



e-Newsletter

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Materiovigilance Programme of India



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Materiovigilance Programme of India
Indian Pharmacopoeia Commission
Ministry of Health and Family Welfare (MoHFW)
Government of India



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Medical Device Monitoring Centres



Training & Education

Department of Pharmacology, Government Medical College, Jammu organised an e-CME training on Materiovigilance Programme of India (MvPI) on August 7, 2020 by virtual mode in order to spread awareness about the programme. Dr. V Kalaiselvan, Principal Scientific Officer, IPC gave the opening remarks. Dr. Shatrúnajay Shukla, Scientific Assistant, IPC sensitized the audience about “**Materiovigilance Programme of India**”. Miss. Amrutha, Scientist C, Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) sensitized the audience about “**Causality Assessment: Medical Device & IVDs**”. The e-CME was attended by around 90 delegates from Government Medical Colleges across India including Jammu & Kashmir. Dr. Jai Prakash, Secretary-cum-scientific Director, IPC gave the concluding remarks.



Glimpse of Doctors & Students during e-CME

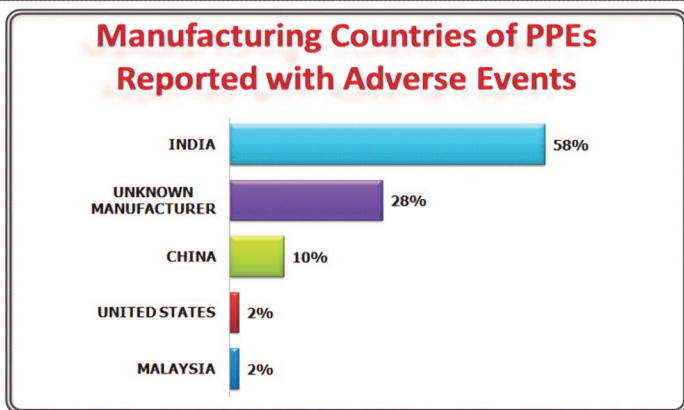
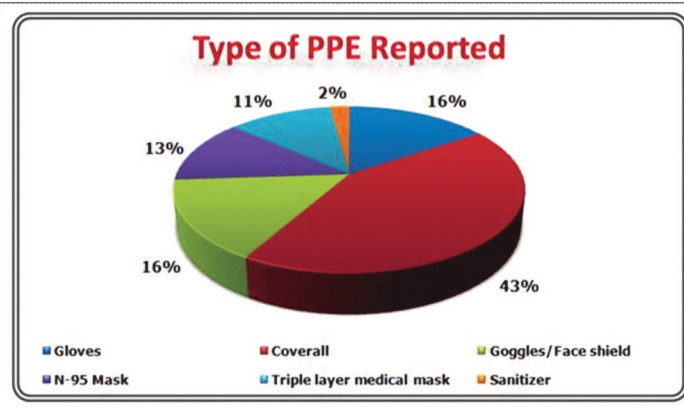
Medical Device Updates

SARS-COV-2 virus outbreak leads to rapid growth in demand and supply of PPEs in the country & abroad. In order to keep up growing demand, several Indian companies started manufacturing PPE Kits. It has been observed that many manufacturers are not complying with the Government guidelines & PPEs are being sold & being distributed in the market without proper testing & non-complying with the required standards. To facilitate boost in adverse event reporting associated with PPEs, NCC-MvPI has developed one page electronically fillable adverse event reporting form specifically for PPEs. In response, Medical Device Adverse Event Monitoring Centres (MDMCs) and Adverse Drug Reaction Monitoring Centres (AMCs) are actively participating in reporting of adverse events associated with PPEs. NCC-MvPI observed that in 64% of the reported PPEs, the essential information including lot number/batch number, unique certification code (UCC), test standards, manufacturing date, expiry date were not mentioned. Which indicates that in most of the PPEs manufacturing, the quality norms are not being followed as per Government of India (GoI) guidelines.

Highest number of reported adverse events (43%) were associated with coveralls causing excessive sweating issue, dehydration, tearing of fabric material and skin allergies.

