

e-Newsletter

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Materiovigilance Programme of India

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

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Training & Education



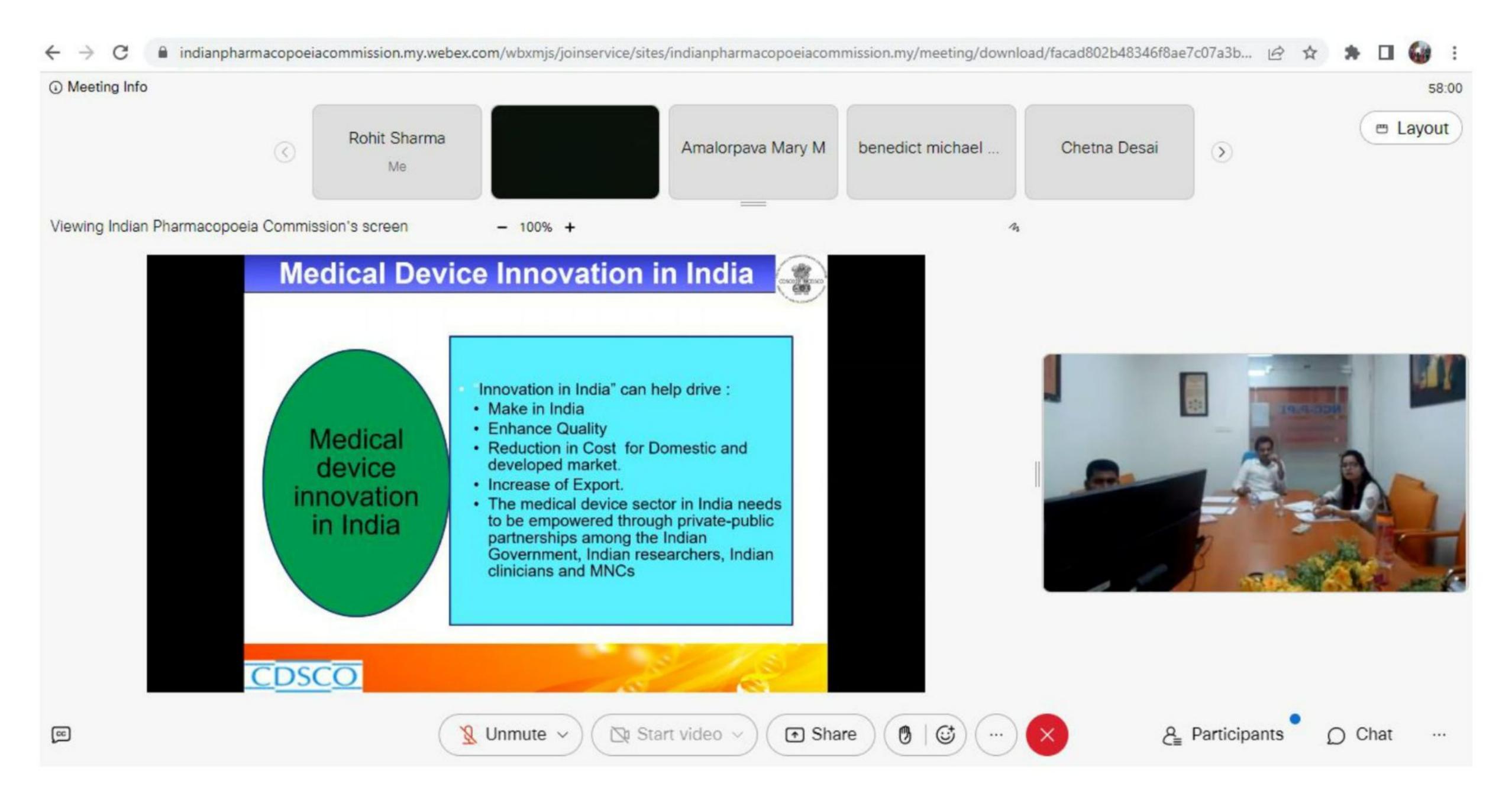


National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) conducted a training programme on "Overview of Materiovigilance Programme of India" at Fortis Hospital, Okhla, New Delhi on October 13, 2022. Ms. Nikita Mishra, Materiovigilance Associate & Mr. Rohit Sharma, Junior Materiovigilance Associate sensitized the healthcare professionals of Fortis Hospital on Materiovigilance programme and

