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ENSURING PATIENT SAFETY: A COMPREHENSIVE OVERVIEW OF MATERIOVIGILANCE IN INDIA

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ABSTRACT

The Materiovigilance Programme of India (MvPI), a pivotal initiative for the assurance of medical device quality and safety in India, was inaugurated on July 6, 2015. The primary objective of this programme is the collection and analysis of data pertaining to adverse events associated with medical devices. This data serves as a foundation for evidence-based regulatory decisions and recommendations, thereby promoting the safe utilization of medical devices. The Indian Pharmacopoeia Commission (IPC) coordinates the MvPI, with the support of the Sree Chitra Tirunal Institute of Medical Sciences & Technology (SCTIMST) and the National Health System Resource Centre (NHSRC). The programme advocates for the reporting and evaluation of adverse events as a means to enhance patient safety. Despite its significance, a considerable number of health facilities remain uninformed about the MvPI and its reporting mechanism. This highlights an urgent need for increased awareness and development to address public health concerns related to medical devices. Materiovigilance Programme of India (MvPI) serves as an essential mechanism in the protection of public health in India, by ensuring that the advantages conferred by medical devices surpass their potential detriments.

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INTRODUCTION

Materiovigilance is the systematic monitoring of assessing the safety and functionality of medical devices to identify and prevent any adverse events or device-related problems [1]. Materiovigilance is an essential component of patient safety and quality of care, as it helps to guarantee the safety, efficacy, and performance of medical devices, and appropriate for their intended use [1]. Materiovigilance also contributes to the improvement of medical device design, manufacturing, regulation, and post-marketing surveillance [1].

In India, the Materiovigilance Programme of India (MvPI) was launched in 2015 by the Indian Pharmacopoeia Commission (IPC) in collaboration with the Central Drugs Standard Control Organization (CDSCO) and the National Health Systems Resource Centre (NHSRC) [2]. The MvPI aims to establish a national system for collecting, analysing, and disseminating information on medical device adverse events and device-related problems [3]. The MvPI also provides guidance and training to stakeholders such as manufacturers, importers, distributors, healthcare professionals, and patients on how to report and prevent medical device adverse events and device-related problems [4].

The MvPI has been recognized as a successful initiative in promoting materiovigilance in India and enhancing patient safety for medical devices [5]. However, there are still some challenges and limitations that need to be addressed, such as the low awareness and participation of stakeholders, the lack of standardized reporting formats and criteria [6], the inadequate feedback and follow-up mechanisms, and the insufficient coordination and collaboration among various agencies and sectors [7]. Therefore, there is a need for further strengthening and expanding the MvPI to ensure its effectiveness and sustainability in the long term [8]. Some of the recommendations and suggestions for improving the MvPI in India are to increase the awareness and education of stakeholders, to develop a uniform reporting system and criteria, to provide timely feedback and follow-up actions, and to foster inter-sectoral coordination and collaboration [9].

MATERIOVIGILANCE PROGRAMME OF INDIA (MvPI)

The MvPI (Pharmacovigilance Programme of India) is a significant initiative sanctioned by the Ministry of Health and Family Welfare (MoHFW) to oversee, evaluate and report significant adverse events associated with medical devices in India under the supervision of the IPC [3]. The MvPI program was launched at the IPC Ghaziabad by the DCGI (Drug Controller General of India) on July 6, 2015. IPC Ghaziabad acts as the National Coordination Centre for MvPI. Materiovigilance refers to the close surveillance and monitoring of any undesirable clinical outcome caused by a medical device. The process involves identifying, collecting, reporting and estimating the incidence to provide evidence to DCGI for post-marketing safety corrective actions against defective biomedical devices [10]. The MvPI program aims to collect and analyse data systematically so that regulatory decisions and recommendations on the safe use of medical devices in India can be made [4]. This initiative also aims to raise awareness among stakeholders about the importance of reporting adverse events on medical devices and tracking the benefit-risk profile of medical devices [8]. A typical hospital uses more than 3000 medical devices, but there is no uniform method to ensure the quality of medical devices and equipment. Currently, the Indian market is filled with many sub-standard medical devices that may pose potential harm to the patient. In this situation, to protect the health for the benefit of Indian citizens, the Government of India has recently brought medical devices within the ambit of the Drug and Cosmetic Acts, and all regulations applicable to drugs will also apply to medical devices [4].

THE MvPI HAS THREE MAIN COLLABORATORS

The Materiovigilance Programme of India (MvPI) is a national initiative to monitor and report Medical Device Adverse Events (MDAEs) in India, launched in 2015. The MvPI aims to improve patient safety and quality of medical devices in India by collecting and analyzing data on MDAEs, generating evidence-based recommendations, and facilitating corrective and preventive actions. The MvPI also aligns with the global efforts to harmonize and enhance materiovigilance systems across countries.

