April 21, 2026

CDSCO

PSUR timelines for new drugs start from the date of marketing

CDSCO's advisory of April 21, 2026 says PSUR timelines for new drugs start from the date of actual marketing, even if approval was granted earlier.

THE CENTRAL DRUGS Standard Control Organization (CDSCO), through the Post Marketing Drugs Safety Monitoring Division of the Office of the Drugs Controller General (India), Directorate General of Health Services, issued an advisory under File No. PSUR/4/2026-eoffice, dated April 21, 2026. Its subject is the submission of Periodic Safety Update Reports (PSURs) for new drugs via the SUGAM portal on a deferred basis where marketing is delayed after approval. It is signed by Dr. R Chandrashekar, Joint Drugs Controller (India), with copies to all stakeholders through the CDSCO website and to all CDSCO zonal and sub-zonal offices.

KEY FACTS

AUTHORITY

CDSCO

PUBLISHED

April 21, 2026

ISSUED BY

Central Drugs Standard Control Organization, Post Marketing Drugs Safety Monitoring Division, Office of the Drugs Controller General (India), Directorate General of Health Services

DOCUMENT

Advisory, File No. PSUR/4/2026-eoffice



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The advisory recalls that, under the Fifth Schedule of the New Drugs and Clinical Trials Rules, 2019 and relevant CDSCO guidelines, manufacturers and importers of new drugs must submit PSURs as part of post marketing surveillance. CDSCO says it has observed that some applicants obtain approval to market a new drug but launch it later, and then submit PSUR data from the date of approval instead of the date of launch, losing valuable safety insights.

CDSCO directs all manufacturers and importers to ensure strict compliance with two points. First, PSUR submission timelines shall commence from the date of actual marketing of the new drug, even if approval was granted earlier. Second, all dosage forms, formulations and indications of a new drug should ordinarily be covered in one PSUR, with separate presentations of data within it for different dosage forms, indications or separate populations, so as to avoid duplicate submission of PSUR applications.

The advisory sets no new PSUR frequency. Its body does not mention the SUGAM portal or explain the "deferred basis" in its subject. It does not say how the date of actual marketing is to be shown to CDSCO, gives no start date, and does not say what applies to PSURs already submitted from the date of approval.

Issued by	Central Drugs Standard Control Organization, Post Marketing Drugs Safety Monitoring Division, Office of the Drugs Controller General (India), Directorate General of Health Services
Document	Advisory, File No. PSUR/4/2026-eoffice
Dated	April 21, 2026
Applies to	Manufacturers and importers of new drugs
Basis cited	Fifth Schedule, New Drugs and Clinical Trials Rules, 2019, and relevant CDSCO guidelines
PSUR timelines start	From the date of actual marketing of the new drug, even if approval was granted earlier

One PSUR covers	Ordinarily all dosage forms, formulations and indications, with separate presentations of data for different dosage forms, indications or separate populations
PSUR frequency	No new frequency set
Takes effect	No date stated
Listed	CDSCO Public Notices and Circulars, April 21, 2026
Related	Draft G.S.R. 504(E), June 22, 2026 (CG-DL-E-25062026-273835): would insert a proviso in the Fifth Schedule after para 1(5)(C)(iii) on how often PSURs are submitted, from approval until the drug product is marketed, for new drugs under clauses (iv) and (v) of rule 2(1)(w); no final rule on CDSCO's list of Gazette notifications, read October 28, 2026
Signed by	Dr. R Chandrashekar, Joint Drugs Controller (India)

The advisory (PDF, 341 KB)

Source: CDSCO's own copy.

Checked against the official copy on October 28, 2026.

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Read online: indusdesk.com/cdsco/insights/psur-timelines-for-new-drugs-start-from-the-date-of-marketing/