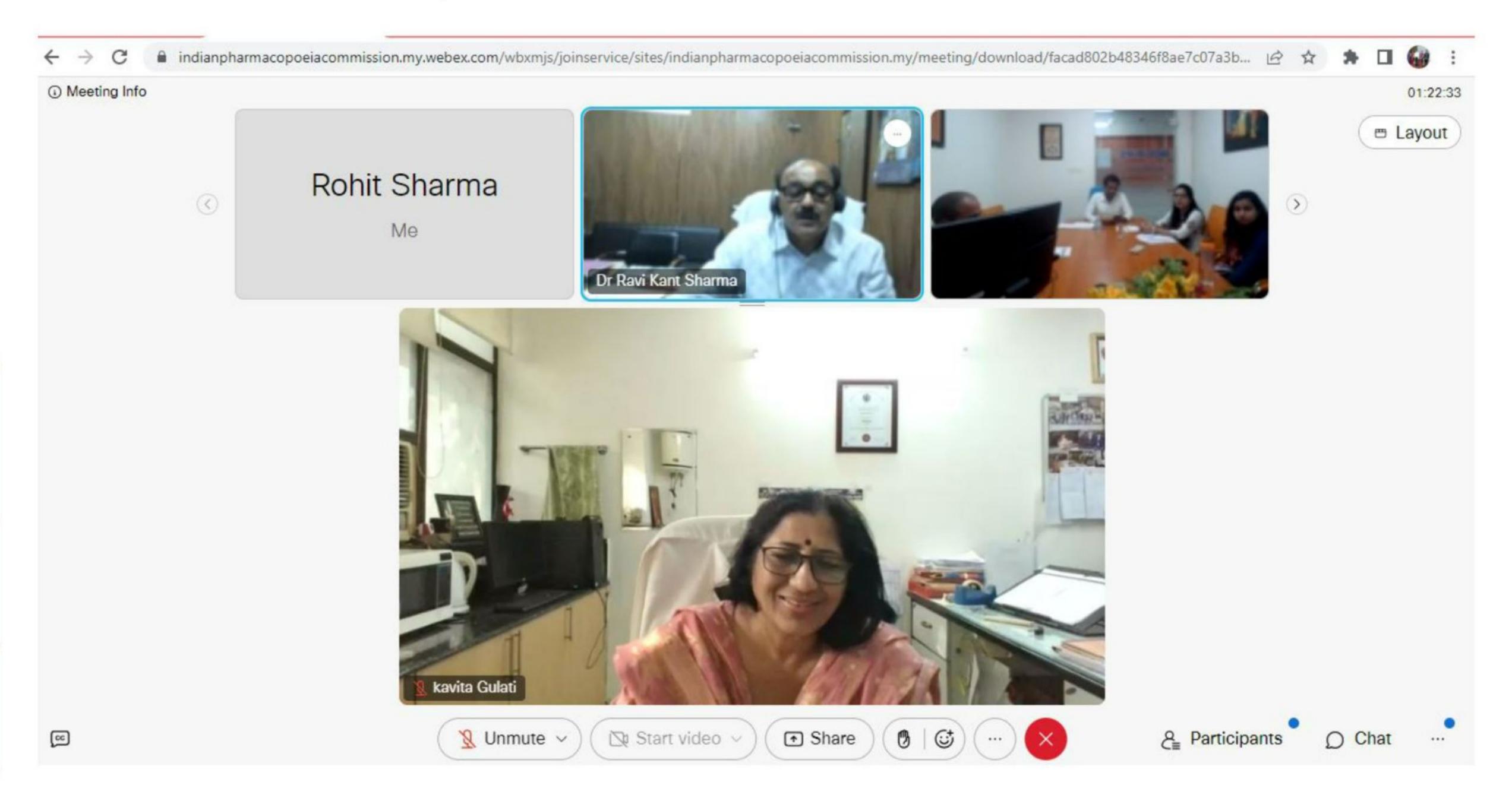
tools for reporting medical device adverse event. In total, 40 healthcare professionals attended this training programme. Overall, this was an interactive training programme that welcomed many questions and queries from the participants. MvPI associates resolved all the queries raised by participants and made them understand about the need of materiovigilance programme in India.



