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

LOK SABHA
UNSTARRED QUESTION NO. 2162
TO BE ANSWERED ON 15TH DECEMBER, 2023

NEW DRUGS AND CLINICAL TRIALS (NDCT)

2162: SHRI K. NAVASKANI:

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

(a) whether the Government has taken cognizance of the fact that even though the New Drugs and Clinical Trials (NDCT) Rules states 90 working days, in reality, the timeline overshoots the stated 90 days working timeline in majority of the cases making India unattractive for clinical development work (Phase I, Phase II, etc. which require very quick review and approval);

(b) if so, the details thereof; and

(c) the steps taken/proposed to be taken by the Government to provide enabling and predictable regulations in order to ensure that India has review and approval timelines in line with some of the advanced economies/regions/countries (USA, EU, SG, AUS, KOREA, etc.)?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a) to (c): Clinical trial and New drugs are regulated in India under the provisions of New Drugs and Clinical Trials Rules, 2019. Timelines for processing of various applications are specified in the New Drugs and Clinical Trials (NDCT) Rules, 2019. Accordingly, applications are processed within the timelines specified under the said rules.

The said rules have the various provisions for improving transparency, accountability & predictability of approval process such as;

  i.   Timelines for processing of clinical trial applications.
  ii.   In case no reply received from CDSCO within the timeline it will be considered as deemed approved. However, the applicant is required to intimate CDSCO about initiation of the clinical trial.
  iii. Provisions for pre-submission meeting for seeking guidance about the requirements of law and procedure and post-submission meeting for seeking guidance with regards to the queries concerning pending application.

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