

e-Newsletter

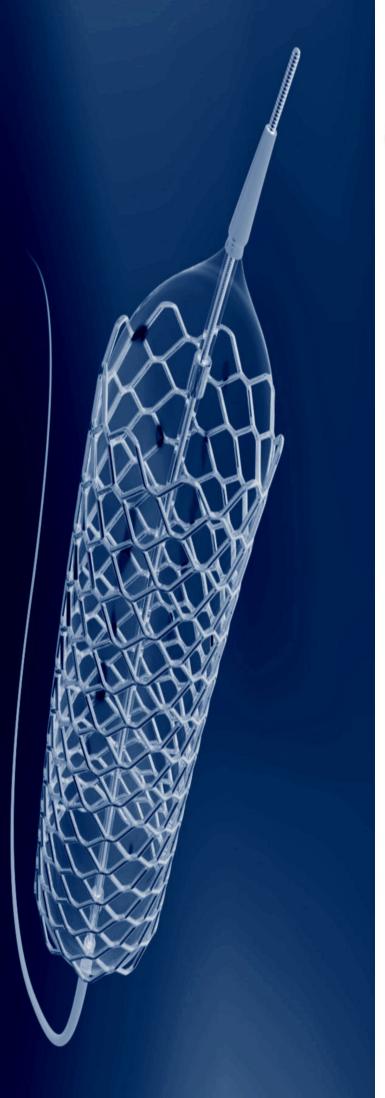
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Ministry of Health and Family Welfare (MoHFW) Government of India



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TRAININGS & EDUCATION

Advancing Materiovigilance: Transformative Al Initiatives and Insights



NCC-MvPI meeting with RailTel

On March 15, 2024, NCC-MvPI (National Coordination Centre- Materiovigilance Programme of India) convened a pivotal meeting with RailTel to explore artificial intelligence (AI) integration in Materiovigilance. The session highlighted AI's potential to enhance efficiency and outcomes in such programs. Participants learned how AI can streamline data analysis, identify patterns, and detect adverse events swiftly. The seminar emphasized AI's role in improving decision-making processes and responsiveness. By leveraging AI, Materiovigilance can proactively mitigate risks to public health. Insights provided underscored AI's transformative power in

revolutionizing Materiovigilance. Integration of AI promises quicker responses to safety concerns and improved patient protection. Materiovigilance stands to benefit from AI's capacity to expedite data analysis and facilitate proactive interventions. Ultimately, AI integration holds the potential to safeguard public health more effectively.

NCC-MvPI meeting with Datafoundry

NCC-MvPI, IPC convened a meeting with the Datafoundry team on March 6, 2024, at the Indian Pharmacopoeia Commission, Ghaziabad, to explore the transformative potential of artificial intelligence (AI) in materiovigilance. The Datafoundry team showcased AI-driven solutions' capabilities, emphasizing its role in signal management and adverse events monitoring. They highlighted how AI can swiftly identify safety signals and analyze adverse event reports with high accuracy, facilitating timely intervention and regulatory action. This meeting underscored AI's potential to enhance Materiovigilance Programme efficiency, accuracy,

and responsiveness, ultimately improving patient safety and public health outcomes.

MvPI Participation in HEALCON 2024 Conference

Mr. V. Hari Haran, Senior Materiovigilance Associate, had the privilege of representing MvPI at HEALCON 2024, on March 1, 2024, a conference focused on sustainable healthcare engineering at Christian Medical College Vellore (CMC). He participated as a speaker, sharing insights on "Medical device safety surveillance system," and the MvPI stall garnered attention, winning the 2nd prize in the poster presentation. The event provided valuable networking opportunities, knowledge exchange, and showcased innovative solutions in healthcare engineering. He emphasized MvPI's commitment to advancing patient safety through technology integration. Overall, HEALCON



2024 was a rewarding experience, fostering collaboration and learning within the healthcare community.

