# 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.

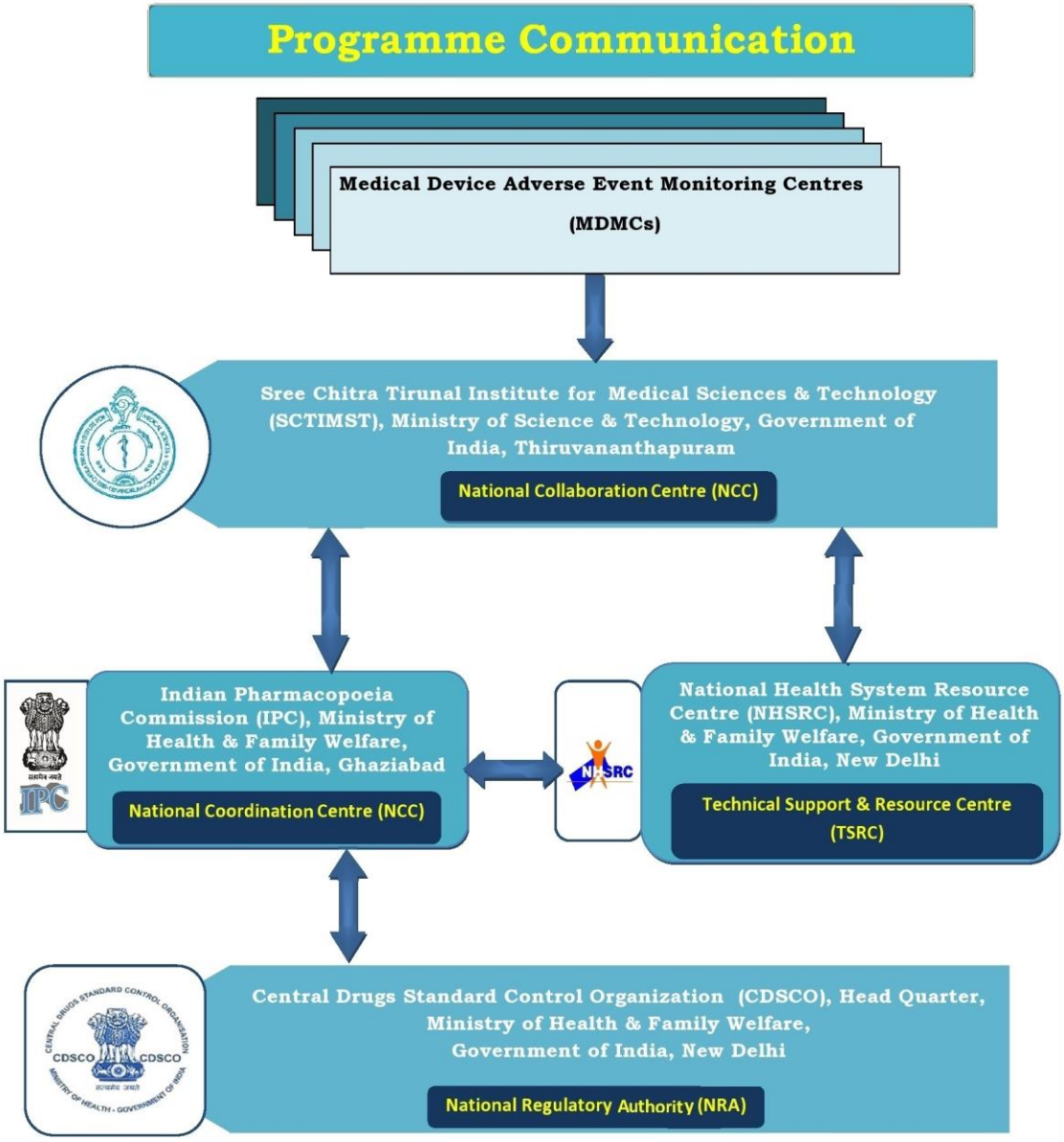
**Working Group**

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)**



## 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 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).

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 and duly filled scanned form can be sent via e-mail on mvpi@sctimst.ac.in and copy to mvpi.ipcindia@gmail.com.