e-Newsletter

VOL 7 | ISSUE 3 | 2025

Materiovigilance Programme of India

Published by :
National Coordination Centre - Materiovigilance Programme of India
Indian Pharmacopoeia Commission
Ministry of Health and Family Welfare (MoHFW), Government of India

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NCC-MvPI team conducted Induction-cum-training program for the newly enrolled MvPI internship batch

The National Coordination Centre (NCC-MvPI) organized an Induction-cum-Training Programme on 2nd July 2025 for the newly enrolled MvPI internship batch (July–September 2025). Conducted virtually from IPC, the training aimed to orient interns towards the fundamentals of materiovigilance and the importance of reporting mechanisms for medical device safety. With 43 participants in attendance, the training enhanced their knowledge, analytical skills, and preparedness for active involvement in MvPI activities, thereby strengthening the national framework for medical device safety surveillance.

NCC-MvPI team conducted 14th Induction-cum-training programme for the newly enrolled 94 MDMCs and also for the 46 MDMCs that were derecognised due to non-functionality

The National Coordination Centre–Materiovigilance Programme of India (NCC-MvPI) organized the 14th Induction-cum-Training Programme on 15th July 2025 for 94 newly enrolled MDMCs and to revitalize 46 previously derecognised MDMCs. The training focused on building capacity to identify, analyze, and report medical device adverse events (MDAEs), with sessions on reporting systems, causality assessment, and the use of ADRMS. A total of 290 participants attended, marking an important step in strengthening MvPI's national network and reinforcing the commitment to patient safety.

NCC-MvPI participated in training session conducted by Apollo South Region Hospital

The NCC-MvPI actively participated in a training session conducted by Apollo South Region Hospital on 16th July 2025, held virtually. During the programme, Mr. Naveen V, Scientific Assistant, IPC, delivered an insightful presentation on the “Overview of Materiovigilance Programme of India, Reporting Modalities, and Reportable & Non-Reportable Adverse Events.” His session provided participants with a deeper understanding of the reporting framework and the distinction between reportable and non-reportable events.

NCC-MvPI conducted a materiovigilance training programme with JCCII

The NCC-MvPI successfully conducted a Materiovigilance Training Programme in collaboration with JCCII on 30th July 2025, aimed at enhancing the awareness and reporting capacity of JMDAI members. The programme brought together 34 participants, providing them with a structured learning platform to understand the fundamentals and practical aspects of materiovigilance. The first session was delivered by Dr. Shatrunjay Shukla, Scientific Assistant at MvPI, on the theme "Overview of the Materiovigilance Programme of India: Concept & Terminologies." The second session was led by Dr. Josmy Maria Job, Junior Materiovigilance Associate, focusing on "Available Modalities for Reporting Medical Device Adverse Events: ADRMS."

NCC-MvPI conducted a training programme virtually at Jagannath Gupta Institute of Medical Sciences and Hospitals, West Bengal.

The NCC-MvPI organized a virtual training programme on 6th August 2025 at Jagannath Gupta Institute of Medical Sciences and Hospitals, West Bengal to enhance awareness on materiovigilance. The session was conducted by Dr. Shatrunajay Shukla, Scientific Assistant, IPC, who presented on the "Overview of Materiovigilance Programme of India" and detailed the modalities for reporting Medical Device Adverse Events (MDAEs). A total of 48 participants attended the training, which improved their understanding and readiness to contribute to the national materiovigilance system.

NCC-MvPI participated in Materiovigilance Awareness Programme at Sawai Man Singh Medical College (SMS), Jaipur, Rajasthan

The NCC-MvPI participated in the Materiovigilance Awareness Programme at Sawai Man Singh Medical College (SMS), Jaipur) on 12th August 2025 to strengthen awareness on medical device safety. Mr. Naveen V, Scientific Assistant, IPC, delivered a session on Causality Assessment, stressing the importance of accurate and timely reporting of medical device adverse events (MDAEs). Mr. Somesh Shukla, Junior Materiovigilance Associate, contributed as a resource person, addressing concerns on ADRMS. With over 450 participants including doctors, nurses, pharmacists, and biomedical engineers, the event significantly promoted the culture of materiovigilance.

NCC-MvPI participated in National Workshop on Equipment Maintenance, Calibration & Testing at National Health Systems Resource Centre (NHSRC), New Delhi.

The NCC-MvPI participated in the National Workshop on Equipment Maintenance, Calibration & Testing held on 25th August 2025 at the National Health Systems Resource Centre (NHSRC), New Delhi. Representing IPC, Dr. Shatrunajay Shukla, Scientific Assistant, attended the workshop, which focused on strengthening biomedical equipment management, standardizing calibration practices, and ensuring regulatory compliance across states. The discussions emphasized the importance of structured systems for reporting KPIs, recalls, and adverse events, highlighting IPC's role in promoting safety and quality.

