



Guidance Document *for* Hospitals in India

for safety monitoring and reporting of medical devices related
incidents/adverse events

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Materiovigilance Programme of India (MvPI)
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Message from Secretary-cum-Scientific Director

The Materiovigilance Programme of India (MvPI), since its inception in 2015, continues to strengthen the safety surveillance framework for medical devices used across healthcare settings in India. India's medical technology landscape is evolving rapidly, with continuous advancements in device design, diagnostic technologies, and the increasing integration of Artificial Intelligence (AI) and Software as a Medical Device (SaMD) into clinical practice. The expanding use of medical devices, including in-vitro diagnostics (IVDs), AI-driven technologies, and software-based medical devices across primary, secondary, and tertiary healthcare settings offers significant benefits for patient care, while also introducing new and evolving categories of risk that require robust and continuous safety monitoring. In this context, the timely identification, documentation, and reporting of suspected device-related incidents and adverse events have become increasingly important for strengthening patient safety and supporting effective regulatory decision-making.

This Guidance Document has been developed by the Indian Pharmacopoeia Commission (IPC), in collaboration with the World Health Organization (WHO) India and other partnering organizations, to support

hospitals and healthcare professionals in establishing systematic and sustainable mechanisms for the identification, documentation, assessment, and reporting of suspected medical device-related adverse events. The document brings together the collective expertise and experience of IPC, WHO India, and other stakeholders to provide practical guidance on medical device safety monitoring and reporting under MvPI.

I am confident that this document will serve as a practical resource for hospitals, healthcare professionals, patients, and other stakeholders, and will further strengthen the culture of medical device safety surveillance and reporting under MvPI. I take this opportunity to express my sincere appreciation to all the contributing institutions and experts for their valuable inputs and support in the development of this document. I also encourage continued engagement and timely reporting of suspected medical device-related incidents and adverse events to help ensure the safe and effective use of medical devices, including the emerging generation of AI-enabled and software-driven medical technologies, across India.

Dr. V. Kalaiselvan

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INTRODUCTION

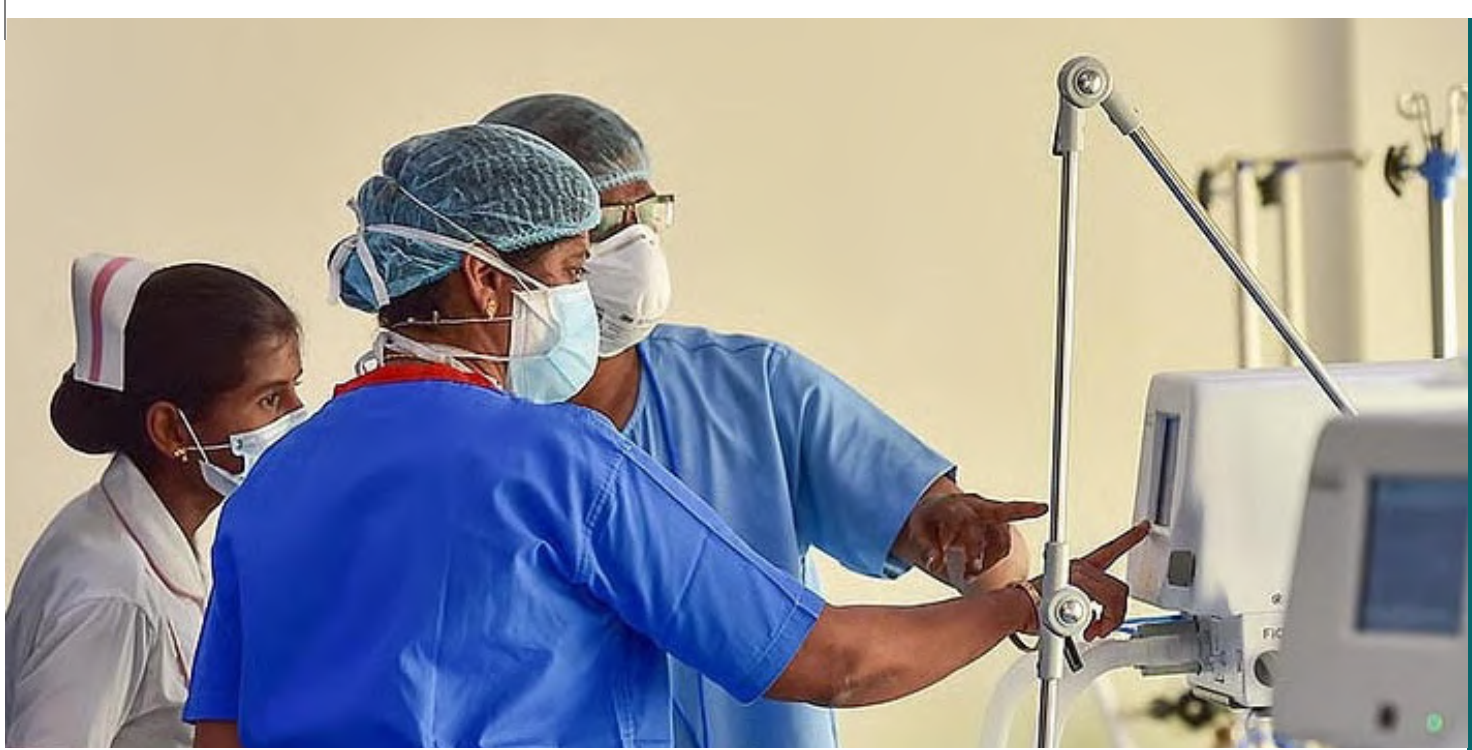
Patient safety is a fundamental pillar of quality healthcare, and ensuring the quality of medical products including medical device is critical in preventing avoidable harm and achieving optimal health outcomes. Medical devices have become an indispensable component of modern healthcare, ranging from basic diagnostic and monitoring equipment to sophisticated implantable, life-supporting, digital, and technology-intensive devices. Their use has expanded significantly across all levels of healthcare delivery, including primary healthcare facilities, district hospitals, tertiary care institutions, specialized centres, and home-based care.

The growing burden of diseases, increasing healthcare needs, advancements in medical technology, expansion of diagnostic and therapeutic services, and wider access to healthcare are driving a substantial increase in the demand and utilization of medical devices in India. At the same time, rapid technological advancements are resulting in the development and introduction of increasingly complex and innovative devices, including software-enabled and connected medical devices, implantable devices, in-vitro diagnostic devices, and devices incorporating artificial intelligence and other emerging technologies. This expanding and evolving medical device landscape, while contributing significantly to improved diagnosis, treatment, monitoring, and rehabilitation, also presents new and emerging challenges related to device safety, quality, performance, usability, and reliability. Unlike pharmaceuticals, medical devices may be subject to a wide range of risks arising not only from their inherent design and material characteristics but also from manufacturing defects, software-related issues, improper maintenance, user error, inadequate training, inappropriate use, device interactions,

and changing conditions of use. Therefore, the continuous monitoring of medical devices throughout their lifecycle is essential to ensure that potential safety signals and device-related risks are identified at the earliest possible stage.

In this context, there is a growing need for robust, systematic, and sustainable mechanisms for the timely identification, monitoring, assessment, documentation, and reporting of medical device-related incidents and adverse events. A standardized surveillance framework can facilitate the early detection of emerging safety signals, enable evidence-based assessment of risks, support appropriate regulatory and corrective actions, and ultimately strengthen the overall safety and effectiveness of medical devices in clinical practice. Such mechanisms are essential not only for protecting patients and healthcare professionals but also for strengthening confidence in medical devices and fostering a culture of continuous post-market safety monitoring in India.

This guidance document, developed by the Indian Pharmacopoeia Commission (IPC), Ministry of Health & Family Welfare, Govt. of India (MoHFW) in collaboration with World Health Organization (WHO), India Country Office and key national stakeholders including Patient Safety Wing, Directorate General Health Services (DGHS), Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Central Drugs Standard Control Organization (CDSCO), National Health Systems Resource Centre (NHSRC), and National Accreditation Board for Hospitals & Healthcare Providers (NABH), provides a comprehensive framework for strengthening the monitoring of medical device-related adverse events in healthcare settings. The document is intended to serve as a practical resource for healthcare professionals, hospitals, healthcare institutions, patients, caregivers, and



other relevant stakeholders involved in the use and monitoring of medical devices. It aims to facilitate the establishment and strengthening of systematic mechanisms for the identification, documentation, assessment, analysis, and timely reporting of adverse events and incidents associated with medical devices.

The guidance further seeks to enhance awareness and understanding of the Materiovigilance Programme of India (MvPI), including its objectives, reporting mechanisms, roles and responsibilities of stakeholders, and the importance of active participation in medical device safety surveillance. By promoting a standardized approach to adverse event reporting and encouraging a strong culture of safety monitoring, the document aims to support the early identification of potential safety signals, generation of reliable evidence, implementation of appropriate risk-minimization and corrective measures, and continuous improvement in the safety and performance of medical devices. The collaborative development of this guidance reflects a coordinated national effort to strengthen patient safety and post-market surveillance of medical devices in India, while fostering greater

engagement and participation of healthcare institutions and other stakeholders in the MvPI framework.

1.1 Objectives:

The objectives of this guidance document are as follows:

- To provide a standardized framework for the safety monitoring, identification, documentation, reporting, assessment, and management of medical device-related incidents including suspected adverse events, device malfunctions, user errors, and other safety concerns. The guidance is intended for all relevant stakeholders, including healthcare facilities, Medical Device Adverse Event Monitoring Centres (MDMCs), healthcare professionals, patients, consumers, caregivers, and other stakeholders involved in the use and safety surveillance of medical devices.
- To provide practical guidance to healthcare facilities and hospitals for the effective implementation of the Materiovigilance Programme of India (MvPI) within their

institutional settings. The document outlines the roles and responsibilities of relevant hospital personnel in the identification, monitoring, documentation, reporting, investigation, assessment, and appropriate management of adverse events and malfunctions associated with medical devices used in healthcare settings.

- To strengthen institutional systems for medical device safety surveillance by encouraging healthcare facilities to establish appropriate processes for incident detection, internal communication, documentation, investigation, corrective and preventive actions, and follow-up of reported events.

- To enhance awareness and participation in MvPI among healthcare professionals and other stakeholders, thereby fostering a culture of proactive medical device safety monitoring and contributing to improved patient safety and the overall quality of healthcare delivery.

1.2 Scope:

- This Guidance Document applies to all medical devices, including In Vitro Diagnostic (IVD) medical devices, that are manufactured, imported, distributed, or otherwise placed on the market in India and are regulated under the Medical Devices Rules, 2017, framed under the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945, as applicable.

- Combination products shall also fall within the scope of this Guidance Document where the principal intended purpose or primary therapeutic/diagnostic function of the combination product is achieved through the medical device component. In such cases, medical device-related incidents, adverse

events, malfunctions, and other safety concerns associated with the device component should be identified, documented, assessed, and reported in accordance with the principles outlined in this Guidance Document.

1.3 Audience:

This Guidance Document is intended for all stakeholders involved in the use, monitoring, reporting, regulation, and post-market surveillance of medical devices in India. The primary audience includes:

- Professional and technical personnel associated with the Indian Pharmacopoeia Commission (IPC), Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), National Health Systems Resource Centre (NHSRC), Central Drugs Standard Control Organization (CDSCO), and Medical Device Adverse Event Monitoring Centres (MDMCs) participating in the Materiovigilance Programme of India (MvPI).

- Public and private hospitals, NABH-accredited healthcare organizations, healthcare professionals, and other healthcare providers who use medical devices in clinical practice, as well as patients, caregivers, and consumers who are users or beneficiaries of medical devices.

- Other relevant stakeholders involved in medical device safety surveillance, including institutional safety committees, biomedical engineering and technical personnel, procurement and quality assurance teams, and other personnel responsible for the safe use, maintenance, monitoring, and reporting of medical device-related incidents and adverse events.

DEFINITIONS

Abnormal use. Conscious, deliberate act or deliberate omission of an act that is counter to or violates normal use and is also beyond any further reasonable means of user interface-related risk control by the manufacturer.

Examples of such acts are reckless use or sabotage or deliberate disregard of information for safety.

Accessory to a medical device: Means an article intended specifically by its manufacturer to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended use.

Accessory to an IVD: Means an article intended specifically by its manufacturer to be used together with a particular IVD medical device to enable or assist that device to be used in accordance with its intended use.

Active & Passive Surveillance: In passive surveillance, criteria are established for reporting diseases, risk factors or health-related events. Health practitioners are notified of the requirements and they report events that come to their attention. This is the more common type of surveillance. Active surveillance, criteria are established for reporting disease (or its absence), risk factors or health events, but those maintaining the surveillance system active to initiate reporting. Active surveillance is used when there is an indication that something unusual is occurring.

Adverse Event: An adverse event is any undesirable experience associated with the use of a medical product in a patient.

Baseline Studies: The purpose of a baseline study is to provide an information base against which to monitor and assess an activity's progress and effectiveness during implementation and after the activity is completed. In MvPI, it helps to understand

manufactures compliance with global regulators action/advice.

Bureau of Indian Standards (BIS): It is the National standards body of India working under the aegis of Ministry of Consumer Affairs, Food & Public Distribution, Government of India. They represent medical devices in International Organization for Standardization (ISO) and formulate medical device standards in India.

Central Drugs Standard Control Organization (CDSCO): It is the National regulatory body for Indian pharmaceuticals and medical devices, and serves parallel function to the European Medicines Agency (CE Marking) and U.S. Food and Drug Administration (US FDA).

Corrective Action and Preventive Action (CAPA): Improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations.

Error: Failure to carry out a planned action as intended or application of an incorrect plan.

Field Safety Corrective Action (FSCA): An action taken by a manufacturer to reduce the risk of death or serious deterioration in the state of health associated with the use of a medical device. Such actions should be notified via a Field Safety Notice (FSN). In assessing the need for FSCA, the manufacturer may use the methodology described in the international standard ISO 14971.

FSCAs may include:

1. **return of a medical device to the manufacturer or its representative;**
2. **device modification;**
3. **device exchange;**
4. **device destruction;**
5. **advice given by the manufacturer regarding the use of the device (e.g. where the device is no longer on the market or has been withdrawn but could still possibly be in use, e.g.**

implants).

Device modifications may include:

1. **Retrofit in accordance with the manufacturer's modification or design change.**
2. **Permanent or temporary changes to the labelling or Instructions for Use (IFU).**
3. **Software upgrades, including those carried out by remote access.**
4. **Modification to the clinical management of patients to address a risk of serious injury or death related specifically to the characteristics of the device. For example, for implantable devices it is often clinically unjustifiable to explant the device.**
5. **Corrective action taking the form of special patient follow-up, irrespective of whether any affected un-implanted devices remain available for return.**
6. **For any diagnostic device (e.g. IVD, imaging equipment or devices), the retesting of affected patients, samples or the review of previous results.**
7. **Advice on a change in the way the device is used (e.g. IVD manufacturer advises revised quality control procedure, use of third-party controls or more frequent calibration).**

Field Safety Notice (FSN): A

communication sent out by a manufacturer or its representative to the device users in relation to an FSCA.

Note: An FSN can also be non-safety related, e.g. quality-related, customer product information.

Instructions for Use (IFU): Information provided by the manufacturer to inform the device user of the medical device's intended

purpose and proper use and of any precautions to be taken.

Incident: Any deviation from usual medical care that either causes an injury to the patient or poses a risk of harm, including errors, preventable adverse events and hazards.

Intended purpose: The use for which the medical device is intended according to the data supplied by the manufacturer on the labelling or in the document containing IFU of such device or in promotional material relating to such device, which is as per approval obtained from the Central Licensing Authority (CLA).

ISO: The International Organization for Standardization is an independent, non-governmental international organization with a membership of 176 national standards bodies who creates standards for products but not limited to medical device.

In Vitro Diagnostic medical device (IVD):

A medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

Note 1: IVDs include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.

Malfunction or deterioration: Failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions.

Manufacturer: Any natural or legal person with responsibility for design and/or manufacture of a medical device with

the intention of making the medical device available for use, under their name; whether or not such a medical device is designed and/or manufactured by that person themselves or on their behalf by another person(s).

Medical Device: All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of

(i) **diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;**

(ii) **diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;**

(iii) **investigation, replacement or modification or support of the anatomy or of a physiological process;**

(iv) **supporting or sustaining life;**

(v) **disinfection of medical devices; and**

(vi) **control of conception.**

Medical Device Adverse Event (MDAE):

Any unexpected or inappropriate medical occurrence, unintended disease or injury, or on inconvenient clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the medical device.

Medical Device Alert (MDA): The prime means of communicating safety information to clinical establishments on medical devices.

National Regulatory Authority (NRA): A government body or other entity that exercises

a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements.

Near Miss Event: A Near miss event is an unplanned event that did not result in injury, illness, or damage – but had the potential to do so.

Post Market Surveillance: A proactive and systematic process used to collect and analyse appropriate data and experience gained from medical devices after they have been placed on the market, in order to identify safety or performance issues, assess risks, and determine the need for corrective or preventive actions and other appropriate measures.

Recall: “Recall” means any action taken by its manufacturer or authorised agent or supplier to remove the medical device from the market or to retrieve the medical device from any person to whom it has been supplied, because the medical device: -

(a) **is hazardous to health;**

(b) **or fails to conform to any claim made by its manufacturer relating to its quality, safety or efficacy; or**

(c) **does not meet the requirements of the Act and these rules (MDR, 2017).**

Root Cause Analysis (RCA): A systematic process of investigating and analysing a patient safety incident to identify what happened, how it happened, and why it happened, including the underlying and contributing factors, and to identify appropriate actions to prevent recurrence.

Reportable Events: A reportable adverse event in medical devices can be any incident where a medical device causes, or could potentially cause, serious injury or deterioration in the health of the subject or

death to a patient, user, or other person, and needs to be reported to health authorities.

Serious Public Health Threat: Any event type or device deficiency which could result in imminent risk of death, serious deterioration in the state of health, serious injury, or serious illness of more than one patient, user or other person that requires prompt remedial action.

Suspected Unexpected Serious Adverse Event (SUSAE): It is the event that does not match with the reference safety information as included in summary of product characteristics.

Serious Adverse Event (SAE): It means an untoward medical occurrence that leads to-

- (i) a death; or
- (ii) a serious deterioration in the health of the subject that either-
 - (A) resulted in a life-threatening illness or injury; or
 - (B) resulted in a permanent impairment of a body structure or a body function; or
 - (C) required in-patient hospitalisation or prolongation of existing hospitalization; or
 - (D) resulted in medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function; or
- (iii) foetal distress, foetal death or a congenital abnormality or birth defect.

Non-Serious Adverse Event (NSAE): An adverse event associated with the use of a medical device that does not meet the criteria for a Serious Adverse Event (SAE).

Service-Life/Shelf-Life: The time for which a device is intended to remain functional after it is manufactured, put to use, and maintained as specified.

Signal Detection: The process of identifying patterns of associations, trends, or unexpected occurrences in adverse event data that may

indicate a previously unrecognized safety concern or a change in the known benefit-risk profile of a medical device and warrant further evaluation.

Unique Device Identification (UDI): A series of numeric or alphanumeric characters created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market. The UDI is comprised of the UDI-DI (Device Identifier) and UDI-PI (Production Identifier).

Use error: User action or lack of user action while using the medical device that leads to a different result than that intended by the manufacturer or expected by the user.

User: The person, either professional or lay, who uses a medical device. The patient may be the user.



MATERIOVIGILANCE PROGRAMME OF INDIA

During the early 2000s, India, like many other countries, witnessed increasing reports of adverse events associated with the use of medical devices, including implants, diagnostic devices, surgical devices, and other healthcare technologies. These events ranged from device malfunction and failure to serious patient injury, prolonged hospitalization, the need for corrective or revision procedures, permanent disability, and, in severe cases, death. Such incidents highlighted that even when medical devices are approved and appropriately used, unforeseen risks may emerge during their routine use in real-world clinical settings.

In India, concerns related to defective or malfunctioning medical devices have included instances in which implantable and other critical medical devices failed to perform as intended, requiring additional surgical intervention or replacement. For example, failures associated with certain implantable devices, such as orthopaedic or cardiovascular implants, can result in device loosening, breakage, premature failure, infection, tissue injury or other complications, potentially requiring revision surgery and prolonged patient care. Similarly, malfunction of critical devices such as infusion pumps, ventilators or diagnostic equipment may result in interruption or inappropriate delivery of therapy, delayed diagnosis, or other serious consequences.

These experiences demonstrated the need for a systematic and coordinated mechanism for the collection, assessment and monitoring of adverse events associated with medical devices. Unlike pre-market evaluation, which is conducted under controlled conditions and within defined study populations, post-market surveillance provides an opportunity to identify

rare, delayed, device-specific or use-related problems that may become apparent only after widespread use in diverse patient populations and healthcare settings.

Recognizing the importance of continuous monitoring of the safety and performance of medical devices, the Ministry of Health and Family Welfare (MoHFW), Government of India, launched the Materiovigilance Programme of India (MvPI) in 2015 at Indian Pharmacopoeia Commission (IPC). The programme was established to create a structured national system for reporting, collecting, analysing and evaluating medical device adverse events, with the ultimate objective of ensuring the continued safety of medical devices available in the Indian market.

The Indian Pharmacopoeia Commission (IPC) functions as the National Coordinating Centre for MvPI. Through a network of Medical Device Adverse Event Monitoring Centres (MDMCs), the programme facilitates reporting of adverse events by healthcare professionals and other stakeholders. The information generated through MvPI supports the identification of emerging safety signals and enables appropriate evidence-based recommendations to the regulatory authorities, including the Central Drugs Standard Control Organization (CDSCO).

The MvPI has three partner organisations apart from IPC supporting in the functioning of this programme.



Figure 1: Partner Organizations for MvPI

Indian Pharmacopoeia Commission (IPC) - National Coordination Centre (NCC)

The IPC, an Autonomous Institution of the Ministry of Health & Family Welfare, Government of India, is entrusted with the responsibilities relating to timely publication of the Indian Pharmacopoeia (IP), National Formulary of India (NFI), and certification of Indian Pharmacopoeia Reference Substances (IPRS) and Impurity Standards. Since April 2011, IPC has also been entrusted with the responsibility as the National Coordination Centre for Pharmacovigilance Programme of India (NCC-PvPI) - the only programme of its kind, aimed at improving patient safety by monitoring drugs-induced adverse reactions.

The PvPI aims to collect, collate and analyse the adverse events with the use of medicines, vaccines and provide appropriate technical inputs to the Indian National Regulatory Authority (NRA) i.e. Central Drugs Standard Control Organisation (CDSCO) besides communicating the risk to the general public. The IPC-PvPI has also been recognized by the World Health Organization

(WHO) as one of its Collaborating Centre (CC) for Pharmacovigilance in Public Health Programmes and Regulatory Services in July 2017 and since then performing its functions as WHO-CC efficiently. As a WHO-CC, IPC-PvPI plays a vital role in providing technical support in establishing and strengthening the PV system in WHO member states.

IPC has also been entrusted with National Coordination Centre responsibilities relating to Materiovigilance Programme of India (MvPI) since 2018 (However the MvPI was launched in July 06, 2015 and coordinated by SCTIMST, Trivandrum till 2017) with an objective to improving Indian patient safety by monitoring, recording, analysing root cause of adverse events or risks associated with use of medical devices including in-vitro diagnostics and suggesting regulatory bodies for appropriate action with a sole intention of improving quality of medical devices and to ensure patient/user safety across the country. MvPI programme promotes and facilitates adverse event reporting of medical devices including in-vitro diagnostics and subsequently evaluating these events. The scientific and systematic evaluation of these medical device event/reports will foster monitoring trends for improving and protecting the health and safety of patients/users.

