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An Overview Of Materiovigilance Programme Of India

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Abstract:

Materiovigilance primarily focuses on the safety and monitoring of devices for medical use. To monitor the safety of medical devices in the Nation, the Central Drugs Standard Control Organization (CDSCO) in India launched the Materiovigilance Programme of India (MvPI) in 2015. It summarizes the main goals, aims, and efforts of India's Materiovigilance Program. Through the collection, analysis, and response to unfavorable occurrences and incidents associated with the use of medical devices, the Materiovigilance Programme of India seeks to guarantee the safety and effectiveness of all of such equipment. Healthcare professionals, manufacturers, and consumers can report unwanted events related to medical devices through a nationwide network of Materiovigilance Centers. These reports are then analyzed to identify potential safety concerns and inform regulatory decisions. The creation of a national database for adverse event reporting, activities aimed at enhancing healthcare professional's capacity, and cooperation with foreign regulatory bodies to promote knowledge exchange and best practices in Materiovigilance are some of the primary initiatives of the Materiovigilance Programme of India. By encouraging openness and responsibility in the medical device industry, the Materiovigilance Programme of India helps to safeguard patient safety and the general public health. Medical device monitoring and evaluation on a continuous basis aid in the identification of new dangers and guarantees prompt regulatory responses to reduce them.

All things looked at the Materiovigilance Programme of India is essential to protecting patient rights and building trust in the nation's usage of medical devices.

Keywords: Adverse event, Medical Device, MvPI, CDSCO.

1. Introduction:

Medical device has an important task in diagnosis, treatment and prevention of several diseases. They range from simple meter dose inhalers to complicated operation theater and radiology devices. Medical devices in particular are crucial in the prevention, diagnosis and treatment of illness and disease, as well as patient rehabilitation. Nearly 5,000 individual classes of medical devices, tens of thousands of medical device suppliers, and millions of healthcare providers exist worldwide, benefits the patients immensely, they also carry significant potential risks.

The adverse event related to medical devices can be serious and result in illness, injury or even death. Therefore, it is crucial to evaluate and determine the risks and benefits associated with the use of device. This can be achieved by a vigorous monitoring system for risk management of medical devices to assess qualitative effective and safe use of medical devices in the market. Keeping the objective in the mind materiovigilance programme of India was launched by the government of India on Materiovigilance comprising two words-materio means the material from which a medical device is made of and vigilance means the great care that is taken to notice any signs of danger or trouble. Hence, the term Materiovigilance is defined as the coordinated system of identification, collection, reporting and analysis of unacceptable performance or characteristics fluctuation of a device and replying them with the “Field Safety Corrective Actions” (FSCA) or the device recall.

In India, medical devices are regulated as per the Drugs and Cosmetics Act, 1940 and Rules 1945. In 2017, the Government of India in consultation with Drug Technical Advisory Board (DTAB) enforced Medical Devices Rule, to import, manufacture, sale, and, distribute medical devices. This rule was notified on January 31, 2017 and came into effect from January 1, 2018. “Materiovigilance programme” of India (MvPI) was launched on July 6, 2015 in Indian Pharmacopoeial Commission (IPC), in Ghaziabad by Drug Controller General of India DCG(I). The fundamental principle of this program is to create awareness about relevance of “Medical Device Adverse Events” (MDAE) among healthcare professionals. It also emphasizes on benefit-risk profile of a device, keep track of MDAE and communicate these findings to all relevant stakeholders. IPC is the National Coordination Centre (NCC) for MvPI and, its responsibility is to supervise adverse events of medical devices detected among Indian population. “Sree Chitra Tirunal Institute for Medical Sciences & Technology” (SCTIMST) operates as “National Collaborating Centre”. Central Drug Standard Control Organization (CDSCO) is a regulator of MvPI and Technical support is rendered by National Health System Resource Centre (NHSRC). Twenty-six Medical Device Monitoring Centres (MDMCs)/ Adverse Drug Reaction Monitoring Centres (AMCs) has been setup for checking completeness of a case, scrutinizing the MDAE reports and sending reports to NCC. The Central Drugs

Standard Control Organization (CDSCO) will receive recommendations based on the safety data gathered, which will help ensure that medical devices are used safely by the Indian population.

