

**F.NoDC-DT-15011(11)/125/2025-eoffice
Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
(BA/BE for Export Division)**

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated

22 MAY 2026

Notice

Subject: BE-NOC Prior Intimation (System of Notification for certain category of new drugs for conduct of “BA-BE Studies” for export purpose under Chapter V, NDCT Rule, 2019) and procedure for obtaining CT-16 application on NSWS Portal.

This office has received representations from various stakeholders regarding the non-availability of system linkage between the Prior Intimation (PI) application submitted through Form CT-05 on the Sugam Portal and the corresponding Form CT-16 application filed through the Sugam portal for import of Reference Listed Drug (RLD)/Investigational Medicinal Product (IMP) intended for conduct of BA/BE studies for export purposes.

In view of the implementation of notification issued vide GSR 50(E) dated 21.04.2026 and considering the operational difficulties faced by applicants, the following procedure shall be followed until further orders.

Procedure for Submission


Applicants intending to import RLD/IMP for conduct of BA/BE studies for export purpose shall submit a stand alone Form CT-16 application through the NSWS portal along with the following documents:

1. Covering letter explaining the purpose of import and reference details of Prior Intimation application;
2. Copy of acknowledged Prior Intimation (Form CT-05) generated through Sugam Portal;
3. Complete details of the proposed RLD/IMP to be imported;
4. Copy of protocol /synopsis/reference details, wherever applicable;
5. Challan of requisite fee as prescribed under Schedule VI of NDCT Rules, 2019, paid through Bharat-Kosh portal;
6. Any other supporting document required in NSWS Checkpoint list by the concerned CDSCO Zonal/Sub-Zonal Office.

Important Clarification

Submission of standalone Form CT-16 application under this notice shall be treated as interim procedural arrangement to resolve the issue faced by applicants on the subject matter and shall not exempt applicants from compliance with provisions of the New Drugs and Clinical Trials Rules, 2019 and other applicable regulatory requirements.

All concerned CDSCO Zonal/Sub-Zonal Offices are requested to process such applications on priority basis till further orders.



(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licensing Authority

To:

BABE centres/ CROs /Concerned stakeholders.

Copy to:

- 1.All Zonal/Sub-Zonal office of CDSCO.
- 2 BA/BE export division, CDSCO HQ.