GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 175
TO BE ANSWERED ON THE 05TH DECEMBER, 2023

Recruitment of people for clinical trials of new medicines

175 Shri Jaggesh:

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

(a) whether it is a fact that several international clinical trials of new medicines have overrecruited participants from India;
(b) the percentage of Indian participants in clinical trials of new medicines;
(c) whether planning to recruit a large number of participants from India for common conditions is justified;
(d) whether all trials in India have received regulatory permission;
(e) whether the process of issuing regulatory permission is being used in a casual manner; and
(f) if so, the details thereof?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a) to (d): Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health & Family Welfare has informed that as per data available for the last 06 years (from June 2017 to Sep 2023), out of 687 Global Clinical Trial (GCT) permissions granted by CDSCO, in 514 clinical trials Indian participants were about 25% or less of global participants.

(e) & (f): Applications for grant of permissions to conduct clinical trial are examined in consultation with subject expert committees. Permissions to conduct the clinical trials are issued by the CDSCO considering the recommendations of subject expert committees.

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