MvPI- CDSCO-CDRH-USFDA Meeting: Materiovigilance & Device Safety Updates

A meeting was conducted with representatives from the United States Food and Drug Administration (US FDA), the Central Drugs Standard Control Organization (CDSCO), and the Indian Pharmacopoeia Commission (IPC) on April 10, 2024, at FDA Bhawan, New Delhi. Dr. V Kalaiselvan, Senior Principal Scientific Officer updated the meeting members on IPC-MvPl activities. Dr. Shatrunjay Shukla, Scientific Assistant at IPC, and Mr. Amol Raj, Junior Materiovigilance Associate at MvPl, also attended the meeting. A team from the Centre for Devices and Radiological Health (CDRH) visited India and expressed interest in meeting with the IPC-MvPl team to exchange

information and further understand Materiovigilance and safety reporting procedures for medical devices. CDSCO provided updates on Medical Devices, while IPC offered updates on Materiovigilance.



Sensitization Programme on Dental Medical Devices

MvPI division has organized a sensitization programme entitled "Navigating Adverse Events in Dentistry: Understanding Risks of Dental Devices and Strategies to Improve Communication" on April 16, 2024. Dr. Shalya Anand, Founder and CEO, iAssisT Health & ADA and visiting researcher at Max Planck Institute of Human Behaviour, Berlin, Germany along with Ajay Basil, ADC, CDSCO addressed the gathering at RS Iyer Hall, IPC.



MvPI Participation in the National Conference



Dr. V. Kalaiselvan, Senior Principal Scientific Officer and Mr. Amol Raj, Jr. Materiovigilance Associate, participated in the National Conference on Pharmacovigilance in Clinical Trials and the Global Market at GLA University, held from April 19th to 20th 2024 in Mathura, Uttar Pradesh. Dr. V. Kalaiselvan, IPC-MvPI, delivered a presentation addressing recent challenges and developments in Materiovigilance to the audience. At the same time, Mr. Amol Raj, provided insights into reporting modalities for communicating adverse events related to medical devices. A riveting question and answer session was also conducted on materiovigilance programme of India. The session fostered productive cross-talk and fruitful discussions among attendees focusing on the challenges and development in Materiovigilance.

NCC-MvPI's Sensitization-cum-Stakeholders Meeting Promotes Medical Device Safety

NCC-MvPI organized a Sensitization-cum-Stakeholders Meeting at the Uttar Pradesh University of Medical Sciences Saifai, Etawah, on April 30, 2024. The focus of the meeting was to address the recent incident involving the implantation of substandard pacemakers at a government hospital and to promote the safety of medical devices.

Dr. V. Kalaiselvan, Senior Principal Scientific Officer at IPC, opened the event with introductory remarks, outlining its objectives. He emphasized the crucial need to uphold the safety and efficacy standards of medical devices within the Indian healthcare system.



National webinar on "Medical Device & Adverse Events"

NCC-MvPI, IPC in collaboration with Amrita Institute of Medical Sciences, Kochi, conducted a national webinar on "Medical Devices & Adverse Events for Health Care Professionals" on May 15, 2024, through virtual mode, attracting 620 delegates, including doctors, PG residents, pharmacy students, clinical pharmacists, and other healthcare professionals. A keynote address by Dr. V. Kalaiselvan, Sr. Principal Scientific Officer, IPC, offered critical insights into the landscape and future of medical device reporting in India. Additionally, Sr. Materiovigilance Associate, IPC, Mrs. Shweta Wachaspati, presented an informative session on the Overview of MvPI, and Mr. Amol Raj, Jr. Materiovigilance Associate, led a practical session on Reporting Medical Device Events: Case Study. The webinar was well-received, providing valuable knowledge and guidance to enhance the skills of healthcare professionals in medical device reporting.



IPC-MvPI participated in the Exhibition on Medical, Surgical Instruments, and Hospital Equipment & Consumables



The Exhibition on Medical, Surgical Instruments, and Hospital Equipment & Consumables at India Expo Mart & Centre, Greater Noida, on May 18-19, 2024, was a success for our delegation. Dr. Shatrunajay Shukla, Scientific Assistant, Ms. Shweta Wachaspati, Sr. Materiovigilance Associate and Mr. Surya Pratap Yadav, Jr. Materiovigilance Associate, engaged in an awareness campaign, networking, and data collection. Over 100 stakeholders were reached, with 200+ brochures distributed and a directory of 100+ medical device manufacturers compiled. Positive feedback received highlights the event's effectiveness in promoting the ICMED scheme and Materiovigilance Programme of India, contributing significantly to improving medical device quality and safety in India.

