सत्यमेव जयते

IPC

e-Newsletter

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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 and Family Welfare (MoHFW), Government of India

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New MDMCs

B.J. Medical College, Ahmedabad (Gujarat)

Bangalore Medical College & Research Institute Bangalore (Karnataka)

JJM Medical College Davanagere (Karnataka)

Jaipur National University,
Institute for Medical Devices
& Research Centre
Jaipur (Rajasthan)

Lovely Professional University
Phagwara (Punjab)

Dr. Vasantrao Pawar
Medical College Hospital &
Research Centre
Nashik (Maharashtra)

Zoram Medical College
Mizoram

Training & Education

National Coordination Centre-Materiovigilance Programme of India (NCC-MvPI) jointly supported & participated in Drug Information Association (DIA) India Medical Devices Conference 2020 "Strategies for the MedTech Revolution" at Leela Ambience Convention Hotel, New Delhi India on February 21-22, 2020.

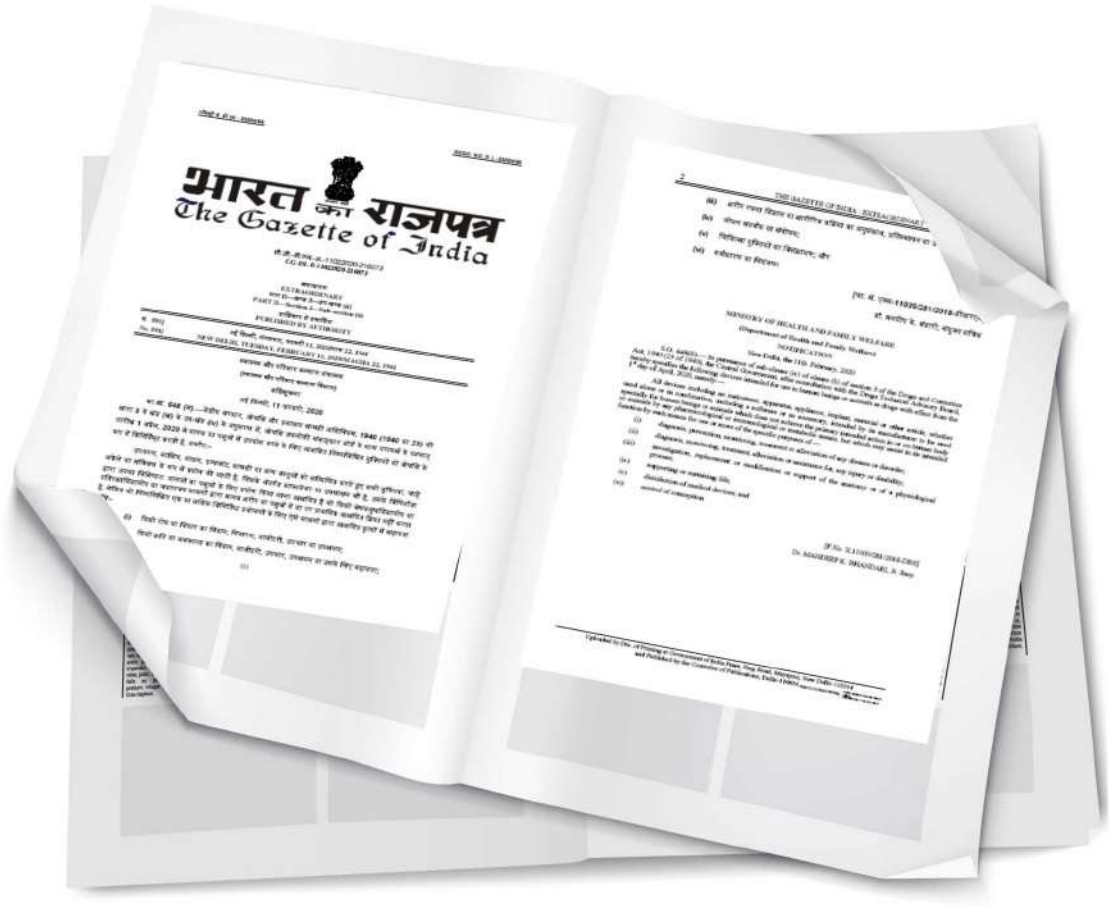
Dr. V Kalaiselvan, Principal Scientific Office (PSO), IPC sensitized the audience on "Medical Device Safety Surveillance System in India".

Seminar on Medical Devices Safety Organised by School of Tropical Medicine, Kolkata on February 20, 2020

School of Tropical Medicine, Kolkata, a Medical Device Monitoring Centre (MDMC) under Materiovigilance Programme of India (MvPI), convened a brief training on Medical Devices Safety on February 20, 2020. The purpose was to sensitize relevant stakeholders regarding the ongoing MvPI activities and to promote the culture of safety among actual/potential device users. Seminar was attended by the doctors, biomedical engineers, hospital administrators, healthcare quality professionals and researchers representing public and private hospitals in Kolkata.

