

# **Materiovigilance Programme of India (MvPI)**

## **Background**

Materiovigilance Programme of India was launched by DCG (I) on 6th July 2015 at Indian Pharmacopoeia Commission (IPC) Ghaziabad. Indian Pharmacopoeia Commission functions as a National Coordination Centre (NCC) for MvPI.

## **Introduction**

After several horrific cases of malfunctioning medical devices, like babies being burnt to death due to short circuits in incubators or hip implants causing blood poisoning, the Ministry of Health & Family Welfare (MoHFW), Govt. of India (GoI) has approved Materiovigilance Programme of India (MvPI) in an effort to ensure safety of medical devices. In addition to protection of health and safety of patients, Materiovigilance program reduces the likelihood of reoccurrence of the harmful incidents elsewhere thereby improving quality of health products.

Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Thiruvananthapuram, shall act as National Collaboration Centre, National Health System Resource Centre (NHSRC), New Delhi shall act as Technical Support & Resource Centre and Central Drugs Standard Control Organisation (CDSCO), New Delhi shall act as regulator.

## **Scope**

- To create a nation - wide system for patient safety monitoring.
- To analyse the benefit-risk ratio of medical devices.
- To generate evidence based information on safety of medical devices.
- To support CDSCO in the decision-making process on use of medical devices.
- To communicate the safety information on use of medical devices to various stakeholders to minimise the risk.
- To emerge as a national centre of excellence for Materiovigilance activities.
- To collaborate with other healthcare organisations for the exchange of information and data management.

## **Committees under NCC**

The following committees are constituted by MoHFW, GoI to give proper direction for efficient functioning of the programme.

## **Steering Committee**

MvPI is administered and monitored by Steering Committee to supervise and give proper direction to the programme.

## **Working Group**

It is constituted to approve major technical issues related to establishment and implementation of programme and giving technical inputs to CDSCO for regulatory intervention of medical devices.

## **Communication under MvPI**

Effective communication channels are the key to successful functioning of MvPI. The following chart depicts the movement of information between the key stakeholders and ensures continuous transfer of data, information, and knowledge.

**Indian Pharmacopoeia Commission (IPC)  
National Coordination Centre (NCC)  
Materiovigilance Programme of India (MvPI)**

**Programme Communication**

**Medical Device Adverse Event Monitoring Centres  
(MDMCs)**



**Sree Chitra Tirunal Institute for Medical Sciences & Technology  
(SCTIMST), Ministry of Science & Technology, Government of  
India, Thiruvananthapuram**

**National Collaboration Centre (NCC)**



**Indian Pharmacopoeia  
Commission (IPC), Ministry of  
Health & Family Welfare,  
Government of India, Ghaziabad**

**National Coordination Centre (NCC)**



**National Health System Resource  
Centre (NHSRC), Ministry of Health  
& Family Welfare, Government of  
India, New Delhi**

**Technical Support & Resource Centre  
(TSRC)**



**Central Drugs Standard Control Organization (CDSCO), Head Quarter,  
Ministry of Health & Family Welfare,  
Government of India, New Delhi**

**National Regulatory Authority (NRA)**

## **Who can Report?**

Under MvPI clinician, biomedical engineers, clinical engineers, hospital technology manager, pharmacists, nurses, technicians can report medical device adverse events. Medical device manufacturers/CDSCO notified medical device manufacturers/ medical device importer-trader can also report adverse events specific for their product to National Collaboration Center i.e. SCTIMST, Thiruvananthapuram.

## **Why to Report?**

Medical devices have been associated with several adverse effects and at times fatal harmful effects to the patients. As a stakeholder it is a responsibility to report adverse events associated with use of Medical Devices and safeguard the health of public.

## **What to Report?**

In order to foster the habit of reporting MvPI encourages reporting of all types of adverse events related to medical devices- irrespective of whether they are known or unknown, serious and non-serious, frequent or rare. Although Materiovigilance is primarily concerned with adverse events associated with medical devices used in India

## **How and Whom to Report?**

Use the 'Medical Device Adverse Event (MDAE) reporting form' which is available at [www.ipc.gov.in](http://www.ipc.gov.in) to report any adverse event. Research Associates from Medical Device Adverse Event Monitoring Centres (MDMCs) after filling the MDAE form would submit it to the National Collaboration Centre ([mvpi@sctimst.ac.in](mailto:mvpi@sctimst.ac.in)).

NCC-PvPI helpline 1800-180-3024 (Toll free) also provides assistance in medical device adverse event reporting.

## **Reporting of medical device adverse events**

Adverse events related to medical devices can be reported by downloading the MDAE form available at [www.ipc.gov.in](http://www.ipc.gov.in) and duly filled scanned form can be sent via e-mail on [mvpi@sctimst.ac.in](mailto:mvpi@sctimst.ac.in) and copy to [mvpi.ipcindia@gmail.com](mailto:mvpi.ipcindia@gmail.com).