The MvPI is coordinated by the Indian Pharmacopoeia Commission (IPC), which is the nodal agency for the MvPI. The IPC works in collaboration with three other agencies: the Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), the National Health System Resource Centre (NHSRC), and the Central Drugs Standard Control Organization (CDSCO).

The SCTIMST is a premier institute for biomedical research and innovation that serves as the National Collaborating Centre (NCC) for the MvPI. It provides technical and scientific support to the IPC in developing and implementing the MvPI. It also conducts training and capacity building programs for the MvPI stakeholders and facilitates research and development on medical device safety.

The NHSRC is a technical support organization under the National Health Mission that serves as the Technical Support & Resource Centre (TSRC) for the MvPI. It offers technical assistance to the IPC in designing and executing the MvPI activities. It also helps in creating awareness and advocacy on materiovigilance among various stakeholders and assists in developing policies and regulations on medical device safety.

The CDSCO is the national regulatory authority for drugs and medical devices that serves as the regulator for the MvPI. It supports the MvPI with its experience and expertise in regulating medical devices in India. It also issues guidelines and notifications on medical device safety and monitors the compliance of the MvPI stakeholders with the regulatory requirements.

The MvPI is a program that monitors the safety and performance of medical devices in India. It was inaugurated in 2017 by several distinguished personalities from the government, industry, academia, and media, such as Dr.G.N.Singh, DCGI; Dr.K.L.Sharma, Joint Secretary, Ministry of Health & Family Welfare; Dr.G.N.Qazi, Director, IPC; Dr.Ashok Kumar, DGHS; Dr.Ashish Kumar Sen, Director, SCTIMST; Dr.SanjayZodpey, Director, NHSRC; Dr.V.Kalaiselvan, Principal Scientific Officer, IPC; Dr.Rajiv Garg, Deputy Drugs Controller; Dr.Suresh Kumar Gupta, Deputy Drugs Controller; Dr.Sanjeeva Kumar Singh, Deputy Drugs Controller; Dr.Rajesh Jain, Joint MD, Panacea Biotec Ltd.; Dr.Rajiv Nath, Forum Coordinator, AIMED; Mr.RajivChibber, VP

External Affairs, Sahajanand Medical Technologies Pvt.Ltd.; Mr.Rajiv Nathwani, Director Regulatory Affairs & Quality Assurance, Transasia Bio-Medicals Ltd.; Mr.Sanjay Jaiswal, President & CEO MTaI; Mr.Pavan Choudary, Director General MTaI; Mr.Anish Bafna , President NATHEALTH; Mr.Anjan Bose , Secretary General NATHEALTH; Mr.Prabal Chakraborty , VP & MD Boston Scientific India Pvt.Ltd.; Mr.Himanshu Baid , MD Poly Medicure Ltd.; Mr.AmitBackliwal , MD Stryker India Pvt.Ltd.; Mr.Sunil Khurana , CEO & MD BPL Medical Technologies Pvt.Ltd.; Mr.Rajeev Arora , Executive Director Trivitron Healthcare Pvt.Ltd.; Mr.Vinod Ramani , CEO Opto Circuits India Ltd.; Mr.Rajiv Nath , Forum Coordinator AIMED; and representatives from various medical device associations, industry, academia, and media.

The MvPI initiated various activities such as setting up MDMCs, developing reporting formats and guidelines, creating a web portal and a helpline number, organizing workshops and training programs, publishing newsletters and reports, and launching research projects. The MvPI has made significant progress in the past six years and has established a robust and effective materiovigilance system in India. The MvPI has also contributed to the formulation and implementation of the Medical Device Rules 2017, which mandate the reporting of all MDAEs in the country.

The MvPI is a dynamic and responsive program that strives to address the changing requirements and expectations of the stakeholders and the society. The MvPI plans to expand its scope and coverage, enhance its quality and efficiency, strengthen its collaboration and coordination, and improve its impact and outcomes. The MvPI is committed to ensuring patient safety and quality of medical devices in India.

The MvPI is a program that adapts to cater to the shifting needs and expectations of the stakeholders and the society. The MvPI aims to increase its scope and coverage, boost its quality and efficiency, consolidate its collaboration and coordination, and amplify its impact and outcomes. The MvPI is devoted to ensuring patient safety and quality of medical devices in India.

OBJECTIVES [1]

- To establish a vigilance system that will assist in regulatory decisions to ensure the quality and safe use of medical devices.
- To design a system for vigilance of medical device adverse event reporting at a national level, that will create a MDAEs database, help in signal detection and/or other regulatory decisions.
- To assess the benefit-risk analysis of reported MDAEs and to perform the causality assessment of the same.
- To evaluate the benefit-risk analysis of reported MDAEs and to perform the causality assessment of the same hospitals.
- To educate and enhance awareness among healthcare professionals all over India towards the importance of MvPI and reporting of MDAEs.
- To provide technical and consultancy support to other countries who are interested to develop medical device vigilance system in their country.