In 58% of total reports, PPEs were manufactured indigenously. Whereas in 28% reports the name of manufacturer were not mentioned on the PPE kit. 10% PPE devices were manufactured in China and 2% PPEs were manufactured in United states of America and 2% from Malaysia.

It was also observed that 84% of the adverse events occurred within the healthcare facility (including 37% in the in-patient service, 11% in the emergency department and 36% in the other department of the hospital). 2% of all the events occurred during home quarantine, whereas in 14% of the reports the location of event was not mentioned.



Trend analysis of reported PPEs with adverse events



Reference Manual for Medical Devices 2020

NCC-MvPI, Ministry of Health & Family Welfare, Govt. of India made available printed version of Reference Manual for Medical Devices to the stakeholders. The interested stakeholder can get a copy at the cost of Rs. 4000/- INR.

MODE OF PAYMENT - The payment can be made either through Demand Draft or NEFT/RTGS :

Through Demand Draft (DD) :

The payment can be made through Demand Draft drawn in favour of "Indian Pharmacopoeia Commission" payable at Ghaziabad (Uttar Pradesh).

Through NEFT/RTGS : The payment can be transfer to the below mentioned account :

A/c Holder Name : Indian Pharmacopoeia Commission

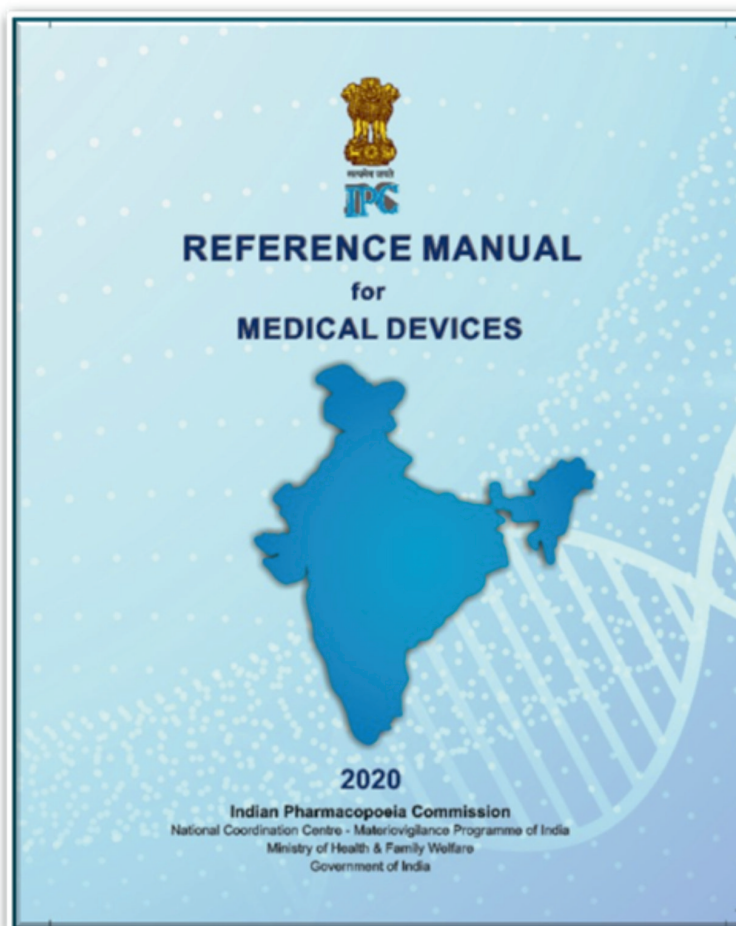
Account No. : 21860100013540

Bank Name : Bank of Baroda

Branch Name : Sanjay Nagar,
Ghaziabad,
Uttar Pradesh, India

IFSC Code : BARB0SANGHA
(0 → Denoting Zero)

Swift Code : BARBINBBGHA



NOTE : Kindly inform us at our e-mail ID: lab.ipc@gov.in and ipcpub@gmail.com before / after money transaction along with GSTIN No. (if registered), UTR No. and complete postal address for further necessary action.