NCC-MvPI, IPC Organized National Stakeholders' Conclave on Materiovigilance and In-Vitro Diagnostics Safety: Strengthening Reporting Frameworks and Collaborative Ecosystems

The National Stakeholders' Conclave on Materiovigilance and In-Vitro Diagnostics Safety was held on 3rd September 2025 at the Indian Pharmacopoeia Commission (IPC), Ghaziabad. The event began with the launch of the new In-Vitro Diagnostic (IVD) Reporting Form (Annexure 1) to streamline incident reporting. The inaugural session featured addresses by Dr. V. Kalaiselvan (IPC), Dr. Madhur Gupta (WHO India), Dr. Bikas Medhi (PGIMER), Dr. Taruna Madan (ICMR), Dr. Sanjay Behari (SCTIMST), Dr. Neelima Mishra (NIB), and Dr. Rajendra Panduranga Joshi (DGHS). The session concluded with a Vote of Thanks by Dr. Shashi Bhushan (IPC).

Technical sessions focused on patient safety, ADRMS in materiovigilance, and training on the new IVD form. Industry perspectives were shared by Dr. Madhur Gupta (WHO India) and Dr. Shatrunajay Shukla (IPC), who highlighted challenges of underreporting and the importance of structured reporting. Representatives from the IVD industry also contributed by addressing practical challenges and opportunities in strengthening vigilance.

Panel discussions enriched the conclave further. The first panel on draft hospital guidance included Dr. Madhur Gupta (WHO India), Dr. Sanjay Behari (SCTIMST), Dr. Syed Ziaur Rahman (JMC-AMU), Dr. Nalini G.K (SABVMCRI, Bengaluru), and Dr. Manisha Sharma (NHSRC). The final panel on building a coordinated materiovigilance ecosystem featured Dr. Bikas Medhi (PGIMER), Mrs. Amrutha C. (SCTIMST), Mr. Sudhakar Mairpady (Becton Dickinson India Pvt. Ltd.), and Mr. Prashanth Prabhakar (MTal).

In conclusion, the conclave fostered multi-stakeholder collaboration to strengthen reporting, improve regulatory frameworks, and ensure quality medical devices and diagnostics, thereby advancing patient safety nationwide.

CME on Device Safety and Reporting during 5th National Pharmacovigilance Week

Government Medical College, Ariyalur, in collaboration with the Indian Pharmacopoeia Commission (IPC), organized a CME on 19th September 2025 to mark the 5th National Pharmacovigilance Week. Mr. Naveen V, IPC Official, delivered an engaging session on "*Device Safety and Reporting*." He highlighted the importance of vigilance, timely reporting, and robust monitoring systems to safeguard patient safety. The programme enriched participants' knowledge of medical device safety and reinforced the vital role of healthcare professionals in pharmacovigilance.

Shri Ramachandra Medical College Hosts Certificate Course on Pharmacovigilance & Materiovigilance

Shri Ramachandra Medical College and Research Institute successfully conducted a two-month online certificate course in Pharmacovigilance and Materiovigilance. On 20th September 2025, Mr. Naveen V, IPC Official, spoke on "Introduction to ADRMS and Reporting Modalities under the Materiovigilance Programme of India," highlighting practical approaches to device safety reporting and strengthening vigilance practices in healthcare.

NIMHANS Conducted Awareness and Strengthening of the Materiovigilance System within the Institution

The Materiovigilance Sensitization Programme held on 4th July 2025 at NIMHANS, Bangalore, focused on awareness and strengthening of the materiovigilance system within the institution. Conducted at Ashwini Hall, the session targeted Assistant Nursing Superintendents (ANS) and Deputy Nursing Superintendents (DNS), with a total of 66 participants. The programme emphasized the need and importance of materiovigilance for patient safety, and the critical role of nurses in reporting Medical Device Adverse Events (MDAEs).

Postgraduate Institute of Medical Education and Research (PGIMER) conducted a one-day awareness programme on materiovigilance at Amrita Hospital, Kochi, Kerala.

The Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh, organized a one-day Materiovigilance Awareness Programme on 7th July 2025 at Amrita Hospital, Kochi, Kerala. The programme was led by Prof. Bikash Medhi, Coordinator of the North Zone Regional Training Centre, PGIMER, who delivered an insightful lecture on the current updates and progress of the Materiovigilance Programme of India (MvPI). A total of 25 participants, including faculty members and students from various departments of Amrita Hospital, attended the session. The programme successfully enhanced awareness, and reinforced the shared responsibility of healthcare providers in promoting medical device safety.

S.M.S Medical College & Hospital conducted Materiovigilance awareness session

S.M.S. Medical College & Hospital, Jaipur organized a materiovigilance awareness and sensitization programme on 8th July 2025 to strengthen understanding of medical device safety. The session was led by Dr. Monica Jain, MDMC Coordinator, Senior Professor, and Additional Principal, who highlighted the importance of adverse event reporting. The event saw participation from over 300 attendees, including paramedical, nursing, and dental students, fostering a strong culture of vigilance and patient safety awareness.

NIMHANS Conducted Sensitizing nurses regarding reporting of adverse events related to medical devices at the institute

The NIMHANS, Bengaluru, conducted a sensitization session on 20th August 2025 at the Nursing Station, OPD Block, focusing on reporting adverse events related to medical devices. The programme aimed to strengthen patient safety and ensure regulatory compliance by educating nurses about the significance of timely and accurate reporting. Ms. Nandini P, Senior Materiovigilance Associate, delivered the session, covering the definition and classification of adverse events, reporting procedures, and the vital role of nurses as frontline observers in identifying device-related complications.