APPLICATIONS OF MVPI [6]

- To construct a system for patient safety monitoring.
- Injuries & complications prevention.
- To produce evidence-based data on medical device safety.
- To support CDSCO in the regulatory actions on medical device use and share conclusive reports with different stakeholders.
- To emerge as national centre of excellence for materiovigilance programs.
- To implement corrective measures in order to prevent potential adverse events in future.

ROLES AND RESPONSIBILITIES OF DIFFERENT UNITS OF MATERIOVIGILANCE PROGRAM OF INDIA [8]

The MvPI program has a network of 10 MDMCs located in various regions of the country, which are responsible for collecting, verifying, and evaluating MDAE reports according to the SOPs. They also send a monthly summary report to the National collaborating centre. The National collaborating centre, which is currently SCTIMST, Thiruvananthapuram, receives, compiles, and analyzes the MDAE reports from the MDMCs and performs signal detection and communication with the National coordinating centre (NCC). It also organizes awareness programs, trainings, and workshops on materiovigilance periodically in different zones of the country. The Indian Pharmacopoeia Commission, which acts as the MvPI-NCC, coordinates with all the stakeholders of the program by holding steering committee and working group meetings. It also prepares and disseminates SOPs, guidance documents, training manuals, and newsletters. It analyzes the data received from SCTIMST and makes recommendations to the CDSCO for appropriate action. The CDSCO, as the regulator, makes the regulatory decisions and communicates them to the different stakeholders. It also participates in IMDRF and other international forums for sharing postmarketing safety information. The National Health System Resource Centre, Ministry of Health and Family Welfare, Government of India, New Delhi, functions as the TSRC. It provides technical support to the NCC and NCC for the preparation of SOPs, guidance documents, newsletters, and training manuals. It also assists in identifying new MDMCs.

MATERIOVIGILANCE PROGRAMME OF INDIA (MVPI): SCOPE AND STRUCTURE

The MvPI program has three main agencies: the Indian pharmacopoeia commission in Ghaziabad, which is the national coordination center; the Sree Chitra Tirunal Institute of Medical Sciences and Technology (SCTIMST) in Thiruvananthapuram, which is the collaborating center; and the National Health System Resource Centre (NHSRC) in New Delhi, which provides technical support. The role of these agencies is to monitor and track MDAEs and to enable the removal of unsafe ones from the market. MvPI is designed as a country-wide programme that involves district hospitals, medical colleges and corporate healthcare institutions.

The objectives of MvPI are to generate evidence-based data on medical device safety, to share information with other stakeholders, to assess the risk-benefit of medical devices, to assist CDSCO (regulator) in making decisions on usage regulations of medical devices and to establish a complete national system of patient safety monitoring. The program also strives to enhance awareness among healthcare professionals about the importance of reporting MDAEs. [8,11,12,13].

The constitution of Materiovigilance programme of India has been depicted in [Fig. 1].

