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IPC

# e-Newsletter

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# Materiovigilance Programme of India

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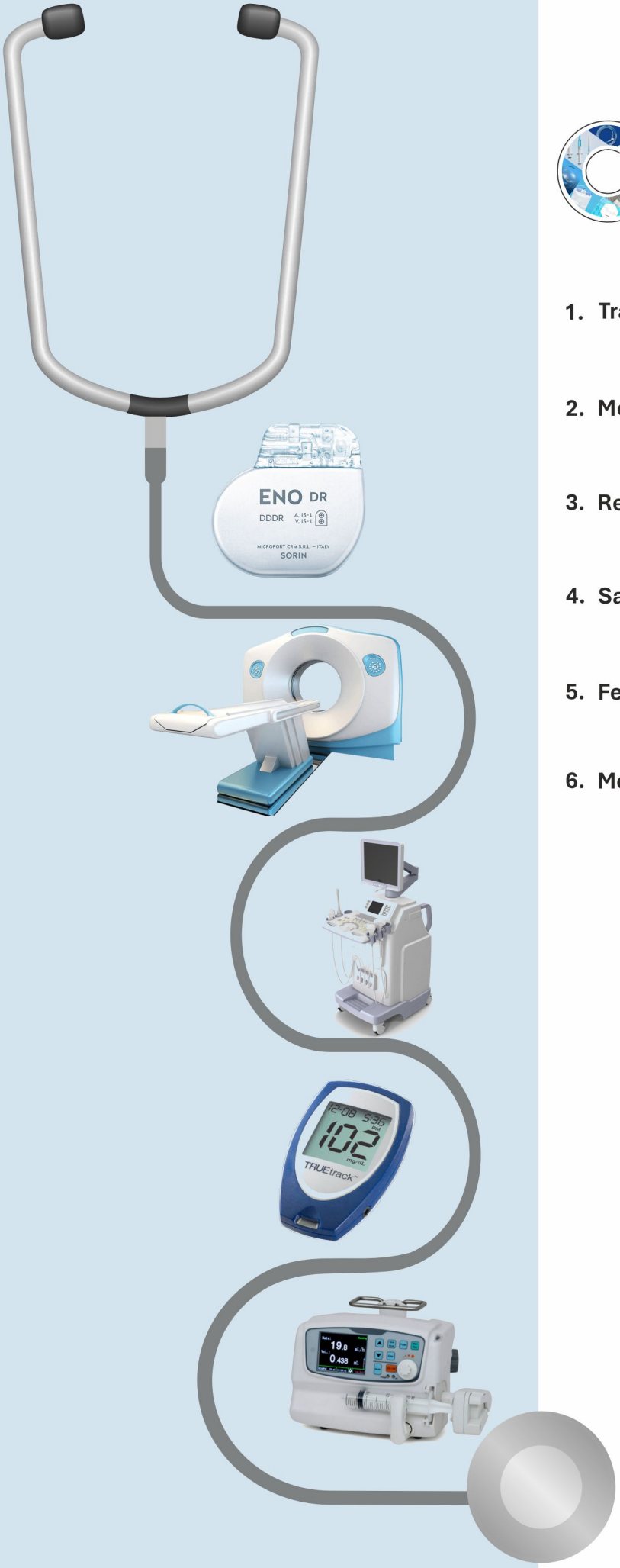


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# Seminar on Strengthening Medical Device Licence Holders on Post Market Safety Surveillance Practices in India


National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) in collaboration with Postgraduate Institute of Medical Education & Research (PGIMER), Chandigarh, hosted a seminar aimed at enhancing post-market safety reporting structures under the MvPI for medical device industry personnel. The event began with a welcome address by Professor Bikash Medhi, who outlined the seminar's objectives cantered on improving understanding and practices related to post-marketing surveillance of medical devices in India. Key sessions included a comprehensive overview of the Medical Device Rules 2017 presented by Mr. Ajai Basil, Assistant Drug Controller at CDSCO. Dr. Shatrunjay Shukla, Scientific Assistant, IPC, provided valuable insights into the MvPI and its role in ensuring medical device safety. Mr. Manish Kapoor, State Drug Controller for Himachal Pradesh, emphasized the importance of quality management system requirements for domestic manufacturers and regulatory compliance. Mr. Naveen V, Scientific Assistant at IPC, introduced MvPI reporting tools, highlighting their functionalities for effective surveillance. The seminar concluded with a session featuring experts from the medical device industry, who shared best practices and practical insights into materiovigilance from the manufacturers' perspective.

