

राजेश भूषण, आईएएस सचिव RAJESH BHUSHAN, IAS SECRETARY





भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health and Family Welfare
D.O.No. X.11035/429/2022-DRS

0. X.11033/429/2022-DR3 14th October 2022

Dear Colleague,

The Indian Pharmacopoeia Commission (IPC), an autonomous body under the Ministry of Health and Family Welfare, has been functioning as the National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) and Materiovigilance Programme of India (MvPI) since April, 2011 and January, 2018 respectively. IPC has also been recognized as a WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes & Regulatory Services in South-East Asia Region. The objective of PvPI and MvPI is to improve the patient safety of Indian population by monitoring the safety of the drug and medical devices and thereby reducing the risks associated with them.

- 2. In pursuance of the mandates given to IPC in so far as PvPI and MvPI are concerned, the IPC is collecting, collating and analyzing the Adverse Reactions on account of usage of drugs & medical devices, and sharing the evidence-based scientific inputs with the Central Drugs Standard Control Organization for further regulatory interventions in order to improve the patient safety.
- 3. So far, PvPI has been able to enroll 567 Adverse Drug Reaction Monitoring Centers (AMCs) and MvPI has enrolled 174 Medical Device Adverse Event Monitoring Centers (MDMCs) across the Country. These Centers are functional health facilities.
- 4. In order to expand both these programmes and scale-up the reporting of Adverse Events with the usage of drugs/medical devices, there is a need to have more and more institutions enrolled as AMCs & MDMCs in each and every district of States/Union Territories in India under PvPI and MvPI.
- 5. Recently Additional Secretary, Government of Kerala has taken an initiative to issue an order on March 10, 2022 to State Mission Director, National Health Mission, Director of Medical Education (DME), Director of Health Services (DHS), Thiruvananthapuram respectively for grant of permission to DME and DHS institutions for enrolling in to MvPI through the institutional arrangements of National Health Mission Kerala (copy enclosed).
- 6. The following are the key benefits of enrolling under MvPI:-
 - (i) Monitoring the safety of medical products through PvPI and MvPI is an ethical and professional duty of healthcare providers and hospitals;

contd 2/-

- Enrollment under the PvPI and MvPI helps minimizing the risk associated (ii) with use of medical devices and thereby ensuring the patient and user safety.;
- (iii) IPC provides technical support for the proper functioning of the Centers:
- AMCs and MDMCs may participate in various national and international (iv) training/sensitization programmes conducted periodically by NCC-MvPI. IPC; and
- It restores public confidence in Government initiatives ensuring the safety of (v) medical devices.
- In view of the above, you are requested to please take steps by issuing directions for the enrollment/active participation of all Government & Private hospitals/Medical Colleges/Clinical establishments in your state/UT for the reporting of adverse events to PvPI and MvPI. The letters of Intent are enclosed and also available on IPC website www.ipc.gov.in for enrollment/ active participation as an AMC/ MDMC under PvPI & Warm Legards. MvPI respectively.

Yours sincerely

(Rajesh Bhushan)

Encls.: A/a

To: ACS/Principal Secretaries/Secretaries (Health) of all the States/UTs