Sensitization Programs on Adverse Event Reporting under MvPI & PvPI at AIIMS Rishikesh

AIIMS Rishikesh organized a series of sensitization programs on adverse event reporting under MvPI & PvPI during August–September 2025. The sessions were conducted by Ms. Mansi Sharma, Junior Materiovigilance Associate, and Mr. Manan Verma, Materiovigilance Intern. On 21st August (Urology IPD) and 26th August (Geriatric Medicine IPD), nursing officers and senior nursing staff were sensitized, while on 2nd September (Pharmacology Department), faculty members and residents participated. The programs focused on reportable adverse events, mandatory reporting fields, addressing gaps, and feedback mechanisms. Notably, 16 adverse event cases were reported immediately and submitted to ADRMS.

National Conference on Advances and Emerging Trends in Oncology Pharmacy Practice and Pharmacovigilance (AETOPP) 2025 Highlights Patient Safety

The Mahamana Pandit Madan Mohan Malaviya Cancer Centre and Homi Bhabha Cancer Hospital, Varanasi, organized the National Conference on Advances and Emerging Trends in Oncology Pharmacy Practice and Pharmacovigilance (AETOPP) 2025 on 14th September 2025. A special session was delivered by Mr. Naveen V, Official, Indian Pharmacopoeia Commission (IPC), on "Ensuring Patient Safety – The Role of the IPC." His talk emphasized strengthening patient safety frameworks and reporting systems in oncology care.

Strengthening Patient Safety through Pharmacovigilance & Materiovigilance at Sri Aurobindo Medical College”

Sri Aurobindo Medical College and PG Institute, Indore, celebrated the 5th National Pharmacovigilance Week (NPW-2025) from 17th to 23rd September 2025 on the theme “*Your safety, just a click away: report to PvPI & MvPI.*” The event aimed to raise awareness on patient safety by highlighting both adverse drug reaction (ADR) reporting and medical device-related adverse events (MDAEs). The celebration featured an inauguration ceremony led by institutional leaders, awareness campaigns through posters, banners, and rangoli, and engaging student activities including street plays, poster competitions, and expert talks

GMC Chamba Strengthens PvPI & MvPI Awareness through Community Outreach

From 19th–24th September 2025, GMC Chamba, in collaboration with IPC-MvPI, organized a series of community outreach programmes. On 19th September, awareness drives at PHCs Chaned and Masroond engaged 70 villagers, ASHAs, and health officers, with ADR registers initiated. On 22nd September, Shakuntala Nursing College students performed a Nukkad Natak at Sarol Anganwadi to spread safety messages creatively. On 23rd September, a hybrid session at CHC Sahoo introduced an ADR register and follow-up system. Finally, on 24th September, at Shakti Dera Temple, focus was given to drug/devices safety and HIV medicines, with community pledges for active reporting.

MGIMS Sevagram Observes 5th National Pharmacovigilance Week with Emphasis on Materiovigilance

The NPW 2025 at MGIMS began on 17th Sept, 2025 with MBBS sensitization sessions led by Dr. Devesh Gosavi and a guest lecture by Prof. Snehalata Gajbhiye. On 18th Sept, 2025 nursing students were trained on drug safety and adaptive study designs. 19th Sept 2025 highlighted materiovigilance with practical device-related examples. On 20th Sept, 2025 pharmacy experts emphasized the pharmacist's role in reporting. 21st Sept, 2025 saw creative competitions and awareness drives. On 22nd Sept, 2025 nursing students engaged in posters, quizzes, and interactive sessions. The programme concluded on 23rd Sept, 2025 with a valedictory ceremony, awards distribution, and reflections on strengthening PvPI and MvPI.

CME on Materiovigilance: Strengthening Healthcare Professionals' Awareness at AIIMS Bhopal

AIIMS Bhopal successfully hosted a CME on Materiovigilance: Essential Insights for Healthcare Professionals on 25th September 2025 at Lecture Theatre 5, Kautilya Bhawan. Organized by the Regional Training Centre for Materiovigilance, the event featured expert talks on the Materiovigilance Programme of India, safety surveillance of medical devices, case-based discussions, and hands-on training in MDAE reporting. Interactive sessions, a quiz, and recognition of top reporting departments highlighted the program, fostering awareness and active participation among healthcare professionals

NCC Celebrates 5th National Pharmacovigilance Week at Bharat Mandapam

The National Coordination Centre (NCC), Indian Pharmacopoeia Commission, organized the Inaugural Ceremony of the 5th National Pharmacovigilance Week (NPW) on 17th September 2025 at Bharat Mandapam, New Delhi, with the theme "Your safety, just a click away: Report to PvPI." The event began with a lamp-lighting ceremony, followed by a welcome address by Dr. V. Kalaiselvan. Distinguished dignitaries including Prof. Y.K. Gupta, Dr. Nilima Kshirsagar, and Dr. Rajeev Singh Raghuvanshi addressed the gathering.

