
August 10, 2026

CDSCO

New drugs approved nowhere go to CDSCO's IND Division

CDSCO's August 10, 2026 circular sends applications to import and market new drugs approved nowhere, based on Phase III global trials, to its IND Division.

THE CENTRAL DRUGS Standard Control Organization (CDSCO), through its New Drugs Division under the Directorate General of Health Services, has issued a circular under F. No. ND-11011(13)/2/2026-eoffice. It is stamped August 10, 2026, signed by Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (I), and addressed to all stakeholders

through the CDSCO website. Its subject is a clarification on the submission of applications for grant of permission to import and market new drugs not approved anywhere in the world, where Phase III Global Clinical Trials (GCT) are ongoing or completed with the participation of Indian subjects, under the New Drugs and Clinical Trials Rules, 2019.

KEY FACTS**AUTHORITY****CDSCO**

PUBLISHED**August 10, 2026**

ISSUED BY

Central Drugs Standard Control Organization, New Drugs Division (Directorate General of Health Services)

DOCUMENT

Circular, F. No. ND-11011(13)/2/2026-eoffice

New drugs approved nowhere go to CDSCO's IND Division

CDSCO · August 10, 2026

The Central Drugs Standard Control Organization (CDSCO), through its New Drugs Division under the Directorate General of Health Services, has issued a circular under F. No. ND-11011(13)/2/2026-eoffice. It is stamped August 10, 2026, signed by Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (I), and addressed to all stakeholders through the CDSCO website. Its subject is a clarification on the submission of applications for grant of permission to import and market new drugs not approved anywhere in the world, where Phase III Global Clinical Trials (GCT) are ongoing or completed with the participation of Indian subjects, under the New Drugs and Clinical Trials Rules, 2019.

The circular records that CDSCO has received various applications for permission to import and market new drugs that are not approved anywhere in the world, on the basis of Phase III Global Clinical Trials that are either ongoing or have been completed with the participation of Indian subjects. The matter was examined by an internal technical committee within CDSCO. After detailed deliberations, the committee opined that such investigational new drug (IND) applications, which are under review by foreign regulatory authorities, are required to be processed by the IND Division.

The reason the circular gives is that these applications require a comprehensive evaluation of non-clinical and clinical data in accordance with the provisions of the NDCT Rules, 2019. On that basis, CDSCO informs stakeholders that all such applications shall be examined and processed by the IND Division as per the applicable regulatory requirements under the NDCT Rules, 2019.

Applicants are directed to submit such applications to the IND Division, CDSCO (HQ), New Delhi. The direction covers applications for new drugs that have no approval anywhere in the world and whose Phase III Global Clinical Trials include Indian subjects, whether those trials are still ongoing or already completed. The circular gives no separate date from which the direction applies.

Issued by	Central Drugs Standard Control Organization, New Drugs Division (Directorate General of Health Services)
Document	Circular, F. No. ND-11011(13)/2/2026-eoffice
Dated	August 10, 2026
Signed by	Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (I)
Applies to	Applications for permission to import and market new drugs not approved anywhere in the world, where Phase III Global Clinical Trials are ongoing or completed with Indian subjects

Processed by IND Division, CDSCO (HQ), New Delhi
Rules New Drugs and Clinical Trials Rules, 2019
Addressed to All Stakeholders through CDSCO website

[The circular](#) (PDF, 400 KB)

Source: [CDSCO's own copy](#).

Checked against the official copy on October 20, 2026.

IndusDesk

hello@indusdesk.com · +91 98917 60000

9th Floor, Hemkunt House, Rajendra Place, New Delhi, Delhi 110008, India

Read online: indusdesk.com/cdscos/insights/new-drugs-approved-nowhere-go-to-cdscos-ind-division/