1.1 Programme Objectives:

Fig 1: Objectives of MvPI

1.2 Definition of Medical Device:

As per WHO, 'Medical device 'means any instrument, apparatus, machine, appliance, implant, reagent for in-vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purposes(s) of:

1. Diagnosis, prevention, monitoring, treatment or alleviation of disease
2. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury
3. Investigation, replacement, modification, or support of the anatomy or of a physiological process
4. Supporting or sustaining life

As per MDR, 2017, 'Medical device' means –

Substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant covered under sub-clause (i) [all medicine for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals including preparations applied on human body to repel insects like mosquitoes].

Substances including mechanical contraceptives (condoms, intrauterine devices, and tubal rings), disinfectants and insecticides notified in the Official Gazette under sub-clause (ii) [such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin's or insects which cause disease or disorder in human beings or animals, as may be specified from time to time by the central government].

Devices notified from time to time under sub-clause (iv) [such devices intended for internal or external use in the diagnostics, treatment, mitigation, or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government], of clause (b) of section 3 of the Act;

1.3 Background

The Indian Government has approved the Materiovigilance Programme to address potential adverse events related to medical devices. The program aims to build a database on adverse events and provide insights into reducing the likelihood of similar incidents occurring elsewhere. Launched on July 6, 2015, it is supported by the Indian Pharmacopoeia Commission (IPC), the Central Drugs Standards Control Organization (CDSCO), Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), and the National Health System Resource Centre (NHSRC). The initiative aims to improve the overall quality of medical devices.

1.4 Adverse Event Reporting

Medical Device Adverse Events are recorded through adverse event reporting system. It is an important tool to improve well-being of patients and medical device users by reducing occurrence of adverse events.

1.4.1 Classification of adverse event on basis of severity

Adverse events are classified into three categories on the basis of severity- Death of patient or device user; Serious injury including life-threatening disease; congenital abnormality/ irreversible impairment; permanent destruction of a body function.

1.4.2 Reporting criteria for adverse event noticed

When manufacturer becomes aware of an adverse event related with their device – Manufacturers initiate root cause of failure and intimate Indian Pharmacopoeial Commission - National Coordination Centre, once they become aware of event. "IPC-NCC" would send this information to the research associate located at nearest 'Medical Device Monitoring Centres'.

When healthcare service provider notices an event or incident– The information's will be passed to the research associate at 'MDMC' and further root cause analysis of event is carried out by committee. Experts

like biomedical/clinical engineers, research associate at MDMC, healthcare professional and technician handling device are part of the committee.

Non-reportable Incidents

If side effect associated with medical devices are predictable by the manufacturer's labelling, documented with proper risk assessment in the device master record and are clinically well known. When the shelf-life of medical device exceeds as specified by manufacture at time of use by patient/end-user. When deficiency is observed by the end user before the use of medical device. When protection mechanism inbuilt in medical device functioned correctly.

