F. No. ND-11011(13)/2/2026-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
New Drugs Division

Circular

10 AUG 2026

Subject: Clarification on the submission of applications for grant of Permission to Import and Market New Drugs not approved anywhere in the world, wherein phase III Global Clinical Trials (GCT) are ongoing or completed with participation of Indian subjects under the New Drugs and Clinical Trials Rules, 2019- regarding.

It is observed that various applications have been received by this office for grant of permission to import and market new drugs that are not approved anywhere in the world on the bases of Phase III Global Clinical Trials (GCTs) are either ongoing or have been completed with the participation of Indian subjects.

The matter was examined through 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, is required to be processed by the IND Division, as these applications require a comprehensive evaluation of non-clinical and clinical data in accordance with the provisions of the NDCT Rules, 2019.

In view of the above, it is informed that all such applications shall be examined and processed by the IND Division as per the applicable regulatory requirements under the NDCT Rules, 2019.

Accordingly, the applicants shall submit such applications to IND, Division, CDSCO (HQ) New Delhi

Yours faithfully,

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

To,
All Stakeholders through CDSCO website