Materiovigilance Programme of India (MvPI)

Products & services of IPC

Indian Pharmacopoeia & Addendum

Indian Pharmacopoeial Reference Substances (IPRS) & Impurity Standards (IMP-RS)

National Formulary of India (NFI)

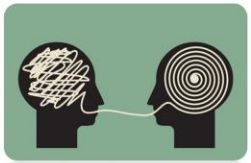
Pharmacovigilance Programme of India (PvPI) & Materiovigilance Programme of India (MvPI)

What is Materiovigilance?

"**Materiovigilance** is the science and activities related to

Detection

Assessment



Understanding

Prevention

of adverse events or any other medical device related problem once the device is available for public use"

What comes under medical device?

As per Medical Devices Rules 2017, medical device means:

- Instruments 
- Apparatus 
- Machines 
- Appliances 
- Implants 
- Reagent for In-Vitro use 
- Software products 
- Materials 

Doesn't

Achieve its primary intended action by pharmacological, immunological or metabolic means

Used

- Alone or in combination
- For human beings

Used for medical purpose

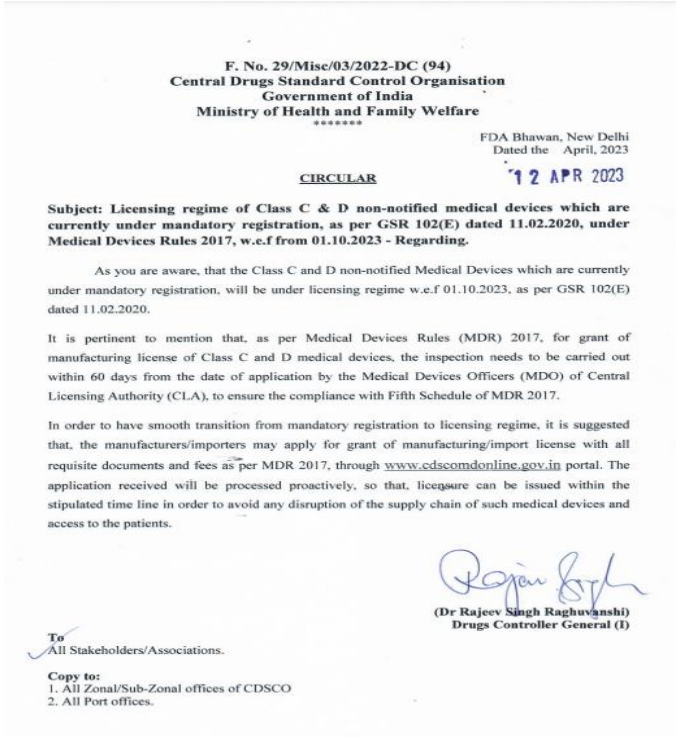
- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- Investigation, replacement, modification, or support of the anatomy or of a physiological process,
- Supporting or sustaining life,
- Control of conception,
- Disinfection of medical devices
- Providing information by means of in vitro examination of specimens derived from the human body;

How medical device differ from drug ?

Drug	Device
Based on Chemistry & Pharmacology	Based on Engineering
Safety and Efficacy	Safety and Performance/Accuracy
Clinical Trials (4 Phases)	Clinical Evaluation (Feasibility)
GMP	QMS
Local and Systemic Toxicity	Biocompatibility
Long Product Life Cycle	Short Product life Cycle
Drug Interactions	Device Malfunction

Regulation of medical devices

Regulation of all Class C & D Medical Devices Under Licensing regime, w.e,f 01.10.2023



F. No. 29/Misc/03/2022-DC (94)
Central Drugs Standard Control Organisation
Government of India
Ministry of Health and Family Welfare
****

FDA Bhawan, New Delhi
Dated the April, 2023

CIRCULAR

12 APR 2023

Subject: Licensing regime of Class C & D non-notified medical devices which are currently under mandatory registration, as per GSR 102(E) dated 11.02.2020, under Medical Devices Rules 2017, w.e.f from 01.10.2023 - Regarding.

As you are aware, that the Class C and D non-notified Medical Devices which are currently under mandatory registration, will be under licensing regime w.e.f 01.10.2023, as per GSR 102(E) dated 11.02.2020.

It is pertinent to mention that, as per Medical Devices Rules (MDR) 2017, for grant of manufacturing license of Class C and D medical devices, the inspection needs to be carried out within 60 days from the date of application by the Medical Devices Officers (MDO) of Central Licensing Authority (CLA), to ensure the compliance with Fifth Schedule of MDR 2017.

In order to have smooth transition from mandatory registration to licensing regime, it is suggested that, the manufacturers/importers may apply for grant of manufacturing/import license with all requisite documents and fees as per MDR 2017, through www.cdscomdonline.gov.in portal. The application received will be processed proactively, so that, licensure can be issued within the stipulated time line in order to avoid any disruption of the supply chain of such medical devices and access to the patients.

(Dr Rajeev Singh Raghuvanshi)
Drugs Controller General (I)

To
All Stakeholders/Associations.

Copy to:
1. All Zonal/Sub-Zonal offices of CDSCO
2. All Port offices.

Regulation of all Class A & B Medical Devices Under Licensing regime, w.e,f 01.10.2022

F. No. 29/Misc/03/2022-DC (257)
Central Drugs Standard Control Organisation
Government of India
Ministry of Health and Family Welfare
****

FDA Bhawan, New Delhi
Dated the 30th September, 2022

CIRCULAR

Subject: Regulation of all Class A & B Medical Devices under Licensing regime, w.e.f 01.10.2022, as per G.S.R. 102(E) dt 11.02.2020 - Regarding.

