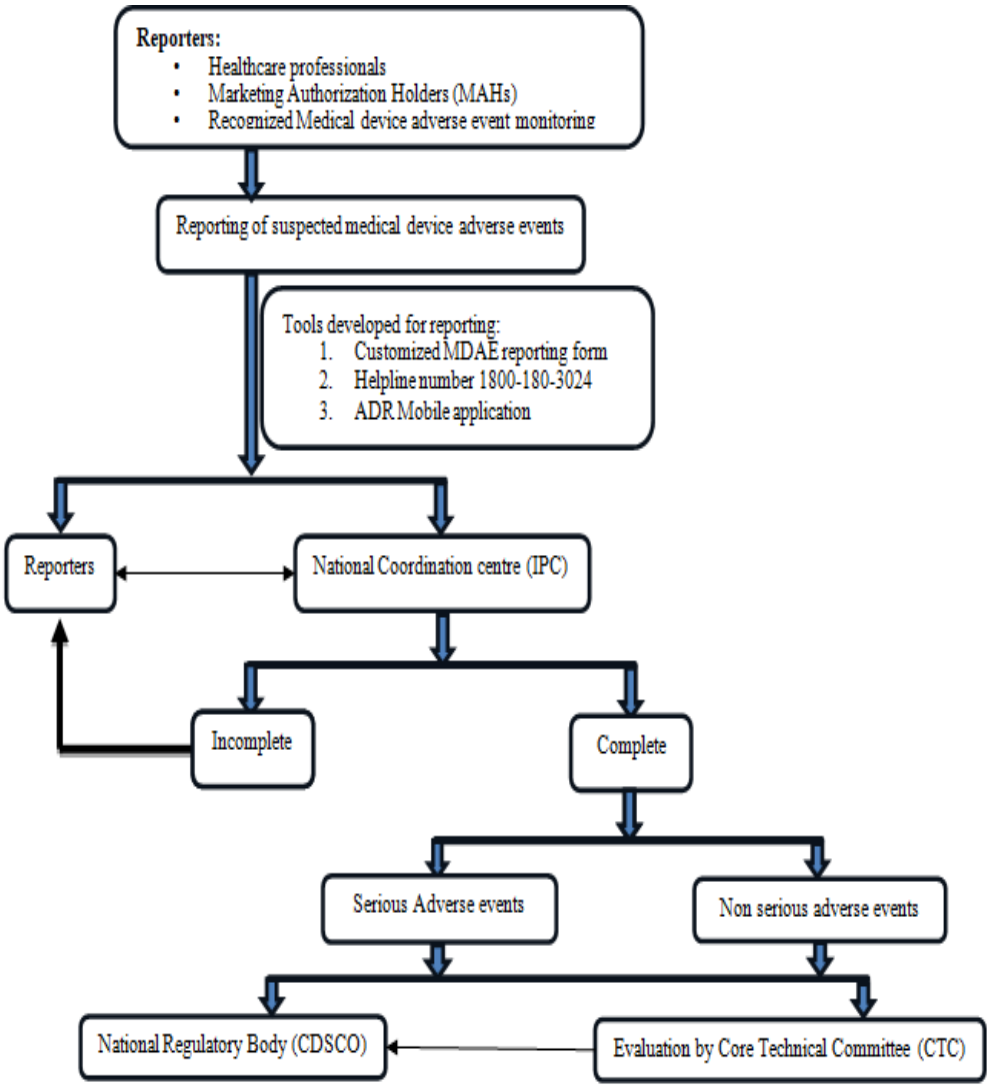

Figure 2: Flow diagram for MDAE monitoring

Medical device adverse event reporting and documentation is a critical process involving many parties. Each stakeholder has a duty to guarantee the efficacy and safety of medical technologies and stop foreseeable negative outcomes. In India, the PvPI and the Medical Device Adverse Event Reporting Form are essential in enabling this procedure. Figure 2 shows a flow diagram for MDAE monitoring.

3. **Different Mvpiunits Role and Responsibilities:** MvPI originally established 10 Medical Device Monitoring Centers (MDMCs) around India to track and report adverse events (MDAEs) associated with medical devices. Since then, there are now 293 centers, and more than 7000 reports have been forwarded to the IPC at an accelerated rate. According to how closely they are related to the medical device, the five categories of suspected or proven MDAEs are divided up into by the MDMCs for identification, collection, and reporting. MDMCs are required to report cases to NCC-IPC on a monthly basis for assessment and analysis, with a deadline of 5 working days to report an MDAE after becoming aware of it and 30 calendar days after determining its root cause. [26].