# International Webinar on Optimizing the Use of ICSRs in Signal Detection Process


On September 18, 2024, the NCC-IPC (National Coordination Center-Indian Pharmacopoeia Commission) hosted an insightful international webinar focused on optimizing the use of Individual Case Safety Reports (ICSRs) in the signal detection process. The session was led by Dr. V. Kalaiselvan, Senior Principal Scientific Officer at IPC, and featured presentations from esteemed experts in the field. The webinar attracted a diverse audience, including representatives from the World Health Organization (WHO) and members of the South-East Asia Regulatory Network (SEARN) from countries such as Sri Lanka, Nepal, Bhutan, Myanmar, Timor-Leste, and Bangladesh, along with pharmacovigilance experts from India. The event concluded with a robust Q&A session, allowing participants from SEARN countries to address their concerns. Discussions underscored the urgent need to improve ADR reporting in the region, with a focus on safe medicines during pregnancy, Pregabalin-related dependence, and Ethambutol-related ocular neuropathy. Looking ahead, the participants expressed a commitment to enhance awareness and training in pharmacovigilance and to gather further evidence on these critical topics to support informed regulatory actions.

# Promoting Safety: Awareness Program on Materiovigilance at AIIMS Rishikesh

In September 2024, an awareness program on "Materiovigilance and Reporting of Adverse Events Due to Medical Devices" was conducted by Ms. Nalini at AIIMS, Rishikesh, on September 19 and 20, across various departments including pulmonary, CTVS, psychiatry, ophthalmology, and gynecology. Key discussions focused on adverse events experienced by inpatients related to medical devices, emphasizing the importance of thorough examination and quality checks. Participants were encouraged to report any adverse events encountered by patients or hospital staff, ensuring all quality issues were documented. This included noting any malfunctions observed prior to device use. Additionally, discarded medical devices due to malfunctioning were collected as samples, with essential information such as batch numbers and expiry dates recorded for future reference. This initiative aimed to enhance awareness and foster a culture of safety and accountability regarding medical device usage in the healthcare setting.

# Training Programme on Materiovigilance and Pharmacovigilance at Pt. Jawaharlal Nehru Government Medical College and Hospital, Chamba

On September 21, 2024, the NCC-MvPI, in collaboration with JLNMC, Chamba, conducted an advanced Continuing Medical Education (CME) training programme on Materiovigilance and Pharmacovigilance. The event aimed to sensitize medical and paramedical staff while providing MBBS students with essential awareness about the Post-Market Safety Surveillance System. Dr. Aditi Chaturvedi welcomed attendees and outlined the programme's objectives, while Dr. V. Kalaiselvan, Senior Principal Scientific Officer, IPC, discussed capacity building for Materiovigilance and the establishment of Medical Device Monitoring Committees. Dr. Shatrunajay Shukla, Scientific Assistant, IPC, introduced the basics of the Materiovigilance Programme of India (MvPI) and its reporting tools. Over 150 participants, including doctors, paramedical staff, and students, attended the session, eager to enhance their knowledge in these critical areas.