The Ministry of Health & Family Welfare (MoHFW) has published notification vide S.O. 648 (E) dated 11.02.2020 specifying all medical devices under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940, which is effective from 01.04 2020.

In order to regulate all the medical devices, MoHFW has published G.S.R. 102 (E) dated 11.02.2020 for regulation of such devices in phase wise manner. As per the said notification the Class A & B medical devices will be under licensing regime from 01.10.2022.

In the meantime, representations from various Associations and Stakeholders have been received by this office, requesting that the business continuity should not be disrupted due to the implementation of licensing regime w.e.f. 01.10.2022 for Class A & B medical devices.

In view of the above, it has been decided that, in case, if an existing importer/manufacturer who is already importing /manufacturing any of Class A or Class B Medical Devices, has submitted application to Central Licensing Authority or State Licensing Authority on or before 30.09.2022, as the case may be, for grant of import /manufacturing licence in respect of the said device(s) under the provisions of MDR, 2017, the said application shall be deemed valid and the importer/manufacturer can continue to import /manufacture the said device(s) up to 6 months from the date of issue of this order or till the time, the Central Licensing Authority or State Licensing Authority, as the case may be, takes a decision on the said application, whichever is earlier.

Digitally Signed by Dr. V G Somani
Date: 30-09-2022 20:41:38
Reason: Approved
(Dr. V. G. Somani)
Drugs Controller General (I)

To
All Stakeholders/Associations.
Copy to:
1. All State Drugs Controllers.
2. All Zonal/Sub-Zonal offices of CDSCO
3. All Port offices.

Classification of medical devices

Low Risk
Class A

Thermometers

Bandages

Wheelchairs

Low-Moderate Risk
Class B

Syringes

Pregnancy Test Kit

Surgical Gloves

Moderate-High Risk
Class C

Ventilator

Intraocular lenses

Bone fixation plate

High Risk
Class D

Implantable Pacemaker

Cochlear Implant

Intra-uterine contraceptive device

Need for Materiovigilance

HOME / NEWS / INDIA / OTHER STATES

New-born baby charred to death in Pune hospital after incubator overheats

September 27, 2017 03:50 pm | Updated 04:06 pm IST – Pune

Johnson & Johnson admitted: Many young patients were affected by faulty hip implants

The Health Ministry committee also found that J&J reported 121 “serious” adverse events to CDSCO from January 2014 to June 2017. But, the report says, “only 48 of such reports are available with CDSCO”.

No medical device is completely devoid of risk. Therefore, it is essential to have a monitoring system to ensure patients and users safety.

Arrow Catheter System Recall Issued Over Risk of Pulmonary Embolism and Death

The manufacturer has received at least 83 complaints of the recalled Arrow Catheter Systems separating while inside a patient’s vein, resulting in more than a dozen injuries.

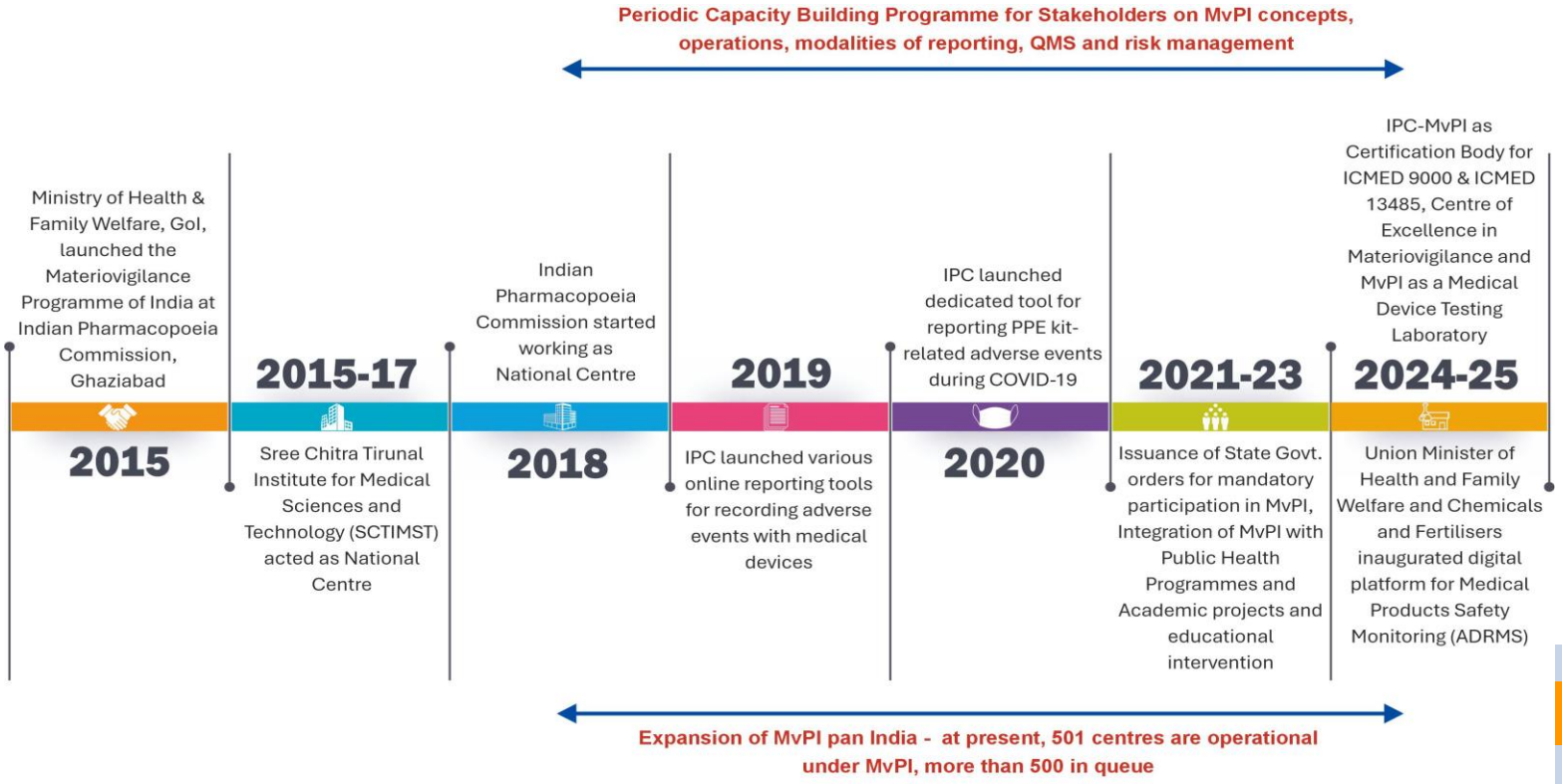
Explained: How an MRI machine killed a man in Mumbai