Highlights included the launch of new digital tools of PvPI (short film, comic series in vernacular languages, and an online reporting platform with QR code access), distribution of Pharmacovigilance Awards, and scientific sessions by national and international experts.

Additionally, the Adverse Drug Reaction Monitoring Centre (AMC) at Mahamana Pandit Madan Mohan Malviya Cancer Centre was honored with the PvPI – Patient Safety Excellence Award for its exemplary ADR reporting and consistent awareness campaigns, setting a benchmark for institutional responsibility in patient safety.

PvPI Patient Connect Award: Honoring Vigilance in Action

A special highlight of the National Pharmacovigilance Week 2025 celebrations was the recognition of individuals and institutions who have demonstrated exemplary commitment to patient safety through active participation in pharmacovigilance.

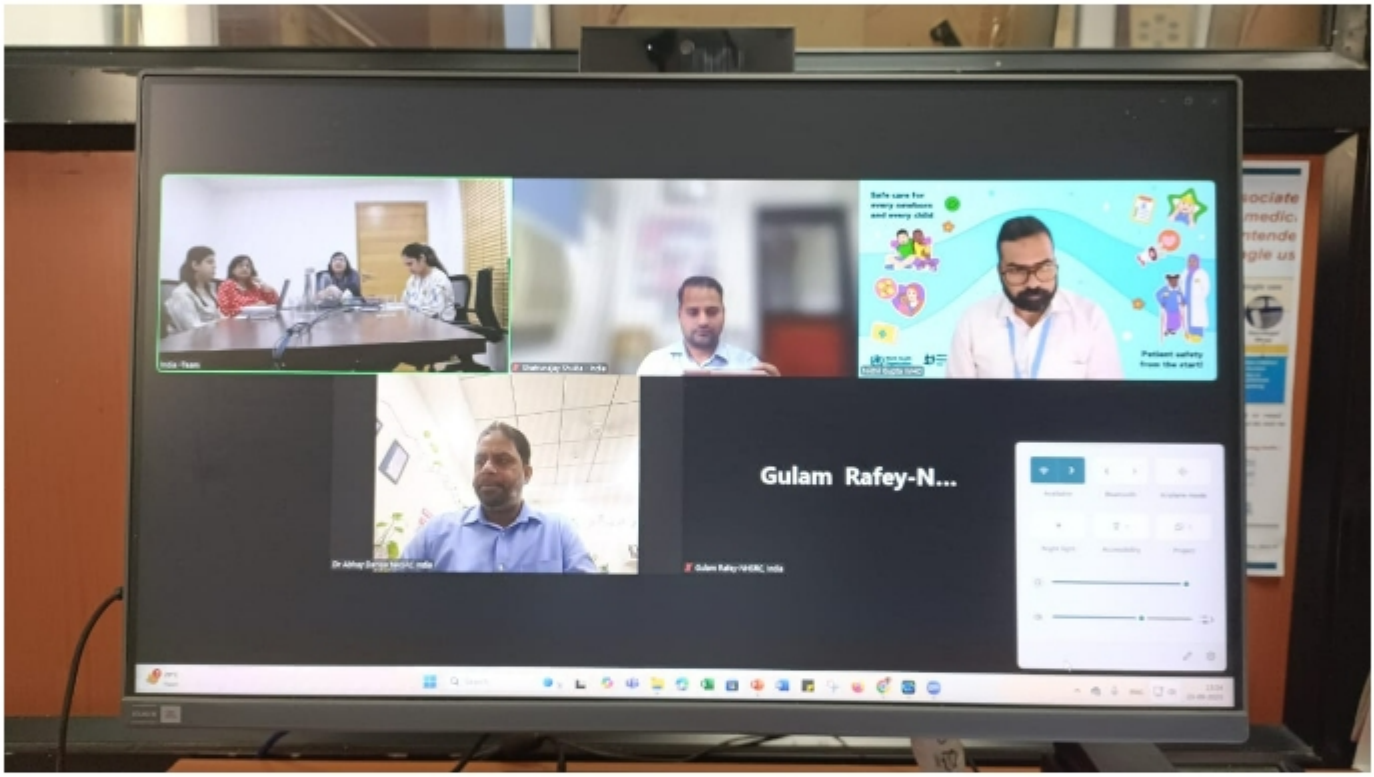
Mr. T. Delli Kumar was conferred the prestigious PvPI – Patient Connect Award for reporting ADRs for his outstanding vigilance in reporting an adverse device-related event. His mother, Mrs. T. Munemma, underwent surgery with a titanium implant, which unfortunately fractured within a few months. Despite the financial and emotional challenges faced by his family during the COVID-19 pandemic, Mr. Kumar ensured that the case did not go unnoticed. He meticulously reported the incident to the Indian Pharmacopoeia Commission – Materiovigilance Programme of India (IPC-MvPI), thereby bringing critical attention to medical device safety and consumer involvement in pharmacovigilance.

This recognition not only honors Mr. Kumar's proactive role but also highlights the importance of patient and consumer participation in improving healthcare outcomes. His contribution serves as a reminder that vigilance at the grassroots level is key to strengthening India's pharmacovigilance ecosystem.