# MvPI Participation in 39th edition Medicall Expo, New Delhi 2024


The 39th Edition Medicall Exhibition was held at Pragati Maidan, New Delhi, from October 5 to 7, 2024. A delegation from the Indian Pharmacopoeia Commission (IPC), including Mr. Lalit Sharma, Mr. Muneer Javed Mohammed, Mr. Naveen V, Mr. Surya Pratap Yadav, and Mr. Sandeep Mewada, set up an informative stall to raise awareness about the Indian Pharmacopoeia (IP), IP Reference Substances (IPRS), and the Materiovigilance Programme of India (MvPI). The stall featured brochures and banners highlighting the importance of materiovigilance in ensuring medical device safety. During the event, the team engaged approximately 100 stakeholders, including manufacturers and healthcare professionals, emphasizing the significance of reporting adverse events and promoting IPC's role in ICMED 9000 and ICMED 13485 certifications. The exhibition successfully increased awareness and interest in adverse event reporting and certification processes, fostering valuable networking and collaboration opportunities for the future.

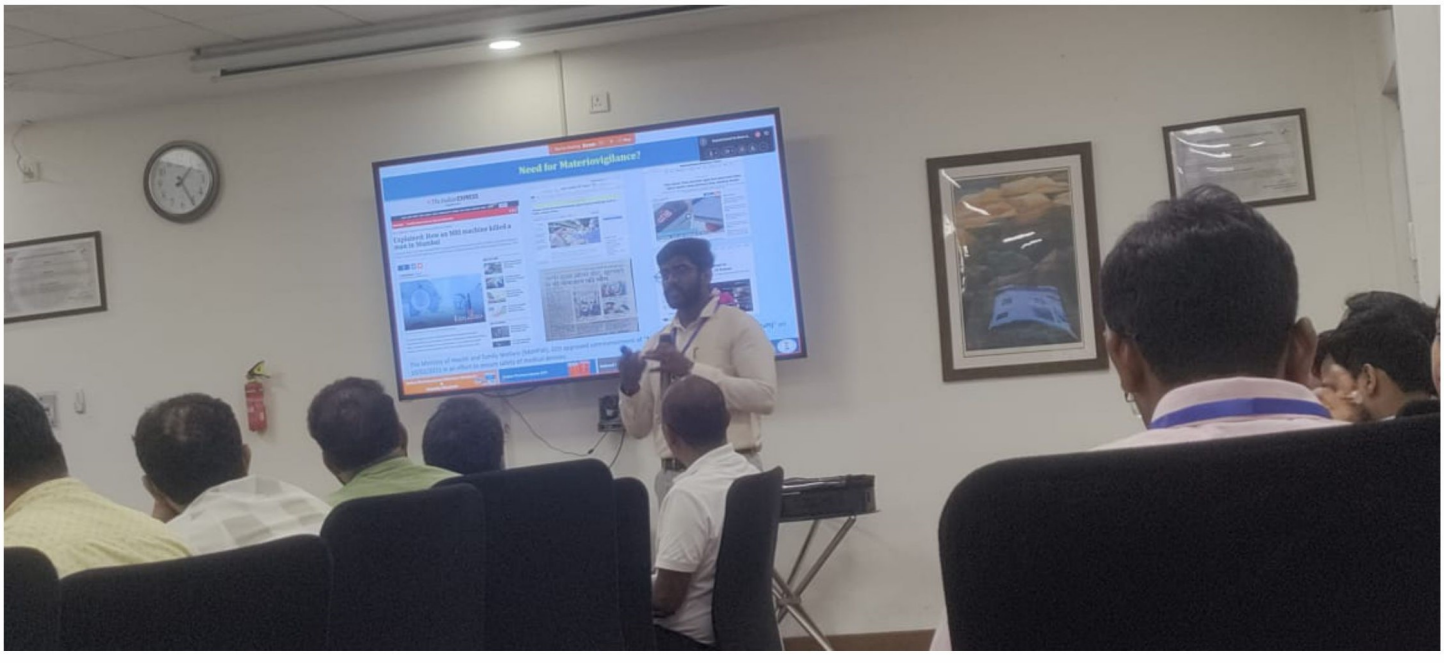
# Enhancing Medical Device Safety: Insights from AIIMS Rishikesh Meeting