Bombay High Court has directed BMC to pay interim compensation of Rs 10 lakh to the family Rajesh Maru, who was killed after he was sucked into an MRI machine at BYL Nair Hospital in January 2018.

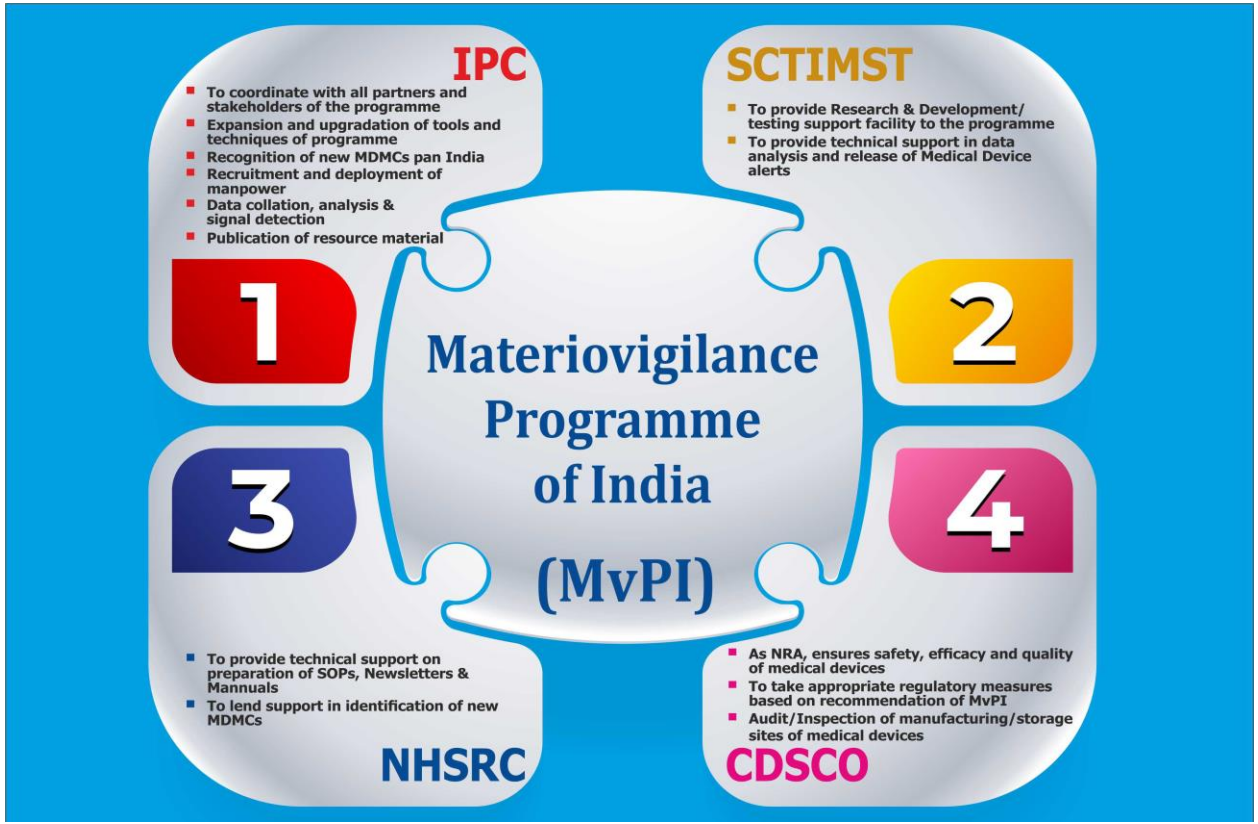
Materiovigilance in India

The Materiovigilance Programme of India (MvPI) to monitor the safety of medical devices manufactured/imported/sold in the country was formally launched on 06th July, 2015 at IPC, Ghaziabad by The Drugs Controller General (India)

