

Materiovigilance Programme of India (MvPI)

Objective: To improve the protection of the health and safety of patients, healthcare professionals and others by reducing the reoccurrence of an adverse event associated with the use of medical devices. Medical device can be an instrument, implant, reagent for in-vitro use intended by the manufacturer to be used, alone or in combination, for human beings.

Yenepoya Medical College Hospital (YMCH) is functioning as a **MDMC**(Medical Device Adverse Event Monitoring Centre) under National Coordination Centre – Materiovigilance Programme of India, Indian Pharmacopoeia Commission (NCC – MvPI, IPC) since Oct 6th, 2021. Each MDMC under MvPI is assigned with a Coordinator / Deputy Coordinator and a Research Associate responsible for its functioning. Coordinator has to check completeness of a valid case, failure mode effect analysis, casualty assessment and scrutinizing the Medical Device Adverse Event (MDAE) reports as per SOPs. The Research Associate is responsible for collection and follow-up of MDAEs.

Materiovigilance Expert Committee (MEC) is constituted as the following:

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| 1. Dr. Habib Rahaman A.A, Medical Superintendent | -- Chairman |
| 2. Mrs. Salma Sulthana, Biomedical Engineer | -- Member Secretary |
| 3. Dr. Zainabath T.A, Clinical Pharmacist | -- Research Associate |
| 4. Dr. ThalangaraMukhthar, SR/AMS | -- Member |
| 5. Mr. Sabith, Deputy Hospital Operations Officer | -- Member |
| 6. Mr. Nelvin Nelson, Deputy Manager, Hospital | -- Member |
| 7. HOD's / Subject Expert based on Medical Device | -- Co-opted member |
| 8. Dr. Khalida Adnan, Director, Central Laboratory | -- Member |
| 9. Mrs. Sathya Devi, Nursing Superintendent | -- Member |
| 10. Dr. VijetaThingalaya, Quality Officer | -- Member |
| 11. Mrs. Vandana, Deputy Manager Purchase/Stores | -- Member |
| 12. Mr. Ashraf, Chief Pharmacist | -- Member |
| 13. Mrs. Divya, Biomedical Engineer | -- Coordinator (MvPI) |

The committee will analyse whether the adverse events is related to suspected medical device or not, shall perform a root cause analysis and causality assessment of the adverse event and ensures the quality of the medical devices adverse events reported to NCC-MvPI. Also, the committee promotes the training or awareness programmes for the stakeholders to ensure patient/user safety.

Approved by

Dr. Habib Rahaman A.A
Medical Superintendent



INDIAN PHARMACOPOEIA COMMISSION

MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF INDIA
SECTOR-23, RAJ NAGAR, GHAZIABAD- 201 002.

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No. P.22014/01/2020-21

Dated: October 07, 2021

To

The Medical Superintendent,
Yenepoya Medical College Hospital,
Mangalore, Karnataka- 575018

Sub: Recognition as Medical Device Adverse Event Monitoring Centre (MDMC) under Materiovigilance Programme of India (MvPI)-Reg-

Sir/Madam,

This is with reference to the letter of Intent received vide your e-mail dated September 21, 2021 to participate as a Medical Device Adverse Event Monitoring Centre (MDMC) under the Materiovigilance Programme of India (MvPI). It is indeed a matter of great pleasure to bring to your kind notice that the Indian Pharmacopoeia Commission (IPC)-National Coordination Centre (NCC) has agreed, in principle, to designate your Institute as one of the MDMCs w.e.f. **October 06, 2021.**

2. Accordingly, your Centre is expected to collect and collate data on adverse events associated with medical devices under MvPI immediately and report the same to NCC, from time to time.

3. In order to ensure smooth functioning of MDMC, NCC-MvPI shall continuously provide logistics and technical support through training programmes, medical device updates, resource materials etc.

4. Based on the performance of your Center, NCC-MvPI, IPC may also provide Materiovigilance Associate at the respective center as and when required, as per norms.

Kindly acknowledge receipt of this letter and convey your acceptance via e-mail- shatrunjay.ipc@gov.in within 15 working days.

With kind regards,

Yours faithfully,

(Dr V. Kataliselvan)

Senior Principal Scientific Officer

Copy for information to: -

1. Mrs. Divya Shenoy, Coordinator, MDMC, Yenepoya Medical College Hospital, Mangalore, Karnataka.

*Indian Pharmacopoeia (I.P.) - The book of standards for drugs.
National Formulary of India (N.F.I.) - The reference book that promotes rational use of generic medicines
On path of evolving a modern scientific institution.*