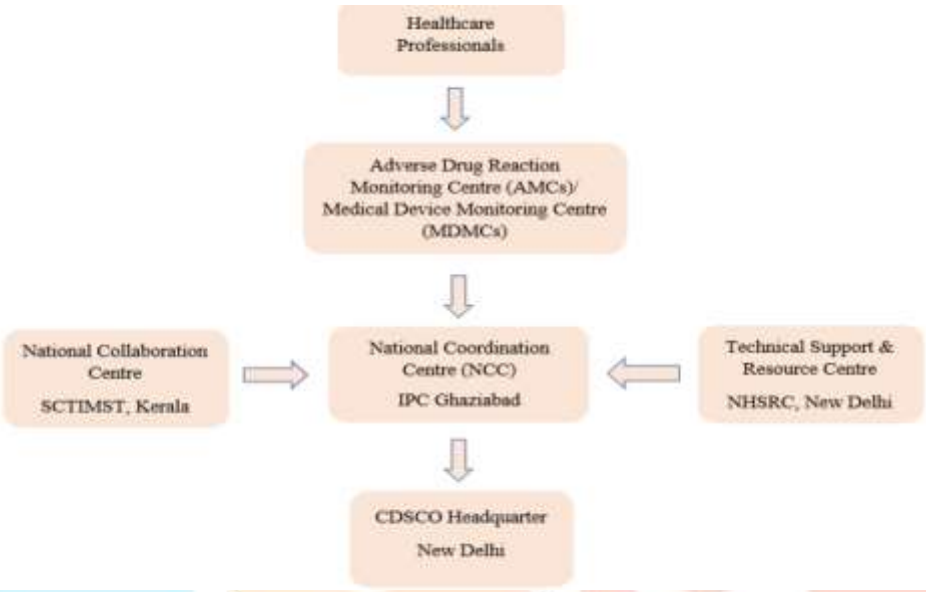

Fig 2: Organisational Structure of MvPI

1.5 Scope of Guidance Document

1. Professional staff at IPC, SCTIMST, NHSRC, CDSCO, MDMC, and the whole citizens of India would serve as stakeholders of the programme.
2. Representatives of Medical Device Adverse Event Monitoring Centres across the country.
3. Policymakers at all levels of healthcare, particularly those concerned with medical device policy.
4. Medical device adverse events can be reported under MvPI by clinical establishment staff members including physicians, biomedical engineers, clinical engineers, hospital technology managers, pharmacists, nurses, and technicians. The National Coordinating Centre may also receive reports from medical device manufacturers, importers, and dealers who have been notified by the CDSCO about adverse incidents about their product.

2. Future Aspects of MvPI

Mission: Safeguard the health of the Indian population by ensuring that the benefits of the use of medical devices outweigh the risks associated with its use.

Vision: To improve patient safety and welfare of the Indian population by monitoring adverse events related to medical devices and thereby reducing the risk associated with the use of medical devices.

2.1 Short-Term Goals

1. To develop and implement a Materiovigilance Programme all over India.
2. To encourage clinicians, biomedical engineers/clinical engineers, hospital technology managers, pharmacists, nurses, technicians, and medical device manufacturers to report adverse events related to medical devices.
3. Compile adverse events reports, and analyze and issue medical device reports to medical device regulators.

2.2 Long-Term Goals

1. To develop and implement an electronic reporting system (e-reporting).
2. To nurture a reporting culture among healthcare professionals, biomedical engineers, medical device manufacturers, etc.
3. To make Materiovigilance reporting mandatory for medical device manufacturers or their authorized representatives for marketing or sale of medical devices in India.
4. To make adverse event reporting of medical devices mandatory for all healthcare providers under the Clinical Establishment Act.
5. To expand the Medical Device Adverse Events Monitoring Centre (MDMC) to all hospitals (Govt. & Private) and centers of public health programs located across India.

3. Classification of Medical Device

(1) Medical devices other than in vitro diagnostic medical devices are classified into four classes based on risk parameters as specified in Part I of the First Schedule of the Medical Devices Rules, 2017 as under:

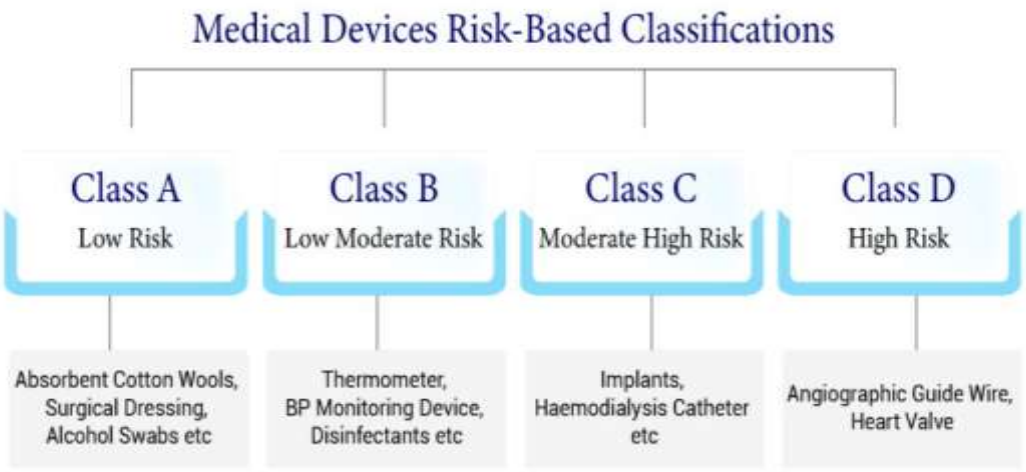

Fig 3: Classification of Medical Devices as per Indian MDR, 2017

(2) In vitro diagnostic medical devices are classified into four classes based on risk parameters specified in Part II of the First Schedule of the Medical Devices Rules, 2017, as under:

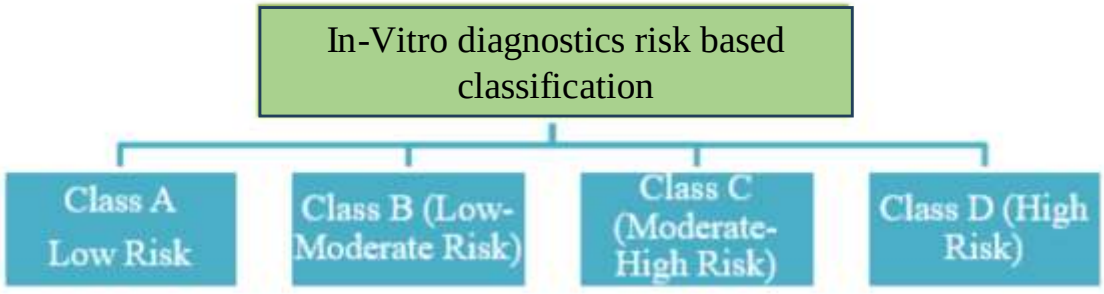

Fig 4: Classification of In-Vitro Diagnostics as per Indian MDR, 2017

4. Regulatory Framework of MvPI

It is an independent institution of Ministry of Health and Family Welfare, Govt. of India and functions as National Coordination Centre (NCC) for MvPI. IPC is mainly responsible for monitoring and assessing the quality of adverse events of medical devices from all over the country. NCC operates under the supervision of various committees which recommend procedures and guidelines for regulatory interventions.

Steering committee

Steering committee is mainly responsible for all administrative issues and to keep track of MvPI programme thus giving proper direction to the MvPI programme.

Working group

It deals with technical issues related to establishment and implementation of programme and giving technical inputs to CDSCO for regulatory intervention of medical devices. Working group may appoint core technical committee for quality, technical, training and adverse event signal-related issue.

Technical core committee

It is mainly responsible for quality assessment, resolving the technical issues, signal generation and validation related to medical devices and organizing and providing training on MvPI.