On October 11, 2024, Ms. Nalini, Materiovigilance Associate, led a meeting with the quality team at AIIMS, Rishikesh, addressing quality issues related to medical devices faced by nursing staff across various departments. This meeting was crucial for the Materiovigilance Programme of India (MvPI), aimed at enhancing medical device safety and effectiveness. Nursing staff shared insights on challenges such as device malfunctions and usability issues impacting patient safety. The discussion identified barriers to effective adverse event reporting, including lack of awareness and insufficient training. Proposed strategies included improved training programs, better communication channels, and a robust feedback loop between healthcare providers and regulatory bodies. This collaborative effort aims to enhance patient care and outcomes in India.

# MvPI Participation in 19th International Conference of Drug Regulatory Authorities (ICDRA), New Delhi


The 19th International Conference of Drug Regulatory Authorities (ICDRA) was successfully held in India from October 15 to 17, 2024, New Delhi. This significant event saw participation from various organizations, including representatives from the IPC-MvPI. Dr. Tanushree Sarvepalli and Dr. Jaishree Suresh, Junior Pharmacovigilance Associates from IPC, engaged in discussions focused on enhancing adverse drug reaction (ADR) reporting, particularly in IPC's capacity as a WHO Collaborating Center. Their presentations highlighted IPC's vital role in the South-East Asian Region, showcasing statistics on ADR reporting and outlining future improvement plans. A notable segment involved a group discussion on pharmacovigilance data analysis, where they contributed to dialogues on past, present, and future approaches, leading to valuable recommendations shared by Dr. V. Kalaiselvan, Senior Principal Scientific Officer, IPC. Ms. Shweta Wachaspati, Senior Materiovigilance Associate, and Mr. Surya Pratap Yadav, Junior Materiovigilance Associate, focused on policies and strategies aimed at improving access to essential drugs and medical devices, with discussions centered around affordability, availability, and innovation. Key activities included a workshop on enhancing access to medical devices, a plenary session on global and regional trends in medical device regulation, and workshops on Quality Management Systems (QMS) for regulators. Overall, the ICDRA served as a pivotal platform for both IPC and MvPI to share knowledge, foster collaboration, and strengthen their roles in improving pharmacovigilance and materiovigilance in India and beyond. The outcomes included increased awareness of their contributions, actionable recommendations for enhancing ADR and device reporting, and valuable networking opportunities with global stakeholders.

# MvPI Participation in Dissemination Workshop on Guidelines on Equipment Maintenance, Calibration & Testing at NHSRC




The National Workshop on the Dissemination of Revised Guidelines on Equipment Maintenance, Calibration, and Testing was held on October 22, 2024, at the National Health Systems Resource Centre (NHSRC), New Delhi. Mr. Amol Raj, Jr. Materiovigilance Associate, IPC-MvPI, participated as a delegate. Mr. Naveen V, Scientific Assistant, IPC, provided valuable insights on the MvPI. His presentation focussed on crucial aspects such as product recalls, key performance indicators associated with MvPI, and the importance of adverse event reporting. This session aimed to enhance participants' understanding and implementation of the revised guidelines.

# Medical Device Stakeholder Consultation Meeting


On September 3, 2024, IPC-MvPI and PGIMER, Chandigarh, hosted the second Medical Device Stakeholder Consultation Meeting focused on enhancing post-market safety reporting in the Materiovigilance Programme of India (MvPI). This meeting provided a valuable platform for stakeholders to discuss current challenges, share experiences, and explore strategies for improving safety reporting practices.

Building on the initial consultation held on May 17, 2024, at FDA Bhawan in Delhi, which focused on identifying key issues and preliminary strategies, this second meeting aimed to review progress, address outstanding challenges, and refine strategies for further improvement.

The event successfully advanced knowledge regarding post-marketing surveillance practices, regulatory requirements, and best practices, contributing to a more robust and effective safety framework for medical devices in India. Stakeholders left with renewed insights and actionable strategies to enhance safety reporting within the MvPI.