National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) conducted a national conference on "Strengthening of Medical Products Safety surveillance System in North Eastern States of India on October 19, 2022 at Government Pharmacy College, Sajong, Sikkim. In this conference, Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific, Director presented the special remarks followed by the sessions given by eminent speakers. Speakers from Central Drugs Standard Control Organization, New Delhi, Andhra Pradesh MedTech Zone, Andhra Pradesh, Bureau of Indian Standard, New Delhi, Sree Chitra Tirunal Institute of Medical Sciences, Thiruvananthapuram & Indian Pharmacopoeia Commission participated in this conference and enhanced the knowledge of participants. Conference sessions were interactive due to the queries raised by the participants. Eminent speakers of this conference resolved their queries and enhanced their knowledge. More than 100 participants participated in this conference and enhanced their knowledge on medical device & in-vitro diagnostics safety surveillance.



National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) conducted an induction-cum-training programme for newly identified coordinators on November 9-10, 2022 via digital platform. NCC-MvPI, IPC has recognized 119 new Medical Device Adverse Event Monitoring Centres (MDMCs) pan India. For the seamless functioning of materiovigilance programme at the newly identified centres, NCC-MvPI organized an Induction-cum-training programme for newly identified coordinators, deputy coordinators and materiovigilance associates. The Induction-cum-training programme organized to develop the basic understanding of newly identified coordinators, deputy coordinators, Materiovigilance associates on Medical Device Rules, Materiovigilance Programme, Available tools for Reporting, Post-marketing surveillance and baseline Study of medical devices.





National Coordination Centre - Materiovigilance
Programme of India (NCC-MvPI) in association
with Ruby Hall Clinic, Pune conducted a national
conference on "Strengthening medical product
safety surveillance" at Sheraton Grand Hotel,
Pune on November 12, 2022. In total, 150
participants including healthcare professionals,
medical device industry and students attended
the national conference. Mr. Om Prakash
Sadhwani, Mr. Pramod Kumar, Dr. Parvesh
Mehra, Mr. Manish Soni, Ms. Nikita Mishra were
the speakers for the conference. All the sessions

of the conference were interactive that raised many queries from the participants and the speakers resolved all the queries asked by the participants. Conference sessions followed by the panel discussion, eminent speakers Mr. Om Prakash Sadhwani, Mr. Pramod Kumar and Ms. Nikita Mishra were the panellist and answered all the questions asked in the panel discussion.



MvPI participation in Indian Pharma Expo

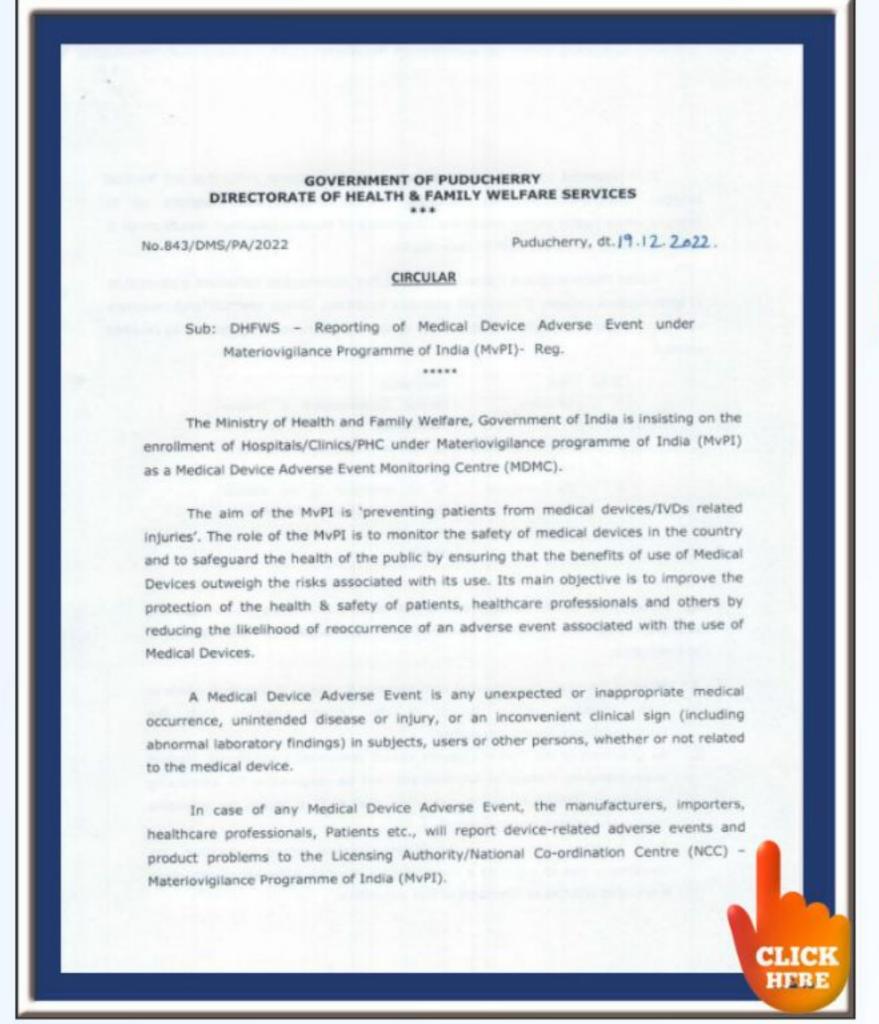
- Pharma Expo from September 30 to October 01, 2022 at Pragati Maidan, New Delhi to showcase the resource material of IPC. Mr. Rohit Sharma, MvPI representative also took part in the event and made aware the visitors about Materiovigilance programme.
- An event on Global Digital Health
 Summit: Expo & Innovation Awards
 organized by Global Digital Health
 Summit on October 28 & 29, 2022 at
 Vigyan Bhawan, New Delhi with a
 theme on "Digital Health for All". Mr.
 Rohit Sharma, MvPI representative
 attended the conference and
 enhanced the knowledge on
 connectivity of healthcare services at
 digital platform such as Telemedicine,
 Ayushman Bharat Digital Mission,
 Google Health, e-sanjeevani
 application.