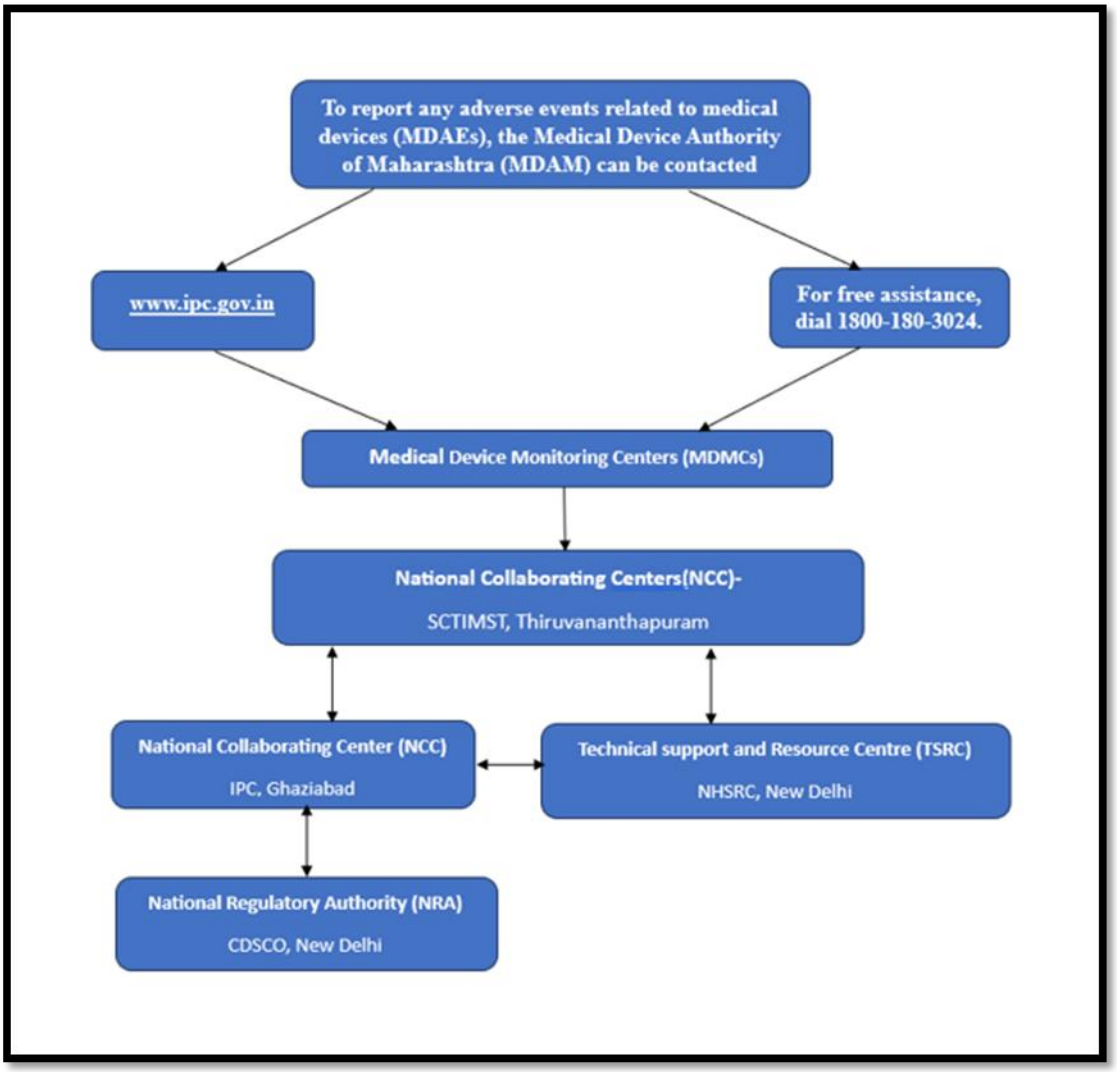

Fig. 1 Constitution of Materiovigilance programme of India.[6]

The IPC, which acts as the NCC, has selected 10 medical colleges as MDMCs (Medical Device Adverse Event Monitoring Centre) for monitoring medical devices in the country, [8] [11] but the number of MDMCs has increased to 26 now. These MDMCs receive MDAEs from the relevant healthcare staff and examine the failure mode effect and casualty. They also send a consolidated report every month to the NCC [5]. [Figure 2] shows the names of the MDMCs. The NCC is currently SCTIMST, Thiruvananthapuram, which performs data analysis and signal detection on the reports and shares the findings with the NCC. The NCC then processes the data and communicates with the CDSCO, which is the Regulator-MvPI, about the necessary actions. The NCC also coordinates with all the stakeholders, organizes the executive committee and conducts group meetings. The NCC is responsible for preparing and distributing Standard operating procedures, training manuals and newsletters. The NHSRC provides technical support to the NCC as the Technical support and resource centre [8][11].