As we mark this year's Pharmacovigilance Week, the PvPI reiterates its call: "Your safety, just a click away – Report to PvPI."

GPSC Webinar Report on Patient Safety Incident Reporting and Learning Systems:

The GPSC webinar focused on Patient Safety Incident Reporting and Learning Systems (PSIRLS) was conducted on 23rd September 2025. Experts from WHO and Imperial College London discussed key guidelines for implementing PSIRLS, with emphasis on country-specific approaches and challenges.



The session included an overview of WHO's resources, followed by a panel on legislation, data analysis, and competency development. Breakout sessions facilitated dialogue among countries like India, Ethiopia, and Sri Lanka, highlighting local experiences and actionable steps to enhance patient safety systems globally.

IPC's Active Participation and Promotional Stall at the 2nd India Med Tech Expo on Medical Devices 2025, New Delhi

The Indian Pharmacopoeia Commission (IPC), Ghaziabad, participated in the 2nd edition of India MedTech Expo on Medical Devices 2025, held from 4th - 6th September 2025 at Bharat Mandapam – Pragati Maidan, New Delhi. IPC set up a promotional stall to showcase its key publications and initiatives, including the Reference Manual for Medical Device, National Formulary of India (NFI), Materiovigilance Programme of India (MvPI), and ICMED 9000/13485 certification schemes. The stall attracted healthcare professionals, biomedical engineers, regulators, and industry representatives, facilitating discussions on patient safety and medical device quality.

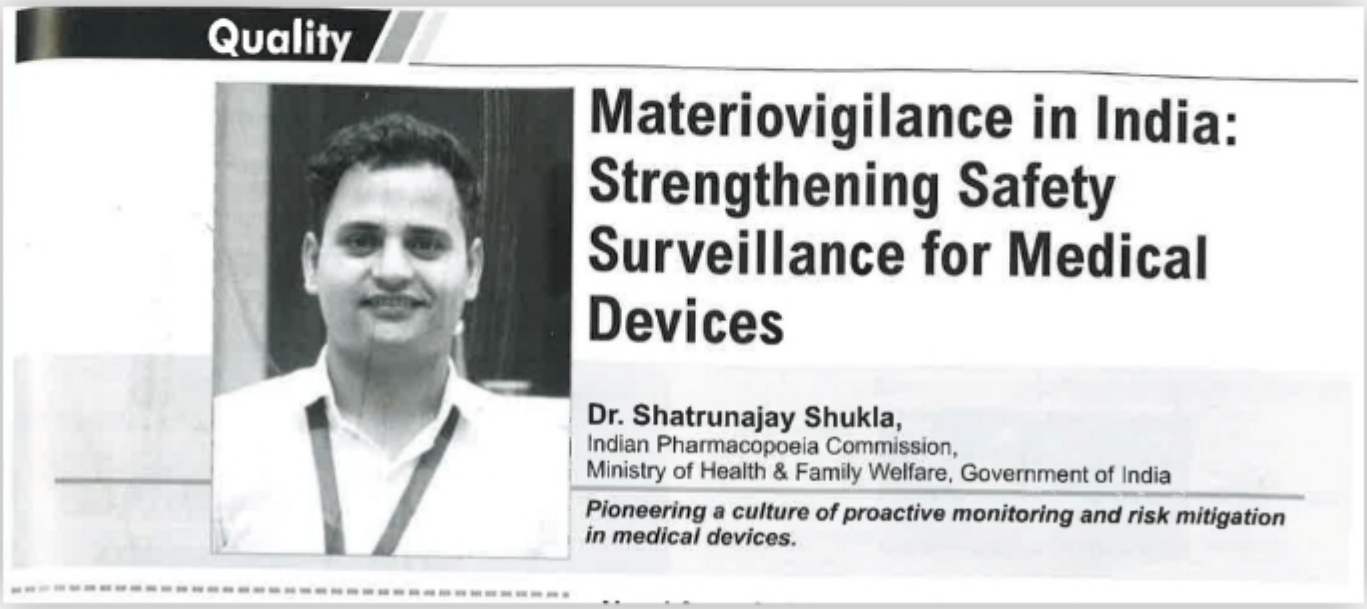
IPC Participation in 43rd Medicall Exhibition: Awareness Training on Pharmacopoeial Standards and Materiovigilance

The IPC delegation, comprising Dr. Sanjay Mendiratta, Shri Muneer Javed Mohammed, Ms. Shweta Wachaspati, and Ms. Urvashi Pal, participated in the 43rd Medicall Exhibition on 19thSeptember, 2025, at Pragati Maidan, New Delhi. An informative stall showcased Indian Pharmacopoeia (IP), IP Reference Substances (IPRS), National Formulary of India (NFI), Materiovigilance Programme of India (MvPI), and ICMED 9000 & 13485 certifications. Brochures were distributed, stakeholders engaged, and awareness on adverse-event reporting and IPC's certification role was enhanced, fostering collaborations and industry relationships.

