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

LOK SABHA
UNSTARRED QUESTION NO. 3668
TO BE ANSWERED ON 13TH MARCH, 2026

CLINICAL TRIALS FOR NEW MEDICINES

†3668. SHRI ANIL FIROJIYA:

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

(a) whether clinical trials for new medicines are being conducted in the country for such serious and incurable diseases for which no complete cure is currently available and if so, the details thereof, disease-wise;

(b) whether the Government is pleased to state the names of the diseases for which trials of medicines have currently been granted approval by the Central Drugs Standard Control Organization (CDSCO) and the stages they are in, if so, the details thereof;

(c) whether the Government has an estimate as to by when the medicines of these ongoing clinical trials are likely to be made available for general use and the expected timeline thereof, disease-wise; and

(d) whether the Government proposes to implement any special policy to provide financial assistance, insurance coverage or accelerated approval mechanisms for patients suffering from incurable and rare diseases during the trials, if so, the details thereof?

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

(SMT. ANUPRIYA PATEL)

(a) to (d): Permissions for clinical trials are approved and regulated by the Central Drugs Standard Control Organisation (CDSCO) under the provisions of the Drugs and Cosmetics Act, 1940 and the New Drugs and Clinical Trials Rules, 2019. These trials cover diseases such as cancer, rare genetic disorders, neurodegenerative diseases, autoimmune disorders, infectious diseases, and other serious medical conditions.

The details of approved clinical trials, including disease indication and trial phase, are available on the Clinical Trials Registry of India (CTRI) on https://ctri.nic.in, an online registry, maintained by the Indian Council of Medical Research (ICMR).

The approval and availability of medicines for general use subsequent to clinical trials depends on the successful completion of required phases by manufacturer/importer and subsequent regulatory evaluation for safety, efficacy and quality by regulator. The timelines vary depending upon the nature of the disease, trial outcomes and regulatory review.

The Government has taken several measures to facilitate clinical research and protect patient interests. The New Drugs and Clinical Trial Rules, 2019 provides provisions for accelerated approval, waiver or relaxation of certain clinical trial requirements in specific cases such as drugs for life-threatening diseases, rare diseases and unmet medical needs under the said rules. Clinical trials conducted are multi-centric, conducted simultaneously across many centres/ states across the country. Serious Adverse Events (SAE) may occur during clinical trials due to multiple reasons depending upon the study drug, conditions of patient, concomitant drugs etc. Each case of SAE reported during conduct of CT/BA-BE study is examined as per the provisions of New Drugs and Clinical Trial Rules, 2019 for payment of compensation and free medical management on case-to-case basis.

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