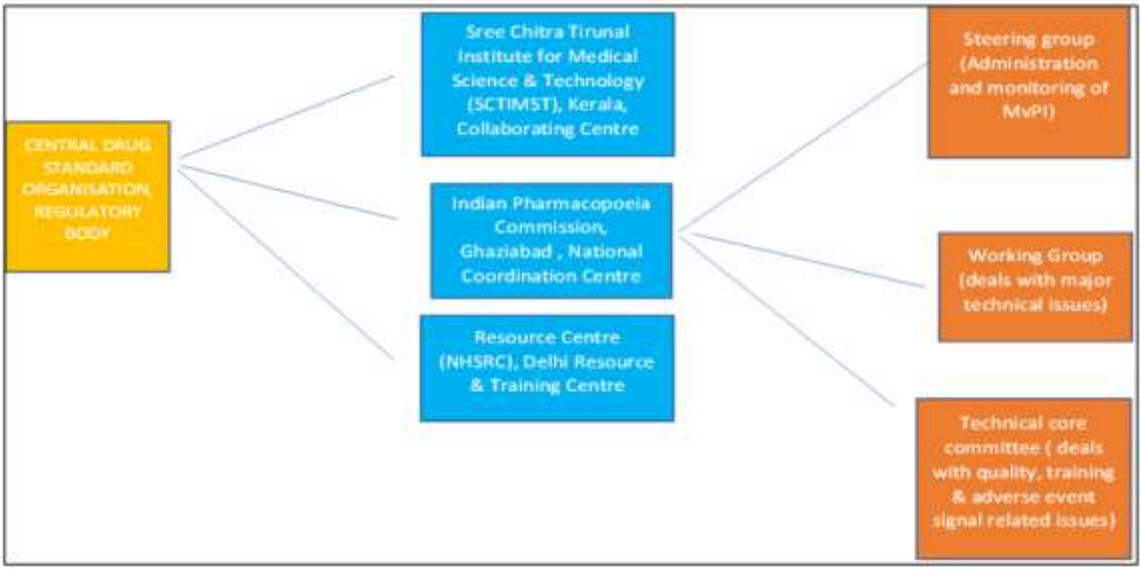

Fig 5: Organisational Framework of MvPI

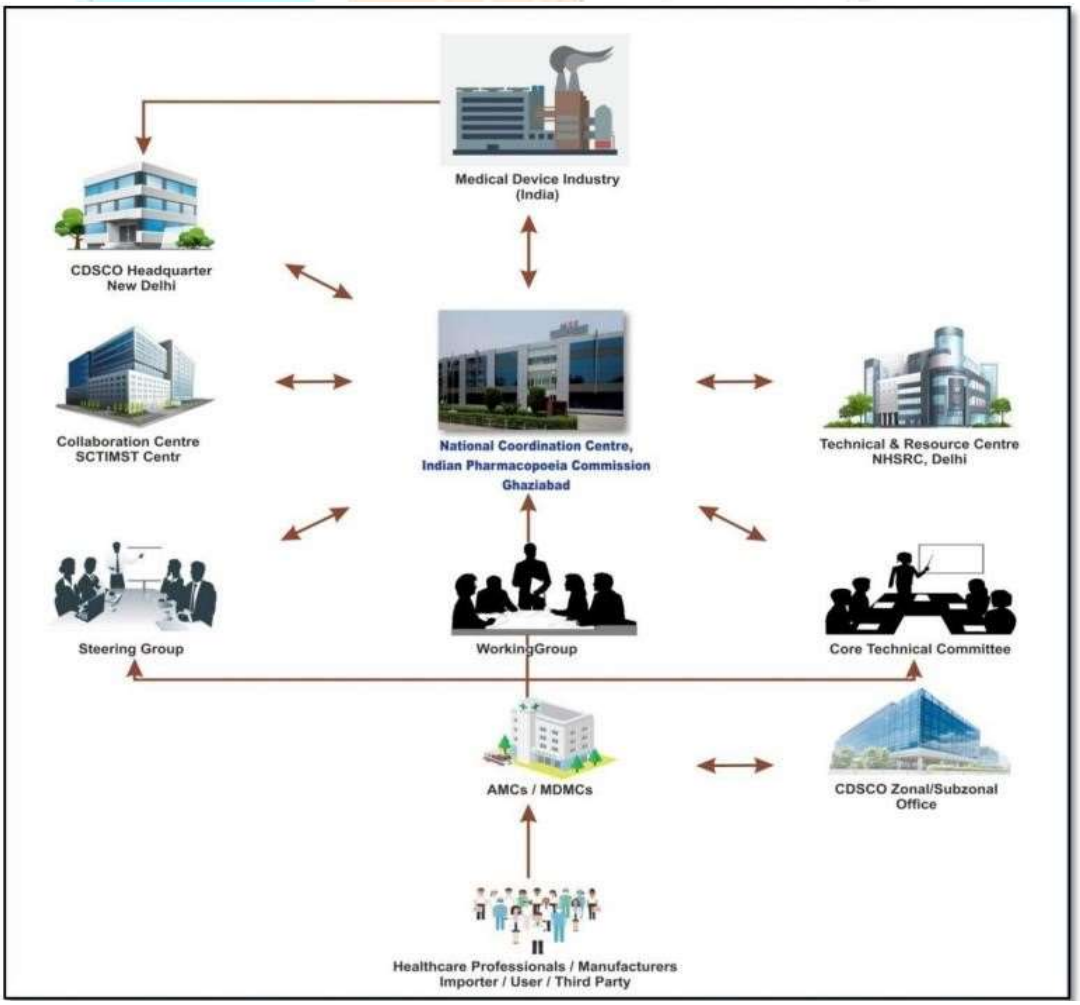

Fig 6: Flow of Information of adverse event related to the medical device

5. Responsibilities of Stakeholders under MvPI:

5.1 Personnel at Medical Device Adverse Events Monitoring Centre (MDMC): Each MDMC under MvPI is assigned a Coordinator and a Research Associate responsible for its functioning. Their roles and responsibilities are: -

1. The designated Coordinator is responsible for the proper functioning of the respective MDMC. In the absence of the coordinator, the designated deputy coordinator is responsible for the smooth functioning of the Centre. Standard operating procedure (SOP) for MDMC, Coordinator, MDMC-RA to be strictly adhered.
2. Other important responsibilities of the coordinator include checking the completeness of a valid case, failure mode effect analysis, causality assessment, and scrutinizing the MDAE reports as per SOPs.