National Coordination Centre (NCC)-MvPI has successfully established and coordinates a nationwide network of 775 Medical Device Adverse Event Monitoring Centres (MDMCs) across India (till Sep 2026) to strengthen medical device safety surveillance and adverse event reporting. Several incident reporting tools have been introduced by the MvPI to help the reporting of the MDAE, including Adverse Drug Reactions Monitoring System (ADRMS) software (ADRMS - IPC), incident reporting forms (MvPI Toolkit - Indian

Pharmacopoeia Commission), helpline (1800-180-3024), PvPI mobile app available on play store, etc. MvPI also plays a crucial role in capacity building and stakeholder training to strengthen the Medical Device Adverse Event (MDAE) reporting system in India. Through structured training programmes, workshops, sensitisation sessions, and hands-on training, MvPI aims to enhance the knowledge and skills of healthcare professionals, MDMCs, Market Authorization Holders (MAHs), regulators, and other relevant stakeholders regarding the identification, documentation, assessment, and timely reporting of MDAEs. These initiatives also promote awareness about the importance of medical device safety surveillance and encourage a culture of proactive and spontaneous reporting, thereby improving the quality, completeness, and timeliness of safety data generated under MvPI.

Under MvPI, there are various committee as mentioned below:

- **MvPI Steering Committee** - MvPI is administered and overseen by a Steering Committee, which provides strategic guidance, supervision, and direction for the effective implementation, monitoring, and continuous strengthening of the programme.
- **MvPI Working Group** - The MvPI Working Group is constituted to approve major technical issues related to the establishment and implementation of the MvPI and to provide technical inputs to the CDSCO for regulatory interventions concerning medical devices. The Working Group may designate core technical committees to address issues related to quality, technical matters, training, and adverse event signal detection. It functions as a policy-making body for the implementation of new and effective plans and strategies for MvPI.

The Working Group also approves strategies to expand the reach of MvPI across the country and create awareness among stakeholders regarding MDAE reporting, as well as strategies for establishing national and international linkages with healthcare institutions and relevant organizations. It also provides opinions and recommendations on any matter related to MvPI brought to its notice for consideration.

- **Technical Support Group (TSG)** - The Technical Support Group (TSG) comprises experts who provide specialized technical inputs, scientific advice, and guidance to support the effective implementation, continuous improvement, and strengthening of the programme

Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) - National Collaborating Centre

Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) functions as National Collaborating Centre for Materiovigilance Programme of India. SCTIMST metamorphosed into an Institute of National Importance with the status of a university in 1980 under the Department of Science and Technology, Govt. of India, by an Act of Parliament. SCTIMST has the Biomedical Technology Wing (BMT Wing), Thiruvananthapuram; broad areas of activities of the wing include Medical Devices, Biomaterials, Biocompatibility, Tissue Engineering, Product incubation and commercialization. DST, Govt of India has identified BMT wing of the institute i.e. technical research centre for Biomedical devices. (approved by the DST, Govt. of India) is a nodal centre undertaking Five Programme for Mission Mode Industrial R&D in areas

of cardiovascular devices, neuro-prosthetic devices, hard tissue devices, in- vitro diagnostics and biological and combinational products. SCTIMST provides valuable scientific, technical, and expert inputs in the field of medical devices to support the effective implementation and strengthening of the programme.

The responsibilities of NCC-SCTIMST are:

- Organizing continuous professional development education programmes on Materiovigilance at various zone;
- Conducting periodic training and workshops for healthcare professionals at various zone;
- Providing research and development/testing support facility to the programme;
- Providing technical support in data analysis and release of medical device alert.

National Health Systems Resource Centre (NHSRC) - Technical Support and Resource Centre

The National Health Systems Resource Centre (NHSRC) is an autonomous body under the Ministry of Health and Family Welfare, Government of India. Established in 2007, NHSRC serves as a technical support institution, primarily aimed at strengthening public health systems and improving healthcare delivery across the country. Its key focus areas include policy development, healthcare system design, capacity building, and monitoring and evaluation of various health programs under the National Health Mission (NHM).

The Healthcare Technology Division of NHSRC is a WHO Collaborating Centre for Priority Medical Devices & Health Technology Policy. This division provides the technical support and acts as a resource centre for the Materiovigilance Program of India.

NHSRC provides technical support on the activities of National Collaboration

Centre - Sree Chitra Tirunal Institute of Medical Sciences & Technology, (SCTIMST) and National Coordination Centre - Indian Pharmacopoeia Commission (IPC) including trainings.

The responsibilities of NHSRC are:

- Providing technical support/guidance for preparation of standard operating procedures, guidance documents, newsletters, training manuals, etc;
- Supporting in Identification of new MDMC and intimating the same to IPC;
- Data mining/data analytics to adverse event reports. Technical advice on setting up of online adverse events data collection and release of medical device alerts via Email/SMS, etc;
- Providing awareness programme among medical device manufacturers/healthcare organizations.

Central Drugs Standard Control Organization (CDSCO) - National Regulatory Authority (NRA)

The Central Drugs Standard Control Organization (CDSCO) is the National Regulatory Authority (NRA) of India, functioning under the Ministry of Health and Family Welfare. It is primarily responsible for ensuring the safety, efficacy, and quality of drugs, cosmetics, and medical devices in the country. CDSCO regulates the approval of new drugs and clinical trials, oversees drug manufacturing and distribution, and enforces drug laws across India. CDSCO plays a pivotal role in the MvPI by providing support in establishing a regulatory framework for reporting, assessing, and managing adverse events associated with medical devices.

The responsibilities of CDSCO (HQ) are:

- Taking appropriate regulatory decisions and action on the basis of recommendations made

by NCC-MvPI;

- Joining International Medical Device Regulators Forum (IMDRF) and Asian Harmonization Working Party (AHWP) and other forums organized by regulatory body of other countries for exchange of post-market safety information globally via NCAR (National Competent Authority Report) form exchange programme;
- Regular meetings with the NCC-MvPI, SCTIMST & NHSRC for continuing monitoring

of medical device safety;

Communication under MvPI

An effective communication channel is a key to successful functioning of MvPI. The following chart depicts the movement of information between the key stakeholders, ensuring continuous transfer of data, information and knowledge. Following figure shows the communication flow of MvPI.



Figure 2: Communication Flow of MvPI

WHO PATIENT SAFETY INCIDENT REPORTING AND LEARNING SYSTEMS

WHO has developed and published guidance on Patient Safety Incident Reporting and Learning Systems, providing a framework for strengthening incident reporting, analysis, learning, and the implementation of corrective and preventive measures to improve patient safety. The purpose of this document is to provide an up-to-date perspective on patient safety incident reporting and learning systems including how to fill in existing gaps in these systems and also provide practical guidance on the establishment and effective use of patient safety incident reporting and learning systems.

Process for Responding to a patient safety incident report

The most important capability of a patient safety incident reporting and learning system must surely be its effectiveness in reducing future harm of the kind that is being reported to it.



Figure 3: Responding to a patient safety incident report

WHO Minimal Information Model for Patient Safety Incident Reporting and Learning Systems - as per WHO Minimal Information

Model for Patient Safety Incident Reporting and Learning Systems, helps to identify minimal data elements to be captured for incident reporting.

PATIENT INFORMATION

Age
Sex

INCIDENT TIME

INCIDENT LOCATION

AGENT(S) INVOLVED

(Suspected) cause?
Contributing factor?
Mitigating factor?

INCIDENT TYPE

INCIDENT OUTCOME

RESULTING ACTION

REPORTER'S ROLE

Figure 4: Minimal Information Model for Patient Safety Incident Reporting and Learning Systems

ROLES AND RESPONSIBILITIES OF STAKEHOLDERS UNDER MVPI

5.1 Personnel at National Coordination Centre - Indian Pharmacopoeia Commission (NCC-IPC):

The main responsibility of NCC-IPC is to coordinate with all partners of the programme and also organizing stakeholders' meetings.

- Recognition of public and private hospitals as new MDMCs and Regional Training Centres (RTCs) across the country with the help of Technical Support Group (TSG).
- Recruitment of manpower for the MvPI shall be done by NCC-IPC, and the appointed MvPI staff shall work under the administrative control of NCC-IPC.
- Any adverse event related to the use of a medical device, received directly by an NCC-IPC representative, shall be immediately communicated to the nearest MDMC for further processing.
- Conducting quality review of all Individual Case Safety Report (ICSR) submitted to NCC-MvPI and signal detection.
- Send recommendations regarding suspected medical device adverse event to CDSCO for appropriate regulatory action.
- Publication and dissemination of standard operating procedures, guidance documents, newsletters, training manuals, etc with technical support.
- Conducting capacity-building programmes for healthcare professionals, MvPI stakeholders, and other relevant personnel to strengthen their knowledge and skills in medical device adverse event reporting and materiovigilance practices.
- Coordinating and conducting the MvPI Internship Programme to provide practical training and exposure to materiovigilance activities, including medical device adverse event reporting, ICSR processing, and related programme activities.
- Publication and dissemination of resource

materials such as training materials, educational resources, awareness materials, and other relevant documents to support and strengthen materiovigilance activities across the country.

5.2 Personnel at Hospital (Public and Private):

The senior leadership and management team of the hospital play a crucial role in establishing, implementing, and sustaining an effective materiovigilance system. In alignment with the Materiovigilance Programme of India (MvPI) and the patient safety and quality standards prescribed by the National Accreditation Board for Hospitals and Healthcare Providers (NABH), hospitals shall ensure the following:

- Ensuring the implementation of a structured system for reporting medical device-related incidents and adverse events in alignment with MvPI. The hospital shall align materiovigilance activities with existing NABH quality and safety processes, including incident reporting systems, equipment management, biomedical engineering procedures, and patient safety programmes.
- Promoting a culture of patient safety, transparency, and non-punitive reporting within the institution, consistent with the principles of quality and patient safety promoted under NABH accreditation standards.
- Allocating adequate resources, including trained personnel, infrastructure, and time, to support materiovigilance activities.
- Designating a nodal officer or establishing a MDMC, where applicable, for coordination of reporting and surveillance activities.
- Ensuring regular training and awareness programs for healthcare professionals on identification and reporting of medical device

associated adverse events. All clinical, nursing, and biomedical staff shall be trained and encouraged to identify device malfunctions, failures, or performance issues. The hospital must ensure timely internal reporting and onward submission of MDAEs as per MVPI guidelines.

- Maintaining complete and accurate records of device-related incidents, preventive maintenance logs, calibration records, and root-cause analysis. Documentation must be aligned with MVPI reporting formats and meet the requirements laid down under NABH standards. All significant or recurrent adverse events must undergo structured root cause analysis (RCA). The hospital shall implement Corrective and Preventive Actions (CAPA) in accordance with NABH's continuous quality improvement framework and monitor their effectiveness.
- Facilitating timely communication and reporting of adverse events to NCC-IPC and relevant regulatory authorities, as required.
- Ensuring compliance with applicable regulatory requirements and institutional policies related to medical device safety and reporting.

5.3 Personnel at Medical Device Adverse Event Monitoring Centre (MDMC):

Each MDMC under MvPI is assigned with a Coordinator and Deputy Coordinator. If approved, a Materiovigilance Associate can also be assigned to the MDMC. Their roles and responsibilities are:

- The designated Coordinator is responsible for proper functioning of the respective MDMC. In absence of the Coordinator, the designated Deputy Coordinator is responsible for the smooth functioning of the centre. Standard

Operating Procedures (SOPs) provided to the MDMC by NCC-MvPI, IPC shall be strictly adhered by the Coordinator, Deputy Coordinator and Materiovigilance Associate (MvA) at respective MDMC.

- Ensuring awareness among healthcare professionals and patients regarding medical device safety alerts and emerging safety signals issued by NCC-IPC, thereby promoting timely action and enhancing patient and user safety. The Materiovigilance Associate is responsible for collection and follow-up of all MDAEs. All scrutinized and signed MDAE reports have to be sent for central assessment to NCC-MvPI, IPC. MDAE reports should be submitted promptly upon completion to ensure timely assessment, signal detection, and appropriate follow-up actions.
- Ensuring timely fulfilment of commitments and responding promptly to requests from competent authorities/NCC-IPC by providing accurate, complete, and relevant information. Ensuring the accuracy, completeness, consistency, and overall quality of data submitted to NCC-IPC. The Coordinator is responsible for compiling and submitting the consolidated monthly reports of the respective MDMC to NCC-MvPI, IPC in a timely and accurate manner. In addition to reactive investigation or report preparation done by MDMC, proactive investigation and risk-based information from global regulators have to be reported as and when it's observed.
- Ensuring the constitution of the Materiovigilance Expert Committee (MEC) and facilitating its meetings at regular and timely intervals for effective review and assessment of medical device adverse events. Maintaining comprehensive records of training, Continuing Medical Education (CME), awareness, and sensitization programmes on materiovigilance

conducted by the MDMC and providing the relevant details to NCC-MvPI, IPC as required. Maintaining the confidentiality of the communications/ correspondence to and from NCC-IPC such as MDAE reports, safety alerts, etc.

- Establishing and maintaining an effective mechanism for the traceability and follow-up of MDAE reports, including causality assessment, while ensuring their proper handling, documentation, and secure storage to facilitate timely retrieval and verification by NCC-MvPI, IPC or competent authorities, whenever required. The MDMC Coordinator shall ensure that appropriate and timely feedback is provided to all healthcare professionals involved in the reporting of MDAEs.

5.4 Personnel at Regional Training Centre (RTC):

Based on the number of MDMCs operating within a particular region, a Regional Training Centre (RTC) may be designated to facilitate the effective coordination and smooth implementation of MvPI activities. The MDMC Coordinator/Deputy Coordinator shall provide consent to undertake the additional responsibilities associated with the RTC. The MDMC proposed for designation as an RTC should demonstrate active and consistent engagement in MvPI activities, including quality and quantity of MDAE reporting, regular materiovigilance training and sensitization programmes, and public outreach and awareness activities. Their roles and responsibilities are:

- The RTC shall fulfil its responsibilities as MDMC and shall also provide training and technical support to MDMCs of their respective region.
- RTC shall engage in the MvPI expansion

activities and encourage institutions/ hospitals to get enrolled under MvPI as new MDMC. RTC shall also assist NCC-MvPI IPC for identifying and evaluating proposal for new MDMCs as and when required.

- RTC shall ensure implementation of materiovigilance system at MDMCs in all states/ UTs under their purview.
- RTC shall coordinate with the concerned regional CDSCO offices, State regulatory authorities, and IPC Zonal Offices to facilitate necessary support, guidance, and assistance for the effective implementation of MvPI activities. RTC shall organize periodic MDMC review meetings with Coordinators/ deputy-coordinators and MvAs to review the performance of MDMCs under their jurisdiction (at least twice in a year), to improve functioning of MDMC and report shall be sent for information to NCC-MvPI, IPC.
- RTC shall convene periodic interactive review meetings (preferably twice in a year or as and when required) with the poor or non-performing MDMCs to encourage them to report MDAEs
- RTC shall develop promotional materials like pamphlets/ poster/ resource material/ radio jingles/ television promotions to sensitize consumer and healthcare professionals in regional languages.
- RTC shall conduct regular sensitization/ awareness programmes for Healthcare Professionals (HCPs) (doctors, nurses, pharmacists, medical & pharmacy students and others), consumers (patients, care-givers and general public) at MDMC or peripheral centres.
- RTC shall organize regular community level consumer awareness programmes to sensitize general public about reporting of MDAE under MvPI.
- RTC shall conduct at least one CME/ Advance Level Training (ALT) per year with prior

approval from NCC-MvPI, IPC.

- The RTC shall establish and maintain effective coordination with officials associated with public health programmes in their respective region to facilitate integration of materiovigilance activities with ongoing public health initiatives.

5.5 Healthcare Professionals (HCP):

HCPs shall educate and inform patients/users about medical device adverse events (MDAEs), including the importance of reporting suspected adverse events, and encourage them to report any device-related concerns or incidents through the appropriate MvPI reporting mechanism. HCPs shall remain vigilant for any medical device malfunction, failure, abnormal performance, or unexpected patient outcome during device use and shall ensure prompt reporting of any suspected device-related incident or adverse event observed in the clinical setting through the appropriate MvPI reporting mechanism. HCPs associated with an MDMC shall promptly report any suspected MDAE to the MDMC Coordinator/ authorized personnel, who shall ensure its timely submission through ADRMS or any other reporting modalities. HCPs who are not associated with any MDMC shall submit the MDAE report through the designated reporting form (available on - Medical Device Adverse Event Reporting form for Licence Holders & Health Care Professionals (English Editable version) - Indian Pharmacopoeia Commission) and email the filled form to mvpi-ipc@gov.in or shatrunajay.ipc@gov.in or can also register on the ADRMS portal as a Healthcare Professional to report MDAEs directly.

5.6 Market Authorisation Holders (MAH):

The MAH shall develop, implement,

document, and maintain an effective Post-Market Surveillance (PMS) plan to systematically monitor the safety, performance, and quality of its medical devices throughout their lifecycle. The MAH shall review all complaints, incident reports, and adverse events associated with its medical devices received from hospitals, healthcare professionals, patients, distributors, and other relevant sources, and shall promptly investigate reported incidents to determine the root cause, contributing factors, and potential risk of recurrence. The MAH shall submit a complete and detailed MDAE report to NCC-MvPI, IPC for any incident that meets the reporting criteria specified under MvPI, within the prescribed timelines.

5.7 Consumers/Patients:

- Patient shall immediately inform the treating hospital, healthcare professional, or clinic if the device does not function properly or if an adverse event occurs.
- Patient shall provide accurate details such as:
- Date and description of the incident
- Time and circumstances under which it occurred
- Device details (name, model, lot/batch number)

Consumers who are Healthcare Professionals associated with an MDMC shall promptly inform the concerned MDMC Coordinator regarding any suspected MDAE to facilitate completion and submission of the MDAE report through ADRMS or other reporting modalities. Consumers who are not associated with any MDMC may directly report any suspected MDAE by completing the 'Consumer MDAE Form' available on the official IPC website -

MEDICAL DEVICE ADVERSE EVENT MONITORING CENTRE

6.1 Enrol as MDMC under MvPI

Any institution/hospital healthcare setting desiring to function as MDMC under the MvPI can enrol themselves on the ADRMS portal. MvPI aims to strengthen the monitoring of medical devices including IVDs across all levels of healthcare, whether in primary, secondary, or tertiary care hospitals. By participating in this programme, hospitals contribute in improving the quality and promoting safety and performance of medical devices through enhanced reporting and systematic tracking of adverse events.

6.2 Medical Device Adverse Events Monitoring System

6.2.1 Tertiary Care Hospitals

Tertiary care hospitals represent the highest level of the healthcare system, providing advanced diagnostic facilities, super-specialty services and comprehensive management of complex & high-risk cases. Given the complexity and intensity of device use, establishing a robust Materiovigilance system in these settings is essential for the timely identification, reporting and analysis of MDAEs.

These centres also serve as important hubs for capacity-building. They can provide opportunities for training HCPs, postgraduate students, nursing personnel and paramedical staff for adverse event reporting. Their multidisciplinary expertise and established reporting mechanisms make them well suited for conducting RCA, identifying device-related safety concerns, generating evidence-based recommendations and facilitating CAPA. Through regular feedback, knowledge sharing and collaboration with national stakeholders, these centres can significantly contribute to strengthening MvPI and the overall medical device safety ecosystem.

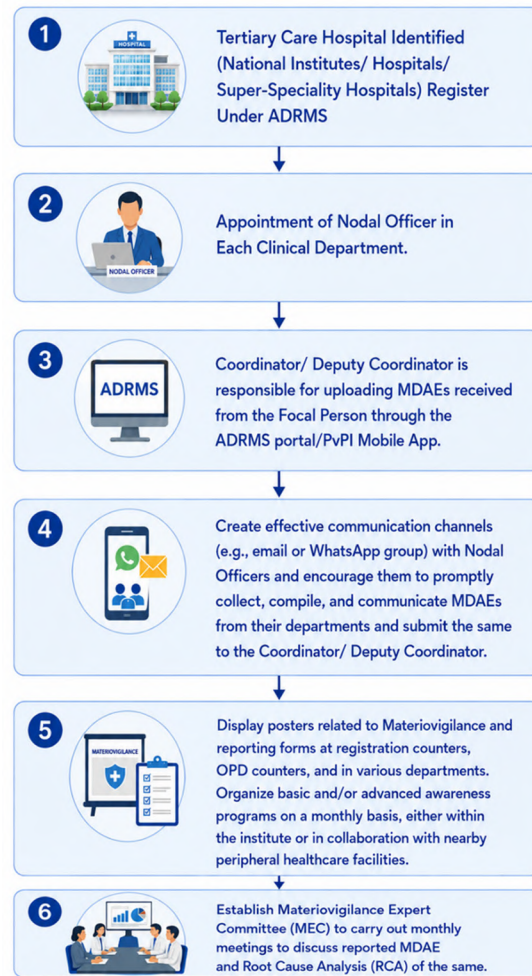


Figure 5: Setup of Materiovigilance System in Tertiary Care Hospitals

6.2.2 Secondary Care Hospitals

Secondary care facilities, including Community Health Centres (CHCs) and sub-district hospitals, generally provide specialized healthcare services, including specialist consultations, diagnostic facilities, emergency care, and inpatient services, typically with approximately 30–100 beds. These facilities serve as an important link between primary and tertiary healthcare and are increasingly equipped with a diverse range of medical devices. Their integration into MvPI can also support capacity-building among healthcare

professionals and enhance awareness and reporting of device-related safety concerns at the district and sub-district levels.

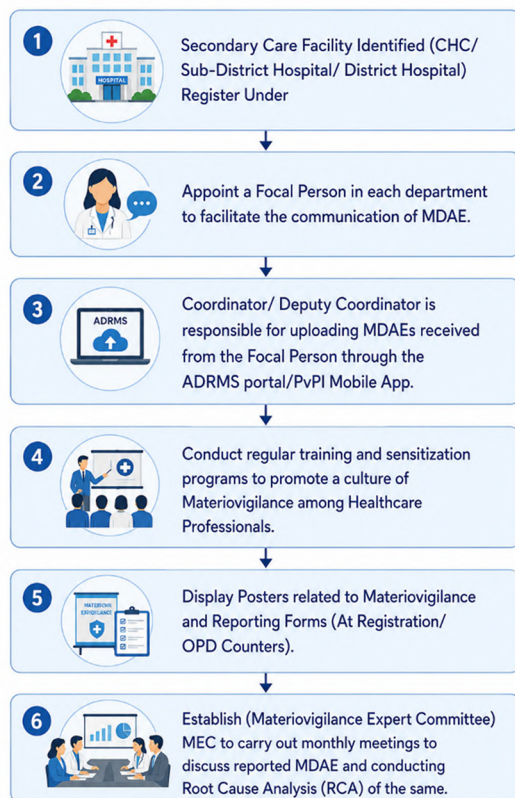


Figure 6: Setup of Materiovigilance System in Secondary Care Hospitals

6.2.3 Primary Care Hospitals

Primary healthcare facilities constitute the first and most accessible point of contact between the community and the healthcare delivery system, particularly in rural, remote, and underserved areas. These facilities include Sub-Centres (SCs), often supported by Auxiliary Nurse Midwives (ANMs), and Primary Health Centres (PHCs), which provide essential services such as basic diagnosis and treatment, immunization, maternal and child healthcare, screening and preventive care.

Establishing a structured Materiovigilance

framework at the primary healthcare level is essential, as MDAEs may first be identified in these facilities. Equipping healthcare personnel with the knowledge and mechanisms to recognize, document, and report MDAEs enables early detection and timely escalation, reducing recurrence and potential patient harm. A functional system also strengthens the national medical device safety surveillance network by promoting a culture of device safety among medical officers, ANMs, nurses, laboratory personnel, technicians, and frontline workers. Strengthening Materiovigilance at the grassroots level is therefore essential for building a comprehensive and patient-centred medical device safety surveillance system.

