सत्यमेव जयते

IPC

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Materiovigilance Programme of India

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National Coordination Centre - Materiovigilance Programme of India
Indian Pharmacopoeia Commission
Ministry of Health & Family Welfare (MoHFW) Government of india

Content

Upcoming MDMCs

Medical Device Adverse Event Monitoring Centres

Apollo Institute of Medical Sciences and Research Telangana, Hyderabad

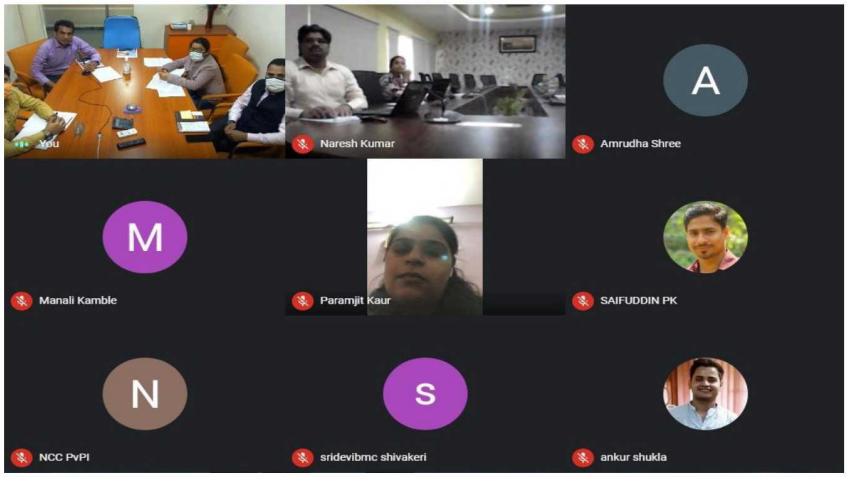
PRS Hospital Private Limited Trivandrum, Kerala

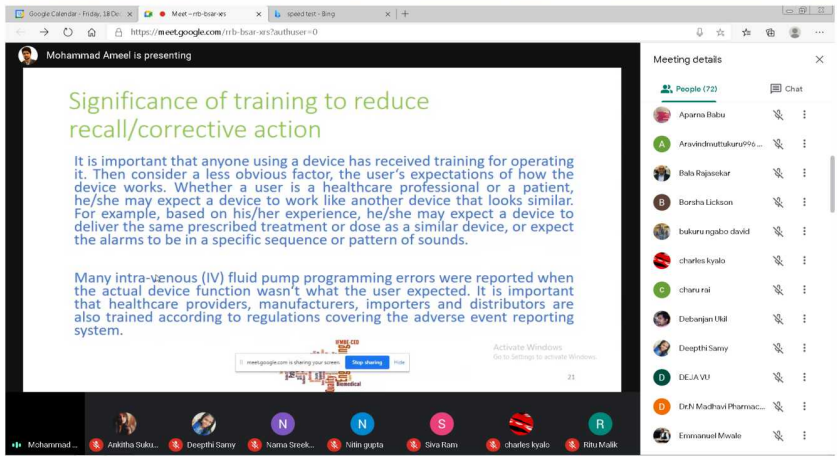
TRAINING & EDUCATION

National Coordination Centre-Materiovigilance Programme of India (NCC-MvPI), Indian Pharmacopoeia Commission (IPC) in association with Association of Indian Medical Device Industry (AIMED) organized a webinar on **"Participation of Medical Device Manufacturers in Materiovigilance Programme of India (MvPI)"** on December 04, 2020 via digital/virtual platform.140 Manufactures from different industries participated and understood the importance of medical device adverse event reporting in this webinar.

Specific Outcomes

- ***Capacity building of the participants about Compliance of Adverse Event Reporting as per Medical Device Rule (MDR) by the industry.***
- ***Educated the participants about modalities of adverse event reporting in Materiovigilance programme.***