5.2 Personnel at National Collaborating Centre (SCTIMST) are responsible for:

1. Conducting periodic training and workshops for healthcare professionals at various zones.
2. To provide research and development/testing support facility to the program.
3. To provide technical support in data analysis and release of medical device alerts.

5.3 Personnel at National Coordination Centre (IPC) are responsible for:

1. The main responsibility of the NCC is to coordinate with all partners of the programme. Organizing steering committee and working group meetings.
2. Providing financial support to SCTIMST and NHSRC for procurement of technical documents.
3. Aiding NHSRC in organizing the MvPI awareness program among medical device manufacturers/healthcare organizations.

5.4 Personnel at Regulatory authority (CDSCO HQ) is responsible for:

1. Regular meetings with the NCC-MvPI, SCTIMST & NHSRC for continuing monitoring of medical device safety.
2. Taking appropriate regulatory decisions and action based on recommendations made by IPC-NCC.
3. Auditing/inspecting MDMCs and National Collaboration Centre with IPC-NCC officials providing administrative support to run MvPI.

5.5 Personnel at NHSRC are responsible for:

1. To provide technical support/guidance for the preparation of standard operating procedures, guidance documents, newsletters, training manuals, etc.
2. Support in the Identification of new MDMC and intimating the same to IPC.
3. Awareness program among medical device manufacturers/healthcare organizations.

6. Post-Market Surveillance:

Post-Market Surveillance Programme is a process that collects information on the quality, safety, or performance of medical devices post-market. It aims to improve the health and safety of patients and users of medical devices by evaluating reported incidents and disseminating information to prevent or alleviate the consequences of such incidents. This process is also known as medical device post-marketing surveillance.

7. Baseline Studies:

Baseline studies on adverse events in medical devices should be conducted using questionnaires based on recalls and safety correction notices from global regulators. This is crucial as the Materiovigilance Programme in India is in its initial stage, and some equipment is recalled but still used in India due to lack of enforcement.

1. Health Facility demographics
2. Medical device information
3. Description of incident
4. Medical Records Tagging
5. Baseline Causality
6. Timeframe and submission of report

8. Data Collection and Analysis:

8.1 Method of Data Collection:

We conducted a thorough search across several websites, including ScienceDirect, PubMed, Google Scholar, and Google. Publications, reviews, research papers or events about medical devices and the adverse occurrences they are linked with were the main focus of our search. To find appropriate literature, we used keywords like "medical device," "materiovigilance," and "AE related to medical devices." For our investigation, we also looked for particular case studies about medical devices.

8.2 Data Analysis Techniques:

The goal of the Materiovigilance Programme of India (MvPI) is to keep an eye on medical device safety.

1. Descriptive statistics:

Using metrics such as percentiles, mean, median, mode, standard deviation, and others to summarize and characterize the data that was gathered.

2. Trend Analysis: Analysing data over time to spot trends or patterns in unfavourable events connected to medical equipment.

3. Comparative Analysis: To find any safety concerns, compare the adverse event rates of various medical device kinds or brands.

4. Signal Detection: This technique looks for possible indicators of safety issues with certain medical equipment by using statistical techniques such as disproportionality analysis (e.g., reporting odds ratios).

5. Risk Assessment: Determining the dangers connected to medical equipment by looking at the number and seriousness of documented adverse events.

6. Cluster Analysis: Locating geographic or other clusters of unfavourable events to find possible safety concerns in particular areas or patient groups.

7. Data mining: The process of extracting links or patterns from massive databases by using sophisticated data mining techniques like machine learning algorithms.

8. Causal Analysis: Evaluating elements like device design, production methods, or user mistakes to determine the underlying causes of unfavourable outcomes.

9. Examining time-to-event data: To determine the duration of an adverse event in order to evaluate the long-term safety profile of medical devices.

10. Quality Improvement Analysis: This technique looks for areas where medical device design, production, or post-market surveillance could be improved by analyzing data.

