F. No. SND-16011(11)/102/2025-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Subsequent New Drugs Division)

FDA Bhawan, New Delhi
Dated: 0 8 OCT 2025

NOTICE

Subject: Inviting comment to ensure a level playing field in new drug approval in India-reg.

As per the New Drugs and Clinical Trials Rules,2019, for approval of a new drug approved in other country, in general, the applicant is required to conduct local clinical trial in Indian population. However, there are certain provisions under the rules under which local clinical trial may be waived.

For approval of a new drug, many a time, CDSCO receives applications from multiple applicants along with the protocol for conduct of clinical trial and bioequivalence study.

CDSCO after reviewing such applications in consultation with the SEC grant permission to conduct the Clinical trial & Bio-equivalence study with the new drug to multiple applicants.

In many such cases, it has been observed that only one applicant actively conducts clinical trial and the bioequivalence study with the new drug and submit the reports to CDSCO for its approval.

Once the new drug is approved for the first applicant based on clinical trial and bioequivalence study data, the other applicants simultaneously submit the BE study report and obtain approval for the same new drug as subsequent application.

Thus, once a new drug has been approved for the first time in India, subsequent applicants seeking approval for the same drug are not required to conduct clinical trial. Approval for such subsequent applicants is granted based on chemical and pharmaceutical data and bioequivalence study data.

Therefore, there is lack of level playing field between the first applicant who obtains approval of a new drug first time in the country based on clinical trial and bioequivalence study data and the subsequent applicants who obtain approval of the same new drug based on bioequivalence study data for whom the cost of regulatory compliance is much lesser as they are not required to conduct the clinical trial.

In order to remove the discrepancy and to encourage the development of new drug, it has been decided to deliberate the matter in consultation with the stakeholders and the concerned departments for taking appropriate decision.

This notice is intended to initiate discussion among the stakeholders. All the stakeholders are requested to provide their comments//suggestions on the subject at dci@nic.in and snd@cdsco.nic.in . This window of opportunity will close within 30 days

from the issue of this notice. Feedback received will help in formulating a balanced policy to ensure level playing field in new drug approval while fostering research and development of new drug in the country.

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

To: All Stakeholders through CDSCO website