Figure 2. [6]: List of MDMCs

Sr. No.	MDMC Name & Address	Status	Year of Recognition
1.	Dept. of Oral and Maxillofacial Surgery, Maratha Mandal's Nathajirao G Halgekar Institute of Dental Sciences & Research centre Belagavi Karnataka – 590010	Non-Government	2019
2.	Lady Hardinge Medical College Department of Pharmacology, C-604 Shaheed Bhagat Singh, Road, DIZ Area, Connaught Place, New Delhi, Delhi 110001	Government	2019
3.	Department of Pharmacology, Hamdard Institute of Medical Sciences & Research Jamia Hamdard, New Delhi -110062	Non-Government	2019
4.	School of Tropical Medicine Department of Clinical & Experimental Pharmacology,108 Chitta Ranjan Avenue, Kolkata – 700073	Government	2019
5.	Yashoda Super Speciality Hospital H1,26,27, Kaushambi, Near, H-1 Metro, Kaushambi, Ghaziabad, Uttar Pradesh 201001	Non-Government	2019
6.	Frontier Lifeline Hospital Pvt Ltd, R30-C, Ambattur Industrial Estate Road, Mogappair, Chennai, Tamilnadu - 600101	Non-Government	2019
7.	Dr Sampurnanand Medical College, Residency Road, Near Sriram Excellency Hotel, Opposite Petrol Pump, Sector-D, Shastri Nagar, Jodhpur, Rajasthan 342003	Government	2019
8.	Dept. of Pharmacology, All India Institute of Medical Science, Patna, Bihar-801507	Government	2019
9.	Dept. of Pharmacy Practice, St. James College of Pharmaceutical Sciences, Chalkudy, Thrissur, Kerala-680307	Non-Government	2019
10.	Biomdical wing, District Hospital Mavelikkara, Near mavelikaraPandalam Road, Thazhakkara, Mavelikara, Alappuzha, Kerala 690102	Government	2019
11.	Dept. of Pharmacology, Veer Surendra Sai Institute of Medical Sciences and Research (VIMSAR) Pg Chowk, Burla, Odisha 768017	Government	2019
12.	Dept. of Pharmacology, SLN Medical College and Hospital, Janiguda, Koraput, Odisha 764020.	Government	2019
13.	Dept. of Pharmacology, Konaseema Institute of Medical Science Amlapuram Andra Pradesh - 533201	Non-Government	2019
14.	Dept. of Pharmacology, All India Institute of Medical Sciences, Saket Nagar, Bhopal, Madhya Pradesh 462020	Government	2019
15.	Mysore Medical College and Research Institute, Irwin Road, Next to Railway Staion, Mysuru, Karnataka 570001 (Affiliated hospitals: K.R. Hospital; Cheluvamba Hospital; PKTB Hospital)	Government	2018
16.	College of Pharmacy, Sri Ramakrishna Institute of paramedical Sciences, 395, Sarojini Naidu Rd, Sidhapur, Coimbatore641044	Non-Government	2018
17.	Department of Quality Systems Royal Care Super Speciality Hospital, SF No:554/555, Neelambur Village, Sulur Taluk, CBE, Tamilnadu-641062	Non-Government	2018
18.	Department of Biomedical Engineering, National Institute of Mental Health & Neuro Sciences (NIMHANS), Hosur Road, Lakkasandra, Wilson Garden, Bengaluru, Karnataka 560029	Government	2017
19.	Department of Biomedical Engineering, Sanjay Gandhi Post Graduate Institute of Medical Science, Luknow, Uttar Pradesh	Government	2017
20.	Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Dhavantri Nagar, Gorimedu, Puducherry-605006Narayana Health, NH Health City,258/A, Bommasandra Industrial Area, Anekal Taluk, Hosur Road, Bangalore-560099 (Affiliated hospitals: Narayana Institute of Cardiac Sciences; Mazumadar Shaw Medical Center)	Government	2017
21.	Narayana Health, NH Health City,258/A, Bommasandra Industrial Area, Anekal Taluk, Hosur Road, Bangalore-560099 (Affiliated hospitals: Narayana Institute of Cardiac Sciences; Mazumadar Shaw Medical Center)	Non-Government	2016
22.	Postgraduate Institute of Medical Education and Research, Room no. 4043, 4th Floor, PGIMER, Sector-12, Chandigarh-160012	Government	2016
23.	Department of Pharmacology, Dayanand Medical College and Hospital, Ludhiana, Punjab,141001	Non-Government	2016
24.	Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), Ansari Nagar East, Gautam Nagar, New Delhi-110029	Government	2016
25.	Glocal Group of hospitals, 3 B 207, Eco-space Business Park action Area II, New town Rajarhat, Kolkata- 700156	Non-Government	2016
26.	Department of Biomedical Engineering, Christian Medical College (CMC), Thorapadi Vellore-6323004	Government	2016

INDIA'S APPROVAL PROCESS OF MEDICAL DEVICES

In India, medical devices usually require 6 steps for registration and are discussed below [14].

DETERMINING WHETHER A PRODUCT REQUIRES REGISTRATION

The initial step is to verify whether the medical equipment requires registration. Only medical devices that are already included in the Drugs and Cosmetic Act of 1940 are eligible for registration. Currently, only 22 medical devices are covered by the Act. The devices that fall under this category are as follows:

- Single-use hypodermic syringes
- Blood typing sera
- Single-use infusion sets
- Ligatures, sutures, and staplers
- Diagnostic testing kit for HIV (In vitro)
- Intra uterine devices
- Cardiac stents
- Condoms
- Drug eluting stents
- Tubal rings
- Catheters
- Surgical dressings
- Intra ocular lenses
- Umbilical tapes
- Bone cement
- Heart valve
- Orthopaedic implants
- Internal prosthetic replacements
- Spinal needles

Some medical devices may not be regulated under the Drugs and Cosmetic Act of 1940, which lists only 22 devices that require registration. For such devices, the manufacturer needs to apply to the CDSCO for a no objection certificate, which indicates that the device is not subject to any regulatory restrictions in India. The CDSCO will evaluate the device and issue the certificate if it meets the criteria. The device will then be approved for marketing in India [15].

APPOINTMENT OF AN AUTHORIZED INDIAN AGENT [14]

For foreign manufacturers, an authorized Indian agent is usually require1. The agent acts as a liaison between the manufacturer and the CDSCO, facilitating the registration and approval of the device. The agent holds a drug license in form 20B and 21B, as per the Indian regulations.

