GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1074
ANSWERED ON:28.11.2014
CLINICAL TRIALS
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the number of clinical trial related applications received and the number of permission granted by the Central Drugs Standard Control Organization (CDSCO) during the current year, till date;

(b) the details of the cases of unauthorised conduct of clinical trial of drugs and vaccines and other irregularities reported from various States and the action taken/proposed to be taken by the Government thereon during the said period;

(c) the number of clinical trial related injuries and deaths reported and the compensation paid in each of these cases during the said period;

(d) the number of complaints for non-payment of compensation received and the action taken/proposed to be taken by the Government thereon during the said period; and

(e) the corrective steps being taken by the Government to strengthen clinical trial related regulatory and monitoring mechanism in order to ensure safety and protection of trial participants in the country?

Answer

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

(a): The number of applications received and permissions granted up to 24.11.2014 during the current year are 213 and 192, respectively.

(b): While no reports about unauthorized conduct of clinical trials or irregularities in such trials during the current year have been reported, six complaints pertaining to clinical trials conducted in the previous years were received during this period.

(c): Serious adverse event reports are required to be examined thoroughly to establish whether injuries and deaths are on account of clinical trials. As such, the findings in respect of such events during the current year and the decision taken about compensation to be paid will be available only after some more time.

(d): No complaint has been received about non-payment of compensation.

(e): Clinical trials are required to be conducted as per the approved protocol and Good Clinical Practices (GCP) guidelines published by Central Drugs Standard Control Organization. A robust framework has been put in place for insuring the safety of trial participants through a series of measures taken to strengthen the regulation of clinical trials in the country. These include the procedures to analyze the reports of Serious Adverse Events occurring during clinical trials, compensation in case of trial related injury or death within the prescribed timelines and recording of audio-visual informed consent in each trial subject in addition to obtaining written informed consent.