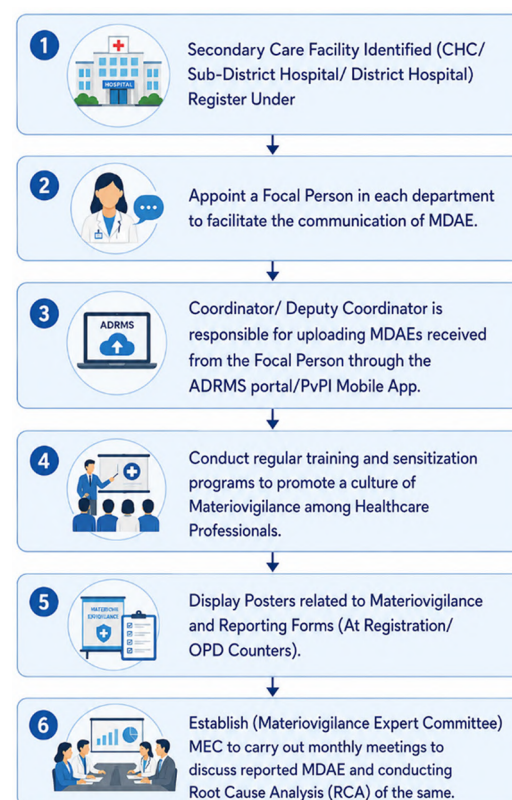


Figure 7: Setup of Materiovigilance System in Primary Care Hospitals

REPORTING, COLLECTION, COMPILATION AND ANALYSIS OF MDAE

Medical devices are an indispensable component of modern healthcare delivery and are widely used for diagnosis, monitoring, treatment, and life-support. However, their use may be associated with adverse events arising from device malfunction, design or manufacturing defects, improper use, or other contributing factors, potentially resulting in patient harm and increased healthcare costs. The primary objective of the Materiovigilance Programme of India (MvPI) is to enhance the safety of patients and users by facilitating the timely identification, assessment, and prevention of adverse events associated with medical devices and reducing their recurrence.

Systematic reporting, comprehensive collection, accurate compilation, and continuous analysis of Medical Device Adverse Events (MDAEs) are fundamental components of an effective Materiovigilance system. Hospitals, particularly those with established multidisciplinary healthcare teams and diverse medical device use, play a pivotal role in this process. Timely reporting from healthcare facilities enables the early detection of emerging safety signals, identification of device-related risks and failure patterns, Root Cause Analysis, and generation of evidence-based recommendations for appropriate corrective and preventive actions.

A robust hospital-based MDAE reporting and surveillance system therefore serves as a critical link between frontline healthcare delivery and the national Materiovigilance framework, ultimately contributing to patient safety, improved quality of healthcare, and protection of public health.

7.1 Reporting an adverse event

An adverse event potentially associated with a medical device may be identified by healthcare professionals, patients, caregivers, or other hospital personnel at any stage of the device lifecycle, including during clinical use, installation, maintenance, servicing, or post-procedure follow-up. All suspected Medical Device Adverse Events (MDAEs) should be reported promptly, irrespective of whether a definitive causal relationship between the medical device and the reported event has been established. Early reporting of suspected events facilitates timely assessment, investigation, signal detection, and implementation of appropriate corrective or preventive measures to enhance patient and user safety.

7.1.1 Reportable Adverse events

A reportable adverse event in medical devices can be any incident where a medical device causes, or could potentially cause, serious injury or deterioration in the health of the subject or death to a patient, user, or other person, and needs to be reported to health authorities.

To promote and strengthen a culture of proactive reporting, the MvPI encourages the reporting of all suspected adverse events associated with medical devices, irrespective of whether the event is known or previously unrecognized, serious or non-serious, common or rare. Such comprehensive reporting enables the timely identification of emerging safety concerns, supports effective signal detection, and contributes to the continuous improvement of medical device safety and patient protection.

The examples and case scenarios for reportable adverse events are mentioned in Annexure- I

7.1.2 Exemption from reporting

Event or Incident not to be reported: An adverse event involving a medical device does not need to be reported under vigilance systems when the root cause is solely due to the device exceeding its specified service-life or shelf-life, and the failure is not unusual. Similarly, if a built-in safety mechanism works as intended and prevents harm, reporting is unnecessary. Expected and well-documented side effects that are clinically acceptable and within assessed risk parameters are also not reportable. Also, an event resulting solely from the reuse or reprocessing of a medical device labelled for single use, contrary to the manufacturer's IFU, is generally not reportable when the event is attributable to such unauthorized reuse.

The examples and case scenarios for events that do not require reporting are mentioned in Annexure- II.

7.1.3 Decision Process

Any suspected adverse event associated with a medical device that fulfils all three basic reporting criteria specified below should be considered reportable and submitted through the appropriate materiovigilance reporting system. As a guiding principle, when there is uncertainty regarding the reportability of an event, the preference should be to report rather than not report. A precautionary approach to reporting supports comprehensive safety surveillance, facilitates early identification of emerging safety signals, and helps prevent recurrence of potentially harmful device-related incidents.

Reporting Criteria:

a) An Event has occurred:

An adverse event or unexpected, undesirable

incident has occurred in association/suspicion with the use of a medical device. Typical adverse events are as follows:

i) **Malfunction/ deterioration in performance/deviation against claim made by manufacturer**

ii) **Incorrect or out of specification test result**

iii) **Design flaw**

iv) **Inaccuracy in labelling**

v) **Discovery of serious public health threat**

vi) **Use error, etc.**

b) **Device is associated with the event: A medical device is suspected to have caused the adverse event.**

During identifying the association between a device and an adverse event, the following can be taken into account:

i) **The opinion, based on available information, from a healthcare professional**

ii) **Information concerning previous similar events**

iii) **Complaint trends**

iv) **Other information held by the manufacturer**

This identification can be difficult when there are multiple devices and drugs involved. In complex situations always assume that device is associated with the adverse event.

c) Event Outcome:

The possible outcomes of the adverse event are as follows:

i) **Death of the patient, user or other person**

ii) **Serious injury of a patient, user or other person**

iii) **No death or serious injury occurred but the event might lead to death or serious injury of a patient, user or other person if the event recurs**

iv) **Near Miss Incident (A Near miss event is an unplanned event that did not result in injury, illness, or damage – but had the potential to do so)**

The flowchart shown in the below image

provides a structured approach to help hospitals and healthcare professionals decide whether an observed medical device–related incident or adverse event should be reported, and to whom and within what timeline.

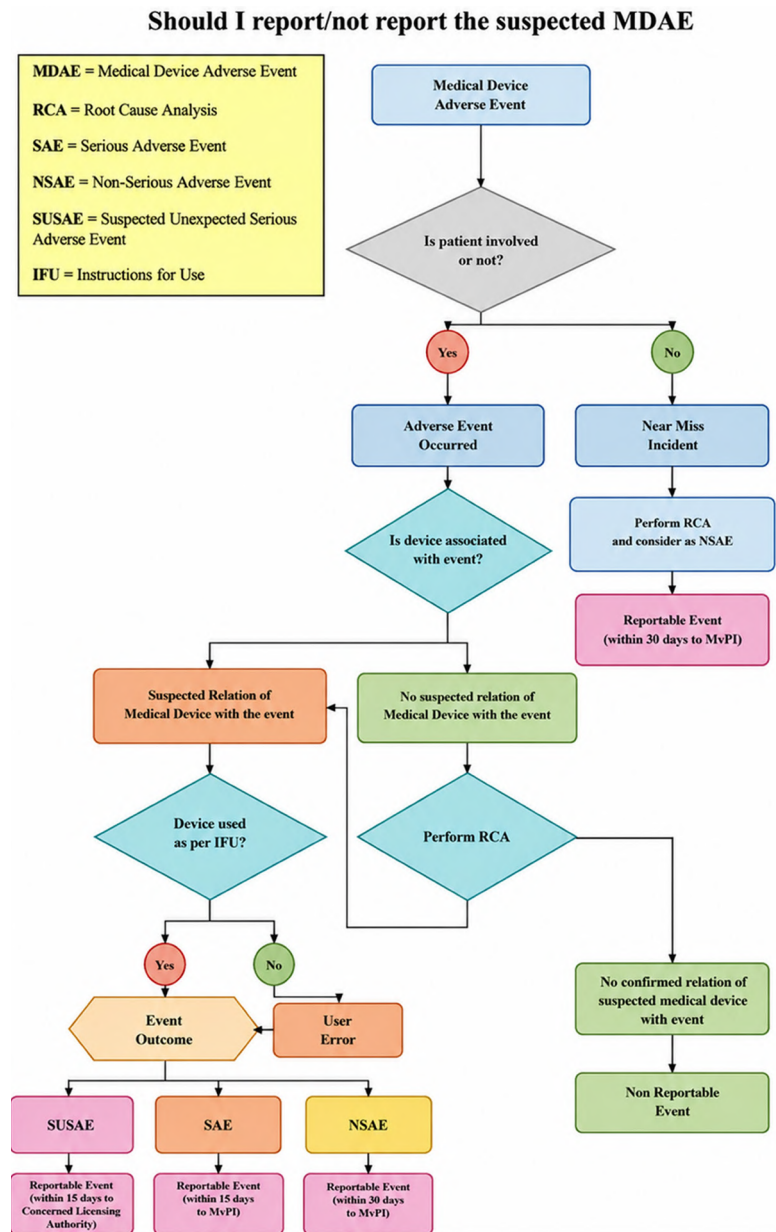


Figure 8: Tree for deciding whether to report/not report the suspected MDAE

1. The process begins when a Medical Device Adverse Event is suspected. Once such an issue is identified, the next step is to assess whether a patient or user was involved.

2. Was a Patient or User Involved?

Yes – Patient/User Involved

If the event occurred during the actual use of a medical device and involved a patient or user, it is classified as an Adverse Event. Such events require further evaluation to determine whether the medical device may have contributed to the occurrence, and the assessment should proceed to the third step of evaluating device association with the event.

No – Patient/User Not Involved

If no patient or user was involved, the incident is classified as a Near Miss Incident, such as a device malfunction or quality issue identified before actual use. In such cases, RCA should be performed to understand the underlying cause and assess the potential risk. If the analysis indicates that the incident could potentially cause harm to a patient or user during future use, the event should be considered a Non-Serious Adverse Event (NSAE). These events are reportable to the MvPI within 30 days, even though no harm has occurred, as reporting helps prevent recurrence and enhances patient safety.

3. Device Association with the Event

The next step is to determine whether the medical device is suspected to be associated with the event.

a) Suspected Relation with the Medical Device

If the device may have contributed to the

event, assess whether it was used as per the Instructions for Use (IFU).

Used as per IFU –Assess event outcome.

Not used as per IFU –Event categorized as User Error, but still reportable depending on outcome.

Based on the severity of the outcome, events are classified as follows:

• SUSAE (Suspected Unexpected Serious Adverse Event)

A serious event that is unexpected based on known device safety information.

Examples include:

- **Death**
- **Life-threatening condition**
- **Permanent disability**
- **Congenital anomaly**

Report to the Concerned Licensing

Authority within 15 days

• SAE (Serious Adverse Event)

An event resulting in:

- **a death; or**
- **a serious deterioration in the health**

of the subject that either-

- **resulted in a life-threatening illness**

or injury; or

- **resulted in a permanent impairment of a body structure or a body function; or**

or

- **required in-patient hospitalisation or prolongation of existing hospitalization;**

- **resulted in medical or surgical intervention to prevent life threatening illness or injury or**

or

- **permanent impairment to a body structure or a body function; or**

- **foetal distress, foetal death or a congenital abnormality or birth defect.**

Report to MvPI within 15 days

- **NSAE (Non-Serious Adverse Event)**

Incidents which might have caused death or serious deterioration in health for the patient, end user or other individual.

Report to MvPI within 30 days

b) No Suspected Relation with the Medical

Device

If, after evaluation and RCA, it is concluded that there is no causal relationship between the medical device and the event

The incident is classified as a Non-Reportable Event

Reporter	What to Report	Regulatory Provision	To Whom	When
Marketing authorization holder/ Medical Device licence Holders	Any suspected unexpected serious adverse event incident like deaths, serious injuries, malfunction etc. and action taken thereon including any recall	As per applicable provisions of the Medical Devices Rules (MDR), 2017	• State Licensing Authority (SLA) or Central Licensing Authority (CLA) (as applicable) • National Coordination Centre – IPC (MvPI)	Within 15 calendar days of becoming aware of an event.
User facilities (Healthcare facilities, Consumers, Healthcare professionals, etc.) and Marketing authorization holder/ Medical Device licence Holders	Any Serious/ Non-Serious/ Near-miss incidents.	Notified under the Materiovigilance Programme of India (MvPI)	National Coordination Centre – IPC(MvPI)	For SAE-Within 15 calendar days of becoming aware of an event. For NSAE- Within 30 calendar days of becoming aware of an event.

Note: Although reporting by healthcare professionals (HCPs) and users is voluntary, MvPI encourages all stakeholders - including MAHs, HCPs, patients/ consumers, caregivers, and other users to promptly report any suspected Medical Device Adverse Event, preferably as soon as it is identified. Timely reporting strengthens safety surveillance, facilitates early signal detection, and supports appropriate corrective and regulatory actions to protect patients and users.

7.1.5 Information required while reporting

- Report Information– Basic case details including report type (initial/final/follow-up or trend), seriousness, date of event/report, place of occurrence, medical confirmation, and supporting documents (if available).
- Reporter / Primary Source Information– Details of the healthcare professional, hospital, patient, or user who first observed or reported the event.
- Medical Device Information– Device category, risk class, license type, device name, manufacturer/importer details, and identification details (batch/serial/lot/Unique Device Identification, if available).
- Device Usage Details – Information on installation, expiry, maintenance, calibration, duration of use, and whether used as per IFU.
- Event Details – Date and location of event, device operator, event description, adverse event category, near-miss (if any), and event outcome.
- Patient Information – Relevant medical history, past drug history, and previous medical device usage, if applicable.
- Hospitalization / Death Details– Hospitalization dates, treatment provided, discharge summary, or death details including cause and supporting documents.
- Tests and Procedures– Relevant diagnostic tests, procedures performed, results, reference ranges, and attached reports.

- Assessment and Action Taken–Causality assessment, investigation findings, root cause, risk analysis, and corrective/preventive actions (if known).

7.1.6 Reporting Modalities

MvPI-IPC has launched various reporting tools to assist the stakeholders in reporting the MDAE. There are 5 different forms which are given below:

1) Reporting Forms – available in the Indian Pharmacopoeia Commission Website (<https://ipc.gov.in/mandates/materiovigilance-programme-of-india-mvpi/mvpi-toolkit.html>).

- i) **Medical Device Adverse Event Reporting form for Licence Holders & Health Care Professionals (English Editable version) (Annexure III)**
- ii) **Medical Device Adverse Event Reporting form for Licence Holders & Health Care Professionals (Hindi Editable version) (Annexure IV)**
- iii) **Medical Device Adverse Event Reporting form for Consumers/Users (Annexure V)**
- iv) **Personal Protective Equipment (PPEs) Form (Annexure VI)**
- v) **In-Vitro Diagnostic (IVD) Form (Annexure VII)**

2) Adverse Drug Reactions Monitoring System (ADRMS) –

ADRMS is an indigenous adverse event reporting and monitoring system developed by the IPC, Ministry of Health & Family Welfare, Government of India, to facilitate the reporting, collection, and monitoring of adverse events associated with medical products, including medicines, vaccines, and medical devices.

There are three types of account in ADRMS such as,

- i) **Program Coordinators:** MDMCs designate a Coordinator and Deputy Coordinator to oversee and facilitate the implementation of Materiovigilance activities at the centre. The designated personnel serve as key points of contact for identifying,

documenting, reviewing, and reporting Medical Device Adverse Events, while also promoting awareness and adherence to MvPI reporting practices among healthcare professionals. These officials can register as “Programme Coordinator” and are responsible for managing the reporting, monitoring, and follow-up of medical device-related adverse events within their respective centres.

ii) Healthcare Professionals: Biomedical Engineers, Nurses, Pharmacists, and other healthcare professionals may register as “Healthcare Professional” and report adverse events associated with medical devices when the healthcare facility where they work is not enrolled as an MDMC. They may also encourage their healthcare facility to enrol as an MDMC and contact MvPI through Mvpi-ipc@gov.in for further information and assistance.

iii) Consumers: Individuals using medical devices or aware of any adverse event linked with medical device, can also register as consumers to directly report such adverse events to the NCC-IPC.

Note: Consumers can report suspected Medical Device Adverse Events without prior registration on ADRMS by directly completing the relevant reporting form available on the IPC website.

The ADRMS can be accessed by visiting the following link -<https://adrmsipc.in/adrms/index.html>.

Refer Annexure VIII for enrolment procedure in ADRMS.

Refer Annexure IX for the procedure to report and fill the MDAE form in ADRMS.

Helpline Number – IPC has established a toll-free helpline (1800-180-3024) to facilitate prompt reporting of suspected adverse events by consumers and other stakeholders. The helpline provides assistance in understanding the reporting process and supports individuals in communicating relevant details of a suspected adverse event in their own regional language, thereby promoting timely

reporting and strengthening patient and consumer participation in Materiovigilance. The helpline is available in the following languages:

- a. English
- b. Hindi
- c. Marathi
- d. Gujarati
- e. Bangla
- f. Telugu
- g. Kannada
- h. Tamil
- i. Malayalam
- j. Odia

3) PvPI Mobile App – The PvPI mobile application 2.0, developed by the IPC, enables hospitals and healthcare professionals and consumers to report medical device-related adverse events easily and promptly. Available in English and Hindi, it supports voluntary, confidential, and non-punitive reporting, thereby strengthening patient safety and



Figure 9: QR Code for PvPI Mobile Application

national Materiovigilance efforts. The application can be accessed by scanning the following QR code.

7.1.7 Online reporting platform - Adverse Drug Reactions Monitoring System (ADRMS)

To strengthen India’s post-market surveillance ecosystem and promote a unified approach for monitoring the safety of medical products, the Adverse Drug Reactions Monitoring System (ADRMS) was launched in August 2024 by the Indian Pharmacopoeia Commission

(IPC), Ministry of Health and Family Welfare, Government of India.

ADRMS is a centralized, web-based digital platform designed to facilitate the reporting, monitoring, evaluation, and analysis of adverse events associated with medical products, including pharmaceuticals, medical devices, vaccines, and IVDs.

For MvPI, ADRMS provides a robust digital infrastructure for systematic reporting and management of medical device-related adverse events and near-miss incidents. The platform enables healthcare professionals, biomedical engineers, manufacturers, distributors, and consumers to report adverse events efficiently while improving the quality, completeness, and timeliness of safety data collection.

Objectives of ADRMS under Materiovigilance

The implementation of ADRMS under MvPI aims to achieve the following objectives:

To establish a centralized and standardized electronic reporting system for medical device adverse events.

- To improve the timeliness and quality of adverse event reporting.
- To facilitate early detection of safety signals associated with medical devices.
- To strengthen evidence-based regulatory decision-making and risk management.
- To improve communication among healthcare institutions, manufacturers, regulators, and other stakeholders.
- To enhance traceability and transparency in post-market surveillance activities.
- To support patient safety initiatives through effective monitoring of medical device performance.

Need for Digital Reporting of Medical Device Adverse Events

The increasing complexity of medical technologies and the widespread use of sophisticated medical devices across healthcare settings necessitate a modern surveillance system capable of handling large

volumes of safety data efficiently. Traditional reporting mechanisms posed several challenges, including:

- Dependence on manual documentation;
- Delayed transmission of adverse event information;
- Incomplete or inaccurate reporting;
- Difficulty in tracking and follow-up of reported events;
- Limited interoperability among stakeholders;
- Challenges in signal detection and trend analysis.

ADRMS addresses these limitations by providing a centralized, digital, and real-time reporting ecosystem that supports the entire lifecycle of adverse event management—from initial reporting to regulatory evaluation and signal detection.

Features of ADRMS

ADRMS incorporates several advanced features that improve the efficiency and effectiveness of medical device vigilance activities:

Web-Based Centralized Platform: ADRMS is a secure, web-based platform accessible through the Indian Pharmacopoeia Commission website. The system allows authorized users to submit and monitor reports electronically from any location.

Standardized Data Collection: The platform uses structured electronic reporting forms to ensure uniform collection of information related to adverse events, device details, patient characteristics, clinical outcomes, and causality assessment.

Real-Time Reporting and Monitoring:

ADRMS enables immediate electronic submission of reports, thereby reducing delays associated with paper-based systems and facilitating rapid assessment of safety concerns.

Improved Data Quality: Built-in validation checks, mandatory data fields, dropdown menus, and error detection mechanisms improve the completeness, consistency, and

accuracy of reported information.

Report Tracking and Follow-up:

The system allows users to track the status of submitted reports and facilitates communication for additional information, follow-up investigations, and regulatory actions.

Enhanced Data Security: ADRMS incorporates secure login credentials, role-based access controls, encryption mechanisms, and protected databases to ensure confidentiality and integrity of patient and reporter information.

Signal Detection and Analytics: The platform supports quantitative analysis and trend identification, thereby enabling early detection of potential safety signals associated with medical devices.

Registration on ADRMS

ADRMS supports multiple categories of users involved in medical product safety surveillance. For reporting medical device adverse events, the following stakeholders may register:

- Healthcare professionals;
- Biomedical engineers and technicians;
- Hospitals and healthcare institutions;
- Manufacturers and Market Authorization Holders (MAHs);
- Distributors and importers;
- Consumers and patients.

Registration involves submission of basic demographic information, organizational details, verification through one-time password (OTP), and approval by the Indian Pharmacopoeia Commission. Refer Annexure- VIII for detailed procedure of registration on ADRMS.

Reporting MDAE through ADRMS

ADRMS facilitates reporting of all suspected or confirmed medical device-related adverse events and incidents, including:

- Device malfunctions;
 - Performance failures;

- Design defects;
- Labeling errors;
- Software-related failures;
- Incorrect or out-of-specification results;
- User interface issues;
- Device-associated injuries;
- Near-miss incidents;
- Serious and non-serious adverse events;
- Public health threats.

The reporting process generally includes the following steps:

- User login into the ADRMS portal.
 - Selection of the appropriate medical device reporting module.
 - Entry of patient information and event details.
 - Documentation of device identification details.
 - Submission of clinical outcomes and investigation findings.
 - Upload of supporting documents, where applicable.
 - Review and final submission of the report.
- Following submission, the report is assigned a unique reference number and becomes available for evaluation by the designated monitoring centres and regulatory authorities.

Refer Annexure – IX for the detailed procedure to report and fill the MDAE form in ADRMS.

Benefits of ADRMS for Hospitals

- The adoption of ADRMS offers several advantages for hospitals participating in the Materiovigilance Programme of India:
 - Electronic reporting substantially reduces the time required for submission, processing, and follow-up of adverse event reports.
 - Structured reporting formats improve data completeness, reduce transcription errors, and facilitate accurate causality assessment.
 - Timely identification and reporting of device-related adverse events contribute to early signal detection and implementation of

corrective actions.

- ADRMS enables tracking of reports throughout the evaluation process and supports retrieval of historical safety information.
- High-quality safety data generated through ADRMS supports evidence-based regulatory interventions, including safety alerts, field safety corrective actions, recalls, and risk communication.



Figure 10: QR Code for ADRMS

7.2 Collection, Compilation and Analysis of MDAE

7.2.1 Process flow of received MDAE

Each MDAE is collected, compiled and analysed as shown below:

7.2.2 Causality Assessment

The relationship between the use of the medical device and the occurrence of each adverse event shall be assessed and categorized.

During causality assessment activity, clinical judgement shall be used and the relevant documents, such as the Brochure, the Clinical Investigation Plan or the Risk Analysis Report shall be consulted, as all the foreseeable serious adverse events and the potential risks are listed and assessed there. The presence of confounding factors, such as concomitant medication/treatment, the natural history of the underlying disease, other concurrent illness or risk factors shall also be considered. Since assessment of causality is undertaken for reported events, it is necessary to ensure a standardized report that meets certain pre-specified quality and content assurance criteria.