The MvPI database is solely managed by IPC, who also coordinates with all MDMCs in India, informs CDSCO of any issues, works with international authorities, and finances SCTIMST, MDMCs and NHSRC. As the NCC, SCTIMST provides technical assistance on all topics, and NHSRC functions as a partner of technical support by supplying advice on SOPs, newsletters, training manuals, and other things [27,28]. The CDSCO, the national regulatory agency in charge of maintaining safety, receives all complaints and relays them to it. The CDSCO then acts appropriately based on advice from the NCC-MvPI. Figure 3 depicts the organizational MvPI structure.

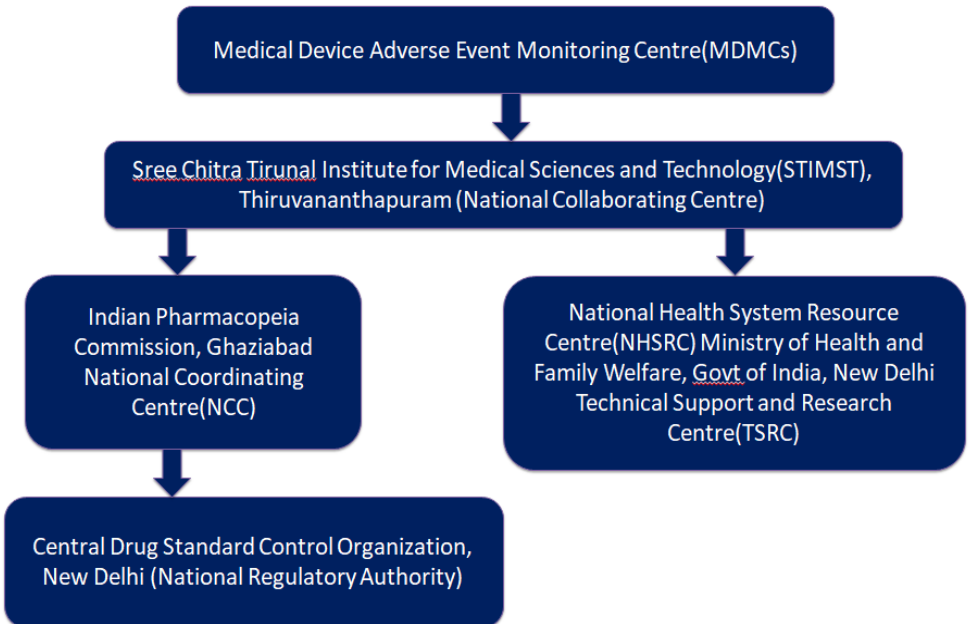

Figure 3: Organizational structure of Materiovigilance Programme of India

4. **Benefits of MvPI**

- Educational initiatives to healthcare professionals for improving safe use of medical devices.
- Generation of Medical Device safety data based on Indian Population
- Benefit risk ratio of medical devices can be assessed
- Public confidence can be stored and enhanced
- Safe and effective use of medical devices can be achieved

Table 2: Difference in Medical Device Vigilance System of India, US, Australia and UK [29]