CDSCO published new definition for Medical Device

https://ipc.gov.in/images/Pdf_for_page_No-6.pdf



ADVISORY NOTICE

NCC-MvPI has observed 23 adverse events including genital hemorrhage and device expulsion associated with the use of Mirena-Intra-uterine Contraceptive Devices (IUCD) of the same batch (TU02H2).Hence, all the stakeholders are to be vigilant while using the said device of similar batch and report such adverse event at earliest.

IPC directs all MDAE centres to keep tab on SAEs due to faulty medical devices used by healthcare staff and patients to tackle COVID-19

The Indian Pharmacopoeia Commission (IPC) on behalf of the Materiovigilance Programme of India (MvPI) has sent circulars to all the 50 medical device adverse event (MDAE) reporting centres in the country to keep a check on serious adverse events (SAEs) due to faulty ventilators or personal protective equipment (PPE) used by the healthcare staff and patients to tackle COVID-19.

It is also in the process of sending circulars across all the Indian Council of Medical Research (ICMR) labs conducting IVD tests to report SAEs to tackle COVID-19 effectively. PPE includes protective clothing, helmets, goggles, or other garments or equipment designed to protect the wearer's body to minimize exposure to specific hazards. PPE also includes respirators, gloves, aprons, fall protection, and full body suits, as well as head, eye and foot protection. Using PPE is only one element in a complete hazard control program that would use a variety of strategies to maintain a safe and healthy environment.

In order to help IPC, facilitate baseline study of products available with medical devices companies in India and assure patient safety, the Union health ministry has also directed medical device manufacturers to register at medical devices information sharing portal through hyperlink -www.mvpi.co.in. This portal which would serve the purpose as an India specific tool has been developed in consultation with Central Drugs Standard Control Organisation (CDSCO) to ensure that safe medical devices are available in the country.

Till now, MvPI has set up 50 exclusive centres under it to collect and disseminate reporting of adverse events due to medical devices at the point of care besides the over 250 adverse drug reaction monitoring centres (AMCs) across the country. MDAE Reporting form launched by IPC will help generate independent, evidence-based recommendations on the safety of medical devices and to communicate the findings to all key stakeholders. The reporting form includes adverse event details, severity of the event, date, location, device category, model of the device available with the organisation, its use after the event, name of medical device, manufacturer, brand name, model number, serial number, batch number etc.

Government

PUBLIC NOTICE

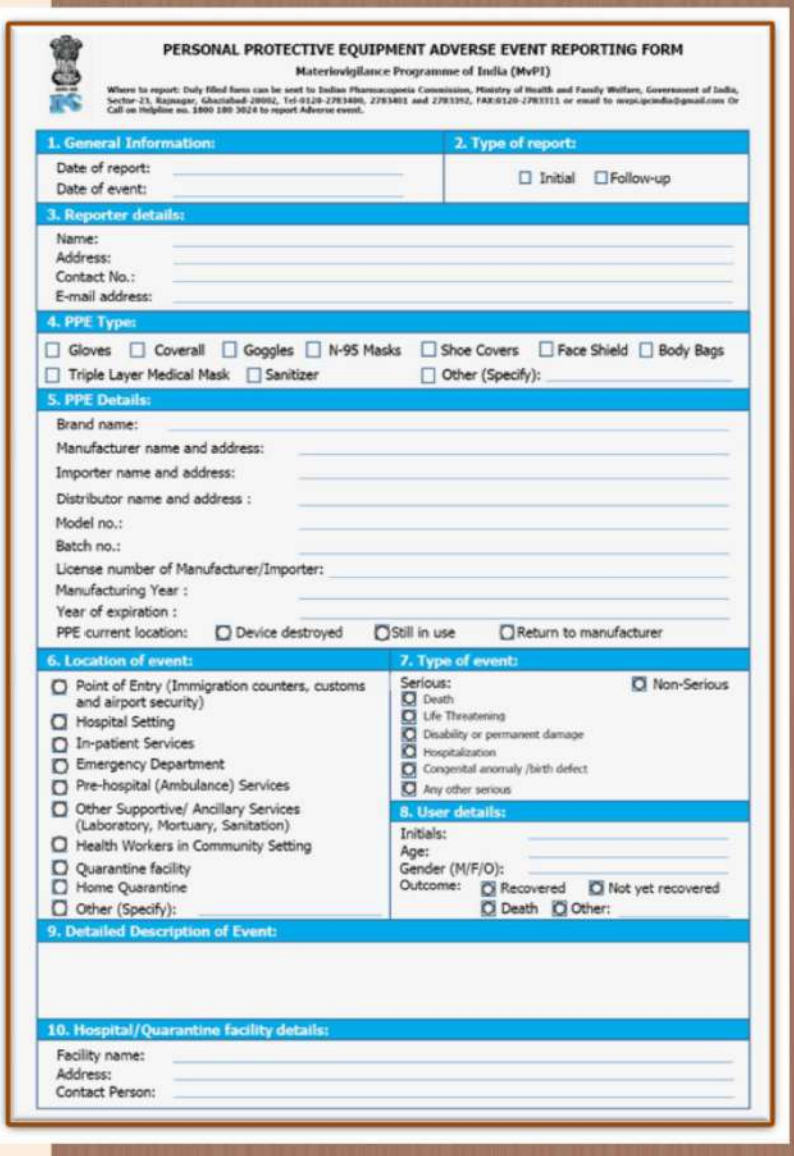
Indian Council of Medical Research (ICMR) Department of Health Research, Ministry of Health and Family Welfare, Government of India approved government as well as private laboratories for the testing of COVID-19 Pandemic