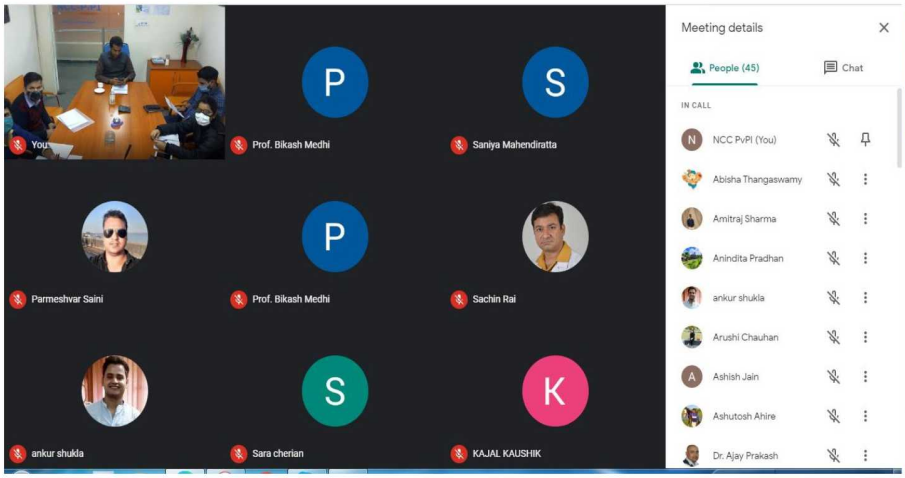




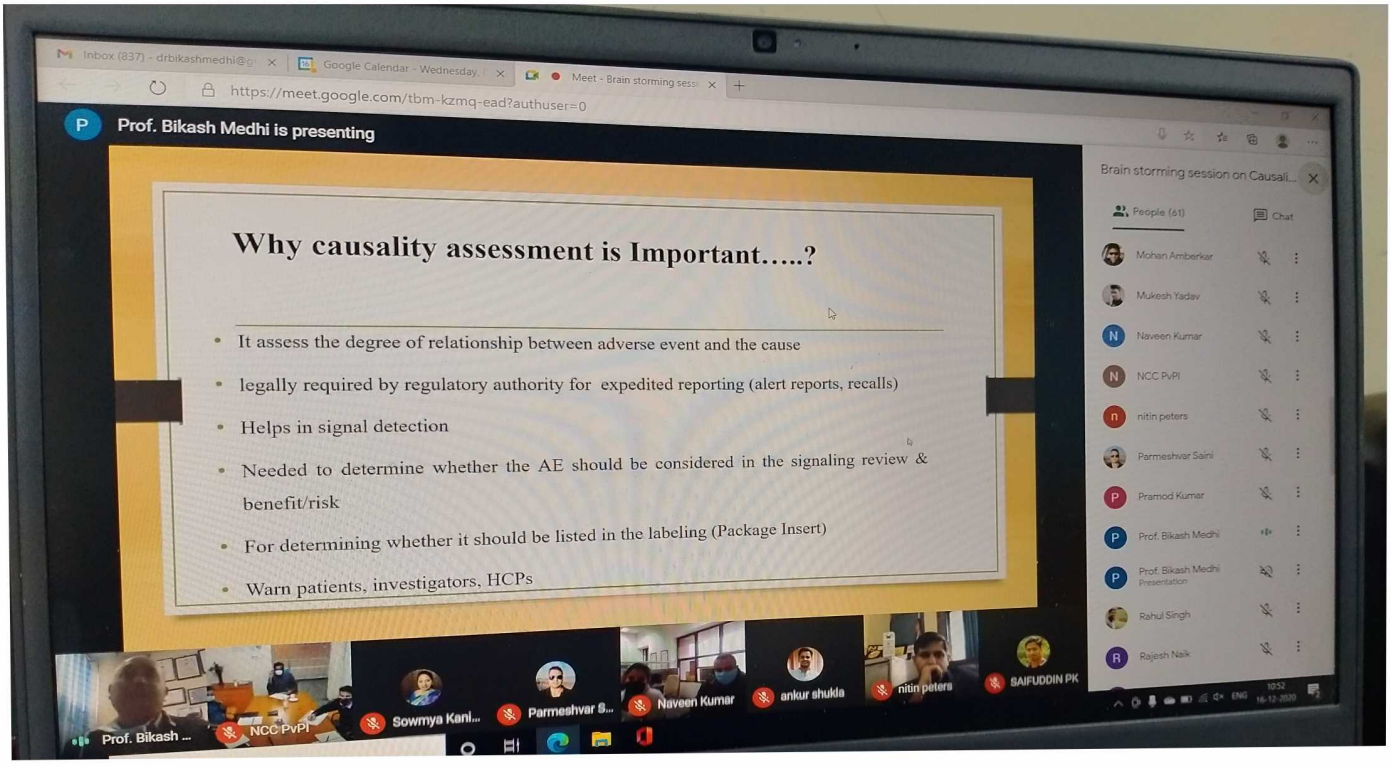
National Coordination Centre-Materiovigilance Programme of India (NCC-MvPI), IPC in association with Andhra Pradesh Med-Tech Zone (AMTZ), Vishakhapatnam organized a training programme on **"Role of Biomedical Engineers in Assessment of Medical Devices Adverse Events"** on December 4, 5, 11, 12, 18, 19, 23 & 24 via digital/virtual platform. Biomedical, clinical and service engineers from different hospitals across India participated and trained in this training programme. Experts from Sree Chitra Tirunal Institute of Medical Sciences, Trivandrum (SCTIMST), Medical Device Adverse Event Monitoring Centres (MDMCs) under MvPI, Kalam Institute of Health Technology and MvPI team educated and guided the participants in this training programme.