Journey of Materiovigilance in India



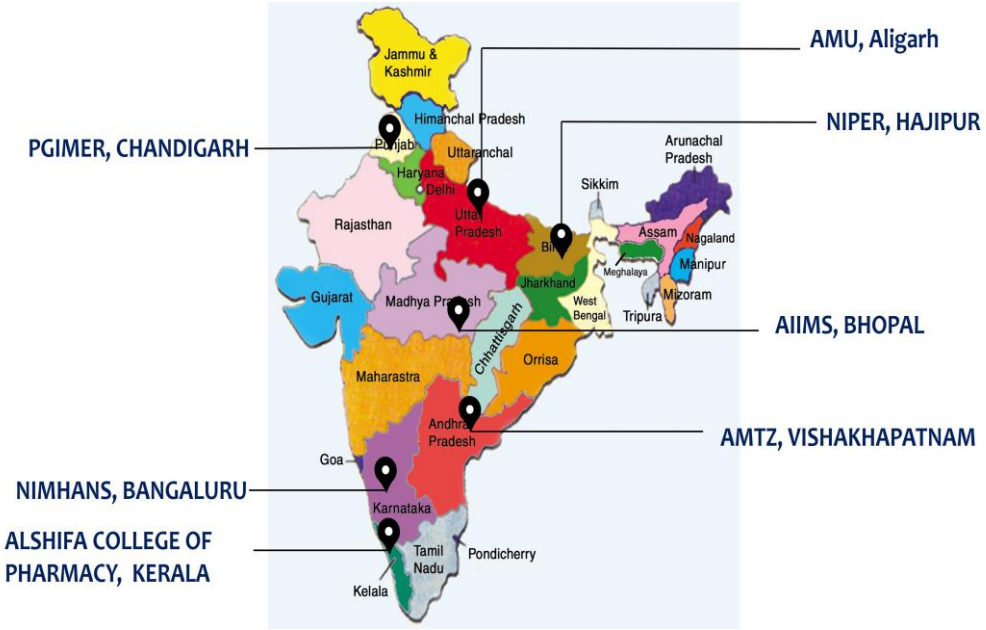
A Collaborative approach



Our presence

Monitoring Centres

Regional Training Centres



Terminologies used in Materiovigilance

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

Type of adverse event

Serious or Non serious, Expected or Unanticipated, Frequent or Rare

Terminologies used in Materiovigilance

Recall means any action taken by its manufacturer or authorized 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,—

(a) is hazardous to health; or

(b) fails to conform to any claim made by its manufacturer relating to its quality, safety or efficacy; or

(c) does not meet the requirements of the Act and regulatory guidelines

Terminologies used in Materiovigilance

Serious adverse event means an untoward medical occurrence that leads to,—

(I) a death; or

(II) a serious deterioration in the health of the subject that either-

(A) resulted in a life-threatening illness or injury; or

(B) resulted in a permanent impairment of a body structure or a body function; or

(C) required in-patient hospitalization or prolongation of existing hospitalization; or

(D) resulted in medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function; or

(III) foetal distress, foetal death or a congenital abnormality or birth defect

Who can report ?









What to report ?

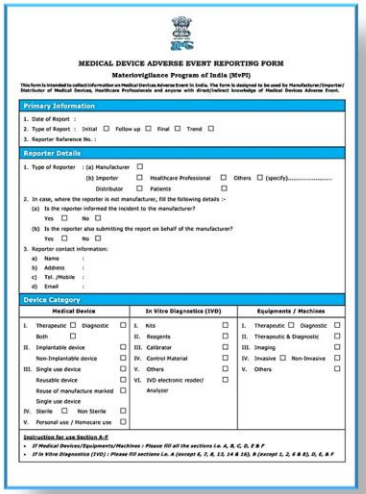
- any dysfunction or any change of the characteristics and/or performance of a device, and any inadequacy in the labelling or instructions, which might lead to or have led to death or serious relapse in the state of health of a patient, a user or a third party
- Not only must one notify serious incidents which have actually taken place but also the cases where there was a risk of a serious incident but that incident was avoided thanks to the attention and action of the relevant people

Why to report ?

“Adverse event (incident) reporting is the communication of an event or an issue to those who can make a contribution towards a meaningful outcome”

“To err is human, but not to learn from mistakes and not to communicate the lessons learnt from those mistakes is inexcusable”

How to report ?


MEDICAL DEVICE ADVERSE EVENT REPORTING FORM

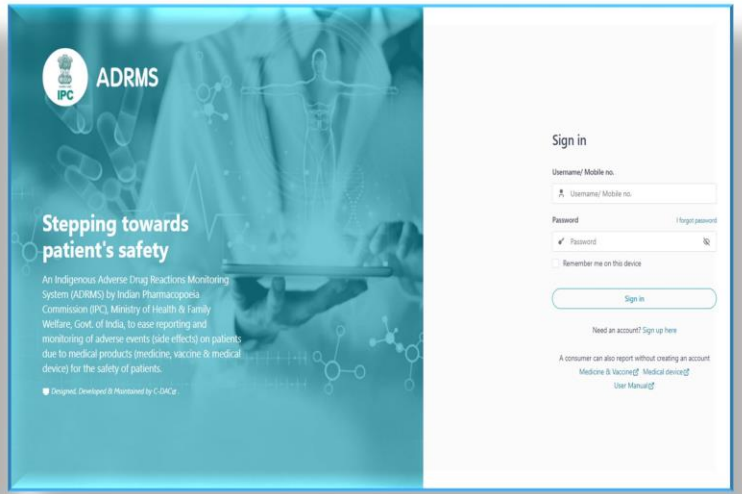
Materiovigilance Program of India (MvPI)