SUBMISSION OF REGULATORY DOSSIER UNDER FORM 40 [14]

To begin the registration process, the dossier should be accompanied by the following documents:

- Form 40
- Authorization letter
- ISO 13485 certificate
- CE design certificate
- Free sale certificate
- Other regulatory approvals
  TR6 challan
- Schedule D (I)
- Full quality assurance certificate
- Declaration of conformity
- Certificate of marketability from GHTF countries
- PMS report
- Device master file
- Plant master file

Form 40 should be filled correctly, signed, and verified by an Indian representative (in case of a foreign manufacturer). Then, an application for medical device approval should be submitted to the DCGI. If the device maker is new in the country, they should also submit Form 45, a new drug licensing application, along with Form 40. The registration of a device usually takes between 6 and 9 months [15].

OBTAINING IMPORT LICENSE IN FORM 10 [15]

To obtain a license for importing medical devices, the distributor should submit an application in Form 10 to the CDSCO as soon as possible. The application should be accompanied by Form 8 and Form 9, which provide the registration certificate number. The processing time of the application may vary from 4 to 12 weeks. The license will be issued within 3 months if the information is complete and accurate4. The license will be valid for 3 years unless it is revoked or suspended by the authority.

OBTAINING REGISTRATION CERTIFICATE IN FORM 41 [15]

After the operation has been submitted, it would be pre-screen using the CDSCO's roster. If the information is correct and full, the authorities will give an instrument of enrolment using Form within 9 months. Unless it's cancelled or suspended, the instrument of enrolment is valid for 3 times.

MARKETING IN INDIA [15]

The device can be introduced in the Indian market after obtaining the registration certificate and the import license. However, any modification, adverse event, or recall related to the device that is being marketed in India must be notified to the authorized Indian agent [14]

REPORTING OF MEDICAL DEVICE ADVERSE EVENTS [16]

The following are the guidelines for reporting medical device adverse events (MDAEs) under the Materiovigilance Programme of India (MvPI):

- Who can report: Any healthcare professional, patient, or technician who has witnessed or experienced an adverse event related to a medical device can report it. Medical device manufacturers can also voluntarily report any adverse event related to their products to the IPC-NCC.
- Why to report: Reporting adverse events related to medical devices is a moral duty of healthcare professionals and ethical medical device manufacturers, as it contributes to safeguarding public health and ensuring safety.
- What to report: MvPI encourages reporting of all kinds of adverse events related to medical devices, regardless of their severity, frequency, or novelty. However, the main focus of MvPI is on adverse events related to medical devices used in India.
- How and to whom to report: Utilize the Medical Device Adverse Event Reporting Form, which is available on the official website of IPC (www.ipc@gov.in), should be used to report any adverse event. Reporters from MDMCs can submit the filled form to the coordinator or Research Associate of their respective MDMC. Reporters who are not part of MDMCs can submit the filled form to the nearest MDMC or directly to the National Collaborating Centre. Reporters can also email the scanned form to lab.ipc@gov.in and copy to mvpi.ipcindia@gmail.com. IPC also has a helpline number 1800-180-3024 to report adverse events related to medical devices and medicines. Reporters can call this number to report MDAEs.

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 a span of 15 calendar days upon becoming aware of an event.
User facilities	Death, serious injuries, malfunction etc.	• National Regulatory body • National Coordination Centre – IPC • Marketing authorization holder	In 15 calendar days from the awareness of an event. For non-serious events reporting to be done within 30 days on the calendar to act.

(A) Device Description

Device Name / Trade Name / Brand Name:

Details	Name	Address	License No.
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. :
3. Catalogue No. :
4. Model No. :
5. Lot / Batch No. :
6. Serial No. :
7. Software Version :
8. Accessories / Associated Devices :
9. GMDN Code & GMDN Term (If applicable) :
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. Age of device from date of manufacturing :
16. How long was device 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 (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. Serious event: ☐

   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 ☐
7. Non serious event: ☐
8. Is device in use after incidence: Yes ☐ No ☐

8. Detail description of Event:-

9. 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 (%)

10. 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. Sex : 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) Product Owner's Investigation & Action taken

1. Product Owners 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 send 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.

GUIDANCE ON HOW TO FILL MDAE FORM [16]

GENERAL INFORMATION

Please fill in all the fields with the requested information, or write "NA" if not applicable, or "unknown" if the data is not known or available. If the form does not have enough space, please use the extra space provided on page 5. You can also attach any additional details that are relevant and not requested elsewhere as "Additional information" at the end of the form.

