



Government of Maharashtra
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File No.: FDA-13015(15)/28/2026

Date: 27/07/2026

CIRCULAR

Subject: Implementation of Pharmacovigilance System as per the provisions of Schedule M of the Drugs and Cosmetics Rules, 1945 and the Circular issued by CDSCO dated 03.06.2026.

Reference: Circular from Drug Controller General (India), File No. PSUR-11/13/2024-eoffice (Comp. No. 17367) dated 03 June 2026

The Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Government of India, has issued a Circular dated 03 June 2026 regarding the implementation of Pharmacovigilance System in accordance with Paragraph 6.11 of Schedule M of the Drugs and Cosmetics Rules, 1945.

Paragraph 6.11 of Schedule M stipulates that every licensee shall have a Pharmacovigilance System in place for collecting, processing and forwarding reports to the Licensing Authority regarding adverse drug reactions emerging from the use of drugs manufactured or marketed by the licensee.

Accordingly, all manufacturers, loan licensees, marketers, importers and other stakeholders holding licences under the Drugs and Cosmetics Act, 1940 and Rules made thereunder are hereby directed to:

1. Establish and maintain an effective Pharmacovigilance System as mandated under Paragraph 6.11 of Schedule M.
2. Collect, document, investigate, evaluate and maintain records of all suspected Adverse Drug Reactions (ADRs) relating to their products.
3. Maintain adequate documentation and Standard Operating Procedures (SOPs) relating to Pharmacovigilance activities and make the same available during inspections.

All concerned Joint Commissioners (Drugs), Assistant Commissioner (Drugs) & Drugs Inspectors are informed that compliance with the above provisions shall be verified during routine inspections and other regulatory activities.

Digitally signed by
TUKARAM H MUNDHE
Date: 03-08-2026
11:54:00

(**Tukaram Mundhe, I.A.S**)
Commissioner
Food & Drug Administration
Maharashtra State

To,

All Stakeholders in the state of Maharashtra for necessary action

Copy to: All Joint Commissioners (Drug), Assistant Commissioner (Drug) & Drugs Inspectors
to ensure compliance with the above provisions.