The following serves as themes to capture the important criteria within an adverse event report:

- Quality check for completeness of a reported case.**
- Validity of the case.**
- Follow up a case, if necessary.**

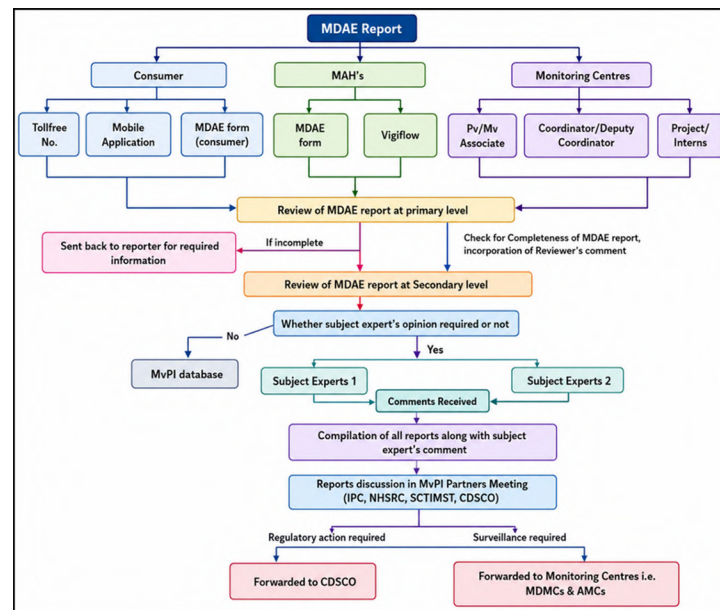


Figure 11: Process flow of received MDAE at NCC-IPC

Causality	Assessment Criteria
Not related	Relationship to the device, comparator or procedures can be excluded when: - the event has no temporal relationship with the use of the investigational device, or the procedures related to application of the investigational device; - the serious adverse event does not follow a known response pattern to the medical device (if the response pattern is previously known) and is biologically implausible; - the discontinuation of medical device application or the reduction of the level of activation/exposure - when clinically feasible - and reintroduction of its use (or increase of the level of activation/exposure), do not impact on the serious adverse event; - the event involves a body-site or an organ that cannot be affected by the device or procedure; - the serious adverse event can be attributed to another cause (e.g. an underlying or concurrent illness/ clinical condition, an effect of another device, drug, treatment or other risk factors); - the event does not depend on a false result given by the investigational device used for diagnosis (If an investigational device gives an incorrect diagnosis, the patient might, for example, receive an unnecessary treatment and incur all the risks that accompany that treatment, or might be incorrectly diagnosed with a serious disease. In other cases, the patient might not receive an effective treatment (thereby missing out on the benefits that treatment would confer) or might not be diagnosed with the correct disease or condition.), when applicable; In order to establish the non-relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious adverse event.
Possible	The relationship with the use of the investigational device or comparator, or the relationship with procedures, is weak but cannot be ruled out completely. Alternative causes are also possible (e.g. an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment). Cases where relatedness cannot be assessed, or no information has been obtained should also be classified as possible.
Probable	The relationship with the use of the investigational device or comparator, or the relationship with procedures, seems relevant and/or the event cannot be reasonably explained by another cause.
Causal relationship/ Related	The serious adverse event is associated with the investigational device, comparator or with procedures beyond reasonable doubt when: - the event is a known side effect of the product category the device belongs to or of similar devices and procedures; - the event has a temporal relationship with investigational device use/application or procedures; the event involves a body-site or organ that - the investigational device or procedures are applied to; - the investigational device or procedures have an effect on; - the serious adverse event follows a known response pattern to the medical device (if the response pattern is previously known); - the discontinuation of medical device application (or reduction of the level of activation/exposure) and reintroduction of its use (or increase of the level of activation/exposure), impact on the serious adverse event (when clinically feasible); - other possible causes (e.g. an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment) have been adequately ruled out; - harm to the subject is due to error in use; - the event depends on a false result given by the investigational device used for diagnosis (f an investigational device gives an incorrect diagnosis, the patient might, for example, receive an unnecessary treatment and incur all the risks that accompany that treatment, or might be incorrectly diagnosed with a serious disease. In other cases, the patient might not receive an effective treatment (thereby missing out on the benefits that treatment would confer), or might not be diagnosed with the correct disease or condition.), when applicable; In order to establish the relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious adverse event.

7.2.3 Signal Detection

There is a substantial difference between signal detection for pharmaceuticals and medical devices, primarily due to the inherent complexity of medical devices. Pharmaceutical products generally contain one or a limited number of active pharmaceutical ingredients (APIs), whereas a single medical device may comprise multiple components, materials, software, and technologies, each potentially contributing to device performance or failure.

Consequently, signal detection in Medication Vigilance often requires a more comprehensive and multidisciplinary approach, involving detailed assessment of device design, materials, manufacturing processes, software, user interaction, maintenance, and clinical use. This complexity makes Root Cause Analysis (RCA) particularly important for identifying the underlying factors contributing to medical device-related adverse events and distinguishing isolated incidents from emerging safety signals.

Signal detection involves identifying patterns of adverse events associated with

a particular device that warrant further investigation.

A medical device safety signal may arise from: -

- a previously unrecognized safety issue
- a change in frequency or severity of a known safety issue
- identification of a new at-risk group
- use of a device other than the intended purpose by the manufacturer

Based on the completed root cause analysis report, events/ incidents would be classified as per above mentioned signals or classification of signals after discussion in core technical committee of MvPI. Signals would be used as markers for trend analysis.

As soon as a safety signal has been detected, it is assessed to determine the nature, magnitude and significance of the concern, and the impact on the overall benefit-risk profile of the device. The complete analysis of the signals detected has to be initiated after getting enough adverse events reports.



ACTIVE SURVEILLANCE OF CRITICAL MEDICAL DEVICES

Active surveillance is essential for the early identification of potential safety concerns associated with critical and life-saving medical devices, particularly those used in high-risk clinical settings such as intensive care, cardiology, neurosurgery, oncology, and emergency care. Hospitals should establish a structured and proactive monitoring mechanism for such devices, including regular review of device performance, adverse events, malfunctions, complaints, and near-miss incidents. Integrating active surveillance into routine patient safety and Materiovigilance activities can facilitate timely signal detection, Root Cause Analysis, and implementation of appropriate corrective and preventive measures, thereby reducing the risk of recurrence and improving patient and user safety.

8.1 Routine Monitoring of Critical Medical Devices

Hospitals shall routinely monitor a list of identified critical medical devices (Annexure X) on a weekly or monthly basis, depending on usage and risk profile. These devices typically include those that are invasive, implantable, life-supporting, or associated with serious outcomes in case of malfunction.

8.2 Display of Monitored Device List

The list of critical medical devices under active surveillance shall be displayed prominently in the respective clinical departments, such as intensive care units, operation theatres, catheterization laboratories, and specialty wards, to ensure awareness among healthcare professionals.

8.3 Departmental Responsibility

A designated nodal person shall be identified in each department to oversee the active surveillance activities. The nodal person shall be responsible for:

- Regular monitoring of device performance
- Sensitizing staff regarding potential risks
- Ensuring timely reporting of incidents or adverse events

8.4 Reporting of Events

Any adverse event, incident, near-miss, or

malfunction related to the monitored devices shall be promptly reported to NCC-MvPI, IPC, in accordance with the prescribed timelines.

8.5 List of Medical Devices Under Safety Alert

As part of active surveillance, hospitals shall give special attention to medical devices for which safety alerts or advisories have been issued by IPC under MvPI. These devices are considered critical for enhanced monitoring due to identified or potential safety concerns.

The list of such medical devices shall:

- Be communicated to hospitals through official IPC safety alerts.
- Be periodically updated based on ongoing signal detection and assessments.
- Form part of the hospital's active surveillance list for critical medical devices.

Hospitals are advised to ensure heightened vigilance, proper documentation, and prompt reporting of any suspected adverse events associated with these devices to support national-level safety monitoring and regulatory decision-making.

Refer Annexure X for the list of critical medical devices.

Note: The list of safety alerts is regularly updated and maintained on the official website of the Indian Pharmacopoeia Commission (IPC). For the latest and updated safety alerts, refer to the IPC website.



COMMUNICATION OF SAFETY ALERTS

The National Coordinating Centre - Materiovigilance Programme of India (NCC-MvPI) at the IPC continuously monitors and analyses reported Medical Device Adverse Events to identify potential safety signals and emerging device-related risks. Suspected signals are subjected to a structured scientific assessment, including evaluation of the available clinical and device-related information, consistency of reported events, frequency, seriousness, and potential causal association.

Potential safety signals identified through this surveillance process are further reviewed during internal scientific review meetings at IPC and through consultations with relevant programme partners and stakeholders. These discussions may involve subject matter experts, medical device specialists, clinicians, investigators, and regulatory representatives, as appropriate. This multidisciplinary review helps strengthen signal assessment, facilitate root cause analysis where required, and support the development of evidence-based recommendations and appropriate regulatory or risk-minimization measures to enhance patient and user safety.

If, based on the available clinical, technical, and scientific evidence, a plausible causal relationship between the medical device and the reported adverse event is established or strongly suspected, NCC-MvPI, IPC communicates its evidence-based assessment and recommendations to the Central Drugs Standard Control Organization (CDSCO) for consideration of appropriate regulatory action.

The recommendations are intended to support timely risk mitigation and help prevent the recurrence of similar adverse events. Depending on the nature, severity, frequency, and potential public health impact of the identified safety concern, the recommended regulatory measures may include initiating or requesting further investigation, seeking additional information or technical assessment from the manufacturer or other relevant stakeholders, issuing safety communications or alerts to healthcare professionals and users, implementing corrective or preventive measures, conducting enhanced post-market surveillance, or initiating product recall or withdrawal from the market. Other regulatory or risk-minimization measures may also be

recommended, as considered appropriate by the competent regulatory authority under the applicable provisions of the Medical Devices Rules, 2017.

In situations where a potential causal association between a medical device and an adverse event is suspected based on the available evidence, but cannot yet be conclusively established, NCC-MvPI, IPC may issue safety alerts to MDMCs and Adverse Drug Reaction Monitoring Centres (AMCs). Such alerts serve as an important risk communication and signal-strengthening mechanism, enabling healthcare professionals to remain vigilant and facilitate the early identification of similar or recurrent adverse events associated with the concerned medical device.

The safety alerts are intended to promote heightened awareness among healthcare professionals and encourage closer clinical monitoring of patients exposed to the suspected device. They also facilitate the systematic collection of additional information, including details regarding the device, patient characteristics, clinical presentation, device-related factors, and outcomes, which may help strengthen or refute the suspected safety signal. Hospitals and healthcare facilities receiving such alerts are encouraged to promptly review and disseminate the information among relevant clinical and technical personnel, particularly those involved in the procurement, use, maintenance, and monitoring of the concerned medical device.

Where appropriate, healthcare facilities should strengthen surveillance of patients using the specified device, review relevant clinical records, and ensure timely reporting of any new or similar adverse events through the established Materiovigilance Programme reporting mechanisms. The additional reports and supporting information generated through enhanced monitoring can contribute to further signal assessment by NCC-MvPI, IPC and may assist in determining whether the observed association represents a consistent and clinically meaningful safety concern. Depending on the strength of the emerging evidence, the findings may subsequently support further investigation, additional risk communication, or evidence-based regulatory action in coordination with the competent regulatory authority.

BASELINE STUDIES
OF RECALL/ FIELD
SAFETY NOTICE ISSUED
BY MEDICAL DEVICE
REGULATORS ACROSS
THE GLOBE

Baseline studies may be undertaken to systematically assess the availability, utilization, distribution, and safety status of medical devices in India that have been subjected to recalls, Field Safety Corrective Actions (FSCAs), Field Safety Notices (FSNs), or other significant safety-related regulatory actions by national or international regulatory authorities. Such actions may include those initiated by authorities such as the U.S. Food and Drug Administration (FDA), European regulatory authorities, Swissmedic, the Therapeutic Goods Administration (TGA), Australia, and other competent regulatory agencies. These studies can serve as a proactive component of post-market surveillance by determining whether affected or potentially affected devices continue to be available or in use within Indian healthcare facilities. Particular attention may be given to devices for which international regulators have identified serious safety concerns, recurring adverse events, manufacturing or design defects, performance issues, cybersecurity vulnerabilities, or other factors that may have implications for patient or user safety.

A structured and standardized questionnaire may be developed for conducting such baseline assessments. The questionnaire may capture key information, including the name and model of the device, manufacturer and importer details, device classification, unique identification or batch/lot information where available, extent of utilization, number of devices in use, patient exposure, reported adverse events, and awareness and implementation of the relevant recall, FSCA, or FSN. Information regarding corrective or preventive measures undertaken by healthcare facilities, such as device replacement, modification, withdrawal from use, enhanced monitoring, or communication to concerned healthcare professionals, may also be documented. Given the large and diverse range of medical devices available in the Indian healthcare system, comprehensive surveillance of every device subject to an international safety action may not be feasible. Therefore, a risk-based prioritization approach should be adopted, with initial focus on high-risk or life-supporting devices, implantable devices, devices associated with serious or fatal adverse events, devices with widespread utilization,

and products for which significant or emerging safety concerns have been identified by national or international regulatory authorities.

The findings from these baseline studies can help establish whether recalled or safety-alerted devices remain in use in India and assess the extent to which recommended corrective actions have been implemented at healthcare facilities. They may also help identify gaps in communication, recall effectiveness, traceability, and post-market monitoring, thereby enabling appropriate follow-up with relevant stakeholders.

Overall, baseline studies can strengthen the proactive surveillance framework of the MvPI by facilitating early identification of potentially affected devices and enabling timely generation of safety signals. The evidence generated through such studies can support risk assessment, targeted surveillance, regulatory decision-making, risk-minimization measures, and, where warranted, further investigation or regulatory action, ultimately contributing to improved safety and protection of patients and medical device users in India.

A sample questionnaire for conducting such baseline studies is provided below:

1. Device Details

- a) Type of Device**
- b) Model Number**
- c) Catalogue Number**
- d) Serial Number**
- e) UDI Number**
- f) Accessories / Associated**

Devices Affected

g) Age of Device/Date of manufacture:
(Indicates the number of years since the manufacturing date of the device)

h) How long was the device in use here: (Indicates how long the device was used)?

i) Packing condition sterile / Non sterile

j) Was the device tested during sale/installation?

k) If the device is meant for reuse

l) Is proper cleaning/ maintenance done

2. Description of incident

a. Date of Incident

b. Patient Consequences: (Includes information on the effect of the event



on patient, user or any other person(s) involved)

c. **Details of Incident: (Includes description of device(s), equipment, or drug-device combination involved in the incident, and a detailed description of what happened in the incident)**

3. Medical Records Tagging

Data would be collected from medical records also to find more details of the incident and to triangulate the findings and increase validity of the data

Baseline Causality

The research team would evaluate whether the event had any temporal relationship with the device, using different causality assessment criteria. This may include qualitative findings also like (a) action taken by licence holders with copy of final report (b) Does licence holders stick to timeframe mentioned in recall

notice or field safety corrective action notice (c) Medical device or equipment of different serial number or model number may also be observed to anticipate probable adverse events. Baseline studies also include documenting the correlation between the devices that are recalled by regulators in any country across the globe and the same model or type or category of medical device sold in India, which could have the potential of causing an adverse event or a near-miss incident to Indian citizen.

Timeframe and submission of report

The study has to be initiated when NCC- IPC or any other MDMC centre alerts about the recall or field safety corrective action notice issued by any medical device regulator across globe. The study has to be completed within 30 days from date of intimation and completed report has to be submitted to NCC- IPC.

EVALUATION OF PERFORMANCE OF THE MATERIOVIGILANCE SYSTEM AT MDMCS

The performance of Medical Device Adverse Event Monitoring Centres and the overall Materiovigilance surveillance system should be evaluated through a combination of quantitative and qualitative indicators. While the number of medical device adverse event reports submitted provides an important measure of reporting activity and engagement, the quality, completeness, clinical relevance, and consistency of the submitted reports are equally important for effective signal detection, assessment, and regulatory decision-making.

Accordingly, the quality of MDAE reports may be assessed using predefined and standardized evaluation parameters. Each report can be systematically reviewed and assigned a score on a standardized scale of 100, reflecting the extent to which the information

provided is complete, accurate, internally consistent, clinically meaningful, and adequate for further assessment. Such a structured scoring system can facilitate objective comparison of reporting quality across MDMCs, identify areas requiring improvement, and support targeted capacity-building and training interventions.

Quality Evaluation Parameters include: Report submitted in the prescribed format, Qualified MDAE, Completeness of Reporter Information, Adequacy of Device Information, Clarity and completeness of Adverse Event Description, Appropriate Seriousness Classification and Description, Completeness of Patient/User Information, Documentation of Event Outcome, Appropriateness of Causality Assessment. Refer Annexure XI.



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APPENDICES

- **ANNEXURE - I- Reportable Adverse Events**
- **ANNEXURE - II- Non-Reportable Adverse Events**
- **ANNEXURE - III- Medical Device Adverse Event Reporting form for Licence Holders & Health Care Professionals (English)**
- **ANNEXURE - IV-Medical Device Adverse Event Reporting form for Licence Holders & Health Care Professionals (Hindi)**
- **ANNEXURE - V- Medical Device Adverse Event Reporting form for Consumers/Users**
- **ANNEXURE- VI- Personal Protective Equipment (PPEs) Form**
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- **ANNEXURE - IX- How to report in ADRMS**
- **ANNEXURE- X-List of Critical Medical Devices**
- **ANNEXURE - XI-Monthly Medical Device Adverse Event Monitoring Centres Performance Report**

ANNEXURE- I

Reportable Adverse Events (Examples are not limited to)

Device Performance Issues

Incorrect Dosage Delivery - A diabetic patient was using an insulin pump for a couple of months but on a certain day the insulin pump malfunctions and delivers too much insulin, leading to hypoglycemia in the patient that resulted in patient hospitalization.

Mechanical Failure - A wheelchair's brakes fail, causing the user to lose control and potentially injure themselves.

Allergic Reaction - Someone experiences a severe allergic reaction to materials used in a medical device, such as a stent or catheter. A patient experiences a severe allergic reaction upon using the urethral catheter. Along with being quite painful, allergic reactions while a catheter is actively in use can actually cause more medical complications.

Infection - A patient had a knee replacement surgery that initially went well. But within a week, he began experiencing intense pain, swelling, and fever. Tests confirmed a serious infection had developed after receiving the surgical implant.

False Positive/Negative Result - A pregnancy test kit/covid testing kit test yields a false positive or negative result, but the clinician verifies the result with a subsequent test, leading to no patient harm.

Labelling and Packaging Issues

Misleading Claims - Sexually Transmitted Disease (STD) Testing Kit used at home, the testing kits are reliable, others may make exaggerated claims about their accuracy and comprehensiveness. Misleading results can lead individuals to either falsely believe they are free of infections or unnecessarily panic, affecting their health choices and relationships.

Mislabeled - A box of contact lenses was mislabeled, indicating that the lenses were suitable for extended wear when they were

actually designed for daily wear. Users may wear the lenses overnight, increasing the risk of serious eye infections or corneal damage due to reduced oxygen permeability.

Inadequate instructions - An insulin pen was packaged without clear instructions regarding dosage adjustments for different patients (e.g., weight-based dosing).

Missing Instructions - Blood pressure monitor, comes without any user manual, leading to incorrect use and inaccurate readings.

Malfunctions Leading to Injury or Potential Injury

Infusion Pump Error - An infusion pump malfunctions and administers medication too quickly, causing adverse reactions in the patient.

Implant Displacement - A hip joint implant shifts out of place due to a design flaw, causing pain and the need for revision surgery.

Incorrect Sensor Readings - A pulse oximeter gives inaccurate readings, leading to delayed treatment for a patient with low oxygen levels.

Defibrillator Failure - An automated external defibrillator (AED) fails to deliver a shock during a cardiac emergency, potentially endangering the patient's life.

Public Health Threats

Data Breach - In recent years, certain models of insulin pumps have been vulnerable to cyberattacks due to inadequate security measures. Hackers could exploit these vulnerabilities to gain unauthorized access to user's health data, including insulin dosing information and personal identifiers.

Faulty Respirators - A batch of respirators fails to filter out harmful particles, putting

healthcare workers and patients at risk during a respiratory outbreak.

Hazardous Materials - Metal Hip implant causes metal poisoning due to the leaching of the material used in the patient.

Poor Quality Issues

Inaccurate Blood Glucose Monitor - A faulty blood glucose monitor provides incorrect readings, resulting in a patient receiving inappropriate insulin doses, causing severe hypoglycemia.

Leaking Catheter - A urinary catheter develops a leak due to substandard materials, leading to urinary retention and an increased risk of infection for the patient.

Cracked Infusion Pump - An infusion pump has a cracked casing, causing medication to leak. This results in inadequate dosing and puts the patient at risk of receiving subtherapeutic levels of medication.

Poorly Designed Orthopedic Implant - An orthopedic implant has design flaws that cause it to fracture within a short period, necessitating revision surgery and causing pain and complications for the patient.

Faulty Pacemaker - A pacemaker malfunctions due to quality control issues in its manufacturing process, leading to irregular heart rhythms and requiring immediate medical intervention.

Off Label Use

Use of Implantable Devices Beyond Approved Duration - Spinal implant is left in place longer than recommended, resulting in adverse reactions or device failure/breakage.

Single use device used multiple time - Cranial perforator is a single use device but due to financial constraints, it is used multiple times leading to complications in patients.

Near Miss Incident

Software Glitch in Imaging Device

- An imaging device displayed incorrect information due to a software glitch. The technician noticed inconsistencies and repeated the scan, obtaining accurate results.

Incorrect Flow Rate - A home healthcare worker was preparing to deliver oxygen to a patient using a portable oxygen concentrator. Upon checking the settings, they noticed the flow rate was set incorrectly due to a previous user's adjustment. They corrected it before administering oxygen, preventing possible respiratory distress for the patient.

Device Breakage - A nurse was preparing to administer a medication using a prefilled syringe. As the nurse was inspecting the syringe before use, they noticed a hairline crack in the plastic body of the syringe. The crack had not been visible during the initial inspection, and the nurse had not yet drawn the medication. The nurse immediately reported the issue to a supervisor and discarded the syringe. They replaced it with a new, intact syringe, allowing for the medication to be administered safely without any risk of breakage during the procedure.

Test Kit Deficiency Not Leading to Harm - A batch of test kits shows a lower sensitivity than expected, but patients are retested using a different method, resulting in no negative outcomes.

Mechanical Failure Without Injury - A device (e.g., a thermometer) malfunctions during use but does not result in patient harm or delay in treatment.

ANNEXURE- II

Non-Reportable Adverse Events

Malfunction Protection Operated Correctly

- After a malfunction of an infusion pump it gives an appropriate alarm and stops (e.g. in compliance with relevant standards). There was no injury to the patient.

- Microprocessor-controlled radiant warmer malfunctions, reverts to an appropriate default condition and provides an audible appropriate alarm (e.g., in compliance with relevant standards). There was no injury to the patient.

- During radiation treatment, the automatic exposure control is engaged. Treatment stops. In accordance with the relevant standards the actual dose is displayed. Although patient receives less than optimal dose, patient is not exposed to excess radiation.

Expected and Foreseeable Side Effects

- A patient who is known to have claustrophobia experiences severe anxiety in the confined space of MRI machine which subsequently led to the patient being injured.

- A patient receives a second-degree burn during the use in an emergency of an external defibrillator. Risk assessment documents that such a burn has been accepted in view of potential patient benefit and is warned in the instructions for use. The frequency of burns is occurring within range specified in the device master record.

- Placement of central line catheter results in anxiety reaction and shortness of breath. Both reactions are known and labelled side effects.

Adverse Events Described in an Advisory Notice

- Manufacturer issued an advisory notice and recall of a coronary stent that migrated due to inadequate inflation of an attached balloon mechanism. Subsequent examples of stent migration were summarized in quarterly

reports concerning the recall action and individual adverse events did not have to be reported.

Temporary Discomfort

- A patient feels temporary discomfort or pain during the use of a medical device, such as a blood pressure cuff, but no long-term effects are noted.

User Confusion

- A clinician misinterprets the display of a medical device but corrects the interpretation quickly without impacting patient safety or outcomes.

