GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
STARRED QUESTION No. 326
TO BE ANSWERED ON 01ST APRIL 2025

Exemption of clinical trials for approval of new drugs

326 Shri Pramod Tiwari:

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) whether Government has specified a set of five categories for new drugs that will be considered for the Indian market;
(b) if so, whether Government has authorised the exemption of local clinical trials for approval of new drugs;
(c) if so, the details thereof and the reasons therefor;
(d) whether genetic, metabolic and other differences in Indian population have been taken into account while exempting local clinical trials; and
(e) if not, the reasons therefor?

ANSWER

THE MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI JAGAT PRAKASH NADDA)

(a) to (e): A statement is laid on the Table of the House.

Statement referred to in the reply to RAJYA SABHA STARRED Q. No. 326 for answer on 1.4.2025, raised by Shri Pramod Tiwari, regarding exemption of clinical trials for approval of new drugs

The Ministry of Health and Family Welfare has informed that as per rule 101 of the New Drugs and Clinical Trials Rules, 2019 ("NDCT Rules"), the Central Licensing Authority, with the approval of the Central Government, has issued an order dated 7.8.2024 specifying the names of countries for considering waiver of local clinical trial for the approval of certain categories of new drugs under Chapter X of the NDCT Rules and for the grant of permission for conducting clinical trials under Chapter V thereof. The countries specified include the United States of America, the United Kingdom, Japan, Australia, Canada and the European Union. A copy of the order is available on the website of the Central Drugs Standard Control Organisation (CDSCO) at the link https://cdsco.gov.in/opencms/opencms/en/Notifications/Public-Notices .

The above notification would help the Central Licensing Authority in taking decision on approval of new drugs in accordance with the NDCT Rules, for improving early access to safe and effective new drugs.

All new drugs are approved by CDSCO through a rigorous process of evaluation of the data submitted and in consultation with the Subject Expert Committee for consideration of waiver of clinical trial on case-to-case basis, in accordance with the NDCT Rules, to ensure the quality, safety and efficacy of the same.

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