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

LOK SABHA
UNSTARRED QUESTION NO.1899
TO BE ANSWERED ON 06TH DECEMBER, 2024

CLINICAL TRIALS OF DRUGS

1899: SHRI MADDILA GURUMOORTHY:

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

(a) whether it is a fact that the recent decision to waive the requirement of clinical trials for drugs approved in countries like the US, UK, Japan, Australia, Canada, or the European Union has been finalized;

(b) if so, the details and the current status thereof;

(c) whether such decision is likely to impact on drug availability and affordability in the country; and

(d) the mechanisms likely to be put in place to monitor the safety and efficacy of drugs introduced in the Indian market without undergoing local clinical trials including any post-market surveillance or testing protocols that is likely to be followed and if so, the details thereof?

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

(a) to (d): As per Rule 101 of the New Drugs and Clinical Trials (NDCT) Rules, 2019, the Central Licensing Authority (CLA), with approval of Central Government, has issued order dated 07.08.2024 specifying names of countries for considering the waiver of local clinical trial for the approval of certain categories of New Drugs under Chapter X and for the grant of permission for conducting clinical trials under Chapter V of NDCT Rules, 2019. The countries specified include USA, UK, Japan, Australia, Canada and EU. The copy of order is available on the website of CDSCO i.e https://cdsco.gov.in/opencms/opencms/en/Notifications/Public-Notices/

The above notification would help CLA for taking decision on approval of New Drugs in accordance with New Drugs and Clinical Trials Rules, 2019, for improving early access of safe and effective New Drugs.

All new drugs are approved by Central Drugs Standard Control Organization through a rigorous process of evaluation of submitted data and in consultation with Subject Expert Committee for consideration of waiver of Clinical trial on case to case basis, in accordance with New Drugs and Clinical Trials Rules, 2019 to ensure the quality, safety and efficacy of such drugs.

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