S. No	Parameters of Countries	F.D. A (U.S)	TGA (Australia)	MHRA (U.K)	CDSCO (India)
1	**Definition of medical device**	Includes all equipment, devices, supplies, machinery, in vitro diagnostic tools, implants, software, add-ons, and cleaning supplies	Excludes tampons and disinfectants fit for a hospital, home, or business	Excludes cleaning supplies for medical equipment	All medical devices in India to be regulated as "drugs" Under the Medical Devices (Amendment) Rules, 2020.
2	**Medical device classificatio n**	There are three classes: class I, class II, and class III.	There are five classes: class I, classes II a And II b, class III, and class AIMD.	There are four classes: class I, class IIa, class IIb, and class III.	The DCGI will perform the CDSCO categorization of all medical devices (Class A, B, C, and D).
3	**Basis of classificatio n**	Based on the risks they pose and the regulatory controls required to offer reasonable assurance of safety and efficacy	Level of harm they may pose to users or patients	level of risk associated with medical device	Risk level associated with medical device
4	**Post marketing surveillance activities**	Tracking of MDRs, documentation of MDR events, written protocols, management of complaints, and recall procedures.	Reporting of AEs, a programme for exchanging information, enforcement actions, records of distribution, and audits	Records, investigations, enforcement, post market clinical follow-up, and FSCA and field safety notices	Reporting of AEs management of complaints, the process for disclosing AEs and recalls, and the procedure for importers
5	**Medical device tracking**	Have a tracking system in place since 1993	IMDTS, newly developed for patient tracking with implantable medical devices	AITS was created to examine the device's failure modes through	Labelling requirements must include the device's batch number for
6	**Who need to report AE**	Importers, Manufacturers, user facilities,distributors, customers, and medical professionals	Manufacturers, sponsors, clients, consumers, medical experts, and TGA	The MHRA, manufacturers, users, medical professionals, and authorized representatives	Manufacturers only
7	**Criteria for reporting**	Death or significant harm devices that don't work User blunder disease or injury requiring medical attention	A thing has happened. Associated medical device with the occurrence Event caused/could cause death or serious injury	A thing has happened. Associated medical device with the occurrence Event caused/could cause death or serious injury	A thing has happened. Associated medical device with the occurrence Event caused/could cause death or serious injury

8	**Not-reportable incidents/ events**	Manufacturers can request RAE for things like inaccurate information. when a different manufacturer creates the product	Defects discovered by the user Because of the patients' previous condition, the adverse event's primary cause is Device's service life has expired After risk assessment, the likelihood of an undesirable event is acceptable. The manufacturer's package and the device master record expressly mention side effects.	Defects discovered by the user Because of the patients' previous condition, the adverse event's primary cause is Device's service life has expired After risk assessment, the likelihood of an undesirable event is acceptable. The manufacturer's package and the device master record expressly mention side effects.	Defects discovered by the user Because of the patients' previous condition, the adverse event's primary cause is Device's service life has expired After risk assessment, the likelihood of an undesirable event is acceptable. The manufacturer's package and the device master record expressly mention side effects.
9	**Reporting time frame**	Death, serious injury, and faults must be reported to the manufacturer within 30 calendar days. Events that require corrective action within 5 working days. User Facilities: 10 working days for fatalities and significant injuries. Importers: Within 30 calendar days of becoming aware of an event	Fatal case to be reported within- 10 calendar days Near-adverse event that must be reported within 30 days Threat to public health that must be handled within 48 hours	No later than two calendar days after the manufacturer becomes aware of a serious public health danger. Death or a catastrophic health decline that was not anticipated: 10 calendar days after the manufacturer is made aware, at the earliest. Not later than 30 calendar days following the manufacturer's become aware.	Within 15 calendar days of becoming aware of an event. All additional reportable incidents, with at least 30 calendar days of becoming aware of an event.
10	**Types of report**	Baseline reporting Reporting 5th day Reporting 30th day Supplemental reporting Annual reports	Reporting of each AEs or incidence or medical device annual report	Initial notification of negative occurrences last reports periodic reporting of a summary trend analysis	first reporting trend analysis complete reporting

11	**Applicable forms**	Online 3500 Form Form 3500A is intended for producers, importers, and distributors. Forms 3419, 3417, and 3381	Form MDIR01 Form UDIR01 – online	Form for reporting incidents to the manufacturer MORE Online Manufacturer Reporting	Adverse event reporting form
12	**Vigilance exchange**	NA	With overseas regulatory agencies	Exchange information about comparable situations and FSCA within and beyond the organization.	Not defined
13	**Vigilance exchange form**	NA	No	Yes	NA
14	**Records**	Evaluation of Adverse event data, inspection of Records and follow-up on the investigation process Copies of test findings, lab reports, and maintenance logs	Distribution records for produced items Records of problems reported, their evaluation, and solutions	Evaluation records for AE Record of user or customer complaints records for manufactured goods Distributor records CAPA	Only importers must adhere to this criterion.
15	**Recall/FSCA**	Manufacturers must start a recall.	Sponsors must start the recall	Manufacturers must start a recall	A required requirement exclusively for importers
16	**Recall communication**	Mailgrams, telegrams, and phone calls First class letters with FDA approval broad public alert through specialized news medium, warning the public	Recall letters are approved within 48 hours of the signing of a recall agreement. The TGA has approved paid retail marketing.	The MHRA accepted the FSN in accordance with the prescribed format within 48 hours of the FSCA agreement. In an emergency, please contact us via phone, fax, or in person.	Depending on the category of risks involved, a time line of within 24 hours up to 72 hours for Class I recall, up to 10 days for Class II recall, and up to 30 days for Class III recall is allowed.

