

Medical Devices Adverse Event reporting Monitoring Centre (MDMCs), AIIMS, Bhopal

Materiovigilance Program of India (MvPI)

Materiovigilance is the coordinated system of identification, collection, reporting, and analysis of any untoward occurrences associated with the use of medical devices and protection of patient's health by preventing its recurrences.

Materiovigilance refers to medical devices as well as In-vitro diagnostics whereas pharmacovigilance refers to medicines. Materiovigilance is targeted to close monitoring of any undesirable performance or characteristics fluctuations of a medical device by means of a system which is capable of identifying, collecting, reporting and reacting to them with field safety corrective actions or device recall during post - marketing phase of a Medical Device.

Wherein "Medical device" means any instrument, apparatus, implement, machine, appliance, implant in-vitro reagent or calibrator, 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 purposes of diagnosis, prevention, monitoring, treatment or alleviation of disease.

Ministry of Health & Family Welfare (MOHFW), Government of India have approved Materiovigilance Programme (MvPI) in February 2015 with 50 Medical Devices Adverse Event reporting Monitoring Centre (MDMCs) established across India till date.

Department of Pharmacology, AIIMS, Bhopal has been approved as a MDMC by IPC Ghaziabad since August 2019,

Mission

The mission of MvPI is to safeguard the health of Indian population by ensuring that the benefits of use of Medical Devices outweigh the risks associated with its use. These devices serve a very important role in their day to day routine for each and every healthcare worker (HCW), hence there is need to encourage them for reporting of adverse events. To promote public and animal health in India by bringing out authoritative and officially accepted active pharmaceutical ingredients, excipients and dosage forms, used by healthcare professionals, patients and consumers. The regulatory requirement mandates that all the adverse events should be notified to the National Coordination Centre- MvPI (NCC-MvPI) via the designated Medical Devices Adverse Events Monitoring Centres (MDMC). There exists a well-coordinated network for reporting and collaboration with other stakeholders in concern. **Strict vigilance of medical devices is needed to eliminate the use of substandard or counterfeit medical devices.** MvPI gives the scope of identifying counterfeit devices in the market & substandard quality medical devices

available in the market that can cause serious risk to the health of patients & healthcare providers. The substandard or counterfeit medical devices can also be recalled from market by manufacturer or authorised agent. 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 is hazardous to health. This helps at large for risk mitigation for these devices.

The vision is to improve patient safety & welfare of Indian population by monitoring adverse events related to Medical devices & thereby the risk associated with use of Medical Devices.

ADVERSE EVENTS CAN BE REPORTED TO MDMC, AIIMS BHOPAL

Telephone : 0755-2902620.

Email ID : mvpi@aiimsbhopal.edu.in

Reporting forms are available at: AMC Centre/ OPD Registration Counter /all OPDs and wards of AIIMS Bhopal.

~ Under MvPI clinician, biomedical engineers, clinical engineers, hospital technology manager, pharmacists, nurses, technicians can report medical device adverse events.

~ As a stakeholder it is a responsibility to report adverse events associated with use of Medical Devices and safeguard the health of public.

~ 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.

For any other queries and suggestions please contact us at the above number or mail id.

For more information on Materiovigilance Program of India lease visit

<http://www.ipc.gov.in/mandates/pvpi/materiovigilance-programme-of-india-mvpi.html>