Primary Information

Reporter Details

Device Category

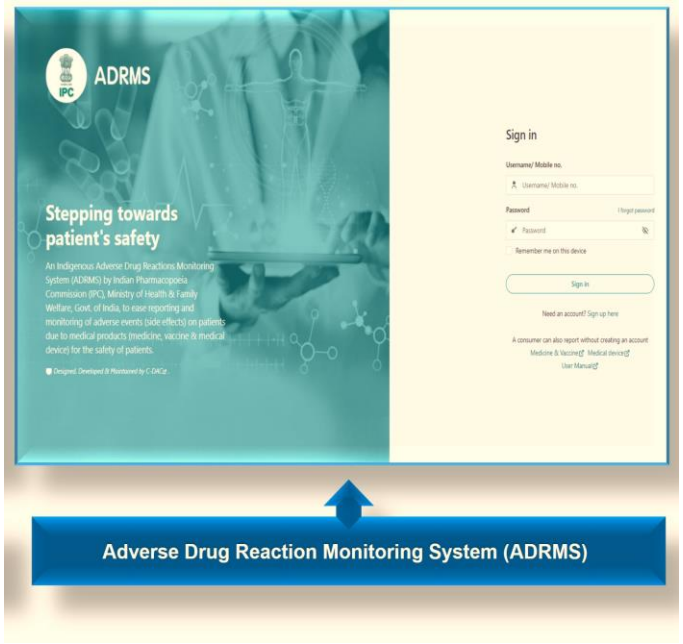
Medical Device Adverse Events (MDAE) Reporting Form



Adverse Drug Reaction Monitoring System (ADRMS)

Helpline Number

Launch of digital platform for medical products safety monitoring

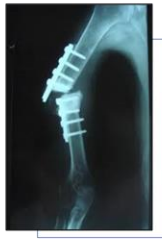


Union Minister of Health and Family Welfare and Chemicals & Fertilizers, J. P. Nadda launched the Indian Pharmacopoeia Online Portal and the Adverse Drug Reaction Monitoring System (ADRMS) software during the 'First Policy Makers' Forum' in New Delhi.

