GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
UNSTARRED QUESTION NO. 5685
TO BE ANSWERED ON 27TH MARCH, 2026

REVISION OF DRUG TESTING NORMS BY CDSCO

5685. SHRI VISHALDADA PRAKASHBAPU PATIL:
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Will the **Minister of HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether the Central Drugs Standard Control Organisation (CDSCO) has revised drug testing norms to expedite approval of pharmaceutical products, if so, the details thereof and if not, the reasons therefor;

(b) the details of the changes introduced in regulatory procedures, including timelines, documentation and testing requirements for drug approvals;

(c) the policy measures undertaken to ensure that fast-track approval mechanisms maintain safety, efficacy and quality standards, if so, the details thereof and if not, the reasons therefor;

(d) the steps taken or proposed to be taken by the Government to strengthen regulatory oversight, laboratory capacity and post-market surveillance of approved drugs; and

(e) the expected impact of these revised norms on improving access to medicines, promoting innovation and strengthening the pharmaceutical regulatory framework in the Country?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE

(SMT. ANUPRIYA PATEL)

(a) to (e): The New Drugs and Clinical Trials Rules, 2019 were amended vide G.S.R. 46(E) dated 20.01.2026 providing system of "prior intimation" instead of obtaining permission from Central Drugs Standard Control Organization (CDSCO) for manufacture of

certain categories of drugs (except certain high risk category of drugs) for analytical and non-clinical testing. This reform removes the existing requirement of pharmaceutical companies to obtain a test licence for the manufacture of small quantities these dugs intended for examination, research, or analysis purposes. This will reduce drug development timelines, and there by promote innovation.

Ministry of Health and Family Welfare and CDSCO have taken following measures to ease the regulatory landscape and fast-track approval for the manufacturing of drugs in the country;

(i) On 25.02.2026, CDSCO has issued a Guidance Document for submission of application for obtaining Manufacturing License by the Applicant based on Dossier based licensing of Drugs. The dossier based approval process promotes the transparency and ensures fairness in the decision making process. The dossier based approach is more efficient than the individual evaluation as it streamlines the process and reduces the need for redundant assessment.

(ii) On 23.02.2026, CDSCO issued a circular to fast-track approvals for new drugs by allowing No-Objection Certificates (NOCs) for laboratory testing to be issued immediately upon receipt of applications a step aimed at reducing delays in the drug approval process. Under the revised procedure, NoCs for testing new drugs at designated government laboratories shall be granted upfront, instead of waiting for prior scrutiny of detailed technical specifications.

(iii) On 21.01.2026, the Central Government notified the replacement of permission system with online intimation mechanism for BA/BE (bioequivalence/bioavailability) studies of unapproved drugs for export purpose. It removes the prior permission requirements for carrying out low risk bioavailability/bioequivalence studies for export purposes. By reducing regulatory timelines and procedural requirements, this reform provides significant benefits to manufacturers and the generic pharmaceutical industry.

(iv) On 02.01.2026, the Central government released the new Indian Pharmacopoeia (IP) 2026. Several new blood products, vaccines and anti-tuberculosis medications have been included in it.

(v) Validity period for Free Sale Certificate issued by CDSCO to exporters, has been made co-terminus with the validity of Manufacturing Licence.

(vi) In order to minimize the requirement of toxicity studies in animals, CDSCO published circular dated 29.07.2024, to accept already generated preclinical toxicity data for review. Further, the requirement of animal toxicity data needed in certain cases shall be determined on the case by case basis depending on the nature of new claims as well as the mechanism of action etc. and non-clinical data already generated with the drug in the approved claim.

(vii) In order to enable faster disposal of applications and licenses, CDSCO has issued orders for delegation of powers of certain powers under the Drugs and Cosmetics

Act, 1940 and rules thereunder to officers of the rank of Joint Drugs Controller (India) and Deputy Drugs Controller (India).

(viii) Online National Drugs Licensing System (ONDLS) portal has been developed by Centre for Development of Advanced Computing (CDAC) in coordination with CDSCO, Government of India and State/UT Drugs Regulatory Authorities which is a single window platform for online processing of various applications for manufacturing and sales licences. An online portal, SUGAM labs is in place since September 2023 for integrating the drug testing labs of the CDSCO. It automates the entire workflow for testing of Medical Products (Drugs, Vaccine, Cosmetics & Medical devices) to meet the quality specification and tracing the testing status in the laboratories.

In order to assess the regulatory compliance of drug manufacturing premises in the country, the CDSCO along with State Drugs Controllers (SDCs) have conducted Risk-Based Inspections of more than 960 premises since December, 2022 and based on findings, more than 860 actions like issuance of show cause notices, stop production order, suspension, cancellation of licenses /product licenses, warning letters have been taken by the State Licensing Authorities.

Further, more than 1100 cough syrup manufacturers and 380 blood centres have been subjected to intense audit in coordination with State authorities. Increased market surveillance sampling of syrup formulations by Central and State drugs regulators has also been done.

To strengthen the drug testing infrastructure and enhance laboratory capacity across the country, Ministry of Health and Family Welfare has implemented a Centrally Sponsored Scheme 'Strengthening of States' Drug Regulatory System (SSDRS). The scheme envisages upgrading existing State laboratories, setting up of new drug testing laboratories and upgradation of existing State drug control offices in the country. Under the SSDRS Scheme, funds totalling Rs. 756 Crore has been released to States/UTs as part of the Central Share and 19 New Drug Testing Labs have been constructed and 28 existing labs have been up-graded in various States/UTs.

For post-market surveillance of approved drugs and medical devices, the National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) at Indian Pharmacopoeia Commission (IPC) at Ghaziabad under the Ministry of Health and Family Welfare, Government of India is collecting the adverse events reports related to the medical products from different Adverse Drug Reaction Monitoring Centres of PvPI and other stakeholders across the country. These reports are analysed from time to time and medical products safety related recommendations are sent to CDSCO for taking appropriate regulatory actions.

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