Government Notification on MvPI

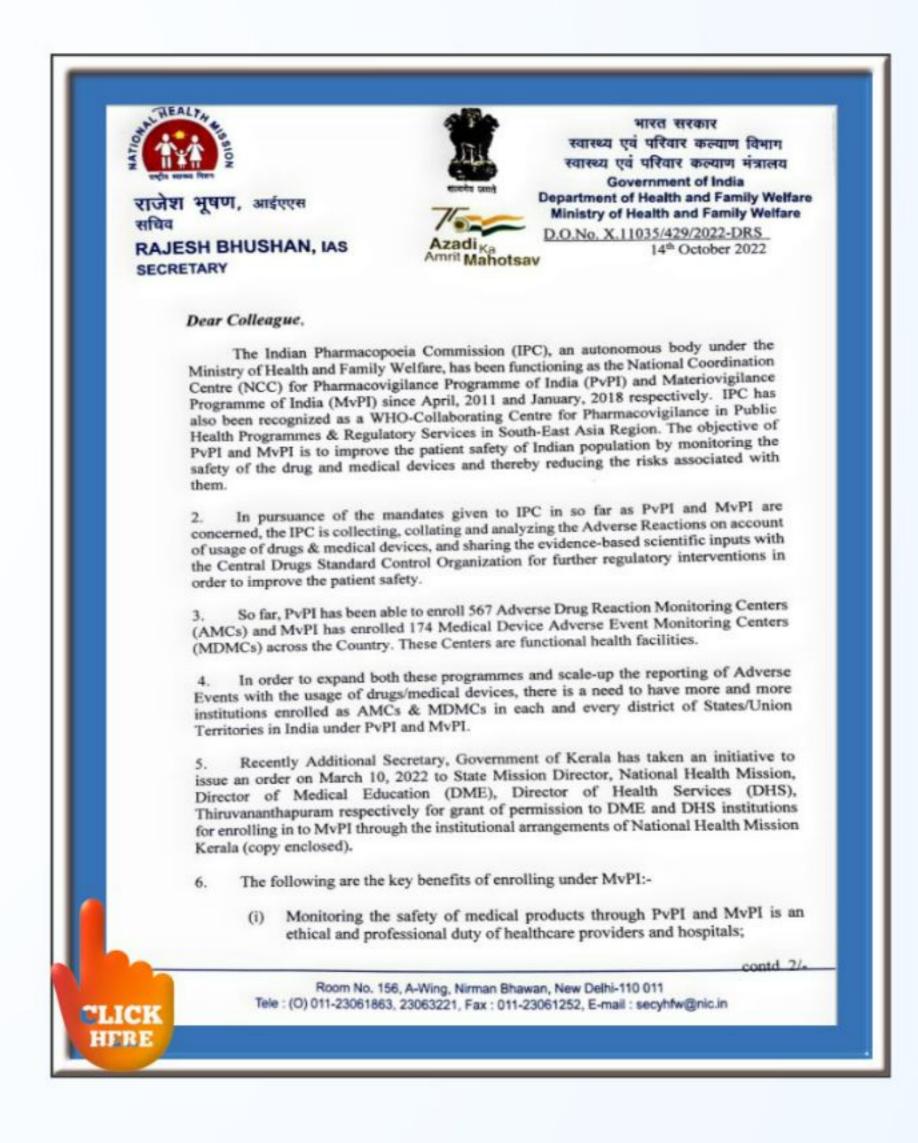


Government of Puducherry Directorate of Health & Family Welfare Services

Government of Puducherry has issued an order to medical superintendents and head of the institutions/hospitals to enroll and report medical device adverse events to Materiovigilance programme of India.

Government of India Department of Health & Family Welfare Ministry of Health and Family Welfare

Secretary, Ministry of Health and Family welfare,
Government of India has issued a letter to
State Secretaries regarding the enrollment of
district level hospitals/institutions under
Materiovigilance programme of India.





National Health Systems Resource Centre Ministry of Health and Family Welfare Government of India

Executive Director, National Health System & Resource System, New Delhi has issued a letter to all MDs National Health Mission States/
Union Territories to enroll & report under Materiovigilance programme.

MEDICAL DEVICE UPDATES



Drugs Controller General (India) Directorate General of Health Services Central Drugs Standard Control Organisation FDA Bhawan, Kotla Road, New Delhi J B DCT 2022 File No. 29/Misc./03/2020-DC (140) Part-5 (a) Subject: Classification of Medical Device pertaining to Dental under the provisions of Medical Devices Rules, 2017- Reg. Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, sale and distribution, clinical investigation, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which is already implemented from 01.01.2018 In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices, based on the intended use, risk associated with the device and other parameters specified in the First Schedule of the Medical Devices Rules-2017 Updated list of medical devices placed at Appendix A subjected to the followings: 1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer. 2. This list is dynamic in nature and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017. (Dr. V. G. Somani **Drugs Controller General (India)** 1. CDSCO Website

Classification of medical devices pertaining to Dental under the provisions of Medical Device Rules, 2017.

Classification of medical devices pertaining to Oncology under the provisions of Medical Device Rules, 2017.

Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road, New Delhi

Notice

File No. 29/MiscJ03/2020-DC (153) – Part 1 Date: 1 1 0CT 2022
Subject: Classification of medical device pertaining to Oncology under the provisions

