August 10, 2026

CDSCO

CDSCO tells states to act on unapproved enclomiphene products

CDSCO's letter of August 10, 2026 says enclomiphene and its combinations are unapproved new drugs and asks states to act against those dealing with them.

THE CENTRAL DRUGS Standard Control Organization (CDSCO), through its Enforcement & Intelligence Cell under the Directorate General of Health Services, wrote to all State/UT Drugs Controllers under F. No. ENFORC-12016(11)/2/2026-eoffice-34479. The letter is stamped August 10, 2026 and signed by Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India). Its subject is the manufacturing and marketing of unapproved drug products containing enclomiphene and its combinations. CDSCO listed it among its public notices on August 11, 2026. Copies went to all CDSCO Zonal and Sub-Zonal Offices, the Indian Drug/Pharmaceuticals Associations Forum and the CDSCO website.

KEY FACTS

AUTHORITY
CDSCO

PUBLISHED
August 10, 2026

ISSUED BY
Central Drugs Standard Control Organization, Enforcement & Intelligence Cell (Directorate General of Health Services)

DOCUMENT
Letter, F. No. ENFORC-12016(11)/2/2026-eoffice-3

CDSCO tells states to act on unapproved enclomiphene products

CDSCO · August 10, 2026

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The letter says certain manufacturers are manufacturing and/or marketing drug products containing enclomiphene and its combinations without the requisite permission from the Central Licensing Authority (CLA), although such products fall within the definition of a "New Drug" under the New Drugs and Clinical Trials Rules, 2019. It cites rule 2(1)(w) read with rule 19 of those Rules: no new drug shall be manufactured for sale or distribution unless the CLA has granted permission. Under rule 80, any person intending to manufacture a new drug, as an Active Pharmaceutical Ingredient (API) or as a pharmaceutical formulation for sale or distribution, must obtain prior permission from the CLA by applying in Form CT-21, with the fee specified in the Sixth Schedule.

CDSCO states that enclomiphene and its combinations have not been approved by the CLA for manufacture and marketing in the country. So any manufacture, sale, distribution or marketing of such products without the CLA's prior approval is to be treated as non-compliance with the New Drugs and Clinical Trials Rules, 2019 and the Drugs and Cosmetics Act, 1940.

State/UT Drugs Controllers are asked to identify, immediately, the manufacturers, marketers, distributors and retailers dealing with such products without the CLA's approval. They are to start regulatory action under the Drugs and Cosmetics Act, 1940 and the rules made under it, including cancellation or suspension of manufacturing permissions wherever applicable, and to ensure the products are not manufactured, sold, distributed or marketed in their jurisdictions. Their action taken report, with details of the manufacturers identified, the regulatory action started and the present status of compliance, is to reach CDSCO "at the earliest". The letter sets no date for it.

The letter does not mention import of enclomiphene or its combinations. It does not identify any manufacturer or product, give any dose, strength or dosage form, or say what is to happen to stock already made or sold. It does not say whether any application for permission is pending, and it sets no date from which it applies.

Issued by	Central Drugs Standard Control Organization, Enforcement & Intelligence Cell (Directorate General of Health Services)
Document	Letter, F. No. ENFORC-12016(11)/2/2026-eoffice-34479
Dated	August 10, 2026 (date stamp)
Addressed to	All State/UT Drugs Controllers
Applies to	Manufacturers, marketers, distributors and retailers of drug products containing enclomiphene and its combinations
Status of enclomiphene	A "New Drug" under the New Drugs and Clinical Trials Rules, 2019, not approved by the Central Licensing Authority for manufacture and marketing in the country
Rules cited	Rule 2(1)(w) read with rule 19, and rule 80, of the New Drugs and Clinical Trials Rules, 2019; the Drugs and Cosmetics Act, 1940
Permission to manufacture	Form CT-21 to the Central Licensing Authority, with the fee in the Sixth Schedule, for a new drug as an API or a pharmaceutical formulation
Action asked of states	Identify manufacturers, marketers, distributors and retailers dealing with the products without the Central Licensing Authority's approval; start regulatory action, including cancellation or suspension of manufacturing permissions wherever applicable
Action taken report	To CDSCO "at the earliest"; no date set
Takes effect	No date stated; states are asked to act immediately
Listed	CDSCO public notices, August 11, 2026
Copies to	All CDSCO Zonal/Sub-Zonal Offices; Indian Drug/Pharmaceuticals Associations Forum; CDSCO website
Signed by	Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India)

The letter (PDF, 588 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/cdsco-tells-states-to-act-on-unapproved-enclomiphene-products/