Accidental Disconnection

- An infusion line is accidentally disconnected, but the nurse notices immediately and reconnects it without any adverse effects on the patient.

Device Exceeded Its Specified Service-Life or Shelf-Life

- A medical device reaches the end of its specified shelf-life and shows deterioration in performance consistent with the expected effects of ageing. The event is solely attributable to use beyond the manufacturer-specified shelf-life.

Unauthorized Reuse or Reprocessing of a Single-Use Device

- A single-use catheter is reused despite the manufacturer's IFU specifying that it must not be reused. The catheter fails during the subsequent procedure due to deterioration associated with prior use and reprocessing, with no evidence of a device defect during its intended single use.

ANNEXURE- III

Medical Device Adverse Event Reporting form for License Holders & Health Care Professionals (English)



Version : 1.2

MEDICAL DEVICE ADVERSE EVENT REPORTING FORM Materiovigilance Program of India (MvPI)

This form is intended to collect information on Medical Devices Adverse Event in India. The form is designed to be used by Manufacturer/Importer/ Distributor of Medical Devices and Healthcare Professionals with direct/indirect knowledge of Medical Devices Adverse Event.

Disclaimer

Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the adverse event. Submission of a Medical Devices Adverse Event (MDAE) Report does not have any legal implication on the reporter.

Confidentiality: The patient/reporter's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the patient/reporter's identity in response to a request from the public.

Primary Information	
1. Date of Report : Initial ☐ Follow up ☐ Final ☐ Trend ☐	
3. Report Reference No. for MDC only : Centre Location Month - Year Case No.	
4. Report Reference No. for MAH only : (For Reference No. Format, kindly refer to Instructions)	
Reporter Details	
1. Type of Reporter : Manufacturer ☐ Importer ☐ Distributor ☐ Healthcare Professional ☐ Others ☐ Specify	
2. In case, Where the Reporter is not the Manufacturer, Fill the Following Details:- a) Has the Reporter Informed the Incident to the Manufacturer? Yes ☐ No ☐ b) Is the Reporter also Submitting the Report on Behalf of the Manufacturer? Yes ☐ No ☐	
3. Reporter Contact Information: a) Name : b) Address : c) Tel./Mobile : d) Email :	
Medical Device Category	
Medical Device	In Vitro Diagnostics (IVD)
I. Therapeutic ☐ Diagnostic ☐ Therapeutic & Diagnostic ☐	I. Kits ☐
Assistive ☐ Preventive ☐ Imaging ☐	II. Reagents ☐
II. Implantable Device ☐ Non-Implantable Device ☐	III. Calibrator ☐
III. Invasive ☐ Non-Invasive ☐	IV. Control Material ☐
IV. Single Use Device ☐ Reusable Device ☐	V. IVD Electronic Reader/ Analyzer ☐
Reuse of Manufacturer Marked Single Use Device ☐	VI. Others ☐
V. Sterile ☐ Non Sterile ☐	
VI. Personal use / Homecare Use ☐	

(A) Medical Device Description		
Common Medical Device Name :		
Trade Name / Brand Name :		
Details	Name	Address
Manufacturer		
Importer		
Distributor		
1. Device Risk Classification as per India MDR 2017 : A ☐ B ☐ C ☐ D ☐		
2. Is the device refurbished : Yes ☐ No ☐		
If Yes then, Refurbishment was Performed By : OEM ☐ Others ☐		
3. License No. (Manufacturer/Importer) :		
4. Model No. :		
5. Catalogue No. :		
6. Lot / Batch No. :		
7. Serial No. :		
8. Software Version (If Applicable) :		
9. Associated Devices / Accessories :		
10. Nomenclature Code (GMDN/UPDONS (If Applicable) :		
11. UDI No. (If Applicable) :		
12. Installation Date (If Applicable) :		
13. Expiration Date (If Applicable) :		
14. Last Preventive Maintenance Date (dd/mm/yyyy) (If Applicable) :		
15. Last Calibration Date (dd/mm/yyyy) (If Applicable) :		
16. Year of Manufacturing :		
17. How long the Device/Equipment/Machine was in Use :		
18. Availability of Device for Evaluation : Yes ☐ No ☐		
If no, was the Device Destroyed ☐ Still in Use ☐ Return to Manufacturer or Importer/Distributor ☐		
19. Is the Usage of Device as per Manufacturer Claim /Instruction for Use/User Manual : Yes ☐ No ☐		
If no Specify Usage		

(B) Event Description	
1. Date of Event/Near Miss Incident (DD/MM/YY)	
2. Type of Event: Adverse Event ☐ Product Problem (i.e., defects/ malfunctions) ☐	
3. For Implantable Medical Devices Only: a) If Implanted, Give Date (DD/MM/YY) b) If Explanted, Give Date (DD/MM/YY)	
4. Location of Event: Hospital ☐ Manufacturer/Distributor Premises ☐ Home ☐ Others ☐ Specify	
5. Device Operator: Healthcare Professional ☐ Problem Noted Prior to Use ☐ Patient ☐ Others ☐ Specify	
6. Device disposition / Current Location: a) Returned to Company ☐ If yes, Date b) Remains Implanted in Patient ☐ c) Within the Healthcare Facility ☐ d) At Patient Home ☐ e) Destroyed ☐ f) Others (Specify)	
7. Is Device in Use After Incident : Yes ☐ No ☐	
8. Serious Event : Yes ☐ If yes, tick the appropriate reason a) Death (DD/MM/YY) ☐ b) Life Threatening ☐ c) Disability or Permanent Damage ☐ d) Hospitalization/Prolongation of Existing Hospitalization ☐ e) Congenital Anomaly ☐ f) Required Intervention to Prevent / Permanent Impairment / Damage Device ☐ g) Other (Imp. Medical Event) ☐	
9. Non Serious Event ☐	
10. Whether Other Medical Devices were Used at Same Time With Above Device If yes, Please Specify Name(s)/Use(s)	
11. Event Outcome and Recurrence Information a) Event Abated after use Stopped/ Reduced? Yes ☐ No ☐ Doesn't Apply ☐ b) Event Reappeared after Reintroduction Yes ☐ No ☐ Doesn't Apply ☐	
12. Detail Description of Event:-	
Notes: Do you have any relevant diagnostic test/laboratory data/pictures/videos related to the events Yes ☐ No ☐ If yes then kindly provide them while submitting the final application form.	
For Manufacturer/Authorized Representative Use Only	
13. Frequency of Occurrence of Similar Adverse Event in India in Past 3 Years	Year No. of Similar Adverse Events Total No. Supplied Frequency of Occurrence (%)
14. Frequency of Occurrence of Similar Adverse Event Globally in Past 3 Years	Year No. of Similar Adverse Events Total No. Supplied Frequency of Occurrence (%)
(C) Patient Information, History & Outcome	
1. Patient Hospital ID : 2. Patient Initial : 3. Age : 4. Gender : Male ☐ Female ☐ Transgender ☐ 5. Weight : 6. Other Relevant History, including Pre-existing Medical Conditions, Treatment, Allergy	
7. Patient Outcomes: a) Death (DD/MM/YY) ☐ b) Recovered Date (DD/MM/YY) ☐ c) Not yet Recovered ☐ d) Stable ☐ e) Others ☐ Please Specify	

(D) Healthcare Facility Information (if available)	
1. Name : 2. Address : 3. Contact Person Name at the Site of Event : 4. Tel. No./Mobile No. : 5. Email :	
(E) Medical Device Adverse Event Assessment	
1. Immediate Action Taken:	
2. Suspected Root Cause of Problem:	
3. In Your Opinion, Which of the Following Best Describe the Association between Suspected Medical Device(s) and Adverse Event? a) Not related ☐ b) Possible ☐ c) Probable ☐ d) Related ☐	
(F) For Manufacturer/Authorized Representative / License Holder Only	
1. Investigation Needed? Yes ☐ No ☐	
2. Investigation Action Taken with Timeline:	
3. Root Cause of Problem (Applicable for follow up / final reports):	
4. Corrective and Preventive action (CAPA) taken:	

Where to report?

Duly filled Medical Device Adverse Event Reporting Form can be sent to Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Sector-23, Rajnagar, Shalimar 20002, Tel-0120-2783400, 2783401 and 2783392, or email to mvpi@gov.in, shatrunjay.ipc@gov.in, Or Call on Helpline no. 1800 180 2024 to report Adverse event.

Partnering Organizations



ANNEXURE- IV

Medical Device Adverse Event Reporting form for License Holders & Health Care Professionals (Hindi)

Version-1.2

हिन्दी संस्करण

MEDICAL DEVICE ADVERSE EVENT REPORTING FORM

चिकित्सीय उपकरण प्रतिकूल घटना सूचना फार्म

Materiovigilance Programme of India (MvPI)

मरीनोविजिलेंस प्रोग्राम ऑफ इंडिया

This form is intended to collect information on Medical Devices Adverse Events in India. The form is designed to be used voluntarily by Manufacturer/Importer/Distributor of Medical Devices, Healthcare Professionals and anyone with direct/indirect knowledge of Medical Devices Adverse Event.

इस फॉर्म का उद्देश्य भारत में चिकित्सीय उपकरणों से होने वाली चिकित्सीय घटनाओं के बारे में जानकारी प्राप्त करना है। फॉर्म को चिकित्सीय उपकरणों के निर्माता/आयातकों/वितरकों, स्वास्थ्यकर्ताओं और चिकित्सीय उपकरणों के उपयोग करने वाले व्यक्तियों द्वारा स्वैच्छिक रूप से प्रयोग करने के लिए बनाया गया है।

General Information (सामान्य जानकारी)

1. Date of Report/ घटना होने की तारीख: _____

2. Type of Report/ घटना का प्रकार: Initial / प्रारंभिक (एकल) Follow up/ अतिरिक्त जानकारी के साथ सूचना Final/ अंतिम Trend/ बढ़ती _____

3. Reporter/ Reference for MDMC only/ रिपोर्टर का पता, (केवल एम. डी. सी. के लिए) Control/ नियंत्रण Location/स्थान _____

Month-Year/ माह-वर्ष: _____ Case No./ घटना क्रम: _____

Reporter Details (घटना करने वाले का विवरण)

1. Type of Reporter/ घटना करने वाले की भूमिका: (a) Manufacturer/ निर्माता (b) Importer/ आयातक (c) Distributor/ वितरक (d) Healthcare Professional/ स्वास्थ्यकर्ता (e) Patient/ रोगी (f) Others/ अन्य (g) Unspecified/ अनिर्दिष्ट _____

2. In case, where the reporter is not manufacturer, fill the following details/ यदि सूचना देने वाला निर्माता नहीं है तो निम्नलिखित विवरण भरें:-

(a) Has the reporter informed the incident to the manufacturer/ क्या सूचना देने वाले ने निर्माता को चिकित्सीय घटना की जानकारी दी है? Yes/ हाँ No/ नहीं _____

(b) Is the reporter also submitting the report on behalf of the manufacturer/ क्या सूचना देने वाला निर्माता की ओर से सूचना प्रस्तुत कर रहा है? Yes/ हाँ No/ नहीं _____

3. Reporter contact information/ घटना करने वाले की संपर्क जानकारी:

a) Name/ नाम: _____

b) Address/ पता: _____

c) Tel./ Mobile/ दूरभाष नंबर: _____

d) Email/ ईमेल: _____

Device Category (उपकरण की श्रेणी)

Medical Device/ चिकित्सीय उपकरण	In Vitro Diagnostics (IVD)/ इन-विट्रो डायग्नोस्टिक्स	Medical Equipment/ Machines/ चिकित्सीय उपकरण / मशीनें
I. Therapeutic/ चिकित्सीय समर्थक: Diagnostic/ डायग्नोस्टिक Preventive/ निवारक	I. Kit/ किट II. Reagents/ अभिकारक III. Calibrator/ अंतर्कालक IV. Control Material/ नियंत्रण सामग्री V. Others/ अन्य VI. IVD electronic reader/ Analyzer/ ऑटोमैटिक इलेक्ट्रॉनिक रीडर/ विश्लेषक	I. Therapeutic/ चिकित्सीय समर्थक Diagnostic/ डायग्नोस्टिक II. Therapeutic & Diagnostic/ चिकित्सीय समर्थक और डायग्नोस्टिक III. Preventive/ निवारक IV. Assistive/ सहायक V. Imaging/ छविजनक VI. Invasive/ परी में प्रविष्ट करने वाले उपकरण Non-invasive/ परी में प्रविष्ट नहीं करने वाले उपकरण VII. Others/ अन्य

(B) Event Description (चिकित्सीय घटना का विवरण)

1. Date of Event / Near miss incident (चिकित्सीय घटना की तिथि/ करीबन चिकित्सीय घटना की तिथि): _____

2. Date of Implant / चिकित्सीय उपकरण प्रत्यारोपण की तिथि: _____

3. Location of Event/ घटना स्थान पर घटित होने का स्थान: _____

4. Device Operator/ चिकित्सीय उपकरण का प्रयोगकर्ता: _____

5. Healthcare Professional/ रोगी स्वास्थ्यकर्मी: _____

6. Device disposition / Current location/ वर्तमान में उपकरण की स्थिति पर ध्यान दें: _____

7. Serious event/ गंभीर चिकित्सीय घटना: _____

8. Non serious event/ गंभीर नहीं चिकित्सीय घटना: _____

9. Whether other medical devices were used at same time with above device if yes, please specify name(s)/ use(s): _____

10. Detail description of Event/ चिकित्सीय घटना का विस्तृत विवरण: _____

(C) Patient Information, History & Outcome (रोगी के पृष्ठ और वर्तमान के परिणाम की जानकारी)

1. Patient Hospital ID/ रोगी की अस्पताल पहचान संख्या: _____

2. Patient Initial/ रोगी का संक्षिप्त नाम: _____

3. Age/ आयु: _____

4. Gender/ लिंग: Male/ पुरुष Female/ स्त्री Others/ अन्य _____

5. Weight/ वजन: _____

6. Other relevant history, including pre-existing medical conditions/ रोगी के पृष्ठ की अन्य प्रासंगिक जानकारी: _____

7. Patient Outcomes/ रोगी के वर्तमान परिणाम: _____

8. Recovered/ घुल-मिल गया हुआ Date (DD/MM/YY): _____

9. Not yet recovered/ अभी तक स्वस्थ नहीं हुआ _____

10. Death/ मृत्यु तिथि: _____

11. Others/ अन्य परिणाम: _____

(D) Healthcare Facility Information (यदि उपलब्ध) (अस्पताल की जानकारी, जहाँ चिकित्सीय घटना घटित हुई (अगर उपलब्ध है))

1. Name/ नाम: _____

2. Address/ पता: _____

3. Contact Person Name at the site of event/ घटना स्थान पर संपर्क करने का नाम: _____

4. Tel./ Mob No./ दूरभाष या मोबाइल नंबर: _____

(E) Causality Assessment/ (चिकित्सीय घटना का कारण विश्लेषण)

1. Investigation action taken/ की गयी जांच-सर्वेक्षण की जानकारी: _____

2. Root cause of problem (Applicable for follow up / final reports)/ समस्या का मूल कारण (तुल्य: फॉलो अप और अंतिम सूचना के लिए अनुवृत्त): _____

(F) Manufacturer/Authorized Representative Investigation & Action taken (निर्माता या अधिकृत प्रतिनिधि द्वारा जांच-सर्वेक्षण की जानकारी)

1. Manufacturer/Authorized Representative device risk analysis report (निर्माता या अधिकृत प्रतिनिधि द्वारा उपकरण के चिकित्सीय घटना की विश्लेषण सूचना की जानकारी): _____

2. Corrective / preventive action taken/ उपकरण के त्रुटिपूर्ण होने से निवारण/ रोकथाम कार्यवाही की जानकारी: _____

3. Device history review/ घटने से उपकरण की इतिहास उपकरण की जांच की जानकारी: _____

For manufacturer/authorized representative use only/ केवल निर्माता/अधिकृत प्रतिनिधि के लिए उपलब्ध है:

11. Frequency of occurrence of similar Adverse Event in India in past 3 years/ भारत में पिछले 3 वर्षों में घटने वाले चिकित्सीय घटनाओं की आवृत्ति का विश्लेषण	Year/ वर्ष	No. of Similar Adverse Events/ समान चिकित्सीय घटनाओं की संख्या	Total No. Supplied/ कुल उपकरणों की आपूर्ति संख्या	Frequency of Occurrence/ घटना की आवृत्ति (%)
12. Frequency of occurrence of similar Adverse Event in globally in past 3 years/ विश्व स्तर पर पिछले 3 वर्षों में घटने वाले चिकित्सीय घटनाओं की आवृत्ति का विश्लेषण	Year/ वर्ष	No. of Similar Adverse Events/ समान चिकित्सीय घटनाओं की संख्या	Total No. Supplied/ कुल उपकरणों की आपूर्ति संख्या	Frequency of Occurrence/ घटना की आवृत्ति (%)

Where to report?
Data from Medical Device Adverse Event Reporting Form can be sent to Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Sector 23, Rajgurunagar, Ghaziabad-20002. Tel: 0120-2783400, 2783401 and 2783392, FAX: 0120-2783311 or email to shahrajay.p@gov.in or shahrajay.p@gov.in or Call on Helpline no. 1800 180 2024 to report Adverse event.

एप फ्रीड वॉर
चिकित्सीय उपकरण समर्थक चिकित्सीय घटना सूचना फॉर्म को डाटाबेस सेवा प्रदाता, स्वास्थ्य एवं परिवार कल्याण विभाग, भारत सरकार, क्षेत्र-23, राजगुरुनगर, गाज़ीबाद-201002 पर भेज सकते हैं। फॉलो अप/ अंतिम सूचना के लिए सूचना फॉर्म को डाटाबेस सेवा प्रदाता को डाटाबेस नंबर - 0120-2783400, 2783401 और 2783392, फॉक्स: 0120-2783311 के माध्यम से भेज सकते हैं। या चिकित्सीय उपकरण समर्थक चिकित्सीय घटना सूचना फॉर्म को डाटाबेस सेवा प्रदाता को डाटाबेस नंबर - 18001802024 पर कॉल कर चिकित्सीय घटना को दर्ज कर सकते हैं।

Partnering Organization सहयोगी संस्थाएं

Disclaimer/ विसंगति:
The reporter's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the adverse event.

अधिसूचना:
सूचना देने वाले की पहचान को पूर्णतः गोपनीय और संरक्षित रखा जाता है। कार्यक्रम के कर्मचारियों से उम्मीद है कि उनसे अनुपेक्षित रूप से सूचना देने वाले की पहचान को उजागर नहीं किया जाता। किसी चिकित्सीय घटना की सूचना देने वाले को दावे करने का अधिकार नहीं है कि चिकित्सीय घटना का कारण, चिकित्सीय कर्म या उपकरण के डिजाइन या अनुवृत्त उपकरण है।

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Instructions for use, see Section A.1.1. अनुपेक्षा A.1.1. के लिए पढ़ें।

• If Medical Device/ उपकरण/ मशीन: Please fill all the sections I.e./ यदि उपकरण उपकरण, चिकित्सीय उपकरण/ चिकित्सीय उपकरण के अंतर्गत आता है तो सूचना सभी अनुपेक्षाओं को भरें: I.e./ A, B, C, D, E, F & P

• If In Vitro Diagnostics (IVD)/ Phase III sections I.e./ यदि उपकरण उपकरण, इन-विट्रो डायग्नोस्टिक्स के अंतर्गत आता है तो सूचना इन अनुपेक्षाओं को भरें: I.e./ A, B, C, D, E, F & P

(A) Details (घटना का विवरण)

Device Name / Trade Name / Brand Name/ चिकित्सीय उपकरण का नाम/ वाणिज्यिक नाम/ ब्रांड नाम में प्रचलित नाम:

Details/ विवरण	Name/ नाम	Address/ पता
Manufacturer/ निर्माता		
Importer/ आयातक		
Distributor/ वितरक		

1. a) Is the device notified/regulated in India/ क्या चिकित्सीय उपकरण भारत में अधिसूचित/नियंत्रित है? : Yes/ हाँ No/ नहीं _____

b) Device Risk Classification as per India MDR 2017/ भारतीय मरीनोविजिलेंस 2017 के अनुसार उपकरण का चिकित्सीय वर्गीकरण: A B C D E F _____

2. License No. (Manufacture/Temporary) लैसंस नंबर (उत्पादन/अस्थायी): _____

3. Catalogue No./ पृष्ठ क्रमांक: _____

4. Model No./ मॉडल नंबर: _____

5. Lot / Batch No./ लॉट/ बैच नंबर: _____

6. Serial No./ सीरियल नंबर: _____

7. Software Version/ सॉफ्टवेयर संस्करण: _____

8. Associated Devices / Accessories/ सम्बंधित/ सम्बंधित उपकरण: _____

9. Nomenclature Code if applicable/ GMDN/USMDN/ नामकरण कोड यदि लागू हो: जो उपकरण का नाम है जो उपकरण _____

10. UDI No. (if applicable)/ यूडी नंबर (यदि लागू हो): _____

11. Installation Date/ चिकित्सीय उपकरण स्थापना तिथि: _____

12. Expiration Date / चिकित्सीय उपकरण के उपयोग की अंतिम तिथि: _____

13. Last preventive maintenance date/ अंतिम निवारण/ रखरखाव की तिथि: _____

14. Last calibration date (date/year)/ अंतिम कलिव्रेशन तिथि: _____

15. Year of manufacturing/ चिकित्सीय उपकरण/ डिजाइन वर्ष: _____

16. How long was the device/ उपकरण/ मशीन का उपयोग किया गया: _____

17. Availability of device for evaluation/ उपकरण की उपलब्धता क्या है? : Yes/ हाँ No/ नहीं _____

If no, was the device destroyed/ यदि नहीं, तो क्या चिकित्सीय उपकरण नष्ट हो गया है? _____

18. Is the usage of device as per manufacturer claim/instruction for use/ उपकरण का उपयोग निर्माता/उपकरण के उपयोग के अनुसार किया गया है? : Yes/ हाँ No/ नहीं _____

19. For devices not regulated / notified in India/ उपकरण के उपयोग के लिए भारत में अधिसूचित/नियंत्रित नहीं है: _____

Regulator / Regulatory status in country of origin/ निवारण/ नियंत्रण स्थिति: _____

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ANNEXURE-V

Medical Device Adverse Event Reporting form for Consumers/Users


Version-1.0

MEDICAL DEVICE ADVERSE EVENT REPORTING FORM
Materiovigilance Programme of India (MvPI)
(For Consumers/Users)

Date of report :

(A) PATIENT INFORMATION, HISTORY & OUTCOME

1. Patient Hospital ID:
2. Patient Initial:
3. Age or (Date of Birth):
4. Gender: Male ☐ Female ☐ Others ☐
5. Weight (in kg):
6. Other relevant medical history, including pre-existing medical conditions:

(B) SUSPECTED MEDICAL DEVICE DETAILS

Medical Device Name / Trade Name / Brand Name:

Details	Name	Address
Manufacturer		
Importer/ Distributor		
Model No.		
Lot / Batch No		
Serial No.		