Enhancing Patient Safety: Materiovigilance Initiative at PGIMER Chandigarh CME





PGIMER Chandigarh serves as the Regional Resource, Training, and Technical Support Centre for North India, overseeing vigilant monitoring of Materiovigilance and Pharmacovigilance cases to bolster patient safety. On May 25, 2024, a CME session for the Department of Pharmacology at PGIMER, Chandigarh, commenced with a discussion led by Prof. Bikash Medhi on PvPI and MvPI, engaging over 200 online and 40 offline participants. The virtual presence of Dr. Bhavneet Bharti, Director Principal of AIMS, Mohali, and Honorable Dr. Rajeev Singh Raghuvanshi, DCG(I), alongside Prof. Y.K Gupta, National Scientific Coordinator of PvPI, added significance to the event. Attendees actively addressed practical issues concerning adverse event reporting in hospitals for drugs and medical devices, with satisfactory resolutions. Overall, the CME successfully tackled crucial aspects of Materiovigilance, contributing to ongoing efforts for the welfare and safety of the Indian population.

MvPI Participation in Obstetrics Critical Care Conference

Mrs. Abirami, Materiovigilance Associate, participated and kept a stall representing NCC - MvPI, IPC in the Obstetrics Critical Care Conference on, 26 May, 2024 which was organised by the Department of intensive care unit, Royal Care Super Speciality Hospital,

Coimbatore. In this conference participants participated from all over the south zone and gained knowledge about the program and the MvPI material was distributed to the participants to learn more about materiovigilance.

MEDICAL DEVICE UPDATES



Implementation of the Materiovigilance Programme of India (MvPI) in Telangana

On April 4, 2024, Mr. V. Hari Haran, Senior Materiovigilance Associate met with Dr. T. Vinay Krishna Reddy, Joint Secretary for the Health, Medical, and Family Welfare (HMFW) Department of the Government of Telangana. They attended a meeting hosted by the Office of the Health Secretary, Telangana, to discuss implementing the Materiovigilance Programme of India (MvPI). During the meeting, they explored MvPI's benefits, emphasizing medical device safety and patient well-being. Discussions included the formation of monitoring committees at various levels and outlining the next steps, such as providing information to the Health Minister's office and assessing feasibility. The

meeting concluded positively, with interest expressed in implementing MvPI pending discussions with the Health Minister. Overall, it showcased a commitment to enhancing healthcare standards in Telangana.

Circular by DCG (I) for all Medical Device License Holders

A circular, dated May 15, 2024, issued by DCG(I), for all medical device license holders to promptly report adverse events to the Materiovigilance Programme of India (MvPI) at the Indian Pharmacopoeia Commission (IPC). This directive aims to bolster safety and vigilance in the healthcare sector by enhancing the timely reporting and analysis of adverse events linked to medical devices. The circular underscores the imperative of robust reporting systems to identify and address risks associated with medical devices, aligning with MvPI's mission to bolster patient safety. It is strongly advised that all license holders actively participate in the MvPI platform to report any adverse events or serious adverse events related to their devices. By fostering a culture of proactive reporting and coordinated analysis, we can collectively bolster the efficacy of risk identification and mitigation measures, thereby safeguarding public health and reinforcing the integrity of medical device regulations.

Link: https://cdsco.gov.in/opencms/opencms/en/Notifications/Circulars/





The stakeholders' consultation meeting held on May 17, 2024, at CDSCO, FDA Bhawan, New Delhi, aimed to address challenges and improve the postmarket safety reporting structure under the Materiovigilance Programme of India (MvPI), in line with the circular issued by DCG(I) on May 15, 2024. Chaired by Dr. Bikash Medhi from PGIMER Chandigarh, the meeting welcomed representatives from CDSCO, State Drug Controllers, industry associations, and IPC-MvPI. Dr. V. Kalaiselvan from IPC-MvPI emphasized the importance of mandatory post-market safety reporting. Dr. Bikash Medhi highlighted the necessity of

adverse event reporting, while Mr. Chandrashekar Ranga from CDSCO stressed the role of such reporting in ensuring public health. State Drug Controllers from Delhi and Haryana emphasized the need to enhance reporting from Class A and Class B device manufacturers. Dr. I. S Hura from CDSCO presented on Materiovigilance and discussed reporting tools and timelines. The discussion revolved around current reporting systems, challenges faced by stakeholders, required support from MvPI and CDSCO, and enhancing post-market safety reporting.

