

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

**LOK SABHA  
UNSTARRED QUESTION NO. 965  
TO BE ANSWERED ON 18<sup>th</sup> SEPTEMBER, 2020**

**ILLEGAL CLINICAL TRIALS**

**965. SHRIMATI DARSHANA VIKRAM JARDOSH:**

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

- (a) the number of cases of illegal clinical trials that came to light during last five years and the action taken by the Government thereon, case-wise;
- (b) the number of clinical trial deaths reported during the said period along with the amount of compensation paid and pending, case-wise; and
- (c) whether Government proposes to put in place a proper regulatory mechanism to ensure time-bound and commensurate compensation to the persons volunteering for clinical trials or the families of persons who die during such trials; and
- (d) if so, the details thereof?

**ANSWER  
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND  
FAMILY WELFARE  
(SHRI ASHWINI KUMAR CHOUBEY)**

(a): Some complaints of violations of Clinical Trials Rules have been received by Central Drugs Standard Control Organisation (CDSCO) as detailed below:

<b>Year</b>	<b>No. of complains</b>
2015	04
2016	Nil
2017	Nil
2018	02
2019	Nil
2020	Nil

Such complaints, as and when received, are investigated and action taken as per the provisions of Drugs and Cosmetics Act, 1940 and Rules thereunder.

(b): The number of Serious Adverse Events (SAE) of death, clinical trials related deaths & compensation paid since 2015 is enclosed as **Annexure-A**.

(c) & (d): Rule 42 of New Drugs and Clinical Trials Rules 2019, provides details of mechanism for reporting and examination of SAEs including death, to decide the relatedness of such events with clinical trial and also to determine quantum of compensation in a time bound manner.

S.No	Year	No. of Serious Adverse Events (SAE) of Death related to Clinical Trial based on available status of examination done.	No. of cases in which Compensation was paid related to Serious Adverse Events (SAE)	Total amount of compensation paid by the applicant/companies/sponsor to Serious Adverse Events (SAE) Death cases till date (INR).
1	2015	18	18	<a href="#">2,05,94,866</a>
2	2016	27	27	1,71,59,902
3	2017	31	29	1,84,00,749
4	2018	54	51	5,06,88,176
5	2019	44	31	3,16,88,355
6	2020 (till 09.09.2020)	2	Nil	Nil
Total		176	156	13,85,32,048