IV. FAILURE OF A MEDICAL DEVICE: PENALTIES

The top ten medical device companies in the US have compensated doctors and their clinics to the tune of more than $600 million as it is essential for pharmaceutical and medical equipment manufacturers to pay their responsibilities. Olympus Corporation of America was sentenced to pay $623.2 million in 2016 as a result of a case brought against them alleging widespread corruption of medical practitioners.

Another firm by the name of Medtronic Inc. was contracted to pay $2.8 million to a patient as compensation because the healthcare system was paying doctors bribes in the form of monthly bonuses to employ subpar and dysfunctional medical equipment, driving up the cost of treatment.[24].

Table 3 is a list of recently recalled medical equipment in chronological order, along with the cause of the recall.[30]

Table 3: List of Recently Recalled Medical Equipment in Chronological Order, along with the Cause of the Recall.

S. No	Recall Period	Country	Medical Equipment	Purpose of Recall
1.	2020	U.S.A	Alaris PC unit 8015	The recall of this item was caused by the potential for Alaris Pc units to display the incorrect type of syringe size. This causes a delay in the infusion or an over-infusion, both of which could be catastrophic.
2.	2020	U.K, Europe	Coronavirus testing kits	The MHRA requested that Randox recall all COVID-19 testing kits that were distributed to people's homes and places of work due to subpar swabs that could result in insufficient findings. Furthermore, 9000 testing kits were returned to China by Spain because insufficient testing was done on them.
3.	2020	India	Coronavirus testing kits	The ICMR ordered COVID-19 antibody testing kits just for Indian companies. Punjab, Rajasthan, and Karnataka were the three states that received the most complaints over the kits' subpar performance.
4.	2020	U.S.A	Alaris system module and pump module door assembly replacement kits	This item was pulled from the market because it might have one or more broken keys. Due to the device's lack of responsiveness, high-risk populations may have delays in infusion, which raises the risk of harm. If the infusion is stopped or delayed, the patient could pass away. 976 reports on this matter have been received, but there have been no reports of fatalities.

5.	2020	U.S.A	Medfusion syringe pumps	Certain software versions of the Medfusion 3500 and 4000 were recalled due to software bug because there was a chance that the patient would get too little or too much fluid. Use of the harmed medical gadget may have fatal health effects.
6.	2020	Japan	Abenomask	Recalls of 7870 defective masks were made in response to reports of stains, insects, and fungus.
7.	2019	U.S.A	Allergan breast implant	Breast implants were taken off the market globally by medical device maker Allergan due to an elevated risk of anaphylactic large cell lymphoma (BIA-ALCL), an immune system cancer. An FDA review found that there were 573 new cases, including 33 fatal ones. 481 of the 573 cases had Allergan breast implants when they were diagnosed. Additionally, 12–13 BIA–ALCL deaths in patients with Allergan breast implants were recorded during the BIA–ALCL diagnosis.
8.	2019	U.S.A	Omni beds and giraffe incubators	GE Health recalled these incubators because the bedside panel was erect and unable to be sealed securely. As a result, the bedside panel may suddenly open if a baby approaches it, letting the baby fall.
9.	2018	China	Fake rabies vaccine	China violated immunity rules and forged paperwork.
10.	2017	U.S.A	Zimmer Biomet spinal fusion stimulators	Zimmer Biomet has voluntarily recalled 33 spinal fusion stimulators. This device, which is typically inserted into the patient's back during spinal fusion procedures, helps to repair broken long bones and increase the likelihood of permanently joining two bones. During normal inspections of these devices, the US company discovered that the product included a significant quantity of dangerous substances that could be harmful to the patient's organs and tissues.
11.	2010	India	ASR XL acetabular hip replacement system (metal-on-metal).	The patients had to have additional surgery as a result of the discharge of metallic particles into the bloodstream in this case, which is typically seen with metal implants. Patients also complained of the prosthetic ball and socket pressing against their skin.

