

IT/MISC/001/2026
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
O/o Drugs Controller General (I)

FDA Bhawan, New Delhi
Date: 06.03.2026

CIRCULAR

Subject: Implementation of Prior intimation System for Forms CT-10, CT-12 and CT-13 in pursuance of G.S.R. 46(E) dated 20.01.2026 – reg.

In pursuance of Gazette Notification G.S.R. 46(E) dated 20th January 2026, amendments have been made to the New Drugs and Clinical Trials Rules, 2019 introducing the system of “**prior intimation**”.

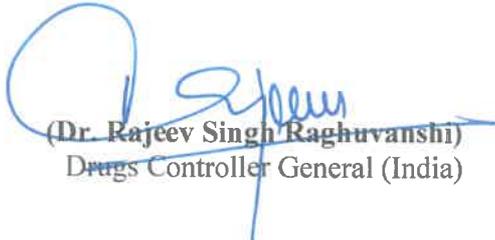
Accordingly, it is hereby informed that all the stakeholders shall submit application for **analytical and non-clinical testing** in Forms CT-10, CT-12 and CT-13 as the case may be at NSWS portal (www.nsws.gov.in) for the “**prior intimation**” purpose as specified in the above gazette notification.

It is hereby further informed that, as mentioned in gazette notification, this **prior intimation system shall not apply** to the following categories:

- Sex hormones
- Cytotoxic drugs
- Beta-lactam drugs
- Biologics containing live microorganisms
- Narcotic and Psychotropic substances

It may also be noted that once the application in requisite form is submitted at NSWS portal, the acknowledgment of application submission received from the portal/email may be treated as a **prior intimation** and the concerned applicant can accordingly use this intimation for further use as required. *For all other purposes or categories not covered under the amended rules, the system of prior approval shall remain applicable.*

This circular is issued for information and compliance by all stakeholders.


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

Copy for information and necessary action to:

1. All Divisions, Zonal/Sub-Zonal offices of CDSCO.
2. All State/UT Drug Controllers.
3. US(DR) Section
4. Office of JS(DR)
5. All stake holders though CDSCO website.