https://ipc.gov.in/images/Pdf_for_page_No-9.pdf

New Adverse Event Reporting Tool

NCC-MvPI

specially designed a one page Adverse Event Reporting form for Personal Protective Equipments (PPEs)



PERSONAL PROTECTIVE EQUIPMENT ADVERSE EVENT REPORTING FORM

Materiovigilance Programme of India (MvPI)

Where to report: Duly filled form can be sent to Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Sector-23, Raj nagar, Ghaziabad-20002, Tel-0120-2783400, 2783401 and 2783392, FAX:0120-2783333 or email to mvpi.ipcindia@gmail.com Or Call on Helpline no. 1800 180 3024 to report Adverse event.

1. General Information:

Date of report:
Date of event:

2. Type of report:

☐ Initial ☐ Follow-up

3. Reporter details:

Name:
Address:
Contact No.:
E-mail address:

4. PPE Type:

☐ Gloves ☐ Coverall ☐ Goggles ☐ N-95 Masks ☐ Shoe Covers ☐ Face Shield ☐ Body Bags
☐ Triple Layer Medical Mask ☐ Sanitizer ☐ Other (Specify):

5. PPE Details:

Brand name:
Manufacturer name and address:
Importer name and address:
Distributor name and address :
Model no.:
Batch no.:
License number of Manufacturer/Importer:
Manufacturing Year :
Year of expiration :
PPE current location: ☐ Device destroyed ☐ Still in use ☐ Return to manufacturer

6. Location of event:

☐ Point of Entry (Immigration counters, customs and airport security)
☐ Hospital Setting
☐ In-patient Services
☐ Emergency Department
☐ Pre-hospital (Ambulance) Services
☐ Other Supportive/ Ancillary Services (Laboratory, Mortuary, Sanitation)
☐ Health Workers in Community Setting
☐ Quarantine facility
☐ Home Quarantine
☐ Other (Specify):

7. Type of event:

Serious: ☐ Non-Serious
☐ Death
☐ Life Threatening
☐ Disability or permanent damage
☐ Hospitalization
☐ Congenital anomaly /birth defect
☐ Any other serious

8. User details:

Initials:
Age:
Gender (M/F/O):
Outcome: ☐ Recovered ☐ Not yet recovered ☐ Death ☐ Other:

9. Detailed Description of Event:

10. Hospital/Quarantine facility details:

Facility name:
Address:
Contact Person:

CLICK HERE

Feedback

Materiovigilance Expert Committee (MEC) was constituted with the approval of Director, AIIMS Bhopal. MEC is working actively for root-cause analysis and completeness of reported MDAE Form. Training was imparted to Materiovigilance Expert Committee (MEC), constituted at AIIMS, Bhopal on February 2020. Training sessions were held for Senior Nursing Officers (SNO) as well as healthcare professionals (HCPs) trained to increase the awareness regarding the materiovigilance activities in our institution. Training was imparted with special emphasis on filling of Materiovigilance Adverse Event Reporting Form. In addition, they were sensitized for Baseline surveys being done and the recalls activities based upon the inputs. Further, disseminated the information regarding Materiovigilance alerts been percolated to us from time to time and the needful to be taken in that regards. Also took inputs regarding similar or any other adverse event experience by them and reporting of the same to MDMC centre. We had also organized sessions for departmental postgraduate students, tutors & faculty in the month of January 2020. Tutors & residents are posted in different clinical departments/ wards and pre & para-clinical departments for reporting of MDAE on day-to-day basis.

www.ipc.gov.in

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For any other Information/Suggestion Query Contact:
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Email : lab.ipc@gov.in, mvpi.ipcindia@gmail.com
Website : www.ipc.gov.in

We have started a journey of Materiovigilance, for saving lives