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices for their with respect to the import, manufacture, clinical investigation, sale and distribution, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (F) dated 31.01.2017 which are to be commence from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices, Appendix A. based on the intended use of the device, risk associated with the device and other parameters specified in the First Schedule.

Updated list of medical devices placed at Appendix A subjected to the followings:

- General intended use given against each of the devices is for guidance to the applicants intends to_furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
 This list is dynamic and is subject to revision from time to time under the
- provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani) Drugs Controller General (India)

1. CDSCO Website

Recommendation to Central Drugs Standard Organization (CDSCO)

- National Coordination Centre Materiovigilance Programme of India (NCC-MvPI), IPC has sent recommendation to CDSCO about loss of capture, high capture threshold & lead dislodgement Issue associated with Pacing lead for their information & necessary action at their end.
- National Coordination Centre Materiovigilance Programme of India (NCC-MvPI), IPC has sent recommendation to CDSCO about Malfunctioning of Incubator associated with Infant Incubator for their information & necessary action at their end.
- National Coordination Centre Materiovigilance Programme of India (NCC-MvPI), IPC has sent recommendation to CDSCO about Non-functioning of cord clamps associated with Umbilical cord clamp for their information & necessary action at their end.
- National Coordination Centre Materiovigilance Programme of India (NCC-MvPI), IPC has sent recommendation to CDSCO about Balloon Deflation Issue associated with Coronary Stent System for their information & necessary action at their end.
- National Coordination Centre Materiovigilance Programme of India (NCC-MvPI), IPC has sent recommendation to CDSCO about Plate Breakage associated with Mandibular Reconstruction (Plate) for their information & necessary action at their end.



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@IPC NCC-PvPI



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



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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.ipcindia@gmail.com
Website: www.ipc.gov.in

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