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

LOK SABHA
UNSTARRED QUESTION NO. 4713
TO BE ANSWERED ON 20TH MARCH, 2026

REGULATION AND APPROVAL OF DRUGS

4713. SHRI KESINENI SIVANATH:

Will the **Minister of HEALTH AND FAMILY WELFARE** be pleased to state:

(a) the measures taken by the Government to ease the regulatory landscape for the manufacturing of drugs in the country;

(b) the number of drug approval applications received by the Central Drugs Standard Control Organisation along with the number of applications approved and currently pending during the last five years, year-wise;

(c) the average time taken for granting drug approvals along with the measures taken by the Government to expedite the approval process and address delays;

(d) the measures taken by the Government to ensure regular and professional training of officials of the Central Drugs Standard Control Organisation in order to enhance regulatory expertise; and

(e) whether the Government has initiated any digitalization efforts to ensure timely grant of drug approvals and if so, the details thereof?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SMT. ANUPRIYA PATEL)

(a) to (e): Ministry of Health and Family Welfare and Central Drugs Standard Control Organization (CDSCO) have taken following measures to ease the regulatory landscape for the manufacturing of drugs in the country;

(i) On 24.04.2025, the Central Government notified the Drugs and Cosmetics (Compounding of Offences) Rules, 2025 creating a process of compounding of certain minor offences under the Drugs and Cosmetics Act 1940. This serves to ease the regulatory burden on the industry by providing a faster and non-adversarial alternative to prosecution for eligible minor and technical offences, thereby saving time and costs and enabling quicker closure of such cases.

(ii) 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.

(iii) The New Drugs and Clinical Trials Rules were amended vide G.S.R. 46(E) dated 20.01.2026 providing system of prior intimation instead of obtaining permission from CDSCO for manufacture of certain categories 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 of certain categories drugs intended for examination, research, or analysis purposes.

(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) Online Risk Classification Module for Medical Devices (including in-vitro diagnostics) has been implemented on CDSCO′s Medical device (MD Online) Portal w.e.f. 27.11.2025. This New Risk Classification Module simplifies regulatory approval procedures for medical devices and in-vitro diagnostics. It enables applicants to seek online risk classification for devices not listed in the published classification list reducing ambiguity and ensures uniform application of Rules.

(vi) Increased the validity of Export NOC for certain drugs moving from consignment-based Export NOC to One year NOC, and automation of the process w.e.f. 15.05.2025.

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

(viii) 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.

(ix) Provisions have been made for pre-submission and post-submission meetings of the applicants with CDSCO for formal discussion and decision about case specific regulatory pathway.

The number of applications received by the CDSCO, the number of applications approved along with the number of applications under process in CDSCO during the last five years is provided below:

Calendar Year	No. of applications received	No. of applications approved	No. of applications under process in CDSCO
2021	1038	729	8
2022	913	600	39
2023	791	366	59
2024	629	237	95
2025	696	95	221

*Certain applications have been withdrawn, rejected or are with the applicants for response.

CDSCO has undertaken extensive digitalization of regulatory processes through the online portals such as cdscoonline.gov.in (SUGAM), cdscomdonline.gov.in (Medical

Devices), statedrugs.gov.in (ONDLS) and National Single Window System (NSWS). Permissions/approvals for drugs are granted by CDSCO as per Drugs & Cosmetics Act, 1940 and Rules framed thereunder based on each case through these portals.

In order to ensure regular and professional training of officials of the CDSCO and in order to enhance their regulatory expertise, a dedicated "Training Cell" division has been set-up at CDSCO Head Quarter to impart training to both Central and State drugs regulatory officials. CDSCO Training Cell has conducted 36 residential training programme at National Institute of Health and Family Welfare from October 2022 to February 2026.

The training programmes cover a wide range of regulatory topics, including new technologies, new therapies, emerging trends, Industry 4.0 technologies (AI, Robotics, Block Chain & Automation), Good Distribution Practices (GDP), revised Schedule M, Regenerative Medicines and gene therapy and other relevant regulatory areas. Training is also imparted on soft skills. In addition, trainings on WHO-GMP and ICH guidelines are conducted to strengthen regulatory capacity and align officers with international standards. Further, CDSCO also sends its officials on international trainings to upgrade their inspection skills. In addition, 13 e-training modules have been developed for regulatory officials.

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