Circular on Enhancing Safety and Quality of Medical Devices in India through BIS Standards

The Bureau of Indian Standards (BIS) plays a crucial role in ensuring the safety and performance of medical devices in India, with over 1000 Indian Standards specifically dedicated to this sector. The NCC-MvPI monitors and reports adverse events related to medical devices, providing valuable insights for standardization efforts. To enhance safety and quality, BIS had meeting with the IPC-MvPI to receive the adverse event data and

incorporate relevant findings into the Indian

Standards. Recently, A circular, dated May 29, 2024, issued by DCG(I), emphasized the importance of testing medical devices in accordance with BIS standards to ensure quality and

performance. Compliance with these standards is essential to strengthen the regulatory framework and safeguard public

health effectively.



File No.: MED/48/2024-eoffice
Central Drugs Standard Control Organisation
Ministry of Health and Family Welfare

FDA Bhavan, New Delhi
CIECULAR

Subject: Testing and evaluation of Medical Devices (MD) in view diagnostics(PO) by
Medical Devices Testing Laboratories in the country. Fig.

In order to ensure the guality, safety and performance of Medical Devices(MD) in view diagnostics(PO), the Ministry of Health and Parally Velders, Covement of India
Device on behalf of a manufacture, under Legistry of Medical Devices (MD) in view diagnostics(PO), the Ministry of Health and Parally Velders, Covement of India
Device on behalf of a manufacture, under Legistry of Medical Devices Rules 2017 to strengthen the testing licelly in the country

It is pertinent to mention that consequent to the implementation of MDR 2017 with effect from 0.01/2018, the Drug Pulles 1545 are no torger applicable for MDB/VDs. Medical Device Rules (MDR) are mandetory as under.

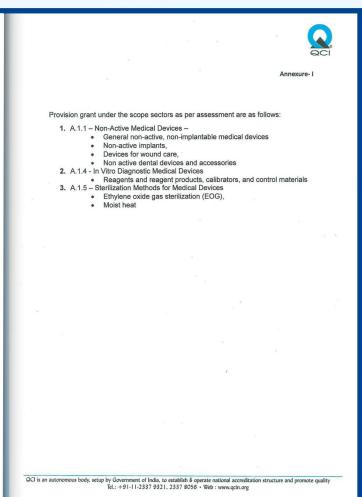
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Indian Pharmacopoeia Commission Materiovigilance Programme of India as Certification Body for ICMED 9000 and ICMED 13485

Indian Pharmacopoeia Commission – Materiovigilance Programme of India (IPC-MvPI) is awarded provisional approval from the Quality Council of India (QCI) to function as a certification body for the ICMED 9000 (ISO 9001 requirements plus additional requirements specified under the scheme) and ICMED 13485 (ISO 13485 requirements plus additional requirements

specified under the scheme) certification schemes. This accreditation will enable IPC-MvPI to assess the quality management systems of medical device industries, ultimately enhancing quality of medical devices and ensuring consumer protection.





SAFETY ALERT

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

S. No.	Suspected Device Details	Event Details
	Device Name	
1.	Urine Bags	Urine Leakage

NCC-MvPI, IPC has observed an adverse event report of Vision Loss associated with the use of Tryapn Blue Dye (IOL Dye) which may lead to serious adverse event.

S. No.	Suspected Device Details	Event Details
	Device Name	
1.	Tryapn Blue Dye (IOL Dye)	Vision Loss

NCC-MvPI, IPC has observed an adverse event report of Leakage/Faulty Regulator/ Malfunction/ Compromised Quality associated with the use of an Intravenous Infusion Set which may lead to serious adverse event.

S. No.	Suspected Device Details	Event Details
	Device Name	
1.	Leakage/Faulty Regulator/Malfunction/Compromised Quality	Intravenous Infusion Set

SAFETY ALERT

NCC-MvPI, IPC has observed an adverse event report Leakage/Piston Breakage/Quality Issue associated with the use of a Hypodermic Syringe which may lead to serious adverse event.

