MED-12/30/2024-eoffice
Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Central Drugs Standard Control Organisation

(Medical Devices Division)

Dated 15 MAY 2024

CIRCULAR

As you may be aware that, currently all the Medical Devices including In-vitro diagnostic medical devices have come under the regulation under the Drugs and Cosmetics Act, 1940 and Medical Devices Rules, 2017. A License/ approval is required for the import/manufacture for marketing of the devices in the country.

The licenses are issued under the said rules with certain conditions, to ensure the quality, safety and performance of Medical Devices available in the market, as well as to ensure compliance of the Quality Management System. It is also imperative that all medical device licence holders establish robust systems and processes for the timely identification, documentation, and reporting of adverse events associated with medical devices. The Post-market surveillance (PMS) of medical devices one of the important aspects to ensure safety and performance of the medical devices. PMS supports to identify and address any potential risk or adverse event associated with the medical device. Timely reporting of the Adverse events allows for the identification of unidentifiable risks, analysing frequency of already identified risks and enabling the manufacturers and regulatory authorities to take appropriate measures to mitigate these risks and safeguard public health.

The Materiovigilance Programme of India (MvPI) launched by the Ministry of Health and Family Welfare, Government of India with the objective to improve Indian patient safety by monitoring, recording and analysing the root cause of adverse events or risks associated with the use of medical devices including in-vitro diagnostics by healthcare professionals or patients/users and suggesting regulatory bodies for appropriate action with the sole intention of improving patient safety. Indian Pharmacopeia Commission (IPC) has been entrusted with National Coordination Centre responsibilities related to Materiovigilance Programme of India (MvPI). Apart from healthcare professionals/general public/users/patients, the Medical devices industries are one of the major stakeholders of MvPI, their participation needs to be encouraged to make significant impact in the outcome.

As the MvPI is an important program for reporting of adverse events, coordinated analysis etc related to the Medical Devices including In-vitro diagnostic devices, therefore it is suggested that all the license holder should also use the MvPI platform for reporting of any Adverse events/Serious adverse events associated with the devices to enhance the procedure for identifying risk associated with Medical Devices.

In view of the above, you are requested to take appropriate action for timely reporting of adverse events related to medical devices to MvPI. Guidance documents developed for effective utilization of MvPI is available on IPC website (https://www.ipc.gov.in.). If any training is required to enhance understanding and proficiency in adverse event reporting processes, you may please contact to mvpi-ipc@gov.in.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

To: All the medical device license holders

Copy for information to:

1. Secretary-cum-Scientific Director, IPC
2. All States and Union Territories - Licensing Authority
3. Zonal/Sub zonal office of CDSCO
4. All Medical Devices Association for circulation to their members.

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