1. **List of Medical device Safety Alerts for Sensitization of Healthcare Professionals (HCP):** The IPC is the regulatory body in charge of guaranteeing the reliability and quality of medical equipment in India. The commission occasionally publishes medical device safety alerts to inform the public about potential hazards related to certain products. By informing manufacturers, customers, and HCP about any adverse occurrences, safety concerns, or product recalls, these safety warnings are essential for preserving public health. The IPC plays a crucial role in protecting patient safety and ensuring that medical devices adhere to strict safety requirements by rapidly disseminating such information [31,32,33,34,35,36,37]. **Table 4** is a list of medical device safety alerts year wise from 2019 to 2023 by IPC.

Table 4: List of Medical Device Safety Alerts by IPC.

S. No	Suspected Device	Safety Alert/Event	Year
1.	Orthopedic Mega prosthesis (Femoral stem)	Stem Breakage	2023
2.	Monofilament synthetic absorbable skin support & filling thread sterile	Atypical Mycobacterial infection	
3.	Implantable Collamer Lens	Toxic anterior segment syndrome	2022
4.	AcrySof Single piece IOL	Infection followed by vision loss after implantation	2022
5.	Syringe Pump	Short Circuit	
6.	Cranial Perforator	Breakage of the drill bit during use results in a disastrous patient outcome.	2021
7.	Orthopedic drill		
8.	Perfluorocarbon Liquid	Acute Blindness Retinal Necrosis Proliferative Vitreoretinopathy Pthysis Subretinal fibrosis Optic nerve atrophy Retinal vascular occlusion Ratinal atrophy	
9.	Heavy Silicone Oils		
10.	Intraocular membrane staining dye		
11.	Perfluoro octane (PFCL)	Blindness/vision loss	2021
12.	Intrauterine contraceptive Devices (IUCD)	Genital Haemorrhage	2020
13.	Absorbs Bio resorbable Vascular Scaffolds	Stent thrombosis Myocardial infraction Stent stenosis	2019
14.	Speed band superview super 7	Device Malfunction	

2. SWOT Analysis

Strength	Opportunities
Proactively monitoring adverse events Ensuring early detection of potential safety concerns Promotes Public awareness	Continuous improvement through data analysis Integration of advanced technology International collaboration and harmonization
Weakness	**Threat/Limitation**
Under-reporting Not all adverse events may be reported Limited resources, including staffing and funding	presence of counterfeit or substandard devices Rapid technological advancements Challenges in global regulatory compliance

V. MEDICAL DEVICE ADVERSE EVENTS REPORTED TO THE INDIAN PHARMACOPOEIA COMMISSION

A study by Shukla et al. reported that 1931 adverse occurrences in total, including 40 in 2015, 53 in 2016, 254 in 2017, 687 in 2018, and 897 in 2019. Of the 1277 occurrences, 654 were deemed to be of a less serious nature. There were 926 occurrences linked to cardiac stents, 226 to IUDs, 179 to orthopedic implants, 75 to intravenous cannulae, 76 to catheters, and 449 to other types of devices. Marketing authorization holders reported 1439 events, of which 419 were reported by medical device adverse event reporting centers, 70 by adverse drug reaction reporting centers, and 3 by consumers. [38].

VI. CONCLUSION

The fact that medical devices are a crucial part of the healthcare system has increased their use in recent years. In spite of this, not enough protections are in place to protect patients against negative situations related to the use of medical equipment. Materiovigilance programmes are designed to examine, track, and stop the recurrence of negative effects brought on by the use of medical equipment. Despite the fact that it is a difficult discipline in and of itself, clinical engineering and biomedical engineering are just two of the many fields that must support it. MvPI is a commendable attempt to guarantee the security of medical equipment among Indian users. The policy guidelines, processes, and roles and duties of various stakeholders have been outlined in the MvPI guidance document in order to facilitate the systematic collecting of safety data by minimizing the occurrence of negative effects and lowering the risk associated with the use of medical devices for the maximum benefit to patients as well as care providers, it is anticipated that successful implementation of this strategy will significantly improve the safety of device users. The association of health care professionals (HCP) is crucial for the effective implementation of the Materiovigilance programme. Sensitization of HCP can be accomplished by CME to raise knowledge of MvPI among HCP.

It is expected that the established reporting mechanisms will increase contact between regulatory authorities and medical device users, allowing for more extensive monitoring of

medical device safety. MvPI has demonstrated the ability to develop a trustworthy and long-lasting system for gathering and documenting AEs associated with devices in order to ensure the quality, safety and efficacy of medical device on Indian Market. As a result, the system is expected to encourage medical personnel, MAHs and consumers to report AEs.

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