(C) EVENT DESCRIPTION / PRODUCT PROBLEM

1. Date of Adverse Event / Near miss incident:
2. Type of report
Adverse Event ☐
Product Problem ☐
(e.g. defect/fault/error/malfunctioning)
3. Date of Implant / Date of device used:
4. Date of Explant / Device used up to date:
5. Location of Event:
Hospital Premise ☐
Home ☐
Others:
6. Is the device in use after the incidence
Yes ☐ No ☐
7. Whether adverse event is
Serious event ☐ / Non serious event ☐
If serious, Tick the appropriate reason
a) Death ☐ b) Life Threatening ☐
c) Disability or permanent damage ☐
d) Hospitalization ☐
e) Congenital anomaly /birth defect ☐
f) Any other serious events ☐
g) Required intervention to prevent / permanent impairment / damage ☐
8. Whether other medical devices were used at the same time with the above device if yes, please specify the name(s)/use(s):

9. Detail Description of Event:

(D) Reporter contact information:

a) Name : b) Occupation (optional): c) Tel./Mobile:
d) Address : e) Email:


Version-1.0
हिन्दी संस्करण

चिकित्सीय उपकरण प्रतिकूल घटना सूचना फार्म
मैटेरिओविजिलेंस प्रोग्राम ऑफ इंडिया
(उपभोक्ताओं/ उपयोगकर्ताओं के लिए)

सूचना की तिथि:

(A) रोगी के विषय में आवश्यक जानकारी

1. रोगी की अस्पताल पहचान संख्या :
2. रोगी का सही नाम :
3. आयु / लिंग :
4. लिंग: पुरुष ☐ स्त्री ☐ अन्य ☐
5. वजन :
6. रोगी के पूर्व की अन्य चिकित्सा संबंधित विधि:

(B) संदिग्ध चिकित्सीय उपकरण का विवरण

चिकित्सा उपकरण का नाम/ वास्तविक नाम/ कार्डर में उल्लिखित नाम:

विवरण	नाम	पता
निर्माता		
आयातकर्ता/ वितरक/वर्डी		
प्रतिरूप क्रमांक		
लॉट/ बैच क्रमांक		
श्रृंखला क्रमांक		

(C) घटित घटना का विवरण

1. चिकित्सा उपकरण प्रतिकूल घटना का तिथि:
2. घटना का प्रकार
प्रतिकूल घटना ☐
उपकरण की समस्या ☐
(e.g. कमी या खराबी)
3. चिकित्सा उपकरण प्रत्यारोपण या उपकरण की तिथि:
4. चिकित्सा उपकरण को चर्दी से निकालने या उपकरण बंद करने की तिथि:
5. घटना किस स्थान पर घटित हुई
अस्पताल/घर में ☐ बाहर ☐
अन्य किसी स्थान पर:
6. क्या घटना के बाद उपकरण उपयोग में है?
हाँ ☐ नहीं ☐
7. प्रतिकूल घटना का प्रकार:
संक्षेप प्रतिकूल घटना ☐ गैर संक्षेप घटना ☐
संक्षेप घटना संक्षेप है, जो अधिक कारण पर निर्भर नहीं है।
गैर संक्षेप घटना ☐
a) घटना के लिए कारण:
b) चिकित्सा उपकरण का ब्यवहार ☐
c) चिकित्सा उपकरण का ब्यवहार ☐
d) अस्पताल में भर्ती ☐
e) अस्पताल में निरीक्षण/ अन्य उपकरण ☐
f) कोई अन्य चिकित्सा उपकरण ☐
g) घटना घटने के लिए आवश्यक दवा/सर्विस्/सर्विस् इत्यादि या चिकित्सा उपकरण (होना) ☐
8. क्या उपकरण उपकरण के साथ एक ही समय में अन्य चिकित्सा उपकरणों का उपयोग किया गया था यदि हाँ, तो कृपया नाम/उपकरण निर्दिष्ट करें:

9. प्रतिकूल घटना का विवरण:

(D) सूचना देने वाले का सम्पर्क:

a) नाम : b) पता (वैकल्पिक): c) दूरभाष क्रमांक:
d) पता : e) ई.मेल :

WHERE TO REPORT?

Indian Pharmacopoeia Commission:
Duly filled Medical Device Adverse Event Reporting Form can be sent to Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Sector-23, Rajnagar, Ghaziabad-20002.

Helpline Number:
Adverse event associated with medical device can be reported via helpline No. i.e. **1800 180 3024**
[Available from: Monday to Friday (9:00 AM to 5:30 PM)]

Email Contact:
Scan copy of this form can be sent via email to mvpi-ipc@gov.in or shatrunjay ipc@gov.in

DISCLAIMER:
Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. A duly filled reporting form will be verified by the nearest monitoring centre of that report than only verified report will be submitted in the MvPI database. Submission of this report does not mean, the reporter /consumer will get compensation. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the adverse event.

कहाँ रिपोर्ट करें?

भारतीय श्रेयज संस्था आयोग:
विधिपूर्वक भरे हुए चिकित्सा उपकरण सम्बंधित प्रतिकूल घटना सूचना फार्म को भारतीय श्रेयज संस्था आयोग, स्वास्थ्य एवं परिवार कल्याण मन्त्रालय, भारत सरकार, सेक्टर-23, राजनगर, गाज़ियाबाद-201002 पर भेज सकते हैं।

सहायता संपर्क :
चिकित्सा उपकरण सम्बंधित प्रतिकूल घटना को टोल फ्री नंबर **18001803024** पर कॉल कर प्रतिकूल घटना को दर्ज करा सकते हैं।
[उपलब्ध: सोमवार से शुक्रवार (सुबह 9:00 बजे से शाम 5:30 बजे तक)]

ईमेल संपर्क:
चिकित्सा उपकरण सम्बंधित प्रतिकूल घटना सूचना फार्म की स्कैन कॉपी को ईमेल mvpi-ipc@gov.in or shatrunjay ipc@gov.in पर भेज कर दर्ज करा सकते हैं।

उद्घोषणा:
गोपनीयता: रोगी की पहचान को पूरी तरह से गोपनीय और संरक्षित रखा जाता है। दर्ज कराई गयी सूचना को, सूचना के निष्कर्ष प्राप्त निगरानी केंद्र से सहायित होने के उपरान्त ही मैटेरिओविजिलेंस प्रोग्राम ऑफ इंडिया के डाटा बेस में शामिल किया जाएगा। इस रिपोर्ट को जमा करने का मतलब यह नहीं है कि रिपोर्टर/उपभोक्ता को किसी तरह का मुआवजा मिलेगा। किसी प्रतिकूल घटना कि सूचना को दर्ज करने का अर्थ बिल्कुल भी यह नहीं है कि प्रतिकूल घटना का कारण, चिकित्सा कर्मी या उपकरण के निर्माता या उपयुक्त उपकरण है।

ANNEXURE-VI

Personal Protective Equipment (PPEs) Form



PERSONAL PROTECTIVE EQUIPMENT ADVERSE EVENT REPORTING FORM

Version no. 1.1

Materiovigilance Programme of India (MvPI)

Where to report: Duly filled form can be sent to Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Sector-23, Rajnagar, Ghaziabad-20002, Tel-0120-2783400, 2783401 and 2783392, FAX:0120-2783311 or email to shatrunjay.ipc@gov.in Or Call on Helpline no. 1800 180 3024 to report Adverse event.

1. General Information:	2. Type of report:
Date of report: _____ Date of event: _____	☐ Initial ☐ Follow-up (Ref. no. _____)
3. Reporter details:	
Name: _____ Address: _____ Contact No.: _____ E-mail address: _____	
4. PPE Type:	
☐ Gloves ☐ Coverall ☐ Goggles ☐ N-95 Masks ☐ Shoe Covers ☐ Face Shield ☐ Body Bags ☐ Triple Layer Medical Mask ☐ Sanitizer ☐ Other (Specify): _____	
5. PPE Details:	
Brand name: _____ Manufacturer name and address: _____ Importer name and address: _____ Distributor name and address: _____ Marketed by: _____ License No. / Registration No.: _____ Model No.: _____ Batch No.: _____ Unique Certification Code: _____ Test Standard: _____ Manufacturing Date: _____ Expiry Date: _____ PPE Current Location: ☐ Device destroyed ☐ Still in use ☐ Return to manufacturer	
6. Location of event:	7. Type of event:
☒ Point of Entry (Immigration counters, customs and airport security) ☐ Hospital Setting ☐ In-patient Services ☐ Emergency Department ☐ Pre-hospital (Ambulance) Services ☐ Other Supportive/ Ancillary Services (Laboratory, Mortuary, Sanitation) ☐ Health Workers in Community Setting ☐ Quarantine facility ☐ Home Quarantine ☐ Other (Specify): _____	Serious: ☐ ☒ Non-Serious ☐ Death ☐ Life Threatening ☐ Disability or permanent damage ☐ Hospitalization / Prolonged Hospitalization ☐ Congenital anomaly / birth defect ☐ Any other serious _____
8. User details:	
Initials: _____ Age: _____ Gender (M/F/O): _____ Outcome: ☐ Recovered ☒ Not yet recovered ☐ Death ☐ Other: _____	
9. Detailed Description of Event:	
10. Hospital/Quarantine facility details:	
Facility Name: _____ Address: _____ Contact Person: _____	

ANNEXURE-VII

In-Vitro Diagnostic (IVD) Form



IN-VITRO DIAGNOSTIC MEDICAL DEVICE ADVERSE EVENT REPORTING FORM

Materiovigilance Programme of India (MvPI)

This form is intended to collect information on In-Vitro Diagnostic Medical Devices Adverse Event in India. The form is designed to be used by Domestic Manufacturer / Importer / Distributor of In-Vitro Diagnostic Medical Devices, Pathology Laboratory, Blood Donation Centre, Government Program In-charge and Healthcare Professionals with direct/indirect knowledge of In-Vitro Diagnostic Medical Devices Adverse Event.

Disclaimer

Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the adverse event. Submission of a Medical Devices Adverse Event (MDAE) Report does not have any legal implication on the reporter.

Confidentiality

The patient/reporter's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the patient/reporter's identity in response to a request from the public.

Primary Information	
1. Date of Report	: Initial ☐ Follow up ☐ Final ☐ Trend ☐
2. Type of Report	: Initial ☐ Follow up ☐ Final ☐ Trend ☐
3. Report Reference No. for MDAE only	: Centre Location Month-Year Case No.
4. Report Reference No. for MAAH only	: MDAE/MC Medical Adverse Event Monitoring Centre, MAAH Market Authorization Holders
Reporter Details	
1. Type of Reporter	: Manufacturer ☐ Importer ☐ Distributor ☐ Healthcare Professional ☐ Pathology Laboratory ☐ Blood Center ☐ Government Program In charge ☐ Others ☐ Specify
2. In case, Where the Reporter is not the Domestic Manufacturer / Importer of the product, Fill the following Details:-	
a) Has the Reporter informed the incident to the Domestic Manufacturer / Importer of the product? Yes ☐ No ☐	
b) If Yes, Event reported to Manufacturer / Importer via, Date of which Manufacturer/ Importer was made aware (DD/MM/YYYY)	
i) Email ☐	
ii) Written communication ☐	
iii) Telephonic communication ☐	
iv) Other ☐ Specify	
c) Is the Reporter also submitting the report on behalf of the manufacturer? Yes ☐ No ☐	
3. Reporter Contact Information	: a) Name : b) Organisation : c) Address : d) Tel./ Mobile : e) Email :

5. Event Description	
1. Date of Event (DD/MM/YYYY)	: 1 of 4
2. Type of Adverse Event:	
Malfunction	☐
Use error	☐
Insufficient or inadequate labelling or instructions for use	☐
Insufficient Reagent	☐
False Positive	☐
False Negative	☐
Invalid Test	☐
Wrong Result	☐
Other	☐ Specify
3. Location of Event:	
Hospital ☐	Blood Centre ☐
Pathology Lab ☐	Home ☐
Other ☐	Specify
4. IVD Medical Device Operator:	
Healthcare Professional ☐	Problem noticed prior to use ☐
Laboratory operator ☐	Patient ☐
Others ☐	Specify
5. IVD Medical Device in use after incidence: Yes ☐ No ☐	
6. Serious Event: Yes ☐ If yes, tick the appropriate reason	
a) Death (DD/MM/YYYY) ☐	
b) Life Threatening ☐	
c) Disability or Permanent Damage ☐	
d) Hospitalization/ Prolongation of Existing Hospitalization ☐	
e) Congenital Anomaly ☐	
f) Required Medical Intervention ☐	
g) Other (Important Medical Event) ☐	
Specify	
7. Non-serious Event ☐	
8. Whether other in-vitro diagnostic medical devices were used at same time with the above device: Yes ☐ No ☐	
If yes, specify the name(s)/ use(s)	
9. Event outcome and recurrence information	
a) Event abated after use is stopped/ reduced? Yes ☐ No ☐ NA ☐	
b) Event reappeared during retesting/ reuse? Yes ☐ No ☐ NA ☐	
10. Detail Description of Event:	
Note: Do you have any relevant diagnostic test/laboratory data/records related to the events? Yes ☐ No ☐	
If yes, kindly provide them with supporting the filed application form.	
For Manufacturer/Authorized Representative Use Only	
11. Frequency of Occurrence of Similar Adverse Event in India in Past 3 Years	Year No. of Similar Adverse Events Total No. Supplied Frequency of Occurrence (%)
12. Frequency of Occurrence of Similar Adverse Event Globally in Past 3 Years	Year No. of Similar Adverse Events Total No. Supplied Frequency of Occurrence (%)

A) In-vitro Diagnostic Medical Device Details	
Category	Sub-category
1. Kits ☐	1. Hematology ☐
2. Reagents ☐	2. Biochemistry ☐
3. Calibrators ☐	3. Microbiology ☐
4. Controls ☐	4. Immunology ☐
5. Analyzers ☐	5. Histopathology ☐
6. Specimen Receptacles ☐	6. Molecular Biology ☐
7. Self-Testing Kit ☐	7. Gastroenterology & Urology ☐
8. IVD Software ☐	8. Gynecological ☐
9. Others ☐ Specify	9. Toxicology ☐
	10. Others ☐ Specify
Generic In-Vitro Diagnostic Medical Device Name:	
Trade Name/ Brand Name:	
Details Name Address	
Manufacturer	
Importer	
Distributor	
Marketed by	
1. IVD-MD Risk Classification as per Indian MDR 2017 : A ☐ B ☐ C ☐ D ☐	
2. License No. (Manufacturer/ Importer) :	
3. Model No. (If applicable) :	
4. Catalogue No. :	
5. Lot/ Batch No. :	
6. Serial No. (If applicable) :	
7. Software Version (If applicable) :	
8. Associated IVDs/ Accessories :	
9. UOI No. (If applicable) :	
10. Manufacturing Date (If applicable) :	
11. Expiration Date (If applicable) :	
12. Last Calibration Date (DD/MM/YYYY) (If applicable) :	
13. How long the IVD Medical Device was in use :	
14. Availability of IVD Medical Device for evaluation: Yes ☐ No ☐	
If no, Status of IVD Medical Device and location (specify) : Destroyed ☐ Still in use ☐	
Returned to the Manufacturer/ Importer/ Distributor ☐	
Other ☐ Specify	
15. Is the IVD Medical Device used as per Manufacturer claim/ Instruction for use/ User manual : Yes ☐ No ☐	
If no, Specify usage:	

Page 2 of 4

C) Patient Information, History and Outcome	
1. Patient Hospital ID :	7. Patient outcomes
2. Patient Initial :	a) Death (DD/MM/YYYY) ☐
3. Age :	b) Recovered (DD/MM/YYYY) ☐
4. Gender : Male ☐ Female ☐ Transgender ☐	c) Not yet recovered ☐
5. Weight :	d) Stable ☐
6. Other relevant history : (including pre-existing conditions, treatment, etc.)	e) Other ☐
	Specify
D) Healthcare Facility Information (If available)	
1. Name :	
2. Address :	
3. Contact/ Person Name at the Site of Event :	
4. Tel. No./ Mobile No. :	
5. Email :	
E) IVD Medical Device Adverse Event Assessment / False Positive / False Negative / Invalid Test / Wrong Result	
1. Immediate Action Taken:	Date of Action Taken:
2. Suspected Root Cause of Problem:	
3. In Your Opinion, Which of the Following Best Describe the Association between Suspected In vitro diagnostic Medical Device(s) and Adverse Event?	
a) Not related ☐ b) Possible ☐ c) Probable ☐ d) Related ☐	
F) For Manufacturer/Authorized Representative / Pathology Laboratory, Blood Donation Center, Government Program In-charge, Healthcare Professionals and License Holder Only	
1. Investigation Needed? Yes ☐ No ☐	
2. Investigation Action Taken with Timeline:	
3. Root Cause of Problem (Applicable for follow up/ final reports):	
4. Corrective and Preventive action (CAPA) taken:	Date of CAPA implemented on: _____
5. Field Safety Notice/ Field Safety Corrective Action Initiated: Yes ☐ No ☐	
If Yes, date of Field Safety Notice issued/ Expected date of completion of Field Safety Corrective Action (DD/MM/YYYY):	

Where to report?

Duly Filled Medical Device Adverse Event Reporting Form can be sent to Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Sector 23, Rajpur, Ghaziabad 200002, Tel: 0120-2783400, 2783401 and 2783392, or email to mpic@ipc.in - pharmainfo@ipc.in or Call on Helpline no. 1800 180 3004 to report Adverse event.

Partnering Organizations



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ANNEXURE-VIII

Procedure for Enrolment of New MDMCs in ADRMS

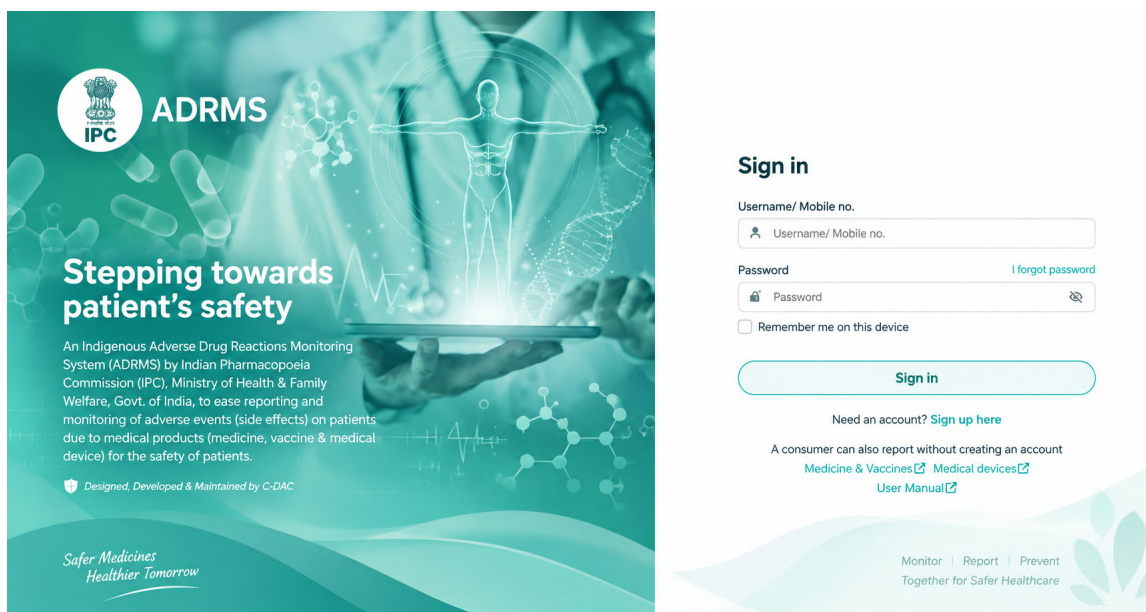
1	Access the ADRMS Portal		
	Access the Adverse Drug Reactions Monitoring System (ADRMS) portal using the link - https://adrmsipc.in/adrms/index.html		
2	Create an Account (If Not Already Registered)		
2.1	Click on "Sign Up Here".		
2.2	Under Account Type, select: "Programme Coordinator".		
2.3	Fill in the following details: a. Name b. Create Username and Password c. Date of Birth (DD/MM/YYYY) d. Gender e. Mobile Number		
2.4	Click on "Get OTP", enter the OTP received on your mobile number.		
2.5	Click on "Create New Account".		
3	Sign In		
3.1	Go back to the login page.		
3.2	Enter your newly created Username and Password to login.		
4	Add Institute Request		
4.1	Once logged in, click on "Add Institute Request".		
4.2	Fill in the following institute details: a. Institute Name b. Address c. Pin Code d. Phone Number e. Email Address f. Select Institute Type g. Institute Category h. District i. State j. Country k. Click "Save".		
4.3	The request will now appear under Request List as 'Approval Pending'.		
5	Approval Request		
5.1	Take a screenshot of the 'Approval Pending Institute request'.		
5.2	Email it to NCC-MvPI (Email ID - shatrunjay.ipc@gov.in or mvpi-ipc@gov.in).		
5.3	NCC-MvPI will review the request and inform IPC's IT team for approval.		
5.4	After approval, NCC-MvPI will send an email stating that the institute has been approved now the applicant can proceed with the MDMC Application.		
6	MDMC Application		
6.1	Log in again to the ADRMS portal.		
6.2	Go to Dashboard → Click "MDMC Application".		
6.3	Fill out all five sections of the form. Fields marked with * are mandatory:		
6.4	Institutional Information a. Name of Institution b. Name of Affiliated Hospital c. Institution Type d. Institution Category and distance between Hospital and Institution (in km) e. Number of Beds in the Hospital f. Patient Statistics (Inpatient/Outpatient) g. Total Number of Departments		
6.5	Logistic/ Infrastructural Facilities to function as a MDMC under MvPI a. Name of Department to function as MDMC b. Availability of Computers & Logistics for MvPI (Yes/No) c. Workplace allocated for MvPI (Yes/No)		
6.6	Details of Proposed Coordinator a. Designation Qualification b. Total Experience (in years) c. Experience in Materiovigilance d. Details of Training/CME on MvPI in the last 2 years		
6.7	Details of Proposed Deputy Coordinator a. Designation Qualification b. Total Experience (in years) c. Experience in Materiovigilance d. Details of Training/CME on MvPI in the last 2 years		
6.8	Contact details a. Principal/Dean/Medical Superintendent/ In charge b. Coordinator c. Deputy Coordinator		
6.9	Terms of Reference a. Read the Terms of Reference. b. Click on "We have undergone terms of reference".		
6.10	Submit the Application a. Click "Next - Preview & Submit". b. After submission, take a screenshot of the submitted application. c. Email the screenshot to NCC-MvPI for further processing.		
7	Evaluation and Probationary Approval		
	NCC-MvPI will evaluate the application. If found satisfactory, IPC will issue a confirmation email approving the MDMC application on a probationary basis for a period of three months. The email will also state that, to receive formal recognition as an MDMC, the institute will be monitored further during this probationary period on the following basis: • Submission of Medical Device Adverse Event (MDAE) Reports. • Conducting training and promotional activities. • Any other outstanding activities promoting MvPI.		
8	Monitoring During Probation		
	NCC-MvPI will monitor institute's work for next 3 months.		
9	Formal Recognition		
	If the performance of MDMC is found satisfactory for the 3 months of probation, then NCC-MvPI will send an email to formally recognize the Institute as MDMC attaching the Approval Certificate and will also add the Institution's name and details in the official list of MDMC centres.		
10	Induction-cum-Training Programme		
	An Induction-cum-Training Programme will be organized by NCC-MvPI for newly enrolled MDMCs.		
11	Change of Coordinator or Deputy Coordinator		
11.1	If the MDMC wants to change the Coordinator or Deputy coordinator due to any reasons, send an email on ID- shatrunjay.ipc@gov.in or mvpi-ipc@gov.in keeping the head of the institution in cc, mentioning the name, designation, email, phone number of the respective person.		
12	Technical Support Group (TSG) Meetings		
	Technical Support Group meeting will be held every 3 months to review the progress of MDMCs. If the performance of any MDMC is found unsatisfactory, it may be derecognized by NCC-MvPI with appropriate justification and the updated list will also be sent to NABH.		
13	Recognition as Regional Training Centre (Optional)		
	If the MDMC demonstrates good performance by regularly submitting reports and conducting training activities, IPC may also consider designating the institute as a Regional Training Centre under MvPI.		

ANNEXURE-IX

How to report in ADRMS

How to log in into ADRMS: To report any Medical Device Adverse Event (MDAE), log in to the Adverse Drug Reactions Monitoring System (ADRMS) portal using the link:

<https://adrmsipc.in/adrms/index.html>



- Enter your username or registered mobile number, input the password and click on “Sign in.”

After signing in, the dashboard will be displayed. Click on ‘ICSR reporting’ to proceed.



Click here to report MDAE

How to fill the MDAE form:

The MDAE reporting form will open, comprising 09 sections including report information, medical device details and usage, event details, patient details, medical and past drug, hospitalization/death, result of tests/procedures and causality assessment. The MDAE reporting is segregated into the following sections. Fill details and proceed accordingly.

Note: Fields marked with * are mandatory.

