File No. PSUR-11/13/2024-eoffice (Comp. No. 17367)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(Post Marketing Drugs Safety Monitoring Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Date: 03 JUN 2026

CIRCULAR

Subject: Implementation of Pharmacovigilance (PV) System as per the requirement of Schedule M of Drugs & Cosmetics Act 1940 and the Rules made there under– regarding.

This is with reference to the Para 6.11 of Schedule M of the Drugs and Cosmetics Act, 1940 and Rules thereunder, which mandates that *"The licensee shall have a pharmacovigilance system in place for collecting, processing and forwarding the reports to the licensing authorities for information on the adverse drug reactions emerging from the use of drugs manufactured or marketed by the licensee."*

In this regard, all the stakeholders are hereby directed to ensure the establishment and maintenance of an effective pharmacovigilance system in compliance with the provision of D & C Act 1940 and the Rules made there under, & the NDCT rules 2019.

Further, officers of the CDSCO/SLA/UT administrations may verify compliance with the above requirements during the routine inspections and the other regulatory activities.

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

To:

1. All Stakeholders.

Copy to for necessary compliance

1. All State/UTs Licensing Authorities.
2. All Zonal/Sub-Zonal offices of CDSCO
3. Concerned division of CDSCO.
4. CDSCO website