August 19, 2024

Minimum requirement of a valid MDAE

An untoward event or outcome

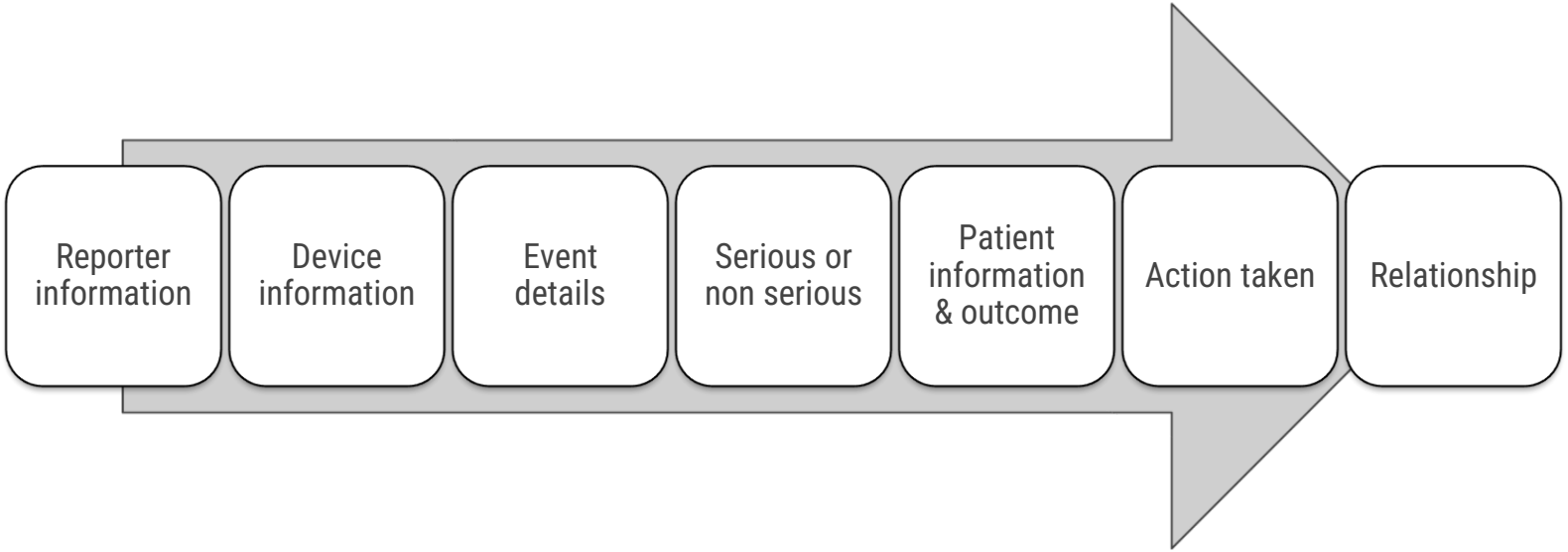


A suspected medical device/IVD

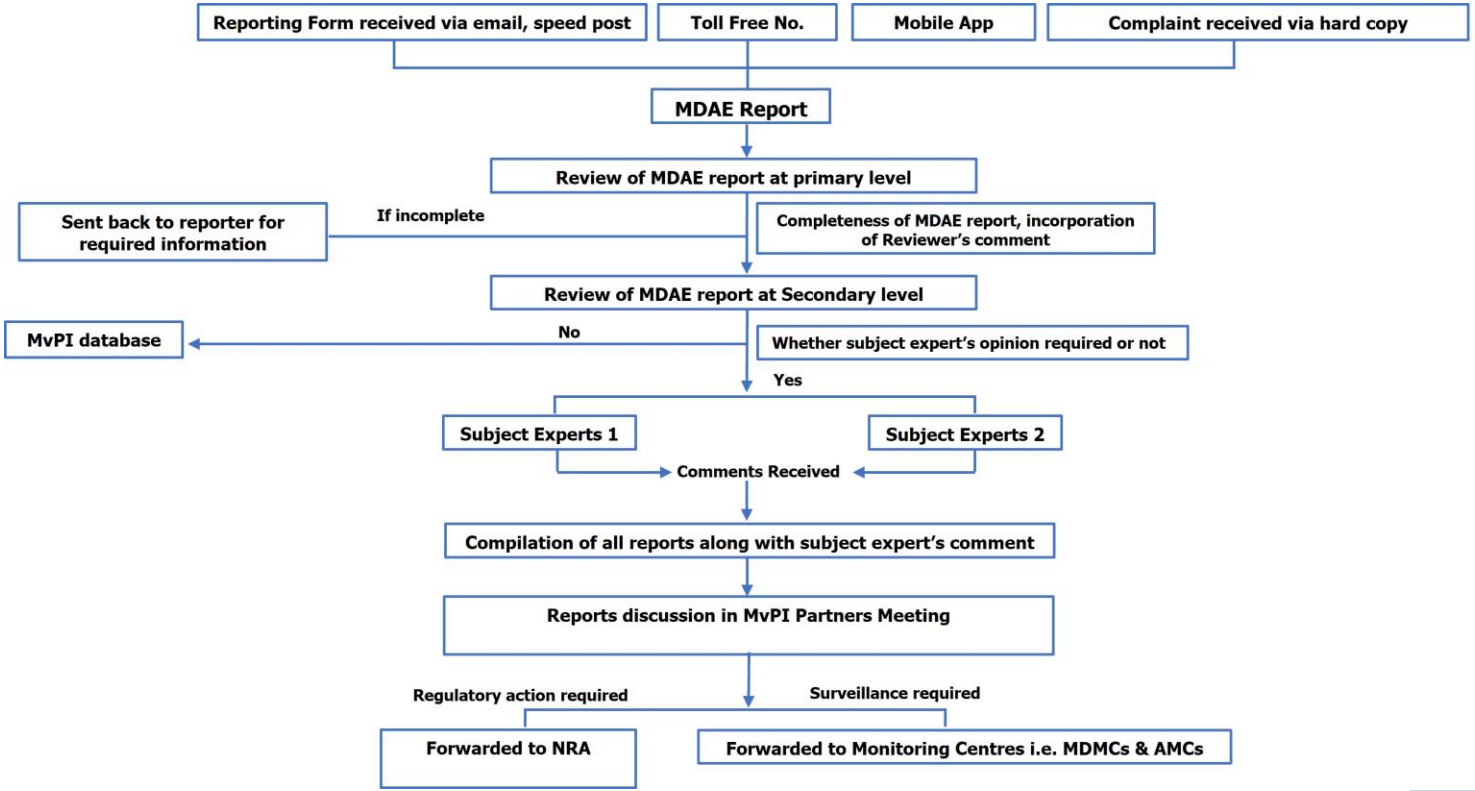
An identifiable reporter/patient

Online MDAE reporting form Is divided in to 09 sections -

Information to be captured in MDAE Form.



Once IPC-MvPI receive Medical Device Adverse Event



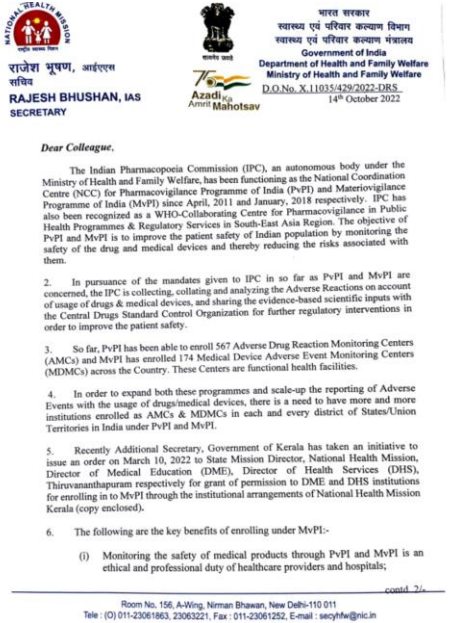
Benefits of Materiovigilance

- Generation of medical device safety data based on exclusive population
- Evidence based regulatory decisions can be taken
- Educational initiatives to healthcare professionals for improving safe use of medical devices
- Benefit risk ratio of medical devices can be assessed
- Updation on patient/user information leaflet - New MDAEs, warnings, contraindications and precautionary measures
- Population specific safety data can be generated- paediatric, geriatric, pregnant and lactating women
- Safe and effective use of medical devices can be achieved
- Public confidence can be stored and enhanced

Why Materiovigilance is important?

- Safety of native people
- To provide safe and effective medical treatment is one of mandate of Nation's Government
- Some of the studies revealed that MDAEs are leading to hospitalization or prolongation of hospitalization and constitutes a significant economic burden on patients as well as on country
- To avoid sub-standard and incompatible devices, flooded in local market, It is of utmost priority to have a vigilance system in place to record feedback from patients and users

Government initiatives for implementation of Materiovigilance Programme



राजेश भूषण, आईएएस
सचिव
RAJESH BHUSHAN, IAS
SECRETARY

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health and Family Welfare

D.O.No. X.11035/429/2022-DRS
14th October 2022

Azadi Ka Amrit Mahotsav

Dear Colleague,

The Indian Pharmacopoeia Commission (IPC), an autonomous body under the Ministry of Health and Family Welfare, has been functioning as the National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) and Materiovigilance Programme of India (MvPI) since April, 2011 and January, 2018 respectively. IPC has also been recognized as a WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes & Regulatory Services in South-East Asia Region. The objective of PvPI and MvPI is to improve the patient safety of Indian population by monitoring the safety of the drug and medical devices and thereby reducing the risks associated with them.

2. In pursuance of the mandates given to IPC in so far as PvPI and MvPI are concerned, the IPC is collecting, collating and analyzing the Adverse Reactions on account of usage of drugs & medical devices, and sharing the evidence-based scientific inputs with the Central Drugs Standard Control Organization for further regulatory interventions in order to improve the patient safety.

