GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2065
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Clinical Trials
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

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

(a) the number of clinical trial related applications received and permissions granted by the Central Drugs Standard Control Organization (CDSCO) during each of the last three years and the current year;

(b) the details of the cases of irregularities and non-compliance of rules/ guidelines relating to conduct of clinical trial of drugs reported and the action taken/ proposed to be taken by the Government thereon during the said period, State/UTwise;

(c) the number of clinical trial related injuries and deaths reported along with the compensation paid in each of these cases during the said period, State/UT-wise;

(d) the number of complaints for nonpayment 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 and harmonize the clinical trial related laws and regulatory/monitoring mechanism with international guidelines and enhance e-governance to enable a company to file, track and receive online approval for clinical trials?

Answer

(a): The number of clinical trial applications received and permissions granted by the Central Drugs Standard Control Organization (CDSCO) during last three years and the current year are as follows:
Year No. of application received No. of permission granted*
2012 480 253
2013 207 73
2014 230 198
2015 (till 30/06/2015) 87 137
* Includes permissions granted for applications received during previous years.

(b): A statement containing details of irregularities reported during 2012, 2013 and 2014 and action taken thereon by the CDSCO is at Annexure. No violation has been reported upto June 30, 2015 during the current year.
(c) & (d): The number of Serious Adverse Events (SAEs) of death and injury (other than death) reported during last three years and the current year are as follows:
Year Nos. of SAEs where death was reported. Nos. where death established to be related to CT. Nos. where SAEs (other than death), i.e., injury was reported. Nos. where injury established to be related to CT. Nos. of cases in which compensation has been paid
2012 436 16 2786 184 Compensation in all 16 death related cases has been paid.
2013 590 46 @ 1122 159 Compensation has been paid in 33 death related cases.
2014 443 # 12 1326 * -
2015$ (as on 27/07/2015) 208 1338 -
* Details of the relatedness of SAE with injury will be available only after causes have been established after examination.
@ The relatedness has been examined in 519 out of 590 cases.
# Out of 443 reports, 300 reports of SAEs of death have been examined and remaining are under examination.
$ Details of the relatedness of SAE with death/injury will be available only after causes have been established after examination.
No complaint of non-payment of compensation has been received by Drugs Controller General (India). However, as per information available, compensation in three cases of SAEs of death related to Clinical Trial, one each for 2005, 2006 and 2010 has not been paid as the whereabouts of the legal heir could not be located.
(e): Rules 122DA, 122DAA, 122DAB, 122DAC, 122DD and 122E of the Drugs and Cosmetics Rules, 1945 specify the requirements for conducting clinical trials in India. Further, Schedule-Y of the said Rules prescribes the responsibilities of the Sponsor, Investigator and Ethics Committee to protect the rights, safety and well-being of clinical trial subjects. The measures taken in the recent past to strengthen the regulation of clinical trials include evaluation of the clinical trial proposals by the Subject Expert Committees/ Investigational New Drugs Committee, review of their recommendations by the Technical Committee and, thereafter, approval by the Apex Committee. Compensation is required to be paid in case of trial related injury or death within the prescribed timelines. It has been made mandatory for the sponsor or his representatives to furnish the details of the contract entered by the sponsor with the investigator with regard to financial support, fees, honorarium, payments, etc. Further, it has also been decided that with effect from 30.11.2013, in all clinical trials, in addition to the requirement of obtaining written informed consent, audio-visual informed consent will

also be recorded in respect of each trial subject.
The task relating to organization wise e-Governance software and clinical trials software has been entrusted to Center for Development of Advanced Computing and National Informatics Center, respectively.