

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

**LOK SABHA
UNSTARRED QUESTION NO. 3711
TO BE ANSWERED ON 24TH MARCH, 2017**

COMPENSATION TO THE VICTIMS OF CLINICAL TRIALS

3711. SHRI S. RAJENDRAN:

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

- (a) the quantum of financial compensation paid by the pharmaceutical companies for clinical trial related injury or death in the country along with the parameters adopted for assessing the compensation amount during each of the last three years and the current year;
- (b) the details of the provisions made by the Central Drugs Standard Control Organisation (CDSCO) in the draft guidelines on the quantum of financial compensation to be paid in case of clinical trial related injury or death of subjects;
- (c) whether there have been any objections to the draft guidelines by various stakeholders; and
- (d) if so, the details thereof and action taken thereon?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)**

(a) The quantum of compensation paid by the pharmaceutical companies for clinical trial related injury or death during last three years and the current year is as under:

(A) Serious Adverse Event of Injury

Year	Compensation Amount
2014	Rs.18,51,647/-
2015	Rs.3,99,272/-
2016	Rs.1,28,428/-
2017 (Till 20.03.2017)	Nil
Total	Rs.23,79,347/-

Contd.....

(B) Serious Adverse Event of death

Year	Compensation Amount
2014	Rs.2,74,74,221/-
2015	Rs.1,14,36,153/-
2016	Rs.30,33,635/-
2017 (Till 20.03.2017)	Nil
Total	Rs.4,19,44,009/-

The above quantum has been arrived at in accordance with the norms prescribed by the Government for payment of compensation in case of serious adverse events of injury and death.

(b): The criteria for deciding quantum of financial compensation in cases of SAEs of clinical trial has already been specified by the Government and it takes into account factors such as age of the trial subject, risk factor depending on seriousness and severity of disease, presence of co-morbidity and duration of disease, congenital anomaly or birth defect, etc. or whether the SAE is reversible or not.

(c) & (d): Do not arise.

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