PUBLICATION

Article on Materiovigilance Published in Medical Plastics Data Service

An article titled "Materiovigilance in India: Strengthening Safety Surveillance for Medical Device", authored by Dr. Shatrunjay Shukla, Scientific Assistant, IPC, was published in the May – June 2025 issue (Vol. 33) of Medical Plastics Data Service, a leading techno-economic magazine for the medical plastics, devices, diagnostics, and pharma industry. The article highlights the evolving landscape of materiovigilance in India and underscores the importance of a robust safety surveillance system for medical devices under the Materiovigilance Programme of India (MvPI).



Quality

Materiovigilance in India: Strengthening Safety Surveillance for Medical Devices

Dr. Shatrunajay Shukla,
Indian Pharmacopoeia Commission,
Ministry of Health & Family Welfare, Government of India

Pioneering a culture of proactive monitoring and risk mitigation in medical devices.

Recommendation to National Regulatory Authority (NRA):

NCC-MvPI sent a recommendation to CDSCO on "Frequent tearing during usage and prior to usage, excessive powder / poor quality" associated with "Latex Examination gloves" for information and necessary actions at their ends.

In March 2016, the United States Food and Drug Administration (US FDA) proposed a ban on most powdered gloves due to the significant health risks they pose to patients, healthcare professionals, and others exposed to them. Echoing these concerns, the NCC-MvPI has also frequently received reports highlighting problems with latex examination gloves. The reported adverse events include skin rashes, itching, contact dermatitis, allergic reactions to latex or powder, and respiratory irritation caused by glove powder. These reports highlight the continued need for vigilance and safer alternatives in healthcare practice.

Timely reporting of such issues helps improve product quality and ensures safer healthcare practices. You can report to us through email at mvpi-ipc@gov.in, via the ADRMS software, or by contacting the MvPI helpline at 1800 180 3024.

We encourage all stakeholders, including healthcare professionals and consumers, to actively report any device-related problems.

Feedback on MvPI

My internship under the National Coordination Centre – Indian Pharmacopoeia Commission (NCC-IPC), Ghaziabad, have gained enriching exposure under the Materiovigilance Programme of India (MvPI). This experience has been highly rewarding, providing me with valuable professional growth and an opportunity to contribute meaningfully to patient safety and public health.

Mohd Atir
NCC-MvPI, IPC

My three-month internship at the Materiovigilance Programme of India (MvPI) was an exceptionally rewarding experience for which I am immensely grateful. The program provided me with a comprehensive understanding of the vital roles and functions of both the Indian Pharmacopoeia Commission (IPC) and MvPI. I truly admire the wonderful work culture here.

Agrim Prakash
NCC-MvPI, IPC

The IPC Materiovigilance (MvPI) training has been very helpful and well-organized, providing me with a clear understanding of why monitoring medical devices is crucial for patient safety. I gained a thorough introduction to the Adverse Drug Reaction Monitoring System (ADRMS), and the hands-on practice sessions made the reporting process easy to follow.

Shivanshu
Jamia Hamdard

The MvPI internship at AIIMS Patna has been an enriching and insightful experience. I especially liked the hands-on exposure to real Medical Device Adverse Event (MDAE) reporting and the opportunity to work closely with healthcare professionals. The mentorship and guidance from faculty members were very supportive and helped me understand the importance of vigilance in patient safety.

Abhishek Kr. Mishra
AIIMS, Patna

Stepping towards patient's safety: ADRMS

Annexure - 1

Version: 1.0

IN-VITRO DIAGNOSTIC MEDICAL DEVICE ADVERSE EVENT REPORTING FORM

Materiovigilance Programme of India (MvPI)

This form is intended to collect information on *In-Vitro Diagnostic* Medical Devices Adverse Event in India. The form is designed to be used by Domestic Manufacturer / Importer / Distributor of *In-Vitro Diagnostic* Medical Devices, Pathology Laboratory, Blood Donation Centre, Government Program In-charge and Healthcare Professionals with direct/indirect knowledge of In Vitro Diagnostic Medical Devices Adverse Event.

Disclaimer

Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the adverse event. Submission of a Medical Devices Adverse Event (MDAE) Report does not have any legal implication on the reporter.

Confidentiality

The patient/reporter's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the patient/reporter's identity in response to a request from the public.

Primary Information

1. Date of Report :
2. Type of Report : Initial ☐ Follow up ☐ Final ☐ Trend ☐
3. Report Reference No. for MDMC[1] only : Centre Location Month – Year Case No.
4. Report Reference No. for MAH[2] only :

[1]MDMC-Medical Device Adverse Event Monitoring Centre, [2]MAH-Market Authorisation Holders

Reporter Details

1. Type of Reporter :
   - Manufacturer ☐
   - Importer ☐
   - Distributor ☐
   - Healthcare Professional ☐
   - Pathology Laboratory ☐
   - Blood Center ☐
   - Government Program In charge ☐
   - Others ☐ Specify_____
2. In case, Where the Reporter is not the Domestic Manufacturer / Importer of the product, Fill the Following Details: -
   a) Has the Reporter Informed the Incident to the Domestic Manufacturer / Importer of the product? Yes ☐ No ☐
   b) If Yes, Event reported to Manufacturer / Importer via, Date of which Manufacturer/ Importer was made aware (DD/MM/YYYY) _____
      i) Email ☐
      ii) Written communication ☐
      iii) Telephonic communication ☐
      iv) Other ☐ Specify_____
   c) Is the Reporter also submitting the report on behalf of the manufacturer? Yes ☐ No ☐
3. Reporter Contact Information :
   a) Name :
   b) Organisation :
   c) Address :
   d) Tel./ Mobile :
   e) Email :