## MEDICAL DEVICE ADVERSE EVENT REPORTING FORM

Materiovigilance Programme of India

FOR MDMC/NCC USE ONLY								
Type of report: Initial <input type="checkbox"/> Follow-up <input type="checkbox"/>				Report No. _____ :				
A. PATIENT DETAILS								
1. Patient Hospital ID -----				3. Age at time of Event or Date of Birth _____				
2. Sex: M <input type="checkbox"/> F <input type="checkbox"/>				4. Weight (Kg) _____				
B. EVENT DETAILS								
1. Event description-								
Reason for the Event(Tick) a) Electrical <input type="checkbox"/> b) Mechanical <input type="checkbox"/> c) Electronic <input type="checkbox"/> d) Biocompatibility <input type="checkbox"/> e) Clinical application error <input type="checkbox"/>								
2. Severity of the event (Yes <input type="checkbox"/> No <input type="checkbox"/> ) if yes please specify following <input type="checkbox"/> Death (---/---/---) <input type="checkbox"/> cause congenital-anomaly <input type="checkbox"/> Life threatening <input type="checkbox"/> Required intervention to prevent death or impairment of body function <input type="checkbox"/> Hospitalization/Prolonged impairment/damage <input type="checkbox"/> Disability <input type="checkbox"/> Other (specify).....								
3. Date of event - (dd/mm/yyyy)								
4. Location of the event- OPD <input type="checkbox"/> IPD <input type="checkbox"/> Others(Please specify).....								
5. Device category: (A) Therapeutic <input type="checkbox"/> Diagnostics <input type="checkbox"/> Both <input type="checkbox"/> (B) Implantable device <input type="checkbox"/> Non Implantable device <input type="checkbox"/> (C). Single use device <input type="checkbox"/> Reusable device <input type="checkbox"/> Reuse of manufacture marked single use device <input type="checkbox"/>								
6. Date-								
Last preventive maintenance			Last calibration					
7. Location of device after the incident: Place of use <input type="checkbox"/> Place of reporter <input type="checkbox"/> Place of Manufacture/vendor <input type="checkbox"/> With patient or end user <input type="checkbox"/>								
8. Is device in use after incident Yes <input type="checkbox"/> No <input type="checkbox"/>								
9. (A) Is same model device available in organisation? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, Quantity..... (B) Organization - Healthcare facility <input type="checkbox"/> Manufacturer <input type="checkbox"/>								
C. MEDICAL DEVICE(S) DETAIL								
Name of Medical Device (1)	Manufacturer (2)	Brand Name (3)	Model No. (4)	Serial No. (5)	Batch No./ Lot No. (6)	Catalogue No. (for instruments only)	Date of installation/ implantation/ explanation (8)	List of Accessories (9)
10. Actions taken immediately after incident				11. A Whether other medical devices were being used at same time with above device for therapeutic or diagnostic service? If yes, please specify.....  11. B. Any history of adverse event(s) from device with same serial/model/catalogue number. If yes please specify.....				

D.REGULATORY DETAILS			E. REPORTER DETAILS of MvPI CENTRE	
Manufacturer name:	Entity legally representing the Manufacture:	Notified Body name in:	Name and Professional Address:_____	
Regulator in Country of origin:	Country:	(I) Country of Manufacturing :	Pin:_____ E-mail_____	
Regulatory status in origin country:		(II) In India:	Tel. No. (with STD code)_____	
			Designation:_____	
			Signature:_____	
			Date of this report ___dd/mm/yyyy	
F. Causality Assessment Details			Completed <input type="checkbox"/>	In Progress <input type="checkbox"/>
			Awaited <input type="checkbox"/>	
Additional Information:				
<p><b>Confidentiality:</b> 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. <b>Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the adverse event.</b></p>				



**National Collaborating centre-Materiovigilance Programme of India.**

**Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST)** under the Department of Science & Technology, Government of India. Biomedical Technology Wing, Poojappura,Thiruvananthapuram 695012,Kerala. Phone: 91- 471 – 2340411, Fax: 91- 471 -2341814, Email: [head-bmtw@sctimst.ac.in](mailto:head-bmtw@sctimst.ac.in).



**National Coordinating Centre-Materiovigilance Programme of India.**

**Indian Pharmacopoeia Commission (IPC)**, Ministry of Health and Family Welfare, Government of India, Sector-23,Rajnagar, Ghaziabad-20002, Tel.:0120-2783400, 2783401, and 2783392, FAX: 0120-2783311, Email: [ipclab@vsnl.net](mailto:ipclab@vsnl.net), [pvpi.ipcindia@gmail.com](mailto:pvpi.ipcindia@gmail.com)



**Technical support and Resource centre- Materiovigilance Programme of India.**

**National Health System Resource Centre (NHSRC)**, NIHFW campus Baba Gangnath marg, Munirka, New Delhi-110067, Phones: 011 26108982 / 83 / 84 / 92 /93, Fax: 011-26108994 Email: [nhsr.india@gmail.com](mailto:nhsr.india@gmail.com).

**Where to report**

- **Duly filled Medical Device Adverse Event Reporting Form can be send to Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), National Collaborating Centre-Materiovigilance Programme of India), Biomedical Technology Wing, Poojappura, Thiruvananthapuram 695012,Kerala,India.**
- **Or can directly email the duly filled form to [mvpi@sctimst.ac.in](mailto:mvpi@sctimst.ac.in).**
- **Call on Helpline no. 1800 180 3024 to report Adverse event.**

**Event description** Details of adverse event including description of device (deficiency or malfunction), clarification of hazards associated with device and the associated risk of patient, user or person any possible risk to patient associated with previous use.

**Additional Information** Other relevant information related to treatment should be provided.