9. Timeframe for reporting an event or incident:

Table 1: Timeframe for reporting an event or incident

Reporter	What to report	To Whom	When
Marketing authorization holder/ Manufacturers/ Importers/ Distributors	Any suspected unexpected serious adverse event incident like deaths, serious injuries, malfunction, etc., and action taken thereon including any recall	National Regulatory body National Coordination Centre – IPC	Within 15 calendar days of becoming aware of an event.
User facilities	Death, serious injuries, malfunction, etc.	National Regulatory body National Coordination Centre – IPC Marketing authorization holder	Within 15 calendar days of becoming aware of an event. For non-serious events reporting to be done within 30 calendar days of becoming aware of an event.

10. Medical device Adverse Event reporting form:

MEDICAL DEVICE ADVERSE EVENT REPORTING FORM

Materiovigilance Programme of India (MvPI)

This form is intended to collect information on Medical Devices Adverse Event 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.

General Information

1. Date of Report :
2. Type of Report : Initial ☐ Follow up ☐ Final ☐ Trend ☐
3. Reporter Reference for MDMC only: • Centre • Location • Month-Year • Case No.

Reporter Details

1. Type of Reporter : (a) Manufacturer ☐ (b) Importer ☐ (c) Distributor ☐ (d) Healthcare Professional ☐
   (e) Patient ☐ (f) Others ☐ specify .....
2. In case, where the reporter is not 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 :

Device Category

Medical Device	In Vitro Diagnostics (IVD)	Medical Equipments / Machines
I. Therapeutic ☐ Diagnostic ☐	I. Kits ☐	I. Therapeutic ☐ Diagnostic ☐
Both ☐ Preventive ☐	II. Reagents ☐	II. Therapeutic & Diagnostic ☐
Assistive ☐	III. Calibrator ☐	III. Preventive ☐
II. Implantable device ☐	IV. Control Material ☐	IV. Assistive ☐
Non-Implantable device ☐	V. Others ☐	V. Imaging ☐
III. Invasive ☐ Non-Invasive ☐	VI. IVD electronic reader/ ☐	VI. Invasive ☐ Non-Invasive ☐
IV. Single use device ☐	Analyzer	VII. Others ☐
Reusable device ☐		
Reuse of manufacture marked Single use device ☐		
V. Sterile ☐ Non Sterile ☐		
VI. Personal use / Homecare use ☐		

Instruction for use Section A-F

- ***If Medical Devices/Equipments/Machines : Please fill all the sections i.e. A, B, C, D, E & F***
- ***If in Vitro Diagnostics (IVD) : Please fill sections i.e. A (except 6, 7, 8, 13, 14 & 16), B (except 1, 2, 6 & 8), D, E, & F***

(A) Device Details

Device Name / Trade Name / Brand Name: .....

Details	Name	Address
Manufacturer		
Importer		
Distributor		

1. a) Is the device notified/regulated in India : Yes ☐ No ☐
   b) Device Risk Classification as per India MDR 2017 : A ☐ B ☐ C ☐ D ☐
2. License No. (Manufacture/Import) :
3. Catalogue No. :
4. Model No. :
5. Lot / Batch No. :
6. Serial No. :
7. Software Version :
8. Associated Devices / Accessories :
9. Nomenclature Code if applicable; GMDN/UMDNS :
10. UDI No. (If applicable) :
11. Installation Date :
12. Expiration Date :
13. Last preventive maintenance date (dd/mm/yyyy) :
14. Last calibration date (dd/mm/yyyy) :
15. Year of manufacturing :
16. How long was device/Equipment/Machine in use :
17. Availability of device for evaluation : Yes ☐ No ☐
    If no, was the device destroyed ☐ Still in use ☐ return to manufacturer or importer/distributor ☐
18. Is the usage of device as per manufacturer claim /Instruction for use/user manual: Yes ☐ No ☐
    If no specify usage .....
    .....
19. For devices not regulated / notified in India : Regulator / Regulatory status in country of origin
    .....