# RECOMMENDATIONS TO CENTRAL DRUGS STANDARD CONTROL ORGANIZATION (CDSCO)

1. NCC-MvPI sent a recommendation to CDSCO on **"Leakage, Blockage, Piston Breakage & Presence of Foreign Particles"** associated with **"Auto Disposable Hypodermic Syringe"** for information and necessary actions at their end.

2. NCC-MvPI sent a recommendation to CDSCO on **"Malfunctioned Regulator resulting in Leakage and Uncontrolled Medication Delivery"** associated with **"Intra Venous Infusion Set"** for information and necessary actions at their end.

3. NCC-MvPI sent a recommendation to CDSCO on the **"Improper Functioning of Regulator/Leakage of Blood"** associated with the **"Blood Transfusion Set"** for information and necessary actions at their end.

4. NCC-MvPI sent a recommendation to CDSCO on **"Poor Adhesive Property/Insufficient Adhesion"** associated with the **"Adhesive Surgical Tape"** for information and necessary actions at their end.

# SAFETY ALERT

**NCC-MvPI, IPC has observed an adverse event report of Prosthesis Leakage associated with the use of Voice Prosthesis which may lead to serious adverse event.**

| S. No. | Suspected Device Details | Event Details |
|---|---|---|
| | Device Name | |
| 1. | Voice Prosthesis | Prosthesis Leakage |

## NOTE

You are requested to closely monitor the adverse events of these devices at your respective monitoring centre. If these devices are being used at your hospital, kindly report all the suspected adverse events related to above mentioned medical devices, if any, using the reporting form, available on www.ipc.gov.in and send via e-mail at: mvpi-ipc@gov.in & shatrunjay.ipc@gov.in

## Message

**The content of this safety alert is highly confidential. It is strictly forbidden to share any part of the message with any third party/vendor or on public platforms such as social media, local newspapers/posters etc., without the written consent of the publisher. Your support in this regard is highly solicited.**

***Your support in this regard is highly solicited.***

# Feedback on MvPI

I, Varsha Sahu would like to express my appreciation for the efforts of the Materiovigilance Programme of India (MvPI) in promoting the safety and effectiveness of medical devices. The program's proactive approach to monitoring and reporting potential risks is commendable, as it helps to build trust in the healthcare system. To further enhance its impact, I suggest focusing on improving public awareness about the importance of reporting adverse events and how to do so effectively. Making reporting channels more accessible and user-friendly could significantly empower consumers to participate in this vital initiative. Additionally, increasing the transparency of the program's processes and outcomes would foster greater confidence among the public. Overall, the MvPI is essential for safeguarding public health, and I appreciate the dedication of the team in prioritizing consumer safety. Thank you for your ongoing commitment to this important work.

**Varsha Sahu**
**Bhopal**
**Madhya Pradesh**

I, Vivek Sharma, would like to commend the Materiovigilance Programme of India (MvPI) for its pivotal role in ensuring the safety and efficacy of medical devices within our healthcare system. The program's comprehensive monitoring and reporting mechanisms exemplify a strong commitment to identifying and addressing potential risks associated with medical devices, thereby safeguarding public health. To enhance its effectiveness further, I recommend that MvPI increase efforts to educate the public about its objectives and the importance of reporting adverse events. Simplifying the reporting process and ensuring that information is readily accessible could significantly encourage consumer engagement. Additionally, providing regular updates on the program's findings and actions would promote transparency and strengthen public trust. In conclusion, the MvPI plays a crucial role in advancing healthcare safety, and I sincerely appreciate the dedication of all involved in this initiative. Thank you for your continued commitment to promoting consumer safety and health.

**Vivek Sharma**
**Ghaziabad**
**Uttar Pradesh**

# Medical Device Monitoring Centers (MDMCs) in MvPI

Under the Materiovigilance Programme of India (MvPI), 501 Medical Device Adverse Event Monitoring Centers (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 centers 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

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