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Government of India
National Medical Commission
Policy & Coordination Division

Pocket- 14, Sector- 8,
Dwarka, Phase-1, New Delhi-77
Dated: 13 July, 2025

PUBLIC NOTICE

Subject:- Monitoring, assessing, and preventing adverse events associated with medical devices - Constitution of Medical Device related Adverse Event Committee in each Medical College.

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Medical devices have become an indispensable part of modern healthcare, contributing significantly to the diagnosis, treatment, and management of diseases. Various incidents involving medical devices causing harm to the patients has created the need of a system to monitor these events and take necessary actions to prevent these from happening again.

2. In response to this the Ministry of Health and Family Welfare (MoHFW), launched the Materiovigilance Programme of India (MvPI) in 2015 at Indian Pharmacopoeia Commission, to monitor adverse events and risks associated with medical devices used across the country. This national initiative is designed to systematically collect, analyse, and respond to adverse events associated with medical devices, ensuring better patient safety and quality healthcare delivery. The program is coordinated by the IPC and operates through a growing network of Medical Device Adverse Events Monitoring Centres (MDMCs) in hospitals and medical colleges.

3. The Medical Devices Rules, 2017 regulate the import, manufacturing, sale and distribution of medical devices in India including post market surveillance of a medical device.

4. **Materiovigilance Programme of India (MvPI)**:

The Materiovigilance Programme of India (MvPI) is a national initiative aimed at ensuring the safety of medical devices across their lifecycle. MvPI enhances device safety through systematic reporting and analysis of adverse events, providing data to CDSCO to support regulatory action and guide improvements in

clinical practice.

5. Advantages of Becoming a Medical Device Adverse Events Monitoring Centre (MDMC):

Medical colleges serve as ideal hubs for Materiovigilance due to their diverse patient populations and access to advanced healthcare technologies. Becoming an MDMC offers multiple strategic advantages:

- **Academic Recognition**: Participation enhances the institution's stature as a contributor to national public health and regulatory science.
- **Professional Development**: Provides faculty and students hands-on exposure to post-market surveillance, risk assessment, and patient safety.
- **Infrastructure Enhancement**: Access to MvPI resources, training modules, and national-level collaboration.
- **Policy Influence**: Opportunities to contribute to evidence-based recommendations and medical device regulations.
- **Patient Safety**: Ensures early detection and response to device malfunctions, directly improving clinical outcomes.

6. Constitution of Medical Device related Adverse Event Committee in each Medical College:

(i) In view of the foregoing, All Medical Institutions are advised to set up a Committee to monitor the Adverse Events Related to Medical Devices. Each medical institution should register this Committee with the Indian Pharmacopeia Commission. The registration /enrolment form is available on the Website of Indian Pharmacopeia Commission viz.-

https://www.ipc.gov.in/mandates/materiovigilance-programme-of-india-mvpi/enrolment-form-for-mvpi.html

(ii) The website of all medical institutions shall also indicate the name of the Coordinator/Convenor of the committee and additional members, if any. The Medical Superintendent will ordinarily be the Chair of this Committee. The website shall also indicate the date of registration of MDAEC.

(iii) Institutions are also reminded to update the Pharmacovigilance Committee members' names in the website of the institution. This process may be completed before **31.07.2025**.

Digitally signed by Dr.Raghav Langer
Date: 13-07-2025 19:33:32

(Dr. Raghav Langer)

Secretary

To

Dean/Principal all the Medical Colleges/Institutions