1. REPORT INFORMATION

a. General information

This section of the form covers:

The screenshot shows the '1. Report information' section of the MDAE form, specifically subsection 'a. General information'. The form contains several fields and dropdown menus. At the top, there is a 'Patient involved *' dropdown menu. Below it is the 'Report title' field with a placeholder 'Enter report title'. To the right of the report title is the 'Report type *' dropdown menu, which currently shows 'Initial'. Below these are two date pickers: 'Date first received' and 'Date of report *', both showing '12th', 'August', and '2026'. Below the dates are two more fields: 'Is this a serious case? *' with a 'Yes' dropdown, and 'Seriousness reasons *' with a text input field 'Enter seriousness reasons'. Below these are three location-related fields: 'City of occurrence' with a text input 'Enter city name', 'Pin code of occurrence' with a text input 'Enter pin code', and 'District of occurrence' with a dropdown menu. Below these are three more fields: 'State of occurrence' with a dropdown menu, 'Country of occurrence' with a dropdown menu, and 'Does this case fulfill local criteria for an expedited report?' with a dropdown menu. At the bottom are two more fields: 'Was the event reported to manufacturer?' and 'Was the case medically confirmed?', both with dropdown menus.

- **Patient involved** – Was the patient involved? Select Yes/No from the dropdown.
- **Report title** – Provide a brief title for the report that includes the report type, seriousness, device name, and adverse event.

Report title: Type of Report_Serious/Non-Serious_Device Name_Adverse Event

Example: Initial_Serious_IUD_Expulsion
- **Report type**– Select the appropriate type of report by ticking the checkbox in the dropdown– initial, follow-up, final, trend.

Initial: The first report that the reporter is submitting about an adverse event.

Follow up: Additional information provided subsequent to a previous report (either initial or follow-up report). If you are submitting a follow-up to a previously submitted report, please select the report type as 'follow-up', enter the original report number, and then proceed to update the relevant details within the existing report.

Final: The last report that the reporter intends to submit about an adverse event. An initial report can also serve as the final report if the reporter possesses all the necessary information about the event.

Trend: The manufacturers/importer/distributors/healthcare professionals are required to monitor trends in the significant increase of any similar adverse events with any medical device. Any notable changes in the frequency or severity of events associated with devices must be reported. These reports are referred to as "trend".

- **Date first received** – Enter the date when the adverse event was initially received by the reporter. This may be the same as the 'date of report' in case the adverse event was received and reported on the same day by reporter.

- **Date of report*** – Enter the date on which the reporter completes and submits the ICSR.

- **Is this a serious case*?** – Determine whether the adverse event qualifies as a serious event and select Yes/No from the dropdown.

If yes, then choose the seriousness reasons* from the dropdown - results in death, life-threatening, caused or prolonged hospitalization, disabling or incapacitating, congenital anomaly or birth defect, other medically important condition, required intervention to prevent permanent impairment.

Serious Adverse Event (SAE) as per MDR 2017: Serious Adverse Event means any untoward medical occurrence that leads to-

(i) a death; or

(ii) a serious deterioration in the health of the subject that either-

(A) resulted in a life-threatening illness or injury; or

(B) resulted in a permanent impairment of a body structure or a body function; or

(C) required in-patient hospitalisation or prolongation of existing hospitalization; or

(D) resulted in medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function; or

(iii) foetal distress, foetal death or a congenital abnormality or birth defect.

- **City/Pin code/District/State/Country of occurrence** – Write the city, pin code, district, state and country of occurrence of the adverse event.

- **Does this case fulfil local criteria for an expedited report?** – Select Yes/No from the dropdown depending on whether the report is an expedited report or not.

Expedited Report: According to the ICH E2D guideline (Post-Approval Safety Data Management by U.S. FDA), an expedited report is an ICSR that meets the requirements for reporting as soon as possible, but no later than 15 calendar days after day zero.

- **Was the case medically confirmed?** – Select Yes/No from the dropdown basis on whether the adverse event was medically confirmed by a healthcare professional or not.

- **Was the event reported to manufacturer?** – Select Yes/No from the dropdown depending on whether the adverse event was reported or conveyed to manufacturer or not.

- **Other Report ID tab** – Use this tab to reference a previously submitted related report.
Report ID: Enter the report ID of the previous case you want to cross-reference.
Source: Specify the origin of the referred report e.g., Marketing Authorization Holder (MAH),

Medical Device Adverse Event Monitoring Centre (MDMC).

Click the ‘+’ (plus) icon next to ‘Tab’ to add multiple report id entries.

Other report id

Link report

Documents

Tab

+

Report id

Source

- **Link Report tab** – Use this tab to link this report to another related case.

Link Report: Select or enter the related report ID to link.

Reason: Mention why the reports are being linked (e.g., same batch, similar device malfunction).

Click the ‘+’ (plus) icon next to ‘Tab’ to add multiple link report entries.

Other report id

Link report

Documents

Tab

+

Link report

Reason

- **Documents tab** – Use this tab to upload supporting files for the case.

Document held: Indicate whether relevant documents are available.

Upload relevant document: Upload files (image/video) in JPG/PNG/PDF/MP4 format (max size: 10 MB/25 MB). Use ‘browse’ to select the file, then click ‘upload’ to attach the file or ‘close’ to exit.

Click the ‘+’ (plus) icon next to ‘Tab’ to add multiple document entries.

The screenshot shows the 'Documents' tab selected. At the top, there are three tabs: 'Other report id', 'Link report', and 'Documents'. Below the tabs, there is a 'Tab +' button. Underneath, the text 'Document attached' is followed by a large, empty text input field. To the right of this field is a button labeled 'Upload relevant document' which contains an upward arrow icon and the text 'Add File'.

b. Information on primary sources

This section of the form covers:

The screenshot shows the 'b. Information on primary sources' section. It has two tabs: 'Reporter information' and 'Literature information'. The 'Reporter information' tab is active. It contains several input fields: 'Sal.' (a dropdown menu), 'First name', 'Middle name', and 'Last name' (all text input fields), 'Organization' and 'Department *' (text input fields), 'Address', 'City', and 'Pin code' (text input fields), 'District' (a dropdown menu), 'State' (a dropdown menu), 'Country' (a dropdown menu), 'Mobile no. *' (a text input field with a small icon), 'Alternate Mobile no.' (a text input field), 'Telephone no.' (a text input field with a small icon), 'Email address' (a text input field), 'Reported by *' (a dropdown menu), and 'Primary reporter *' (a dropdown menu). A 'Next' button is located at the bottom right of the form.

- **Salutation (Sal.)** – Select the appropriate salutation (Mr., Mrs., Ms., Dr., Prof.) from the dropdown.
- **Enter reporter’s full name** – Fill in the first name, middle name (if any), and last name.
- **Organization and department** – Enter the name of the reporter’s organization and their department*.
- **Address and contact details** – Fill the address, city, pin code, district, state, country*, mobile no.*, telephone no., and email address of the reporter.

- **Reported by*** – Select the specific category of the person or organization submitting the report from the dropdown - Pharmaceutical Company, Regional Pharmacovigilance /Materiovigilance Centre, Health Professional, Patient /Consumer, Regulatory Authority, Other (e.g., Distributor, Study Sponsor, Contract Research Organization, or Non-Commercial Organization), Medical Device License Holder.

Primary reporter*: Select Yes/No based on whether the person or organization marked under “Reported by” is the primary reporter

Primary reporter: Person who directly observed or was involved in the adverse event.

Note: If a hospital or patient shares an adverse event with a license holder who subsequently submits the report, the primary reporter must be the hospital’s healthcare professional/ consumer/user—not the license holder.

In such cases, enter the healthcare professional’s details in the ‘Reporter Information’ section. The license holder should then add their own details as a secondary reporter by clicking “Tab +” and entering the required personal and organizational information.

- **Literature information** – Navigate to the ‘Literature Information’ tab to add any literature references

Click on ‘Next’ to move on to the next section of the form.

2.MEDICAL DEVICE INFORMATION

a.Device category

This section of the form covers:

- **Device category*** – Select the category of the device from the dropdown: Medical Device or In Vitro Diagnostics (IVD).

2. Medical device

a. Device category

Device category *

Select device category

Device Risk Classification as per India MDR 2017

Select risk classification

- Medical device name*** – Enter the name of the medical device associated with the reported adverse event. Once the medical device name is entered (e.g., “Digital Thermometer”), the system will automatically fetch the corresponding device risk classification (e.g., “Low-Moderate Risk, Class B”) as per the Medical Devices Rules (MDR), 2017 and medical device category. If the medical device is not available in the list, select “Others” and manually enter the specific name of the medical device along with the corresponding risk class, as per the MDR, 2017.

a. Device category

Device category *

Medical Device

Medical Device Name *

Select Medical Device

Device Risk Classification as per India MDR 2017

a. ☐ Therapeutic ☐ Diagnostic ☐ Preventive ☐ Assistive ☐ Imaging

b. ☐ Implantable device ☐ Non-Implantable device

c. ☐ Invasive ☐ Non-Invasive

d. ☐ Single use device ☐ Reusable device ☐ Reuse of manufacture marked single use device

e. ☐ Sterile ☐ Non-Sterile

f. ☐ Personal Use /Homecare Use

- Salutation (Sal.)** – Select the appropriate salutation (Mr., Mrs., Ms., Dr., Prof.) from the dropdown.
- Enter reporter’s full name** – Fill in the first name, middle name (if any), and last name.
- Organization and department** – Enter the name of the reporter’s organization and their department*.
- Address and contact details** – Fill the address, city, pin code, district, state, country*, mobile no.*, telephone no., and email address of the reporter.

Medical Device (as per MDR 2017) — All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of:

- (i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
- (ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;
- (iii) investigation, replacement or modification or support of the anatomy or of a physiological process;
- (iv) supporting or sustaining life;
- (v) disinfection of medical devices; and
- (vi) control of conception.

- **In-Vitro Diagnostic device**– Select “In Vitro Diagnostics (IVD)” from the Medical Device Category dropdown if the suspected device is an IVD. Select the applicable risk classification according to MDR, 2017 and IVD sub-category (Kits, Reagents, Calibrator, Control Material, or IVD Electronic Reader/ Analyzer) from the available options. The specific name of the IVD should be entered under the “Others” option.

In Vitro Diagnostics (IVD): A medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

a. Device category

Device category *

In Vitro Diagnostics (IVD) ▾

Device Risk Classification as per India MDR 2017

A - Low risk ▾

a. ☐ Kits

b. ☐ Reagents

c. ☐ Calibrator

d. ☐ Control material

e. ☐ IVD electronic reader/ Analyzer

Others

- **Device risk classification as per India MDR, 2017** – Select the risk classification (A, B, C, D) from the dropdown.

Classification of medical devices (as per MDR 2017):

(1) Medical devices other than in vitro diagnostic medical devices shall be classified on the basis of parameters specified in Part I of the First Schedule of MDR, 2017, in the following classes:

- (i) low risk - Class A;
- (ii) low moderate risk- Class B;
- (iii) moderate high risk- Class C;
- (iv) high risk- Class D.

(2) In vitro diagnostic medical devices shall be classified on the basis of parameters specified in Part II of the First Schedule of MDR, 2017, in the following classes:

- (i) low risk - Class A;
- (ii) low moderate risk- Class B;
- (iii) moderate high risk- Class C;
- (iv) high risk- Class D.

Every device marketed in India is regulated and classified as per MDR 2017. Kindly visit www.cdsco.gov.in to see the classification of suspected medical device.

b. Device details

This section of the form covers:

b. Device details

License type *

Select

Nomenclature code (If applicable)

Select

Device information *

Select

Manufacturer name

Manufacturer address

Importer name

Importer address

Distributor name

Distributor address

Catalogue no.

Model no.

Lot/ Batch no.

Serial no.

Software version

Year of manufacturing

UDI no. (If applicable)

Associated devices/ accessories

Any other relevant information

Upload relevant document

Add File

- **License type** – Select the license type from the dropdown: Manufacture license or Import license. Write the license number after selecting the license type.

- **Nomenclature code (If applicable)** – Select the nomenclature code from the dropdown: Global Medical Device Nomenclature (GMDN) or Universal Medical Devices Nomenclature System (UMDNS). Write the code after selecting the nomenclature type.

Global Medical Device Nomenclature (**GMDN**) and Universal Medical Device Nomenclature System (**UMDNS**) are both systems used for classifying and identifying medical devices. These codes are the international naming and grouping convention used to identify and consistently describe medical device.

- **Device information*** – Select whether you want to mention the device name/trade name/brand name from the dropdown.

Provide details of Manufacturer/Importer/Distributor including name & address.

- **Device identification details:** Enter the catalogue no., model number, lot/batch number, serial number, software version (if applicable), year of manufacture, and UDI (Unique Device Identification) number (if applicable) of the medical device.

- **Associated devices/accessories** – Mention if any additional equipment or components were used in conjunction with the primary medical device.

- **Any other relevant information** – Mention if any other relevant information is available for the medical device.

- **Upload relevant document** – Upload any relevant document (image/video) in JPG/PNG/PDF/MP4 format (max size: 10 MB/25 MB). Use 'browse' to select the file, then click 'upload' to attach the file or 'close' to exit.

c. Device usage

Installation date: [dropdown] [dropdown] [dropdown]

Expiration date: [dropdown] [dropdown] [dropdown]

Last preventive maintenance date: [dropdown] [dropdown] [dropdown]

Last calibration date: [dropdown] [dropdown] [dropdown]

How long has device/ equipment/ machine in use? [dropdown]

Is the usage of device as per manufacturer claim/ instruction for use/ user manual? [dropdown]

Any other relevant information: [text area]

Previous [Next]

- **Installation date** – Mention the date when the device was set up and made operational.

- **Expiration date** – Mention the expiry date of the device.

- **Last preventive maintenance date** – Mention the most recent date when the device underwent scheduled maintenance to ensure proper functioning.
- **Last calibration date** – Mention the most recent date when the device was calibrated to maintain accuracy and performance.
- **How long was device/equipment/machine in use?** – Mention the total time period that the device/equipment/machine has been in use.
- **Is the usage of device as per manufacturer claim/instruction for use/user manual?** – Select Yes/No depending on whether the device was used according to the manufacturer’s guidelines and instructions provided in the user manual. If no, specify the usage.
- **Any other relevant information** – Mention if there is any other relevant information available.

Click on ‘Next’ to move on to the next section of the form.

3.EVENT DETAILS

a.Event description

This section of the form covers:

3. Event details

a. Event description

Date of event/ Near-miss incident *

Day Month Year

Date of implant (If applicable)

Day Month Year

Date of explant (If applicable)

Day Month Year

Location of event

Select location

Device operator

Select

Is device in use after incidence?

Select

Device disposition/ current location

Select

Problem noted prior to use/ near miss event

Select

Adverse Event Category *

Select

Detailed description of event ⓘ *

Enter detailed description of event

- **Date of event/Near-miss incident*** – Mention the exact date when the event or near-miss incident occurred.

Near-miss incident: A ‘Near miss event’ is an unplanned event that did not result in injury, illness, or damage – but had the potential to do so.

Reference- Guidance Document: Materiovigilance Programme of India (version 1.2)

- **Date of implant (If applicable)** – Mention the date (DD/MM/YYYY) when the implantable device was initially inserted into the patient body or body orifice (for implantable medical devices only).
- **Date of explant (If applicable)** – Mention the date (DD/MM/YYYY) when the implantable device was removed from the patient body or body orifice (for implantable medical devices only).
- **Location of event** – Select the appropriate setting where the event occurred - hospital premise, manufacturer/distributor premise, home or others - and provide the full address of the location.
- **Device operator** – Select the appropriate option depending on who was operating the medical device when the event took place from the dropdown – healthcare professional, patient, others.
- **Is device in use after incidence?** – Select Yes/No from the dropdown depending on whether the device is still being used after the reported incident.
- **Device disposition/current location** – Select the current status of the device after the event- returned to company, remains implanted in patient, within the healthcare facility, at patient's home, destroyed, others.
- **Problem noted prior to use/near miss event** – Select Yes/No depending on whether the problem was noted prior to use/near miss event.
- **Adverse event category*** – Select the adverse event category from the dropdown.
- **Detailed description of event*** – Write a detailed description of the event, including what happened, how it occurred and any relevant circumstances or observations.

Description of event: The reporter should try to ensure that the event description captures all relevant details, including:

a. Date when patient joined or visit the hospital; b. Presenting symptoms; c. Medical device used; d. Adverse event observed; e. Patient outcome; f. Immediate action taken; g. Documents attached (Proof/Videos, if applicable)

For ex: On 31/10/2025, patient 'X' visited the hospital with complaints of severe abdominal pain. The patient was administered IV medication using the 'XYZ Infusion Set'. During administration, it was observed that the set was faulty and the medicine was leaking. A new infusion set of the same (or different) brand was immediately used to continue the administration. The patient did not suffer any injury.

- **Frequency of occurrence of similar adverse event in India & globally in past 3 years** – Mention details of similar adverse events in India and globally in the past 3 years, including the number of similar events, total no. of devices supplied, and frequency of occurrence (%).

Frequency of occurrence of similar Adverse Event in India in past 3 years			
Year	No. of similar events	Total no. supplied	Frequency of Occurrence(%)
2023	No. of similar events	Total no. supplied	Frequency of Occurrence(%)
2024	No. of similar events	Total no. supplied	Frequency of Occurrence(%)
2025	No. of similar events	Total no. supplied	Frequency of Occurrence(%)

Frequency of occurrence of similar Adverse Event in globally in past 3 years			
Year	No. of similar events	Total no. supplied	Frequency of Occurrence(%)
2023	No. of similar events	Total no. supplied	Frequency of Occurrence(%)
2024	No. of similar events	Total no. supplied	Frequency of Occurrence(%)
2025	No. of similar events	Total no. supplied	Frequency of Occurrence(%)

• **Upload relevant document** – Upload any relevant document (image/video) in JPG/PNG/PDF/MP4 format (max size: 10 MB/25 MB). Use ‘browse’ to select the file, then click ‘upload’ to **attach the file** or ‘close’ to exit. • **Last calibration date** – Mention the most recent date when the device was calibrated to maintain accuracy and performance.

b.Event outcome

This section of the form covers:

b. Event outcome

Patient outcome

Select

Any other relevant information

Enter any other relevant information

Previous

Next

• **Patient outcome**– Select the appropriate option from the dropdown to indicate the patient’s status- recovered, not yet recovered, death, others, stable.

• **Any other relevant information** – Mention if there is any other relevant information available.

Click on ‘Next’ to move on to the next section of the form.

4.PATIENT DETAILS

a.Patient information

This section of the form covers:

4. Patient Info

a. Patient information

Sal. First name Middle name Last name

Patient initials Father's name Mother's name

Address City Pin code

District State Country

Mobile no. Telephone no. Email address

GP medical record no. Specialist record no. Hospital record no. (IPD/ OPD) Investigation no. Protect confidentiality

- **Salutation (Sal.)** – Select the appropriate salutation (Mr., Mrs., Ms., Dr., Prof.) from the dropdown for the patient.
- **Patient details** – Fill in the patient’s name or initials.
- **Father’s name** – Enter the patient’s father’s name.
- **Mother’s name** – Enter the patient’s mother’s name.
- **Address and contact details** – Enter the address, city, pin code, district, state, country, mobile no., telephone no., and email address of the patient.
- **GP medical record no.** – Enter the patient’s General Practitioner (GP) record number.
- **Specialist record no.** – Enter the patient’s specialist consultation record number.
- **Hospital record no. (IPD/OPD)** – Enter the inpatient department (IPD) or outpatient department (OPD) hospital record number.
- **Investigation no.** – Enter the laboratory or radiology investigation reference number.
- **Protect confidentiality** – Select Yes/No from the dropdown to protect confidentiality or not.
- **Patient characteristics** – Enter the patient’s age information, gender, body weight (kg), body height (cm), and indicate whether concomitant therapies were present at the time of the event.

Patient characteristics	Patient habits	Patient allergic, mutation and resistance
Age information Select		Concomitant therapies i Select
Body weight kg	Body height cm	Gender Select

• **Patient habits** – Select the patient’s habits from the dropdown. Multiple options can be selected: alcohol/contraceptives/drug abuse/nicotine use/special diet.

Patient characteristics	Patient habits	Patient allergic, mutation and resistance
Habits Enter habits		Others Enter others

• **Patient allergic, mutation and resistance** – Indicate whether the patient has any known drug allergies by selecting Yes or No from the dropdown and enter the drug name(s) in the text field; use the “+” button to add multiple entries if required. Mention any known food allergies, relevant genetic mutations, and documented resistance in the respective text fields.

Patient characteristics	Patient habits	Patient allergic, mutation and resistance
Allergic to drug Tab * Fixed drug combination (FDC) Select Drug name (WHODrug) Enter drug name		
Allergic to food Enter allergic to food		Mutation Enter mutation
Resistance Enter resistance		
Previous		Next

Click on ‘Next’ to move on to the next section of the form.

5. MEDICAL AND PAST DRUG HISTORY

a. Medical history

This section of the form covers:

The screenshot shows a form titled 'A. Medical and past drug history'. Inside, there is a sub-section 'a. Medical history'. At the top of this sub-section is a 'Tab' button with an asterisk. Below it are three input fields: 'Past illness' with a dropdown menu showing 'Select', 'Family history' with a dropdown menu showing 'Select' and an information icon, and 'Any other history' with a text input field showing 'Enter details'. Below these is an 'Additional remarks' section with a text input field showing 'Enter additional remarks'.

- **Start date** – Select the date when the condition began.
- **Continuing** – Choose Yes/No/Unknown from the dropdown depending if the ‘medical condition’ provided is still present at the time of the report or not.
- **Detailed description** – Write detail description or any additional information about the ‘medical condition’ provided.
- **Family history** – Select Yes/No depending on whether the ‘medical condition’ provided is reported also to be present in another family member (such as hereditary diseases.)

b. Past drug history

This section of the form covers:

The screenshot shows a form titled 'b. Past drug history'. Inside, there is a sub-section 'b. Past drug history'. At the top of this sub-section is a 'Tab' button with an asterisk. Below it are two input fields: 'Relevant past drug name (WHODrug)' with a text input field showing 'Enter drug name', and 'Relevant drug, indication and reaction name.' with a text input field showing 'Enter indication and reaction'. Below these are two date selection sections: 'Start date' and 'End date'. Each date section has three dropdown menus for 'Day', 'Month', and 'Year'.

- **Relevant past drug name (WHO Drug)** – Write the name of the relevant past drug.
- **Relevant drug, indication and reaction name** – Write the name of the drug, indication and reaction.
- **Start date** – Select the date when the patient began using the drug.
- **End date** – Select the date when the patient stopped using the drug.

c. Past medical device history

This section of the form covers:

The screenshot shows a form titled 'c. Past medical device history'. It features a teal header bar with the title. Below the header is a light blue box containing the text 'Relevant past medical device history' and a large text input field with the placeholder 'Enter relevant past medical device history'. At the bottom of the form, there are two buttons: 'Previous' on the left and 'Next' on the right, both with a teal gradient.

- **Relevant past medical device history** – Write any relevant past medical device history. Click on 'Next' to move on to the next section of the form.

6.HOSPITALIZATION/DEATH INFORMATION

a.Hospitalization related information

This section of the form covers:

The screenshot shows a form titled '6. Hospitalization / Death' with a teal header bar. Below the header is a light blue box titled 'a. Hospitalization related information'. It contains two date selection fields: 'Hospitalization date' and 'Discharge date'. Each field has three dropdown menus for 'Day', 'Month', and 'Year'. Below these is a text input field for 'Treatment details' with the placeholder 'Enter treatment details'. At the bottom, there is a section for 'Upload discharged summary' with an 'Add File' button that includes a cloud upload icon.