- **Date of Report:** The date when the event is reported to IPC-NCC MvPI/MDMC/AMC Report type.
- **Initial:** The first report that the reporter submits about an event.
- Follow-Up: More information to a previous (initial or follow-up) report.
- **Final:** The last report that the reporter expects to submit about an event. The initial report can be a final report if the reporter has all the information about the event.
- **Trend:** Significant changes in frequency or severity of events related to devices must be reported. These reports are called trend reports.
- **Reporter Reference No.:** The reference number assigned by the MDMC/Manufacturer/Authorized Representative.

REPORTER INFORMATION

- Type of Reporter: Indicate whether the reporter is a manufacturer/ importer/ distributor / healthcare professional / patient or other (specify if other). If the reporter is not the manufacturer, state whether the information is also reported to the manufacturer or on behalf of the manufacturer.
- Reporter Contact information: Provide the reporter's such as your full name, where you live, how to contact you by phone or email.

DEVICE CATEGORY

A possible paraphrase of the text in a scientific manner and with uniqueness is:

Please follow the instructions below to fill in the Medical Device Adverse Event Reporting Form:

- Medical Device: Check the boxes according to the usage of the medical device.
- In Vitro Diagnostic (IVD): Check the boxes for the in-vitro analysis of specimens obtained from the human body.
- Medical Equipment: Check the boxes according to the usage of the medical devices that need regular maintenance, calibration and commissioning/decommissioning activities.

A. DEVICE DETAILS

- Device Name/Trade Name/Brand name: Provide the brand or trade name of the device involved in the event.
- Provide the name and address of the manufacturer, importer and distributor.
- Provide the regulatory status of the device along with other details such as device risk classification (mandatory for manufacturer, importer & distributor, optional for consumer if known), license number (manufacture/import), catalogue number, model number, lot/batch number, serial number, software version, associated devices/accessories, nomenclature code (if applicable); GMDN/UMDN (Global Medical Device Nomenclature Code and explanatory term), UDI number (if applicable), installation date, expiration date, last preventive maintenance/ last calibration date, year of manufacturing, duration of device use and availability of device for evaluation. For devices not regulated in India, provide the regulatory status in the country of origin.

B. EVENT DESCRIPTION

- Provide the date of the event and the date of implant or explant (if applicable).
- Check the boxes to indicate the location of the event and the operator of the device at the time of the adverse event.
- Device disposition/current location: Indicate where and in what condition the device is at the time of the report, e.g. destroyed, returned to manufacturer or within the health care facility.
- Serious event: Check this category if the adverse event results in death, life threatening, disability or permanent damage, hospitalization or prolongation of hospitalization, any birth defect or serious deterioration in the health of a patient, user or other person.
- Provide the name and uses of other medical devices that were used with the reported device at the same time. Detailed description of event: Give a detailed description of the adverse event.
- Section 11 & 12 (for manufacturer or authorized representative only) report the frequency of occurrence of similar adverse events in the last three years in India and globally.

C. PATIENT INFORMATION, HISTORY & OUTCOME

- Provide the patient's hospital ID (given by hospital), initial (e.g. if the patient's name is Rajesh, then the initial is RAJ), age, gender, weight and other relevant medical history.
- Provide the patient's outcome details, e.g. recovered, not recovered, death, etc.

D. HEALTHCARE FACILITY INFORMATION

- Provide the information of the healthcare facility where the adverse event occurred, such as the name, address and contact details of the person at the site of the event.

E. CAUSALITY ASSESSMENT

- Investigation Action Taken: Specify the details of the investigation methods carried out by the clinical specialists at the healthcare facility or the manufacturer. Include the immediate action taken to correct the adverse effect if possible. If no investigation is done, provide a rationale here.
- Root cause of problem: Indicate the root cause that would determine the most probable cause of the problem with the medical device.

F. MANUFACTURER/AUTHORIZED REPRESENTATIVE INVESTIGATION &ACTION TAKEN

- (Only for Manufacturer/Authorized Representative) Manufacturer/Authorized Representative device risk analysis report: Provide the details of the investigation methods, results and conclusions for this event. Include the rationale for the course of action taken to investigate the incident. Also include the details of the actions to be completed and the timelines for their completion. If no investigation is to be done, provide a rationale here. Identify the root cause of the problem. The root cause would determine the most probable cause of the problem with the medical device. This may not be available at the time of reporting.
- Corrective/Preventive Action taken: Provide information on actions taken to correct the problem, including any post-market surveillance, recalls, or corrective or preventive actions, as well as the design and manufacturing of the device. Also provide the rationale for performing the corrective action. If no corrective action is to be taken, provide a rationale here. This may not be available at the time of reporting.
- Device History Review: Provide a review of other similar events involving the same lot/batch. It should also include a review of device history records for each batch, lot or unit to ensure that the device was manufactured according to specifications, no anomalies during the manufacturing process etc.

