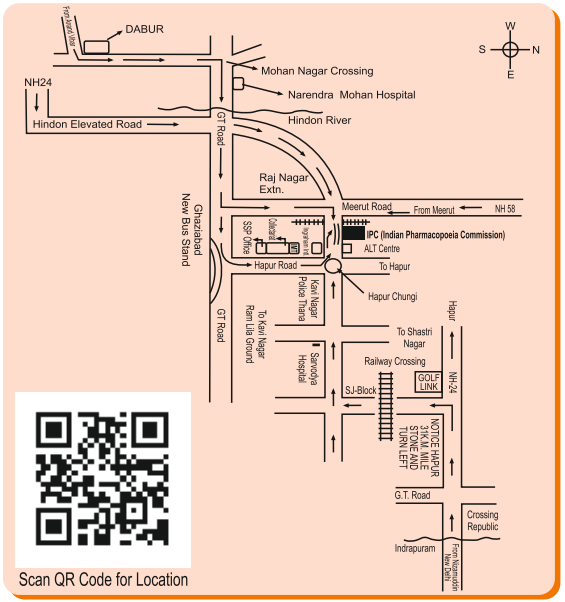
CONNECT & CONTACT US

www.ipc.gov.in

ipclab@vsnl.net

Toll Free No.: 1800 180 3024



Scan QR Code for Location

Indian Pharmacopoeia Commission

National Coordination Centre (NCC)
Materiovigilance Programme of India (MvPI)
Ministry of Health & Family Welfare, Govt. of India,
Sector-23, Raj Nagar, Ghaziabad-201 002
Email: mvpi.ipcindia@gmail.com, ipclab@vsnl.net
Tel.: 0120-2783400, 2783401, 2783392, Fax: 0120-2783311

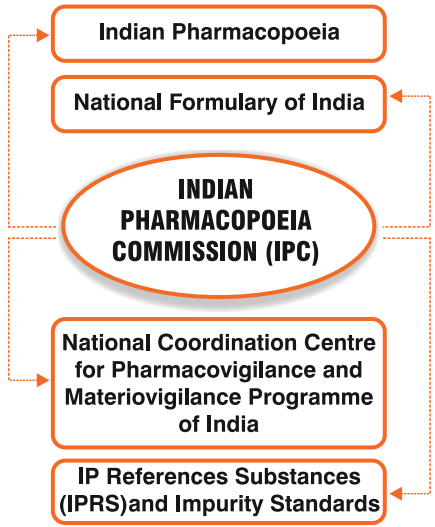
MATERIOVIGILANCE
Programme of India

Step towards Promoting Safety of Medical Devices

Indian Pharmacopoeia Commission

Ministry of Health & Family Welfare, Government of India, Ghaziabad

Indian Pharmacopoeia Commission (IPC) is an Autonomous Institution of the Ministry of Health and Family Welfare, Govt. of India. Its basic function is to update regularly the standards of drugs commonly required for the treatment of diseases prevailing in the country.



VISION

"To promote the highest standards of drugs for use in human and animals within practical limits of the technologies available for manufacture and analysis."

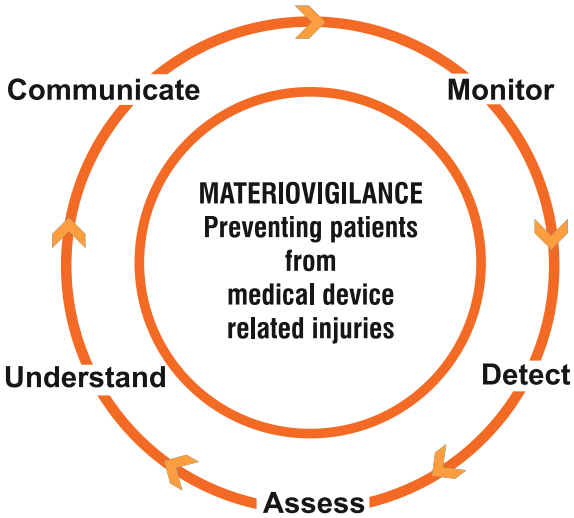
MISSION

"To promote public and animal health in India by bringing out authoritative and officially accepted standard for quality of drugs including active pharmaceutical ingredients, excipients and dosage forms, used by healthcare professionals, patients and consumers."

MATERIOVIGILANCE PROGRAMME OF INDIA (MvPI)

Ministry of Health and Family Welfare, Government of India has approved the commencement of "MvPI" with Indian Pharmacopoeia Commission, Ghaziabad as National Coordinating Centre.

The MvPI to monitor the safety of medical devices in the country was formally launched on July 6, 2015 at Indian Pharmacopoeia Commission (IPC).



MISSION

Safeguard the health of Indian population by ensuring that the benefits of use of Medical Devices outweigh the risks associated with its use.

VISION

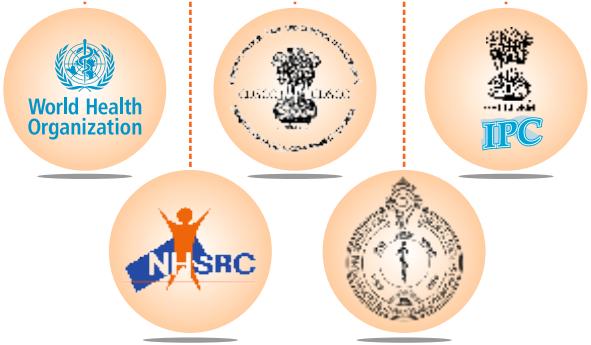
To improve patient safety & welfare by monitoring adverse events related to Medical Devices & thereby reducing the risk associated with use of Medical Devices.

OBJECTIVE

To improve the protection of the health & safety of patients, healthcare professionals and others by reducing the likelihood of reoccurrence of an adverse event associated with the use of Medical Devices.

