CDSCO

New adverse reactions for lithium, phenytoin and furosemide inserts

DCGI letters of November 10, 2026 ask State and UT licensing authorities to have makers add DRESS, AGEP and dermatitis lichenoid to package inserts.

THE DRUGS CONTROLLER General (India) (DCGI) has asked every State and Union Territory licensing authority to direct manufacturers of three drugs to add a new adverse drug reaction to the package insert and promotional literature. Three letters dated November 10, 2026, all under File No. PSUR-13011(14)/1/2025-eoffice, came from the Post Marketing Drugs Safety Monitoring Division of the Central Drugs Standard Control Organization (CDSCO). Dr. Rajeev Singh Raghuvanshi, DCGI, signed them, and asked that action taken be reported back to his office.

KEY FACTS

AUTHORITY

CDSCO

PUBLISHED

November 10, 2026

ISSUED BY

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

DOCUMENTS

Three letters, File No. PSUR-13011(14)/1/2025-eoffice



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CDSCO · November 10, 2026

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Makers of Lithium Carbonate formulations are to mention "Drug Reaction with Eosinophilia and Systemic symptoms Syndrome (DRESS)". Makers of Phenytoin formulations are to mention "Acute Generalised Exanthematosus Pustulosis (AGEP)". Makers of Furosemide formulations are to mention "Dermatitis Lichenoid". The letters' subjects call these recommendations for the change in Prescribing Information Leaflets (PILs).

Each signal was found when CDSCO evaluated Periodic Safety Update Report (PSUR) data for the drug's formulations. It was examined with the Individual Case Safety Reports in the Pharmacovigilance Programme of India (PvPI) database, and discussed at the 9th Signal Review Panel of the Pharmacovigilance Programme of India (NCC-PvPI), held on November 29, 2016, which recommended adding the reaction to the PIL.

A Subject Expert Committee (SEC) then reviewed each recommendation: the SEC on Neurology & Psychiatry on March 17, 2017 for lithium carbonate and phenytoin, and the SEC on reproductive & urology on April 20, 2017 for furosemide. Each recommended that CDSCO ask the State Drugs Controllers to direct manufacturers to add the reaction to the PIL. The letters say CDSCO has considered those recommendations.

The letters give no deadline for the change and don't say whether stock already labeled may still be sold. Copies went to all Zonal and Sub Zonal Offices of CDSCO and CDSCO-HQ, JS(R) at the Ministry of Health and Family Welfare, and PvPI at the Indian Pharmacopeia Commission, Ghaziabad.

Issued by	Office of Drugs Controller General (India), Central Drugs Standard Control Organization (Post Marketing Drugs Safety Monitoring Division)
Documents	Three letters, File No. PSUR-13011(14)/1/2025-eoffice
Dated	November 10, 2026
Addressed to	All State/UT Licensing Authorities

Lithium Carbonate	Add Drug Reaction with Eosinophilia and Systemic symptoms Syndrome (DRESS)
Phenytoin	Add Acute Generalised Exanthematosus Pustulosis (AGEP)
Furosemide	Add Dermatitis Lichenoid
Where	Package insert/Promotional Literature of the drug
Signal review	9th Signal Review Panel, NCC-PvPI, November 29, 2016
Expert review	SEC Neurology & Psychiatry, March 17, 2017 (lithium carbonate, phenytoin); SEC reproductive & urology, April 20, 2017 (furosemide)
Deadline	Not stated
Signed by	Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India)

The three letters of November 10, 2026

Drug	Adverse drug reaction to add	Subject Expert Committee and meeting date
Lithium Carbonate	Drug Reaction with Eosinophilia and Systemic symptoms Syndrome (DRESS)	Neurology & Psychiatry, March 17, 2017
Phenytoin	Acute Generalised Exanthematosus Pustulosis (AGEP)	Neurology & Psychiatry, March 17, 2017
Furosemide	Dermatitis Lichenoid	Reproductive & urology, April 20, 2017

The letter (PDF, 563 KB)

Source: CDSCO's own copy.

Checked against the official copy on November 17, 2026.

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Read online: indusdesk.com/cdsco/insights/new-adverse-reactions-for-lithium-phenytoin-and-furosemide-inserts/