F. No. ENFORC-12016(11)/2/2026-eoffice-34479
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Enforcement & Intelligence Cell)

FDA Bhawan, New Delhi

10 AUG 2026

To,

All State/UT Drugs Controllers.

Sub: Manufacturing and marketing of unapproved drug products containing Enclomiphene and its combinations – Reg.

Sir/Madam,

It has been brought to the notice of this Directorate that certain manufacturers are manufacturing and/or marketing drug products containing **Enclomiphene and its combinations** without obtaining the requisite permission from the Central Licensing Authority (CLA), despite such products falling within the definition of a **"New Drug"** under the provisions of the New Drugs and Clinical Trials Rules, 2019.

As per Rule 2(1)(w) read with Rule 19 of the New Drugs and Clinical Trials Rules, 2019, no new drug shall be manufactured for sale or distribution unless it has been granted permission by the Central Licensing Authority. Further, as per Rule 80 of the said Rules, any person intending to manufacture a new drug, whether as an Active Pharmaceutical Ingredient (API) or as a pharmaceutical formulation for sale or distribution, shall obtain prior permission from the Central Licensing Authority by submitting an application in **Form CT-21**, along with the prescribed fee specified in the Sixth Schedule.

It has been observed that **Enclomiphene and its combinations have not been approved by the Central Licensing Authority for manufacture and marketing in the country**. Accordingly, any manufacture, sale, distribution, or marketing of such products without prior approval of the Central Licensing Authority shall be treated as non-compliance with the provisions of the New Drugs and Clinical Trials Rules, 2019, and the Drugs and Cosmetics Act, 1940.

In view of the above, all State/UT Drugs Controllers are requested to immediately identify manufacturers, marketers, distributors, and retailers dealing with drug products containing **Enclomiphene and its combinations** without the requisite approval of the Central Licensing Authority, initiate appropriate regulatory action as per the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder, including cancellation or suspension of manufacturing permissions, wherever applicable, and ensure that such unapproved products are not manufactured, sold, distributed, or marketed within their respective jurisdictions.

The action taken report, including details of manufacturers identified, regulatory action initiated, and the present status of compliance, may kindly be furnished to this Directorate at the earliest.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Copy for information and necessary action to:

1. All CDSCO Zonal/Sub-Zonal Offices.
2. Indian Drug/Pharmaceuticals Associations Forum.
3. Website of CDSCO