INDIAN PHARMACOPOEIA COMMISSION

National Coordination Centre- Pharmacovigilance Programme of India (PvPI)

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

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IPC/NCC-PvPI/AMC/2017-2018/ **Date: April 20, 2017**

CIRCULAR

Ministry of Health & Family Welfare (MOHFW), Government of India (GOI) has approved commencement of "Materiovigilance Programme of India (MvPI)" during February 2015 with Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Thiruvananthapuram to act as a National Collaboration Centre, Indian Pharmacopoeia Commission (IPC) Ghaziabad to act as a National Coordination Centre and National Health System Resource Centre (NHSRC), New Delhi to act as a Technical Support. Accordingly the Materiovigilance Programme of India was launched by DCG (I) on 6th July 2015 at IPC, Ghaziabad.

The Materiovigilance Programme is meant to enable safety data collection in a systematic manner so that regulatory decisions and recommendations on safe use of medical devices being used in India could be based on data generated and to monitor the "Medical Device Adverse Events (MDAE)", create awareness among health care professionals about the importance of MDAE reporting in India and to monitor the benefit-risk profile of medical devices. It is also meant to generate independent, evidence-based recommendations on the safety of medical devices and to communicate the findings to all key stakeholders.

Materiovigilance Programme of India (MvPI) specifically emphases to monitor the safety of the medical devices. The causality assessment will be taken care by the NCC-MvPI with the help of biomedical engineers, technical partners and health care professionals.

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In view of the forgoing, there is an urgent need to monitor and record Adverse Events due to use of the Medical Devices in the prescribed "Medical Device Adverse Event (MDAE)" reporting form and report to the National Coordination Centre (NCC) through VigiFlow.

Till a dedicated manpower provided and system established in MvPI, all AMCs/Pharmacovigilance Associates are hereby directed to coordinate with biomedical engineering/cardiac/orthopedic departments etc. of their respective AMCs and report Medical Device Adverse Events on day to day basis with immediate effect.

This is for strict compliance.

(Dr G. N. Singh)
Secretary-cum-Scientific Director

Copy to:

1. JS (R), MoHFW, Nirman Bhawan, New Delhi – for information
2. Dr Eshwara Reddy, JD(C), CDSCO, HQ – for information
3. Prof Y. K. Gupta- National Scientific Coordinator, IPC – for information
4. All CDSCO Zonal offices – for information
5. All AMC Coordinators – for necessary action