A) *In-vitro Diagnostic* Medical Device Details

Category		Sub-category	
1. Kits	☐	1. Hematology	☐
2. Reagents	☐	2. Biochemistry	☐
3. Calibrators	☐	3. Microbiology	☐
4. Controls	☐	4. Immunology	☐
5. Analyzers	☐	5. Histopathology	☐
6. Specimen Receptacles	☐	6. Molecular Biology	☐
7. Self-testing Kit	☐	7. Gastroenterology & Urology	☐
8. IVD software	☐	8. Gynecological	☐
9. Others	☐ Specify_____	9. Toxicology	☐
		10. Others	☐ Specify_____

Generic *In-Vitro Diagnostic* Medical Device Name:

Trade Name/ Brand Name:

Details	Name	Address
Manufacturer		
Importer		
Distributor		
Marketed by		

1. IVD-MD Risk Classification as per Indian MDR 2017	:	A ☐ B ☐ C ☐ D ☐	
2. License No. (Manufacturer/ Importer)	:		
3. Model No. (If applicable)	:		
4. Catalogue No.	:		
5. Lot/ Batch No.	:		
6. Serial No. (If applicable)	:		
7. Software Version (If applicable)	:		
8. Associated IVDs / Accessories	:		
9. UDI No. (If applicable)	:		
10. Manufacturing Date (If applicable)	:		
11. Expiration Date (If applicable)	:		
12. Last Calibration Date (DD/MM/YYYY) (If applicable)	:		
13. How long the IVD Medical Device was in use	:		
14. Availability of IVD Medical Device for evaluation	:	Yes ☐	No ☐
If no, Status of IVD Medical Device and location (specify)	:	Destroyed ☐	Still in use ☐
		Returned to the Manufacturer/ Importer/ Distributor ☐	
		Other ☐ Specify_____	
15. Is the IVD Medical Device used as per Manufacturer claim/ Instruction for use/ User manual	:	Yes ☐	No ☐

If no, Specify usage_____

B) Event Description

1. **Date of Event (DD/MM/YYYY)** :
2. **Type of Adverse Event:**
   - Malfunction ☐
   - Use error ☐
   - Insufficient or Inadequate labelling or Instructions for use ☐
   - Insufficient Reagent ☐
   - False Positive ☐
   - False Negative ☐
   - Invalid Test ☐
   - Wrong Result ☐
   - Other ☐
     Specify_____
3. **Location of Event:**
   - Hospital ☐ Blood Centre ☐
   - Pathology Lab ☐ Home ☐
   - Other ☐ specify_____
4. **IVD Medical Device Operator:**
   - Healthcare Professional ☐ Problem noticed prior to use ☐
   - Laboratory operator ☐ Patient ☐
   - Others ☐ specify_____
5. **IVD Medical Device in use after incidence:** Yes ☐ No ☐
6. **Serious Event:** Yes ☐ If yes, tick the appropriate reason
   - a) Death (DD/MM/YYYY) _____ ☐
   - b) Life Threatening ☐
   - c) Disability or Permanent Damage ☐
   - d) Hospitalization/ Prolongation of Existing Hospitalization ☐
   - e) Congenital Anomaly ☐
   - f) Required Medical Intervention ☐
   - g) Other (Important Medical Event) ☐
     Specify_____
7. **Non-serious Event** ☐
8. **Whether other *in-vitro diagnostic* medical devices were used at same time with the above device:** Yes ☐ No ☐
   If yes, specify the name(s)/ use(s)
9. **Event outcome and reoccurrence information**
   - a) Event abated after use is stopped/ reduced?
     Yes ☐ No ☐ NA ☐
   - b) Event reappeared during retesting/ reuse?
     Yes ☐ No ☐ NA ☐
10. **Detail Description of Event:**

Note: Do you have any relevant diagnostics test/laboratory data/pictures/videos related to the events Yes ☐ No ☐
If yes then kindly provide them while submitting the filled application form.

For Manufacturer/Authorized Representative Use Only

11. Frequency of Occurrence of Similar Adverse Event in India in Past 3 Years	Year	No. of Similar Adverse Events	Total No. Supplied	Frequency of Occurrence (%)
12. Frequency of Occurrence of Similar Adverse Event Globally in Past 3 Years	Year	No. of Similar Adverse Events	Total No. Supplied	Frequency of Occurrence (%)

C) Patient Information, History and Outcome

1. Patient Hospital ID :
2. Patient Initial :
3. Age :
4. Gender : Male☐ Female☐ Transgender☐
5. Weight :
6. Other relevant history :
   (including pre-existing conditions, treatment, allergy)

7. Patient outcomes
   a) Death (DD/MM/YYYY) ☐ _____
   b) Recovered (DD/MM/YYYY) ☐ _____
   c) Not yet recovered ☐
   d) Stable ☐
   e) Other ☐
   Specify_____