3. So far, PvPI has been able to enroll 567 Adverse Drug Reaction Monitoring Centers (AMCs) and MvPI has enrolled 174 Medical Device Adverse Event Monitoring Centers (MDMCs) across the Country. These Centers are functional health facilities.

4. In order to expand both these programmes and scale-up the reporting of Adverse Events with the usage of drugs/medical devices, there is a need to have more and more institutions enrolled as AMCs & MDMCs in each and every district of States/Union Territories in India under PvPI and MvPI.

5. Recently Additional Secretary, Government of Kerala has taken an initiative to issue an order on March 10, 2022 to State Mission Director, National Health Mission, Director of Medical Education (DME), Director of Health Services (DHS), Thiruvananthapuram respectively for grant of permission to DME and DHS institutions for enrolling in to MvPI through the institutional arrangements of National Health Mission Kerala (copy enclosed).

6. The following are the key benefits of enrolling under MvPI:-

(i) Monitoring the safety of medical products through PvPI and MvPI is an ethical and professional duty of healthcare providers and hospitals;

contd. 2/-

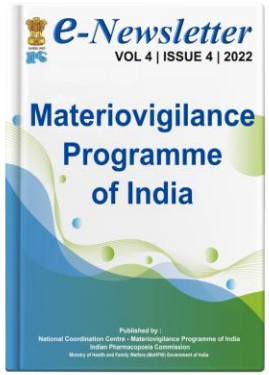
Room No. 156, A-Wing, Nirman Bhawan, New Delhi-110 011
Tele : (O) 011-23061863, 23063221, Fax : 011-23061252, E-mail : secyhfw@nic.in

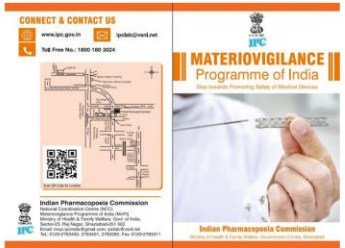
- Secretary, Ministry of Health & Family Welfare, Government of India has issued a letter dated **October 14, 2022** to State Secretaries regarding the enrollment of district level hospitals under Materiovigilance programme of India.

Subsequent to Health Secretary Letter, following states government has issued the G.O. to medical superintendents and head of the hospitals to enroll and report medical device adverse events to MvPI.

State	Government Order No.	Issued Date	Impact
Kerala	No.533/2022/H&FWD	March 10, 2022	NCC-MvPI has received **43** enrolment form from hospitals
Puducherry	No.843/DMS/PA/2022	December 19, 2022	NCC-MvPI has received **01** enrolment form from hospitals
Tamil Nadu	No.21189/M-1/2022-2	November 16, 2022	NCC-MvPI has received **15** enrolment form from hospitals
Karnataka	ME/Tender/39/2022-23	January 31, 2023	NCC-MvPI has received **07** enrolment form from hospitals

Educational & Communication Materials





Information sharing

Research Article Type	Quantity
Knowledge, Attitude & Practice Based Study	1
Review Article	5
Research Article	1
Policy & Practices	1
Guest Editorial	1
Book Chapters	2
Total	**11**

Policy & practice

How to improve regulatory practices for refurbished medical devices

Shatrunajay Shukla,[a] Vivekanandan Kalaiselvan[a] & Rajeev Singh Raghuvanshi[a]

Abstract Modern health-care facilities rely on medical devices and equipment. However, keeping up with the development of new technology is unfeasible for many health facilities, especially in low-resource settings. Thus, the demand for refurbished medical devices is increasing worldwide, especially in low- and middle-income countries. Refurbished medical devices are restored devices that are rebuilt to meet safety and performance requirements comparable to their condition when new, without changing the intended use of the original device. While new medical devices are controlled by well-established and stringent safety and quality regulations, a great variation in the regulations of refurbished medical devices exists across countries. Here we discuss the different regulations and practices specific to refurbished medical devices in countries of major markets. We also explore the opportunities and challenges for expanding the refurbished medical device market. Finally, we suggest that regulatory guidelines pertaining to the import, sale, labelling and use of a refurbished medical product are needed, and authorities should implement these guidelines to ensure a high quality and safety standard of refurbished devices.

Abstracts in عربي, 中文, Français, Русский and Español at the end of each article.

Introduction

Medical devices are an indispensable part of health-care systems and are used for prevention, diagnosis, treatment, monitoring, rehabilitation and palliation.[1] Examples of such devices

devices of that same kind, so as to create a medical device that can be used for the purpose originally intended by the product owner of the original medical device, and which may have had the following work carried out on it: (i) stripping into component parts or sub-assemblies; (ii) checking their suitability for reuse;

Indian J Ophthalmol. 2020 Nov; 68(11): 2343–2345. PMCID: PMC7774212
doi: 10.4103/ijo.IJO_298_20 PMID: 33120612

Intraocular devices associated adverse events reporting system in India

Vivekanandan Kalaiselvan and Rohit Saxena[1]

Author information · Copyright and License information PMC Disclaimer

Lessons from the field

Implementation of adverse event reporting for medical devices, India

Shatrunajay Shukla,[a] Madhur Gupta,[b] Sabitri Pandit,[a] Milu Thomson,[a] Abhimanyu Shivhare,[a] Vivekanandan Kalaiselvan[a] & Gyanendra Nath Singh[c]

Problem Rapid growth in the use of medical devices has drawn attention to gaps in the systematic monitoring of medical device-associated adverse events in India.

Approach Implementation of national regulations on medical devices started in January 2018. Supported by a nationwide network of monitoring centres, the Indian Pharmacopoeia Commission coordinates adverse event reports from manufacturers, legal representatives and patients or users. The commission follows-up and reviews reports with subject expert groups and sends recommendations on necessary action to the national regulatory authority.