PARTNERING ORGANIZATIONS

MATERIOVIGILANCE PROGRAMME OF INDIA (MvPI)



REGULATION

Medical devices in India are regulated by Medical Devices Rules (MDR), 2017. It came into force with effect from January 1, 2018. The new rules are in line with Global Harmonization Task Force (GHTF) framework and confirm to best international practices. Special provisions for the regulation of clinical investigational device and separate provisions for medical device management for the subjects of the trials have been introduced to achieve patient safety.

These rules shall be applicable in respect of:

Substances used for in vitro diagnosis & surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant covered under sub-clause (i);
Substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified under sub-clause (ii);
Devices notified from time to time under sub-clause (iv), of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940);

What is a Medical Device?

Medical device means any instrument, apparatus, implement, machine, appliance, implant, reagent for *in-vitro* use, 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 medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury
- investigation, replacement, modification, or support of the anatomy or of a physiological process supporting or sustaining life
- control of conception
- disinfection of medical devices
- providing information for medical purposes by means of *in-vitro* examination of specimens derived from the human body
- devices for *in-vitro* fertilization or assisted reproduction technologies and which does not achieve its primary intended action by pharmacological, immunological or metabolic means



What is a Medical Device Adverse Event?

Any unexpected or inappropriate medical occurrence, unintended disease or injury, or on inconvenient clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the medical device.

What is Medical Device Adverse Event reporting?

A procedure for manufacturers, importers,healthcare professionals and device user facilities to report certain device-related adverse events and product problems to the Licensing Authority/National Co-ordination Centre (NCC) - Materiovigilance Programme of India (MvPI), Indian Pharmacopoeia Commission (IPC).

Who Can Report?

Clinical Specialist

Biomedical/ Clinical Engineers

Nurse

Pharmacist

Hospital Technology Manager

Patient

Medical device manufacturers/ importers/distributors

Technician

What to Report?

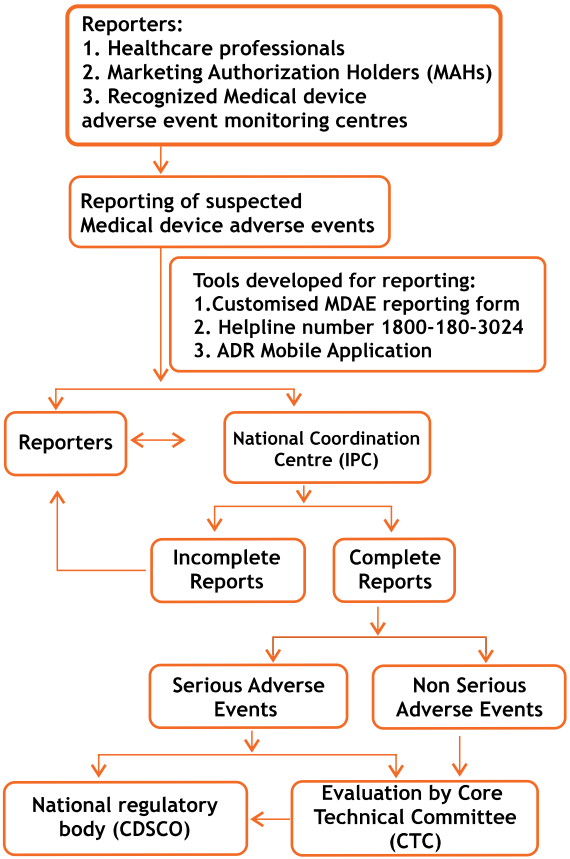
- serious or non-serious
- known or unknown
- frequent or rare

and all types of suspected adverse events associated with medical device disregarding of an established causal relationship between event and medical device

How and Whom to Report?

- The 'Medical Device Adverse Event (MDAE) reporting form' is available at www.ipc.gov.in and may be used to report any adverse event due to the use of medical devices.
- A reporter can send filled MDAE reporting form directly to NCC-MvPI via e-mail ipclab@vsnl.net/ mvpi.ipcindia@gmail.com or their nearest Medical Device Adverse Event Monitoring Centre (MDMC)/ Adverse Drug Reaction Monitoring Centre (AMC). The list of MDMCs/AMCs is available on **IPC.GOV.IN**
- A toll free **(1800 180 3024)** number is also available to report adverse event associated with use of medical devices to NCC-MvPI (on weekdays from **9:00 am - 5:30 pm**).

Flow diagram for Medical Device Adverse Event (MDAE) Reporting:



Benefits of MvPI:

- Generation of Medical Device safety data based on Indian Population
- Information from spontaneously reported MDAEs, published literature, clinical studies is used as the primary basis for evidence based regulatory decisions such as field safety corrective action, added warnings or recall related to the potentially affected medical device.
- Educational initiatives to healthcare professionals for improving safe use of medical devices
- Benefit risk ratio of medical devices can be assessed
- Safe and effective use of medical devices can be achieved
- Public confidence can be stored and enhanced

Why Materiovigilance is Important in India?

- Safety of more than 1.33 billion Indian people is a concern
- To provide safe and effective medical treatment is one of the mandate of Indian Government
- Some of the studies revealed that MDAEs in India are leading to prolongation of hospitalization and there constitutes a significant economic burden on patients as well as on country
- To avoid sub-standard and incompatible devices flooded in Indian market, it is of utmost priority to have a vigilance system in place to record feedback from patients and users

- MvPI of India being voluntary in nature, user facilities and healthcare facilities are encouraged to report Medical Device related Adverse Events for protection of the health and safety of patient by ensuring reduction of Device related incidents. The patient and reporter identity are held in strict confidence to the fullest extent. Reporting of adverse events does not bring any legal implications on the reporters in any manner.