- **Hospitalization date** – Select the date of hospitalization of the patient in case the patient was hospitalized.
- **Discharge date** – Select the discharge date in case of hospitalization.
- **Treatment details** – Write the details of the treatment given to the patient.
- **Upload discharged summary** – Upload the discharge summary documents. Upload any relevant document (image/video) in JPG/PNG/PDF/MP4 format (max size: 10 MB/25 MB). Use 'browse' to select the file, then click 'upload' to attach the file or 'close' to exit.

b.Death related information

This section of the form covers:

b. Death related information

Death date: Day, Month, Year

Death time: Hour, Minute

Death cause: Enter death cause

Autopsy performed?: Select

Upload relevant document: Add File

Previous Next

- **Death date** – Select the date of death of the patient.
- **Death time** – Select the time of death of the patient.
- **Death cause** – Write the cause of the death of the patient.
- **Autopsy performed?** – Select Yes/No/Unknown from the dropdown depending on whether the autopsy was performed or not or is unknown to the reporter.
- **Upload relevant document** – Upload any relevant document (image/video) in JPG/PNG/PDF/MP4 format (max size: 10 MB/25 MB). Use 'browse' to select the file, then click 'upload' to attach the file or 'close' to exit.

Click on 'Next' to move on to the next section of the form.

7. TESTS AND PROCEDURES

a. Results of tests and procedures

This section of the form covers:

7. Tests and procedures

a. Results of tests and procedures

Test date: Day, Month, Year

Test name: Enter test name

Test result: Select

Test result (code): Select

Low range: Enter low range

High range: Enter high range

Result: Enter result

Comments: Enter comments

Upload relevant document: Add File

- **Test date** – Select the date of test done for the patient.
- **Test name** – Write the name of the test

- **Test result and code** – Write the result of the test in units (as g, g/l, bq). Select the unit from the dropdown. If you could not find the required unit in the dropdown then select others from the dropdown, a text field will appear, enter the required unit there. Select the result code of the test from the dropdown- positive/negative/borderline/inconclusive.

- **Range** – Mention the low and high range.

- **Result** – Write the result of the test.

- **Comments** – Write any relevant comments (by the reporter) for the test.

- **Upload relevant document** – Upload any relevant document in JPG/PNG/PDF format.

Click on 'Next' to move on to the next section of the form.

8.ASSESSMENT

a.Causality Assessment

This section of the form covers:

The screenshot shows a digital form titled '8. Assessment' with a teal header. Below the header is a section titled 'a. Causality assessment'. This section contains four text input fields, each with a label and an information icon (i):

- Reporter's comments**: The input field contains the placeholder text 'Enter reporter's comments'.
- Sender's comments**: The input field contains the placeholder text 'Enter sender's comments'.
- Investigation action taken**: The input field contains the placeholder text 'Enter investigation action taken'.
- Root cause of problem**: The input field contains the placeholder text 'Enter root cause of problem'.

- **Reporter's comments** – Reporter can write his comments on the diagnosis, causality assessment or other issues considered relevant.

- **Sender's comments** – Write if there are any sender's comments for the assessment of the case or any disagreement with, and/or alternatives to the diagnosis given by the reporter.

- **Investigation action taken** – Write the specific actions taken during an investigation and the corresponding dates or deadlines when these actions were carried out or completed.

- **Root cause of problem** – Mention the root cause of the event.

Root Cause Analysis: RCA is a defined process that seeks to explore all of the possible factors associated with an incident by asking what happened, why it happened and what can be done to prevent it from happening again

b.MAH Investigation & action taken

This section of the form covers:

The screenshot shows a digital form titled "b. Manufacturer/ Authorized representative investigation & action taken (For manufacturer/ authorized representative use only)". The form contains three text input fields with placeholder text: "Enter manufacturer/ authorized representative device risk analysis report", "Enter corrective/ preventive action taken", and "Enter device history review". At the bottom of the form, there are two buttons: "Previous" on the left and "Next" on the right.

- **Manufacturer/Authorized representative device risk analysis report** – MAH is requested to write about the device risk analysis report summary.
- **Corrective/Preventive action taken** – Write the measures implemented to address and rectify the identified issue (i.e. corrective action) and to prevent its recurrence in the future (i.e. preventive action).
- **Device history review** – Write about the device history (such as quality tests etc.).

Click on '**Next**' to move on to the next section of the form.

PREVIEW & SAVE

New ICSR under MvPI

1REPORT INFORMATION2MEDICAL DEVICE3EVENT DETAILS4PATIENT5MEDICAL AND PAST DRUG HISTORY6HOSPITALIZATION/DEATH7TESTS AND PROCEDURES8ASSESSMENT9REVIEW & SUBMIT

1. Report information

2. General information

3. Information on primary source

4. Medical device

5. Device usage

6. Event details

7. Patient

8. Tests and procedures

9. Assessment

10. Assessment information

On this page

1. Report information

2. General information

3. Medical device

4. Event details

5. Patient

6. Medical and past drug history

7. Tests and procedures

8. Assessment

9. Review & submit

Previous

Save

Report type	Initial
Date first received	12 August 2024
Date of report	12 August 2024
Is this a serious case?	Yes
Worldwide unique id	IN-RO-142367

Reporter information

Department	IPC
Country	India
Mobile no.	9822334455
Reported by	Other (e.g. Students, Study sponsor, Contract Research Organization, or non commercial organization)
Primary reporter	Yes

4a. Device category

Device Tax Classification as per India MDR 2017	C. Moderately high risk
Device category	Medical Device
Medical Device Group	Abdominal decompression chamber pump

4b. Device details

Generic type	Manufacture Name - MP
Trade name/brand	Device name - XL

6a. Event description

Date of event/ New India incident	27 January 2025
Adverse Event Category	Business Related Issue
Detailed description of event	1

6b. Event outcome

✓

7. Patient

Patient confidentiality	Yes
-------------------------	-----

Patient Characteristics

8. Tests and procedures

9. Assessment

10. Assessment information

Verify and edit the report details in the **Preview** section as required. Once all information has been confirmed, click **“Save”** to submit the MDAE report directly to NCC-MvPI, IPC.

100 MvPI-IPC

ANNEXURE-X

List of Critical Medical Devices

Sr. No.	Device	Adverse event reported	Sr. No.	Device	Adverse event reported
1.	Antero medial distal femur locking plate	Device break	38.	Ophthalmic Solution (pre filled sterile syringe)	Contamination with foreign particles (Pseudomonas aeruginosa)
2.	Artificial Urinary Sphincter (AUS), Artificial Urinary Prosthesis	Prosthesis Failure & Infection	39.	Orthopaedic Mega prosthesis (Femoral Stem)	Stem Breakage
3.	Auto-Disable (AD) Syringes or Reuse Prevention (RUP) Syringes, Auto disable Hypodermic Syringe	1. Quality issues like plunger breakage, blockage, Leakage, presence of foreign particles 2. Poor Quality, Blockage, Plunger & Piston Breakage, Presence of Foreign Particles	40.	Orthopedic drill	Drill bit breakage during use leading to serious patient outcome.
4.	Blood Transfusion Set or Blood Administration Set	1. Contaminated with fungus, leaky 2. Separated Drip Chamber & Obstructed Blood regulation 3. Regulator Malfunctions Causing Free Flowing of Blood, Loosened at the Point of Insertion 4. Improper Functioning of Regulator/Leakage of Blood	41.	Pacing Lead	High Capture threshold, loss of capture, and Lead dislodgement
5.	BONE WAX	Poor quality and suture frequently get cut off during use	42.	Pacing system analyzer	lead Impedance, threshold-related issue, lead related issues and screw related issue during use
6.	Breathing Circuit/Ventilator Circuit Voice Prosthesis	Prosthesis Leakage	43.	Perfluorocarbon Liquid, Heavy silicone oils, Intracocular membrane staining dye	1. Acute blindness 2. Moderate intraocular inflammatory reactions 3. Retinal necrosis 4. Retinal vascular occlusion 5. Optic nerve atrophy 6. Retinal atrophy 7. Subretinal fibrosis 8. Proliferative vitreoretinopathy 9. Vision Loss
7.	Breathing Circuit/Ventilator Circuit	Water is Entering the Patient Trachea	44.	Phakic Intraocular Lens (PIOL) Implantable Collamer Lens	Toxic Anterior Segment Syndrome (TASS)
8.	Central Venous Catheter	Guidewire Breakage Inside the Body	45.	Pregnancy Test Kit	Reading Errors
9.	Circular Stapler or Intraluminal Stapler Auto Suture Circular Stapler	1. Mechanical malfunction/failure 2. Improper pin placement 3. Device disassembly inside the patient during use 4. Misfiring of the suture 5. Bleeding and suture line leakage	46.	Nasogastric Tube	Struck in Trachea
10.	Basic Male Condom	Counterfeit Device	47.	SARS-CoV-2 Antigen Rapid Test Kit Pan bio COVID-19 Ag rapid test device	False negative result
11.	Continuous Positive Airway Pressure (CPAP) and Bilevel Positive Airway Pressure (BiPAP/BiPA) CPAP, BiPAP, Continuous and non-continuous ventilators	1. Headache, upper airway irritation, cough, chest pressure and sinus infection, nausea/vomiting 2. Skin, eye, and respiratory tract irritation, inflammatory response, headache, asthma 3. Adverse effects to other organs (e.g. kidneys and liver) 4. Toxic carcinogenic affects	48.	Single piece Intraocular Lenses (IOL)	Infection followed by vision loss after Implantation
12.	Cranial perforator	Drill bit breakage during use leading to serious patient outcome.	49.	Single-Use Sterile Hypodermic Syringe	1. Poor Quality, Blockage, Plunger Breakage 2. Leakage/Piston Breakage/Quality Issue 3. Leakage, Loose Piston, Semi Blocked Plunger, Foreign Particles in Syringe, Vacuum Creation While Loading Medication
13.	Digital Blood Pressure Monitor, BP Monitor	BP cuff leakage, Inflation Bulb damage, Reading error, Pressure holding issue	50.	Spinal Implant	Implant Breakage
14.	Drug Eluting Stent	1. Stent Couldn't cross the lesion site 2. Balloon would not deflate during use, malfunctioning of the device	51.	Spinal Needle	Severe Headache/Fever/Vomiting due to bacterial contamination
15.	Drug-Eluting Coronary Stent System (DES) Coronary Stent System	Balloon Deflation Issue	52.	Sterile Disposable Hypodermic Syringes/ Disposable Syringes Single Use Syringe	Foreign particle/Contaminated/Needle cap missing/ Broken syringe/Drug Leakage/Suction and vacuum issues/ Broken Hub/ Blunt edges/Needle dislocates on its own/Improper functioning of Piston
16.	Grey Top Tube Vacutainers (Glucose FX) 2ml	Defective devices (Leaky)	53.	Sterile Latex Surgical Gloves Latex Surgical Gloves	Black discoloration of skin/Rashes/Itching/Redness/ Irritation/Frequent Tearing/Skin erosion due to Excessive Powder/Not comfortable in wearing/One-handed/Single Size available/White skin peeling/Perforations
17.	Hemodialysis Catheter	Foreign Particles Present/Leakage/Poor Quality	54.	Sterile Latex Surgical Gloves or Disposable Surgical Rubber Gloves	Severe rashes, Contact Dermatitis, Poor Quality
18.	Infant Incubator	Malfunctioning (Heating Issue)	55.	Sterile Umbilical Cord Clamp or Disposable Umbilical Cord Clamp Umbilical cord clamp	Non-functioning of clamps
19.	Inflatable artificial urinary sphincter artificial urinary sphincter	Device erosion following the implantation Other common adverse events: 1. Implant placement related issues 2. Mechanical malfunction associated with the device 3. Fluid leak (de-incontinence) recurring incontinence	56.	Syringe pump	Short circuit
20.	Inflatable Penile Prosthesis	Pump failure and implant related infection	57.	Three way stop cock with extension line	Breakage/Leakage/Detached/Stop cock with extension line missing/Improper fluid control/Loose Connector/Excess sticky/Foreign Particle/Contaminated/ Non-sterile
21.	Inflatable Penile Prosthesis (IPP) or a Prosthesis, penis, Inflatable Penile Prosthesis	Pump failure causing difficulty in achieving cylinder inflation Other common adverse events: 1. Severe scrotal and penile pain during full activation of the implant 2. Corporal perforation 3. Bleeding at the site of implant 4. Device migration out of the position 5. Device and/or tissue erosion	58.	Total Knee Replacement	Implant Deformation/failure
22.	Inhaler	Delivering Improper dose/ Medicament not released/Issue with the pipe of inhaler/ Dose Counter Error/ not working/ Pin Broken etc.	59.	Trans Catheter Pulmonary Valve	Bacterial Infection
23.	Intra Ocular Lens	1. IOL Breakage & Infection 2. IOL Breakage Post Implantation 3. IOL Opacification Post Implantation 4. Persistent Peripheral /side blockage obstruction in Left eye and constant visual discomfort & uneasiness, Negative dysphotopsia/Persistent blurred, unclear and distorted vision for near, intermediate and distance vision. 5. Unable to see things clearly even at a distance/Difficulty performing routine visual tasks including reading, working and/or driving/Reddening of the sclera and/or conjunctivitis/ Constant irritation/ malodorous secretions and itches in eyes/ Breakage of Intraocular lens into 3 pieces during cataract surgery which damaged the cornea and other structures of the eye like capsular bag. 6. Toxic Anterior Segment Syndrome (TASS)	60.	Transcatheter Atrial Septal Defect Occlusion Device Septal Occluder	Cobra deformation during implant
24.	Intra Venous Infusion Set	1. Outpouring, Obstruction & Irregular Flow 2. Blockage, Leakage/ Faulty Regulator/Malfunction/ Compromised Quality 3. Uncontrolled Flow/Poor Quality 4. Fungal Contamination & Leakage	61.	Ultrasound Biopsy Needle	1. Mechanicad deformation of needle during use 2. Device break and needle deformation during use
25.	Intrauterine Contraceptive devices (IUCD)	Device expulsion, Genital Hemorrhage	62.	Ultrasound Transminison Gel	Bacterial Contamination/Non-sterile
26.	Intravenous Cannula	1. Blister Formation, Blue & Hypopigmented Patch at the Insertion Site, Leakage Through Cannula during Drug Administration, Suboptimal/Low Quality Stylet, Stylet & Catheter Wings Sticking Together 2. Blister Formation, Skin Ulcers, Redness, Leakage, Blockage, Swelling, Irritation, Thrombophlebitis	63.	Urine Collection Bag or Urine Drainage Bag Urine Bag	Urine Leakage
27.	IV Infusion Set or Intravenous Administration Set Infusion Set with needle	Disconnect automatically during the Medication /Faulty Dropper/Leakage at tubing or connector junction/Regulator failure/Overflow of medication/Drug wastage/Needle missing/ Dislodgement			
28.	Latex Examination Gloves	Frequent Tearing During Usage and Prior to Usage, Excessive Powder/Poor quality			
29.	Latex Surgical Gloves or Sterile Latex Surgical Gloves Rubber Surgical Gloves	Allergic Reactions (Redness, Drying, Itching), Poor Quality, (Tearing of Gloves During Medical Examination), excessive Absorption of Powder on Hands			
30.	Locking Compression Plates (LCP), Internal orthopedic fixation system	Implant break/Implant bent after implantation			
31.	Lumbar Titanium Interbody Cage/Spacer with Nano-surface Technology.	Displaced fusion device			
32.	Mandibular Reconstruction (Plate)	Mandibular plate breakage			
33.	Mechanical Heart Valve or Bioprosthetic (Tissue) Heart Valve Heart valves & Tibial Bearing Insert	Device break, Malfunction, Leaflet dislodgement			
34.	Mechanical Ventilator	1. Ventilator Associated Pneumonia (VAP)- Company was not found to be registered on CDSCO portal of approved medical device manufacturers and importers. 2. Cytec Healthcare Private Limited was not found to be registered or recorded on the CDSCO online portal as an approved medical device manufacturer or importer			
35.	Meter-dose Inhaler (MDI)	Less dosage delivery; Dose meter Error & others - 65 reports			
36.	Microporous Surgical Tape or Surgical Paper Tape Adhesive Surgical Tape	Poor Adhesive Property/Insufficient Adhesion			
37.	Monofilament synthetic absorbable skin support e.g. filing thread sterile	Atypical Mycobacterial Infection			

Note: The list of safety alerts is regularly updated and maintained on the official website of the Indian Pharmacopoeia Commission (IPC). For the latest and updated safety alerts, refer to the IPC website.

ANNEXURE-XI

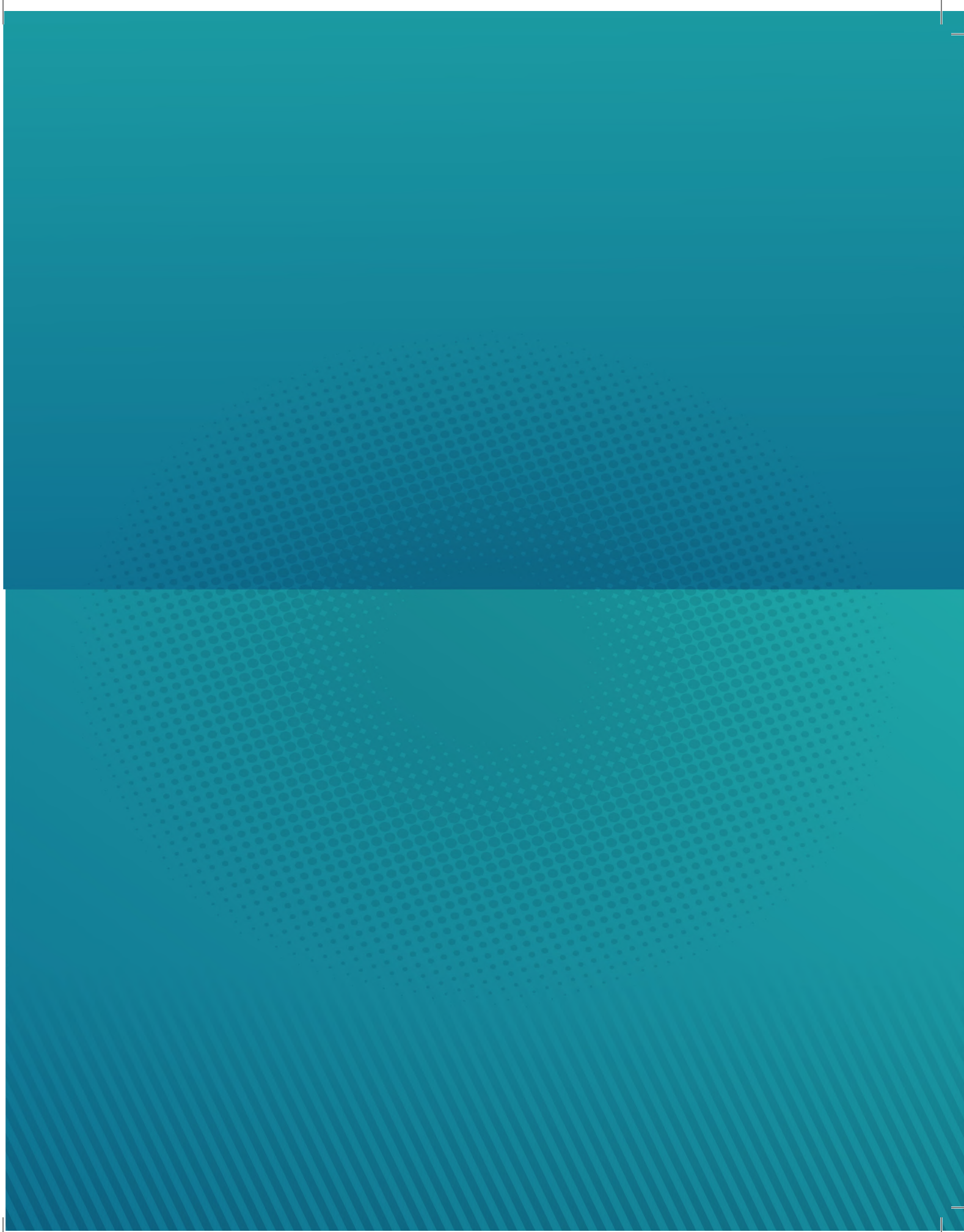
Monthly Medical Device Adverse Event Monitoring Centres Performance Report

Sr. No.	State	MDMC Name & Address	No. of reports submitted	No. of reports in preceding month	Report in prescribed format	Qualified MDAE	Reporter Information	Device Information	Adverse event description	Seriousness Description	Patient/User Information	Event Outcome	Causality Assessment
					Out of 100%	Out of 100%	Out of 100%	Out of 100%	Out of 100%	Out of 100%	Out of 100%	Out of 100%	Out of 100%

ABBREVIATIONS

Abbreviations

Abbreviation	Full Form	Abbreviation	Full Form
AD	Auto-Disable	MoHFW	Ministry of Health & Family Welfare
ADRMS	Adverse Drug Reactions Monitoring System	MRI	Magnetic Resonance Imaging
AE	Adverse Event	MvA	Materiovigilance Associate
AHWP	Asian Harmonization Working Party	MvPI	Materiovigilance Programme of India
AIIMS	All India Institute of Medical Sciences	NABH	National Accreditation Board for Hospitals & Healthcare Providers
ALT	Advance Level Training	NCAR	National Competent Authority Report
AMC	Adverse Drug Reactions Monitoring Centre	NCC	National Coordination Centre
ANM	Auxiliary Nurse Midwives	NFI	National Formulary of India
API	Active Pharmaceutical Ingredient	NHM	National Health Mission
AUS	Artificial Urinary Sphincter	NHSRC	National Health Systems Resource Centre
BIS	Bureau of Indian Standards	NRA	National Regulatory Authority
BMT	Biomedical Technology	NSAE	Non-Serious Adverse Event
BP	Blood Pressure	OTD	Outpatient Department
BPAP	Bilevel Positive Airway Pressure	OTP	One-Time Password
CAPA	Corrective and Preventive Action	PHC	Primary Health Centre
CDSCO	Central Drugs Standard Control Organization	PIOL	Phakic Intraocular Lens
CHC	Community Health Centre	PMS	Post-Market Surveillance
CLA	Central Licensing Authority	PvPI	Pharmacovigilance Programme of India
CME	Continuing Medical Education	QCI	Quality Council of India
CPAP	Continuous Positive Airway Pressure	QR	Quick Response
DADG	Deputy Additional Director General	R&D	Research and Development
DCGI	Drugs Controller General of India	RCA	Root Cause Analysis
DGHS	Directorate General of Health Services	RTC	Regional Training Centre
DES	Drug-Eluting Stent	RUP	Reuse Prevention
DST	Department of Science and Technology	SAE	Serious Adverse Event
FSCA	Field Safety Corrective Action	SC	Sub-Centre
FSN	Field Safety Notice	SCTIMST	Sree Chitra Tirunal Institute for Medical Sciences and Technology
GMDN	Global Medical Device Nomenclature	SLA	State Licensing Authority
HCP	Healthcare Professional	SOP	Standard Operating Procedure
ICSR	Individual Case Safety Report	SUSAE	Suspected Unexpected Serious Adverse Event
IFU	Instructions for Use	TASS	Toxic Anterior Segment Syndrome
IMDRF	International Medical Device Regulators Forum	TGA	Therapeutic Goods Administration
IP	Indian Pharmacopoeia	TSG	Technical Support Group
IPC	Indian Pharmacopoeia Commission	UDI	Unique Device Identification
IPP	Inflatable Penile Prosthesis	UDI-DI	Unique Device Identifier – Device Identifier
IPRS	Indian Pharmacopoeia Reference Substances	UDI-PI	Unique Device Identifier – Production Identifier
ISO	International Organization for Standardization	UMDNS	Universal Medical Devices Nomenclature System
IVD	In Vitro Diagnostic	US FDA	U.S. Food and Drug Administration
IOL	Intraocular Lens	VAP	Ventilator-Associated Pneumonia
IUCD	Intrauterine Contraceptive Device	WHO	World Health Organization
MAH	Marketing Authorization Holder	WHO-CC	World Health Organization Collaborating Centre
MDA	Medical Device Alert		
MDAE	Medical Device Adverse Event		
MDD	Medical Device Division		
MDMC	Medical Device Adverse Event Monitoring Centre		
MDR	Medical Devices Rules		
MEC	Materiovigilance Expert Committee		
MDI	Meter-Dose Inhaler		





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