S. No.	Suspected Device Details	Event Details
	Device Name	
1.	Hypodermic Syringe	Leakage/Piston Breakage/Quality Issue

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 in medical device adverse event, if any using reporting form after the use of these devices to NCC-MvPI, IPC via e-mail: shatrunjay.ipc@gov.in.

Message

The content of the 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 a written consent of the sender.

Your support in this regard is highly solicited.



Recommendations to Central Drugs Standard Control Organization (CDSCO)

S. No.	Suspected Medical Device	Associated Adverse Event
1.	Intra Ocular Lens	IOL Breakage & Infection
2.	Urine Bag	Urine Leakage
3.	Hypodermic Syringe	Leakage/Piston Breakage/ Quality Issue
5.	Intravenous Infusion Set	Leakage/Faulty Regulator/ Malfunction/ Compromised Quality
6.	Tryapn Blue Dye (IOL Dye)	Vision Loss

EXPECTED ACTION AT YOUR END

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 in medical device adverse event, if any using reporting form after the use of these devices to NCC-MvPI, IPC via e-mail: shatrunjay.ipc@gov.in.

Message from Executive Director of AlIMS Guwahati



As the Executive Director of AIIMS Guwahati, it's crucial to emphasize the pivotal role of Materiovigilance Programme of India (MvPI) in safeguarding the safety and efficacy of medical devices used in healthcare settings.

Primarily, materiovigilance acts as a proactive mechanism for identifying and addressing potential risks linked with medical devices. By facilitating the reporting and analysis of adverse events, it empowers healthcare professionals to promptly detect any anomalies or adverse events associated with specific devices. This early detection is essential in mitigating potential harm to patients

and averting further complications.

Additionally, MvPI fosters transparency and accountability within the healthcare industry by promoting the transparent reporting of adverse events. This encourages manufacturers, regulatory authorities, and healthcare providers to uphold stringent quality standards and comply with regulatory guidelines. Such accountability not only enhances patient safety but also builds trust and confidence in the medical device ecosystem.

Moreover, MvPI serves as a valuable tool for continuous improvement and innovation in medical devices. Through the analysis of reported adverse events and identification of trends or patterns, it allows stakeholders to pinpoint areas for enhancement in device design, manufacturing processes, and usage protocols. This iterative process of feedback and refinement leads to the development of safer and more effective medical devices.

In conclusion, the significance of MvPI in ensuring the safety and efficacy of medical devices cannot be overstated. It is our collective responsibility as healthcare professionals to actively engage in the reporting and analysis of adverse events through MvPI. By doing so, we demonstrate our commitment to patient safety and contribute to the ongoing advancement of healthcare quality and innovation.

(Prof. (Dr.) Ashok Puranik)
Executive Director,
All India Institute of Medical Sciences
Guwahati, Asam

Fredback on MODI

I, Palak, would like to commend the initiative's dedication to ensuring the safety and efficacy of medical devices through the Materiovigilance Programme of India (MvPI). The systematic monitoring and reporting mechanisms in still a sense of security, knowing that potential risks are actively identified and addressed. However, I believe there is room for improvement in enhancing public awareness and accessibility to reporting channels. Streamlining processes and increasing transparency would empower consumers further in contributing to the program's success. Overall, MvPI plays a crucial role in safeguarding public health, and I sincerely appreciate your efforts. Thank you for your commitment to consumer safety.

Palak Verma
Chemical Engineer
New Delhi

During my internship with MVPI, I had the opportunity to contribute to adverse event reporting of medical devices in India. This experience not only educated me on the importance of reporting adverse events but also enabled me to improve the reporting rate of such events. The learning from this internship has been instrumental in my daily work at Philips, where I am responsible for handling adverse event reporting of medical devices.



Medical Device
Monitoring
Centers
(MDMCs) in
MvPI

Under the Materiovigilance Programme of India (MvPI), 451 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



NCC-PvPI IPC



@IPC NCC-PvPI



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ADR Mobile-app



Indian Pharmacopoeia Commission

Ministry of Health & Family Welfare Government of India

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