Specific Outcomes

1. **Sensitized and well-educated the participants on following topics-**
   - *Causality Assessment: Medical Devices and IVDs*
   - *Risk Minimization and risk management guidelines: Medical devices*
   - *Post-market surveillance: Challenges and opportunity*
   - *Overview of Materiovigilance programme of India*
   - *Adverse Event Reporting: Medical Devices and IVDs*
2. **Provided hands on training to the participants on medical device adverse event reporting.**

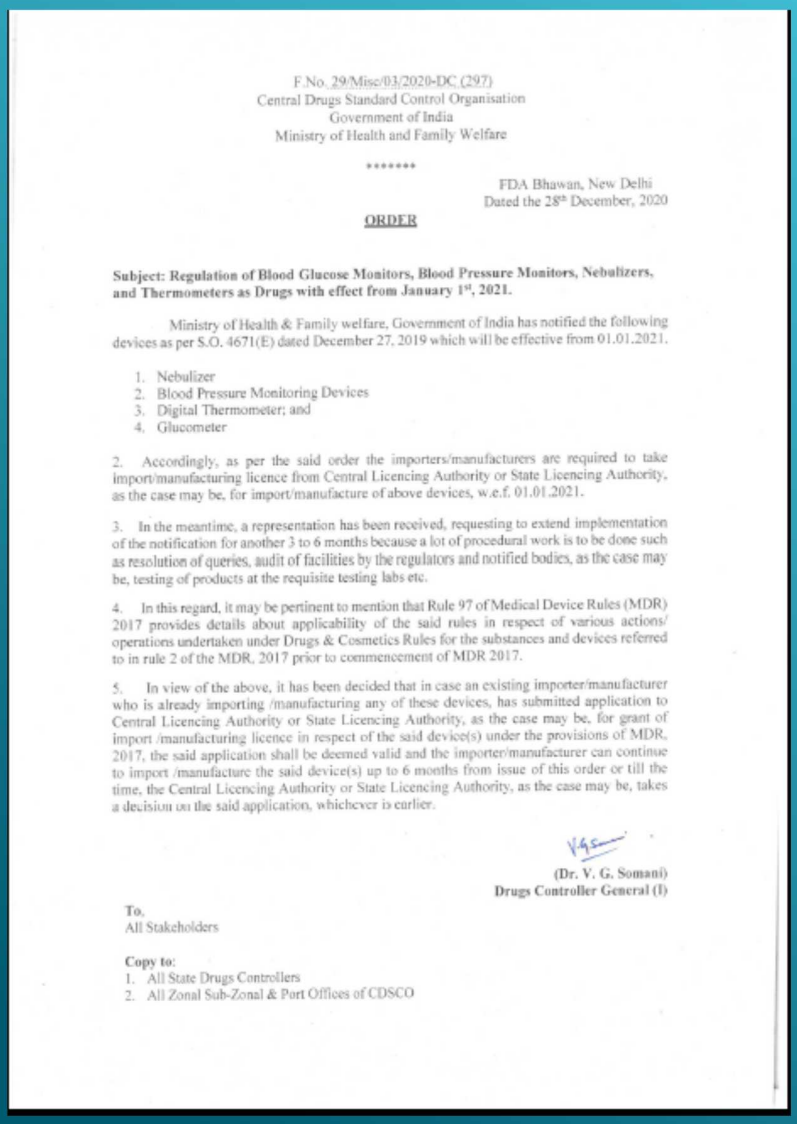


National Coordination Centre-Materiovigilance Programme of India (NCC-MvPI), IPC in association with Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh organized a webinar on**"Brain Storming Session on Causality Assessment of Medical devices"** on December 16, 2020 via digital/virtual platform. Coordinators, deputy coordinators and research associates of 52 Medical Device Adverse Event Monitoring Centres (MDMCs) participated in this webinar. Dr. V Kalaiselvan, Principal Scientific Officer (PSO), IPC gave the opening/ welcome remarks in this webinar. Dr. Bikas Medhi from PGIMER, Chandigarh sensitized the participants on Causality assessment of medical devices: Gray areas and challenges.



Doctors from different department of PGIMER, Chandigarh actively participated in this webinar. Dr. Sachin Rai from Dental department, Dr. Vishal Kumar from Orthopaedics department, Dr. Nitin James Peter from Paediatrics department, Dr. Manjul Tripathi from Neurology department and Dr. Navjot Kaur from Cardiology department respectively sensitized the participants on case studies associated with medical devices.

MEDICAL DEVICE UPDATE



F.No. 29/Misc/03/2020-DC (297)
Central Drugs Standard Control Organisation
Government of India
Ministry of Health and Family Welfare

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FDA Bhawan, New Delhi
Dated the 28th December, 2020

ORDER

Subject: Regulation of Blood Glucose Monitors, Blood Pressure Monitors, Nebulizers, and Thermometers as Drugs with effect from January 1st, 2021.

Ministry of Health & Family welfare, Government of India has notified the following devices as per S.O. 4671(E) dated December 27, 2019 which will be effective from 01.01.2021.

1. Nebulizer
2. Blood Pressure Monitoring Devices
3. Digital Thermometer; and
4. Glucometer

2. Accordingly, as per the said order the importers/manufacturers are required to take import/manufacturing licence from Central Licencing Authority or State Licencing Authority, as the case may be, for import/manufacture of above devices, w.e.f. 01.01.2021.