PROGRESS AND ACHIEVEMENTS MADE BY MvPI SO FAR [17]

- The MvPI has set up 250 Materiovigilance Associated Centres (MACs) across the country to report adverse events related to medical devices. The MvPI has also developed a web-based online reporting system called Indian Medical Device Adverse Event Reporting Form (IMDAERF) to enable easy and timely reporting of adverse events.
- The MvPI has issued guidelines for reporting adverse events, performing root cause analysis, and taking corrective and preventive actions for medical devices.
- The MvPI has organized several training programmes, workshops, and awareness campaigns to educate the stakeholders about the importance of materiovigilance.
- The MvPI has collaborated with international agencies such as World Health Organization (WHO), International Medical Device Regulators Forum (IMDRF), and Asian Harmonization Working Party (AHWP) to exchange information and best practices on materiovigilance.
- The MvPI has supported the regulation and standardization of medical devices in India by providing inputs to the Central Drugs Standard.

CONCLUSION

Materiovigilance in India stands an integral element of the healthcare system, committed to safeguarding the well-being of patients by closely monitoring and addressing adverse events related to medical devices. Through the diligent efforts of various units and stakeholders, this program has made significant strides in improving healthcare safety. The framework's objectives and applications have been instrumental in strengthening the regulation and approval of medical devices in India, and the reporting of adverse events has enhanced transparency and accountability. While challenges persist, the progress and achievements of the Materiovigilance program are commendable, and they highlight the commitment of India's healthcare community to ensuring the highest level of safety and excellence in patient care. The ongoing dedication to Materiovigilance underscores its importance in preserving public health and underscores the nation's unwavering commitment to advancing healthcare safety.

REFERENCES

1. Rehman, S. Materiovigilance: Its impact on patient's safety.
2. Kakkar, S., & Dadhich, J. Overview of Materiovigilance Programme of India.
3. Kumar, M., Sharma, A. R., Singh, A., PK, S., Raja, A., & Medhi, B. An Overview on surveillance of Biomedical Devices under Materiovigilance Program of India.
4. Chauhan, P. R. A. T. I. B. H. A., Zarreen, A. A. L. I. A., &Iqubal, M. K. (2019). Current status of materiovigilance globally—an utter overview with clinical case perusal. Int J Pharm Pharm Sci, 11(10), 1-8.
5. Shukla, S., Gupta, M., Pandit, S., Thomson, M., Shivhare, A., Kalaiselvan, V., & Singh, G. N. (2020). Implementation of adverse event reporting for medical devices, India. Bulletin of the World Health Organization, 98(3), 206.
6. Hoda, F., Verma, R., Arshad, M., Siddiqui, A. N., Khan, M. A., Akhtar, M., & Najmi, A. K. (2020). Materiovigilance: concept, structure and emerging perspective for patient's safety in India. Drug Research, 70(09), 429-436.

7. Kumar, P., Kalaiselvan, V., Kaur, I., Thota, P., & Singh, G. N. (2016). Materiovigilance programme of India (MVPI): A step towards patient safety for medical devices. Eur J Biomed Pharm Sci, 12, 497-501.
8. Meher, B. R. (2018). Materiovigilance: An Indian perspective. Perspectives in clinical research, 9(4), 175.
9. Saifuddin, P. K., Tandon, M., Kalaiselvan, V., Suroy, B., Pattanshetti, V., Prakash, A., & Medhi, B. (2022). Materiovigilance Programme of India: Current status and way forward. Indian Journal of Pharmacology, 54(3), 221.
10. Wathoni, N., Alfauziah, T. Q., & Rantika, N. (2018). Evolution of contraceptive implants: A review. International Journal of Applied Pharmaceutics, 16-22.
11. Rani, S., & Singh, K. (2018). Materiovigilance: An emerging discipline.
12. Mal, D. K., Ehsan, I., & Mukherjee, B. MATERIOVIGILANCE and HAEMOVIGILANCE.
13. Singh, K. N. M., &Kanase, H. R. (2017). Pharmacovigilance programme of India: The beginning, current status and recent progress. Adv Pharmacoepidemiol Drug Saf, 6(4), 219.
14. Sanjana, P., Kirti, A. H., & Begum, A. S. (2016). Medical devices and their approval procedure in India. International Journal of Drug Regulatory Affairs, 4(3), 19-29.
15. Joshi, D., Sharma, I., Gupta, S., Singh, T. G., Dhiman, S., Prashar, A., ... & Singh, S. K. (2021). A global comparison of implementation and effectiveness of materiovigilance program: overview of regulations. Environmental Science and Pollution Research, 1-22.
16. Research associate, National Coordination Centre. (n.d.-b). https://www.ipc.gov.in/images/Guideline_-_11-03-2020.pdf
17. Pharmacovigilance Programme of India (PVPI). (n.d.). https://ipc.gov.in/images/e PvPI_Annual_Performance_Report_2018-19.pdf