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

RAJYA SABHA
UNSTARRED QUESTION NO. 2966
TO BE ANSWERED ON 8TH JANUARY, 2019

GUIDELINES FOR CLINICAL TRIALS

2966. SHRI MD. NADIMUL HAQUE:

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

(a) whether Government has devised guidelines for clinical trials by pharmaceutical companies;

(b) if so, the details thereof;

(c) the details of the total number of cases resulting in deaths or permanent disabilities of patients due to clinical trials in the last three years, year-wise;

(d) the details of the compensation paid by Government and pharmaceutical companies for cases of deaths and permanent disabilities due to clinical trials in the last three years, year-wise; and

(e) the details of clinical trial sites, IECs (Institutional Ethics Committees) and principal investigators being accredited in the last three years?

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

(a) & (b): Clinical trials of new drugs are regulated under Rules **122** DA, **122**DAB, **122**DAC, **122**DD, **122**E and Schedule-Y of the Drugs and Cosmetics Rules, **1945**. The detailed requirements and guidelines for permission to conduct clinical trials are specified in Schedule Y of Drugs & Cosmetics Rules, 1945.

Draft New Drugs & Clinical Trials Rules, 2018 were published on 01-02-2018 for inviting public/stakeholder comments.

(c) & (d): Serious Adverse Events (SAEs) of death/injuries/disabilities in clinical trials may occur due to various reasons like life threatening disease, cancer, cardiovascular diseases, side effects of the investigational products etc. Such SAEs may or may not be related to clinical trials. The number of Serious Adverse Events (SAEs) of deaths, clinical trials related deaths & compensation paid since 2016 is enclosed as **annexure-I** and in respect of permanent disabilities is as **annexure-II.**

Contd……..

(e): There is no provision under Rule 122DD of the Drugs & Cosmetics Rules, 1945 for accreditation of clinical trial sites, IECs (Institutional Ethics Committees) and Principal Investigator.

However, there are provisions for registration of Ethics Committee. As per Rule 122DD, no Ethics Committee shall review and accord its approval to a clinical trial protocol without prior registration with Central Drugs Standard Control Organisation (CDSCO).

Detailed guidelines and requirements for registration of Ethics Committee are specified in Rule 122DD & Appendix-VIII of Schedule Y of the Drugs & Cosmetics Rules, 1945. The number of Ethics Committees registered under the said Rules during the year 2016, 2017 & 2018 are 136, 578 & 345 respectively.

……..

Annexure-I

S.No	Year	No. of Serious Adverse Events (SAE) of Death reported	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/spons or to Serious Adverse Events (SAE) Death cases till date (INR).
1	2016	378	27	25	1,62,14,668
2	2017	345	27	18	1,19,59,933
3	2018	339	5	1	4,87,270

Annexure-II

Year	Total Nos of Permanent disabilities reported	Total Nos of SAE-Permanent disabilities Established to be related to Clinical Trial	Compensation paid to related SAE Permanent disabilities cases	Amount Paid by the sponsor to the legal heir/nominee of the subject
2016	Nil	Nil	Nil	Nil
2017	1	1	1	47,49,996
2018	Nil	Nil	Nil	Nil