3. In the meantime, a representation has been received, requesting to extend implementation of the notification for another 3 to 6 months because a lot of procedural work is to be done such as resolution of queries, audit of facilities by the regulators and notified bodies, as the case may be, testing of products at the requisite testing labs etc.

4. In this regard, it may be pertinent to mention that Rule 97 of Medical Device Rules (MDR) 2017 provides details about applicability of the said rules in respect of various actions/ operations undertaken under Drugs & Cosmetics Rules for the substances and devices referred to in rule 2 of the MDR, 2017 prior to commencement of MDR 2017.

5. In view of the above, it has been decided that in case an existing importer/manufacturer who is already importing /manufacturing any of these devices, has submitted application to Central Licencing Authority or State Licencing Authority, 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 issue of this order or till the time, the Central Licencing Authority or State Licencing Authority, as the case may be, takes a decision on the said application, whichever is earlier.

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

To,
All Stakeholders

Copy to:
1. All State Drugs Controllers
2. All Zonal Sub-Zonal & Port Offices of CDSCO

CLICK HERE

Existing importer/ manufacturer who is already importing/ manufacturing of these devices (blood glucose monitors, blood pressure monitors, nebulizers and thermometers) has submitted application to Central Licencing Authority or State licencing Authority, the said application shall be deemed valid and importer/ manufacturer can continue to import/manufacture the said devices up to 6 months.

Therefore, all healthcare providers are encouraged to report adverse events associated with the use of blood glucose monitors, blood pressure monitors, nebulizers to MvPI by using the reporting form.

Safety ALERT

Perfluoro Octane (PFCL)

Perfluoro octane (PFCL) is a medical device which is used in retina surgery of eye. This device is causing adverse events (blindness/vision loss) in many countries like - Spain, Italy, Holland, Chile, Saudi Arab etc. In Spain there are more than 120 cases reported for visual loss after surgery using PFCL. The PFCL are manufactured in several countries including India and they are in market with several commercial names AlaOcta, Bio Octane etc. AlaOcta is from German Alamedics company and Bio Octane plus is made in India. Hence all the healthcare professionals are need to be vigilant while using the device and report such adverse event at the earliest to NCC-MvPI.

www.ipc.gov.in

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Website : www.ipc.gov.in

We have started a journey of Materiovigilance, for saving lives