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

RAJYA SABHA
UNSTARRED QUESTION NO. 277
TO BE ANSWERED ON 1ST DECEMBER, 2015

COMPENSATION FOR VICTIMS OF CLINICAL TRIALS

277. SHRI MANSUKH L. MADAVIYA:

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

(a) what action has been taken by Ministry as on date to strictly monitor clinical trials of poor patients by pharmaceutical companies;

(b) whether Hon.Supreme Court has advised the Ministry in this regard, if so, what further action has been taken by Ministry;

(c) what action has been taken by Government to provide adequate compensation to poor patients who expired during clinical trials;

(d) whether Government has any specific data of poor patients expired during clinical trials within last three years and the details thereof; and

(e) whether Government has checked that in such cases sufficient and timely compensation are paid to these aggrieved families?

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

(a): All Clinical Trials are monitored strictly in accordance with the provisions contained in Rules 122DA, 122DAA, 122DAB, 122DAC, 122DD, 122E of the Drug and Cosmetics Rules, 1945 and Schedule Y to these Rules.

(b): The Hon'ble Supreme Court, in its Order dated 03/01/2013, directed that until further orders, clinical trials of new chemical entities be conducted strictly in accordance with the procedures prescribed in Schedule Y to the Drugs and Cosmetics Rules, 1945 and these be undertaken under the direct supervision of Secretary, Department of Health and Family Welfare, Government of India. The directions of the Supreme Court have been complied with and the Drugs and Cosmetics Rules amended accordingly.

(c): Elaborate provisions have been made in the Drugs and Cosmetics Rules, 1945 to analyse the reports of Serious Adverse Events (SAEs) of death or injury (other than death) occurring during

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clinical trials. These rules also lay down the procedure for payment of compensation in case of clinical trial related injury or death within prescribed timelines. Detailed guidelines have been issued for examination of the reports of deaths and a formula for determining the quantum of compensation in case of clinical trial related deaths. Similarly, a formula has been finalized to determine the quantum of compensation to be paid in case of clinical trial related injury other than death.

(d): The data regarding Serious Adverse Events (SAEs) of death is not maintained separately for poor patients undergoing clinical trial. As per available data, the total number of SAEs of death reported during last three years are as under:

Year	No. of SAE-deaths reported	No. of related SAE-deaths	No. of cases in which compensation has been paid
2012	436	16	Compensation in all 16 death related cases has been paid
2013	590*	46	Compensation in 41 death related cases has been paid. The remaining 5 are in process.
2014	443#	22	Compensation in 18 death related cases has been paid. The remaining 4 are in process.

*The relatedness has been examined in 534 out of 590 cases.

Out of 443 reports, 345 reports of SAEs of death have been examined.

(e): Yes.

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