(B) Event Description

1. Date of Event / Near miss incident:
2. Date of Implant/Explant (If applicable):
3. Location of Event:
   Hospital Premise ☐ Manufacture/Distributor premise ☐
   Home ☐ Others ☐
4. Device Operator:-
   Healthcare Professional ☐ Patient ☐ Others ☐
   Problem noted prior to use/near miss event ☐
5. 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) ☐
6. Is device in use after incidence : Yes ☐ No ☐
7. Serious event: ☐
   If serious, Tick the appropriate reason
   a) Death (DD/MM/YY) ☐ ...../...../.....
   b) Life Threatening ☐
   c) Disability or permanent damage ☐
   d) Hospitalization ☐
   e) Congenital anomaly /birth defect ☐
   f) Any other serious (Imp. medical event) ☐
   g) Required intervention to prevent / permanent Impairment / damage device ☐
8. Non serious event ☐
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:-

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 in 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 ☐ Others ☐
5. Weight :
6. Other relevant history, including pre-existing medical conditions.....
   .....
   .....
   .....
   .....
7. Patient Outcomes:
   a) Recovered Date (DD/MM/YY) ☐ ...../...../.....
   b) Not yet recovered ☐
   c) Death ☐ (DD/MM/YY) ☐ ...../...../.....
   d) 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. :

(E) Causality Assessment

1. Investigation action taken:

2. Root cause of problem (Applicable for follow up / final reports):

(F) Manufacturer/Authorized Representative Investigation & Action taken

1. Manufacturer/Authorized Representative device risk analysis report:

2. Corrective / preventive action taken:

3. Device history review:

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, Ghaziabad-20002, Tel-0120-2783400, 2783401 and 2783392, FAX:0120-2783311 or email to mvpi.ipcindia@gmail.com Or Call on Helpline no. 1800 180 3024 to report Adverse event.

Partnering Organizations

Disclaimer

Confidentiality: The patient'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.

11. Comparative Materiovigilance Programme for India, US, Europe and Japan:

Table 2: Comparison of Materiovigilance Programme in India, US, Europe and Japan

Requirements	USA	Europe	Japan	India
Classification of medical devices	Class I, II, III	Class I, IIa, IIIb, III	General class, I Specified control class II-controlled class II Highly controlled-class III Highly controlled class IV high risk	Class A (low risk), Class B (Low moderate risk), Class C (moderate-high risk) Class D
Procedure for market authorization	Pre-market notification market approval	Annex II-VII of the MDD	MAH DMHA	Drugs Controller General of India (DCGI)
Registration of economic operators and devices	Register annually with the FDA	European EUDAMED	Pharmaceuticals and Medical Devices Agency (PMDA)	Importers and distributors
Involvement of government	Direct involvement of government FDA	national competent authority	Third-party certification, The pharmaceutical and medical device agency	National competent authority
Marking of medical devices	no official mark for FDA-approved devices	CE mark on the product	No official marking required	CE mark required
Standards for medical devices	FDA; Centre for devices and radiological health	European committee for standardization	Translated international standards or other recognized standards like IEC or ISO	CDSCO released Indian Medical Device Rules, 2017
Decision making	Decision to allow a device to the market is made by FDA	national competent authority	PMDA, MHLAW	CDSCO authority
Authorization status of products	No mark on the product to identify an approved device	Advice that has successfully gone through the conformity assessment procedure	No official marking required	CE mark required

Device Tracking	As a form of post-marketing monitoring and device tracking are used. Depending on the device's classification, manufacturers are obligated to furnish information within either a 3-day or 10-day timeframe.	Through the Adverse Incident Tracking System, the EMA oversees device tracking (AITS). The manufacturer or authorized representative is responsible for tracking incident reports.	Reports for the items are produced by sponsors using information gathered from medical professionals, clinical trials, and published studies, such as international and local observational research or experiences from registries.	Lot/batch numbers must be displayed on a medical device's label.
Adverse event reporting	Under MDR regulations, manufacturers and importers have a responsibility to promptly report any incidents involving serious injury or death within 30 days from the time they become aware of these occurrences. Manufacturers are obligated to disclose faults that have been discovered within 30 days.	At post-marketing surveillance, manufacturers are accountable for disclosing concerns related to the medical equipment.	The Marketing Authorization Holder (MAH) is obliged to notify the MHLW about serious ADR within 15 days. However, for newly introduced drugs on the market for less than 2 years, this reporting period extends to 30 days.	Adverse events can be reported by a range of stakeholders, including manufacturers, importers, distributors, and even customers.
Timeline of reporting	To report death=30 days, to report injuries and malfunction=5days	To report death=10 days to Competent Authorities	The mandatory reporting period for AEs is 15 days (in some situations, 30 days).	Immediate reporting ASAP
The time frame for approval	To FDA to process PMA approvals	210 days are laid down for the scientific opinion	3-4 months	6-9 months

12. References:

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