File No. PSUR/4/2026-eoffice
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, New Delhi
Date: 21st April 2026

Advisory

Subject: Submission of Periodic Safety Update Reports (PSURs) for New Drugs via SUGAM portal on deferred basis in case of delayed Marketing after Approval – regarding

As per the provisions of the Fifth Schedule of New Drugs and Clinical Trials Rules, 2019, and relevant guidelines issued by the Central Drugs Standard Control Organisation (CDSCO), manufacturers/importers of new drugs are required to submit Periodic Safety Update Reports (PSURs) as part of post marketing surveillance.

It has been observed that in certain instances, applicants obtain approval for marketing a new drug but launch the drug in the market at a later date and the applicant submits the PSUR data from the date of approval instead of date of launch thereby loosing valuable safety insights.

In view of the above, all manufacturers/importers are hereby directed to ensure strict compliance with the following:

1. PSUR submission timelines shall commence from the date of actual marketing of the new drug, even if approval was granted earlier.
2. Ordinarily all dosage forms and formulations as well as indications for new drugs should be covered in one periodic safety update reports. Within the single periodic safety update reports separate presentations of data for different dosage forms, indications or separate population need to be given so as to avoid duplicate submission of PSUR applications.

21/04/26
(Dr. R Chandrashekar)
Joint Drugs Controller (India)

Copy to: - **1.** All Stakeholders through the website of CDSCO.
2. All Zonal, Sub-zonal Offices of CDSCO.