GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:347
ANSWERED ON:20.03.2015
CLINICAL TRIALS
Dubey Shri Nishikant ;Yadav Shri Dharmendra

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

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

(b) the instances of clinical trial related irregularities and contravention of rules/ guidelines by Indian and foreign pharmaceutical companies reported 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 along with the parameters adopted for assessing the compensation paid in each of these cases during the said period;

(d) whether the compensation has not been paid in a number of cases of clinical trial related deaths/injuries, if so, the details thereof and the reasons therefor; and

(e) the corrective measures being taken by the Government to strengthen clinical trial related rules/regulations /guidelines and ensure their compliance for safety and protection of trial participants?

Answer

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

(a) to (e): A statement is laid on the Table of the House

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO 347 FOR 20TH MARCH, 2015

(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 applications received	No. of permission granted
2012	480	253
2013	.207	73
2014	230	198
2015 (till 17/02/2015)	17	27

Includes permissions granted for applications received during previous years.

(b): A statement containing details of irregularities reported during 2013 and 2014 and action taken thereon by the CDSCO is at Armexure. No violation had been reported in 2012, and upto March 15, 2015 during the current year.

(c) & (d):

(i) 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), 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	44 @	1122	109#	Compensation has been paid in 33 death related cases.
2014	443		1326		
2015	84		347		

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Details of the relatedness of SAE with death/injury will be available only after causes have been established after examination.
@ The relatedness has been examined in 500 out of 590 cases.
# The relatedness has been examined in 980 out of 1122 cases.

(ii) The amount of compensation payable is decided as per the formula approved by the Department of Health and Family Welfare.

(iii) 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): Adequate provisions have already been made in the Drugs and Cosmetics Rules, 1945, as amended from time to time, to ensure that clinical trials are conducted in an ethical manner and all concerned adhere to,and discharge their responsibilities as per these rules.