Local setting Before 2015, no systematic structure was in place to collate adverse events associated with medical devices. Several reports of deaths and hospitalization due to faulty hip implants, cardiac stents and poor-quality devices prompted the health ministry to launch the materiovigilance programme.

Relevant changes From July 2015 to October 2019, the commission received 1931 adverse event reports, mostly from marketing authorization holders; 1277 were serious events. Reporting increased markedly after 2017. Cardiac stents were the most reported device (926 events; 47.95%). To encourage a culture of reporting, the commission has raised awareness about the programme among stakeholders, developed user-friendly reporting tools and guidelines, and conducted training for hospital personnel on medical device adverse event reporting.

Lessons learnt Regular training to stakeholders develops a sense of responsibility towards reporting medical device adverse events and ensures quality data reporting. Reporters must be assured that reporting adverse events does not have any legal implications for them and given acknowledgement of their role in high-quality device associated adverse event reporting.

Abstracts in عربي, 中文, Français, Русский and Español at the end of each article.

Indian Heart Journal 72 (2020) 316–318

Contents lists available at ScienceDirect

Indian Heart Journal

journal homepage: www.elsevier.com/locate/ihj

Opinion Paper

Materiovigilance Programme of India: A scheme to assure cardiovascular devices safety surveillance

V. Kalaiselvan [a, *], Santanu Kumar Tripathi [b], Jai Prakash [a]

[a] Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Government of India, Sector 23, Raj Nagar, Ghaziabad, UP, 201002, India
[b] Department of Clinical and Experimental Pharmacology, School of Tropical Medicine, Kolkata, 700073, India

Graefe's Archive for Clinical and Experimental Ophthalmology (2022) 260:2103–2110
https://doi.org/10.1007/s00417-022-05578-w

REVIEW ARTICLE

Acute intraocular toxicity caused by perfluorocarbon liquids: safety control systems of medical devices

Girish K. Srivastava[1,2] · Vivekanandan Kalaiselvan[3] · Cristina Andrés-Iglesias[1] · Shatrunajay Shukla[3] · Rohit Saxena[4] · Jose Carlos Pastor[1,2,5]

Received: 8 November 2021 / Revised: 20 January 2022 / Accepted: 24 January 2022 / Published online: 5 February 2022
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Brief Research Article

Health-care Professionals' Perception toward Medical Device Postmarket Surveillance Practices: A Cross-sectional Study in India

Shatrunajay Shukla[1], Bikash Ranjan Meher[2], Archana Mishra[3], Shubhang Arora[3], Vivekanandan Kalaiselvan[3], Rajeev Singh Raghuvanshi[3]

[1]Assistant Scientist, [2]Senior Principal Scientific Officer, [3]Secretory-Cum-Scientific Director, Department of Materiovigilance Programme of India (MvPI), Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, [3]Executive Director, Department of Hospital Administration and Management, Yashoda Super Speciality Hospital, Ghaziabad, Uttar Pradesh, [3]Assistant Professor, Department of Pharmacology, All India Institute of Medical Sciences, Bhubaneswar, Odisha, India

Summary

A cross-sectional, web-based survey was conducted to assess the health-care professionals (HCPs)' perception toward existing medical device postmarket surveillance (PMS) practices in India. A total of 1756 responses (medical practitioners [19.8%], nurses [22.5%], pharmacists [21.4%], and biomedical engineers [13.8%]) were recorded and analyzed. About 71.2% of participants were aware about the ongoing PMS program, 87.5% were aware that medical devices are under regulation in India, and 83.3% were aware about who can report medical device adverse event (MDAE). About 56.3% of participants agreed that they take regular feedback from patients after using high-risk medical device. Majority of participants (69.4%) were aware about tools for reporting MDAE and the online reporting form is the most preferable tool among users. About 76.2% of participants were agreeing that reporting of MDAE is their professional/ethical responsibility. This study reveals that Indian HCPs show a good understanding of PMS practices and a positive perception toward MDAE reporting. However, underreporting still remains a challenge in India.

Key words: Adverse events, Materiovigilance Program of India, medical device, postmarket surveillance

Review › Indian J Pharmacol. 2022 May-Jun;54(3):221-225. doi: 10.4103/ijp.ijp_837_21.

Materiovigilance Programme of India: Current status and way forward

P K Saifuddin [1], Moksh Tandon [1], Vivekanandan Kalaiselvan [2], Benjamin Suroy [1], Vidya Pattanshetti [3], Ajay Prakash [1], Bikash Medhi [1]

Affiliations + expand

PMID: 35848694 PMCID: PMC9396683 DOI: 10.4103/ijp.ijp_837_21

Abstract

› Indian J Pharmacol. 2023 May-Jun;55(3):162-166. doi: 10.4103/ijp.ijp_818_22.

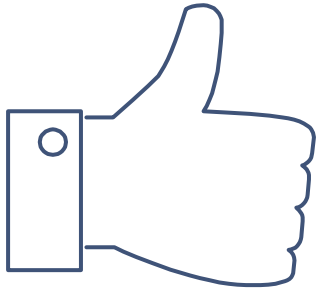
A cross sectional analysis of medical device associated adverse events with radiotherapy devices – A materiovigilance study

M V Raghav [1], A Geetha [1], V S Purushotham [1], K Mamatha [1], J Rajesh [2], Rajeev Raghuvanshi [3], Vivekananda Kalaiselvan [3], Shatrunjay Shukla [3], V Hariharan [3], B Naveen Gowda [1]

Affiliations + expand

CREDITS

Team IPC - MvPI



THANKS!

Any questions?

You can find me at
mvpi-ipc@gov.in