May 22, 2026

CDSCO

Imports for export BA/BE studies need a standalone CT-16 on NSWS

A CDSCO notice of May 22, 2026: applicants importing an RLD or IMP for export BA/BE studies file a standalone Form CT-16 on NSWS, with the CT-05 acknowledgment.

THE CENTRAL DRUGS Standard Control Organization (CDSCO), Directorate General of Health Services, Ministry of Health & Family Welfare, issued this notice from its BA/BE for Export Division under F.No. DC-DT-15011(11)/125/2025-eoffice, with a date stamp of May 22, 2026. It deals with prior intimation for bioavailability and bioequivalence (BA/BE) studies of certain new drugs for export, under Chapter V of the New Drugs and Clinical Trials (NDCT) Rules, 2019. It also sets how to file the Form CT-16 application on the National Single Window System (NSWS) portal. It is addressed to "BABE centres/ CROs /Concerned stakeholders" and signed by Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India) and Central Licensing Authority.

KEY FACTS

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CDSCO says it received representations from stakeholders that there is no system linkage between a prior intimation (PI) application submitted in Form CT-05 on the Sugam portal and the matching Form CT-16 application, also filed on Sugam, to import a Reference Listed Drug (RLD) or Investigational Medicinal Product (IMP) for export BA/BE studies. Citing the implementation of the notification "GSR 50(E) dated 21.04.2026" and the operational difficulties applicants face, it sets a procedure to be followed until further orders. CDSCO's circular of April 20, 2026 gives G.S.R. 50(E) as dated January 21, 2026, with its prior intimation system for Form CT-05 (for export purpose only) in force from April 21, 2026.

Applicants who intend to import an RLD or IMP for BA/BE studies for export must submit a standalone Form CT-16 application through the NSWS portal. They attach six documents: a covering letter explaining the purpose of import and the reference details of the prior intimation application; a copy of the acknowledged prior intimation in Form CT-05, generated through the Sugam portal; complete details of the RLD or IMP to be imported; a copy of the protocol, synopsis or reference details, wherever applicable; the challan for the fee prescribed under Schedule VI of the NDCT Rules, 2019, paid through the Bharat-Kosh portal; and any other supporting document the concerned CDSCO zonal or sub-zonal office requires in the NSWS checkpoint list.

The notice treats a standalone Form CT-16 application under it as an interim procedural arrangement to resolve the issue applicants face. It does not exempt applicants from complying with the New Drugs and Clinical Trials Rules, 2019 and other applicable regulatory requirements. CDSCO's zonal and sub-zonal offices are asked to process these applications on priority basis till further orders. Copies went to them and to the BA/BE export division at CDSCO headquarters.

The notice sets no end date and no processing time, and states no fee amount. It does not say what happens to Form CT-16 applications already filed on Sugam. A later draft, G.S.R. 790(E) of September 3, 2026, would omit the words "(for export purpose only)" from the proviso to rule 31(2) of the NDCT Rules, 2019, which provides for prior intimation; it does not mention Form CT-16 or the NSWS portal.

Issued by	Central Drugs Standard Control Organization (BA/BE for Export Division), Directorate General of Health Services, Ministry of Health & Family Welfare
Document	Notice, F.No. DC-DT-15011(11)/125/2025-eoffice
Dated	May 22, 2026
Applies to	Applicants importing a Reference Listed Drug (RLD) or Investigational Medicinal Product (IMP) for BA/BE studies for export, after a prior intimation in Form CT-05 on the Sugam portal
Application	A standalone Form CT-16 application through the NSWS portal
Documents to attach	Covering letter with the purpose of import and the prior intimation's reference details; acknowledged prior intimation (Form CT-05) from Sugam; details of the RLD or IMP; protocol, synopsis or reference details, wherever applicable; fee challan under Schedule VI of the NDCT Rules, 2019, paid through Bharat-Kosh; any other document in the NSWS checkpoint list
Takes effect	Not stated; the procedure is to be followed until further orders
Status	An interim procedural arrangement; no exemption from the New Drugs and Clinical Trials Rules, 2019
Processing	CDSCO zonal and sub-zonal offices to process these applications on priority basis till further orders
Cites	"GSR 50(E) dated 21.04.2026"; CDSCO's circular of April 20, 2026 dates G.S.R. 50(E) January 21, 2026, in force from April 21, 2026
Related	Draft G.S.R. 790(E), September 3, 2026: would omit "(for export purpose only)" from the proviso to rule 31(2) of the NDCT Rules, 2019
Signed by	Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India), Central Licensing Authority

The notice (PDF, 3.5 MB)

Source: CDSCO's own copy.

Checked against the official copy on October 28, 2026.

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