New Update

Personal Protective Equipment Adverse Event Reporting Form



NCC-MvPI updated Personal Protective Equipment (PPEs) adverse event reporting form to collate all the relevant information related to PPEs.

Version no. 1.1

PERSONAL PROTECTIVE EQUIPMENT ADVERSE EVENT REPORTING FORM
Materiovigilance Programme of India (MvPI)

Where to report: Daily filled form can be sent to Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Sector-13, Rohtak, Haryana-124001. Tel: 011-2783400, 2783401 and 2783392, Fax: 011-2783311 or email to ncpi@ipcd@gmail.com Or Call on Helpline no. 1800 180 3024 to report Adverse event.

1. General Information:		2. Type of report:	
Date of report:		<input type="checkbox"/> Initial <input type="checkbox"/> Follow-up (Ref. no. _____)	
Date of event:			
3. Reporter details:			
Name:			
Address:			
Contact No.:			
E-mail address:			
4. PPE Type:			
<input type="checkbox"/> Gloves <input type="checkbox"/> Coverall <input type="checkbox"/> Goggles <input type="checkbox"/> N-95 Masks <input type="checkbox"/> Shoe Covers <input type="checkbox"/> Face Shield <input type="checkbox"/> Body Bags <input type="checkbox"/> Triple Layer Medical Mask <input type="checkbox"/> Sanitizer <input type="checkbox"/> Other (Specify):			
5. PPE Details:			
Brand name:			
Manufacturer name and address:			
Importer name and address:			
Distributor name and address:			
Marketed by:			
License No. / Registration No.:		Batch No.:	
Model No.:		Test Standard:	
Unique Certification Code:		Expiry Date:	
Manufacturing Date:			
PPE Current Location: <input type="checkbox"/> Device destroyed <input type="checkbox"/> Still in use <input type="checkbox"/> Return to manufacturer			
6. Location of event:		7. Type of event:	
<input type="checkbox"/> Point of Entry (Immigration counters, customs and airport security) <input type="checkbox"/> Hospital Setting <input type="checkbox"/> In-patient Services <input type="checkbox"/> Emergency Department <input type="checkbox"/> Pre-hospital (Ambulance) Services <input type="checkbox"/> Other Supportive/ Ancillary Services (Laboratory, Mortuary, Sanitation) <input type="checkbox"/> Health Workers in Community Setting <input type="checkbox"/> Quarantine facility <input type="checkbox"/> Home Quarantine <input type="checkbox"/> Other (Specify):		<input checked="" type="checkbox"/> Non-Serious <input type="checkbox"/> Serious: <input type="checkbox"/> Death <input type="checkbox"/> Life Threatening <input type="checkbox"/> Disability or permanent damage <input type="checkbox"/> Hospitalization / Prolonged Hospitalization <input type="checkbox"/> Congenital anomaly / birth defect <input type="checkbox"/> Any other serious	
8. User details:			
Initials:			
Age:			
Gender (M/F/O):			
Outcome: <input type="checkbox"/> Recovered <input type="checkbox"/> Not Recovered <input type="checkbox"/> Death <input type="checkbox"/> Other:			
9. Detailed Description of Event:			
10. Hospital/Quarantine facility details:			
Facility Name:			
Address:			
Contact Person:			





Publication

NCC-MvPI published an article entitled “*Materiovigilance Programme of India : A scheme to assure Cardiovascular Devices Safety*” in *Indian Heart Journal*.

[\(doi.org/10.1016/j.ihj.2020.06.009\).](https://doi.org/10.1016/j.ihj.2020.06.009)



ELSEVIER

Indian Heart Journal

Available online 1 July 2020

In Press, Corrected Proof 



Opinion Paper

Materiovigilance Programme of India: A scheme to assure cardiovascular devices safety surveillance

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<https://doi.org/10.1016/j.ihj.2020.06.009>

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Website : www.ipc.gov.in

We have started a journey of Materiovigilance, for saving lives