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

LOK SABHA
UNSTARRED QUESTION NO.3425
TO BE ANSWERED ON 18TH DECEMBER, 2015

TESTING NORMS FOR CLINICAL TRIALS OF DRUGS

3425. SHRI BHOLA SINGH:
SHRI G. HARI:
DR. SUNIL BALIRAM GAIKWAD:
KUNWAR HARIBANSH SINGH:
SHRI SUDHEER GUPTA:
SHRI GAJANAN KIRTIKAR:
SHRI ASHOK SHANKARRAO CHAVAN:
SHRI V. PANNEERSELVAM:

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

(a) whether the Government proposes to ease the norms for clinical trials of new drugs including those already approved in other countries and fast track their approvals in the country;

(b) if so, the details thereof and the reasons therefor;

(c) whether the Ethics Committee has been given more freedom and responsibilities to monitor clinical trials of new drugs;

(d) if so, the details thereof along with the trials approved by the Ethics Committee till date; and

(e) the other steps taken/proposed to be taken by the Government to ensure patient safety while approving clinical trials of new drugs?

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)

(a) & (b): The process of approval of new drugs and conduct of clinical trials has been rationalized by the Government with a view to ensure a careful assessment of the risk versus benefit to the patients, innovation vis-à-vis existing therapeutic options and unmet medical needs in the country. These criteria have been made an integral part of the approval process. Besides, a module for online submission of Clinical Trial applications has been operationalized. Further, the pool of Subject Experts has been increased manifold and time-lines fixed for all activities. At the same time, adequate measures have been put in place to ensure the safety and welfare of patients / clinical trial subjects. It has also been decided that due consideration will be given to the fact that the drug has been approved and is in use in other countries.

(c) & (d): In order to put the clinical trial processes on a scientific footing and ensure closer supervision of such trials Ethics Committees are now required to be registered with the Drugs Controller General (India) [DCG(I)]. These Committees are entrusted with the responsibility to analyse Serious Adverse Events during Clinical Trials. As on 15/12/2015, 1027 Ethics Committee(s) are registered with the DCG (I). Most of the permissions granted for conduct of clinical trials by Central Drugs Standard Control Organization (CDSCO) are in multiple sites across the country. Clinical Trial on a new drug at any site can be initiated only after permission has been granted by the Licensing Authority and the approval obtained from the respective Ethics Committee(s). The number of permission(s) granted by CDSCO for clinical trial of new drug(s) during year 2012, 2013, 2014 and current year (as on 27/11/2015) is 253, 73, 198 and 191, respectively.

(e): Other steps taken include laying down the formulae for determining compensation in all cases of Serious Adverse Events of injury or death, obligation to pay compensation where payable within the stipulated time-frame and recording of audio-visual informed consent of the trial subject.