D) Healthcare Facility Information (If available)

1. Name :
2. Address :
3. Contact Person Name at the Site of Event :
4. Tel. No. /Mobile No. :
5. Email :

E) IVD Medical Device Adverse Event Assessment / False Positive / False Negative / Invalid Test / Wrong Result

1. Immediate Action Taken: Date of Action Taken:

2. Suspected Root Cause of Problem:

3. In Your Opinion, Which of the Following Best Describe the Association between Suspected In vitro diagnostic Medical Device(s) and Adverse Event?
   a) Not related ☐ b) Possible ☐ c) Probable ☐ d) Related ☐

F) For Manufacturer/Authorized Representative / Pathology Laboratory, Blood Donation Center, Government Program In charge, Healthcare Professionals and License Holder Only

1. Investigation Needed? Yes☐ No☐
2. Investigation Action Taken with Timeline:
3. Root Cause of Problem (Applicable for follow up/ final reports):

4. Corrective and Preventive action (CAPA) taken: Date of CAPA implemented on:

5. Field Safety Notice/ Field Safety Corrective Action Initiated: Yes☐ No☐
   If Yes, date of Field Safety Notice issued/ Expected date of completion of Field Safety Corrective Action (DD/MM/YYYY):

Where to report?

Duly filled Medical Device Adverse Event Reporting Form can be send to Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Sector-23, Rajnagar, Ghaziabad-20002, Tel-0120-2783400, 2783401 and 2783392, or email to mvpi-ipc@gov.in , shatrunjay.ipc@gov.in or Call on Helpline no. 1800 180 3024 to report Adverse event.

Partnering Organizations

List of Document to be attached

	Healthcare professionals	Domestic Manufacturer	Importer	Government Program	Blood Centre	Pathology Laboratory
Product/ premises license copy	-	✓	✓	✓	✓	-
Copy of Invoice	-	-	✓	✓	✓	✓
Copy of purchase bill	-	-	-	✓	✓	✓
IFU/ Operator Manual/ Product Brochure/ Product labels	✓	✓	✓	✓	✓	✓
Video/ Photograph of used/ tested kit	✓	✓	✓	✓	✓	✓

Feedback: kind provide your feedback in respect to the usage of this form and regarding Materiovigilance Programme of India

(Your valuable feedback will help us progress effectively)

Dr. Deepak Maheshwari
MBBS, MD (Med.) D.M. (Cardiology)
Principal & Controller & Senior Professor,
Department of Cardiology
SMS Medical College & Attached Group of Hospitals, JLN Marg, Jaipur-302004

Materiovigilance represents a vital and rapidly expanding dimension of healthcare safety, ensuring that medical devices are continuously monitored for their performance and safety profiles. It is encouraging to see that the Materiovigilance Programme of India (MvPI) team members at IPC Ghaziabad has been actively working to create awareness and strengthen reporting systems across the country, with the ultimate aim of improving patient outcomes.

At our institution, S.M.S. Medical College and Hospital, Jaipur, we firmly believe in nurturing a culture of responsibility and vigilance among our students and faculty. This initiative provides an excellent opportunity for healthcare professionals, academicians, and budding researchers to actively participate in reporting and analyzing device-related concerns. Such collective efforts not only safeguard patients but also contribute to building a robust healthcare ecosystem in India.

I deeply appreciate the editorial team for creating a newsletter that not only informs but also inspires action. I am hopeful that the insights shared will motivate healthcare professionals and students to actively engage in strengthening this vital initiative.

It is indeed a privilege to extend my wholehearted support to IPC and its ongoing efforts in advancing Materiovigilance, and I look forward to witnessing its continued growth and impact in the years ahead.

MvPI Network Pan India

Under the Materiovigilance Programme of India (MvPI), **596** Medical Device Adverse Event Monitoring Centres (MDMCs) have been enrolled, comprising both government and non-government hospitals. The participation of both government and non-government hospitals in MvPI highlights the collaborative effort to uphold medical device safety standards nationwide. These centres play a crucial role in ensuring the safety and efficacy of medical devices used in healthcare settings. By enrolling MDMCs across a wide spectrum of healthcare providers, MvPI aims to comprehensively monitor the performance of medical devices, facilitate early detection of adverse events, and ensure prompt reporting and appropriate action to enhance patient safety and healthcare quality.

Scan QR code to check out the List of MDMCs

www.ipc.gov.in

NCC-PvPI IPC

@IPC NCC-PvPI

mvpi-ipc@gov.in, shatrunjay.ipc@gov.in

Helpline

1800 180 3024

Indian Pharmacopoeia Commission
Ministry of Health & Family Welfare
Government of India
Sector-23, Raj Nagar, Ghaziabad - 201002
Tel. : 0120-2783400, 2783401, 2783392
Fax : 0120-2783311

For any other Information/Suggestion Query Contact:

Materiovigilance Programme of India
Email : lab.ipc@gov.in, mvpi-ipc@gov.in
Website : www.ipc.gov.in

We have started a journey of Materiovigilance, for saving patient's lives