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

LOK SABHA
UNSTARRED QUESTION NO. 6486
TO BE ANSWERED ON 6TH APRIL, 2018

DEATHS DUE TO CLINICAL TRIALS

6486. SHRI DUSHYANT CHAUTALA:

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

(a) whether it is a fact that a total of 24,117 cases of deaths have been reported during the last ten years due to clinical trials across the country and there is a serious lack of transparency in the availability of data;

(b) if so, the details thereof;

(c) whether the Government has constituted any mechanism to regularise clinical trials and to monitor the clinical trial of pharma companies; and

(d) if so, the details thereof and the steps taken by the Government in this regard?

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

(a) & (b): No. A total of 4604 Serious Adverse Events (SAEs) of death including those related and not related to clinical trials were reported from 2008 to 2017.

Drugs and Cosmetics Rules, 1945 were amended in January, 2013 and December, 2014 incorporating provisions for reporting of Serious Adverse Events (SAEs) of injuries including death and examination within prescribed timeline to determine the cause of death and quantum of compensation in cases of clinical trial related deaths. Cases of SAEs of deaths reported by the sponsor, investigator and Ethics committee are examined as per the above provisions and maintained at Central Drugs Standard Control Organisation (CDSCO) in a transparent manner.

(c) & (d): Clinical trials of new drugs are regulated under Rules 122 DA, 122DAB, 122DAC, 122DD, 122E and Schedule-Y of the Drugs and Cosmetics Rules, 1945.

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Various measures have been taken by the Government for strengthening the regulatory provisions in respect of clinical trials including amendments in the Drugs & Cosmetics Rules, 1945 laying down:

i. the procedures to analyse the reports of Serious Adverse Events (SAEs) and payment of compensation in case of trial related injury or death;
ii. conditions for conduct of clinical trials, authority for conducting clinical trial inspections and actions in case of non-compliance;
iii. requirements and guidelines for registration of Ethics Committee;
iv. audio-video recording of informed consent process in case of vulnerable subjects in clinical trials of new chemical entity/new molecular entity (NCE/NME).In case of anti-HIV and anti-Leprosy drugs, only audio recording of the informed consent has been specified;
v. further, it has been made mandatory to submit the following details in the clinical trial/new drug application of New Chemical Entity and Global Clinical Trials:-

- Assessment of risk versus benefit to the patients.

- Innovation vis-à-vis existing therapeutic option.

- Unmet medical need in the country.

vi. Expert Committees have been constituted to examine the reports of deaths in clinical trials. These Expert Committees have prepared detailed guidelines for examination of reports of deaths and also prepared formula(s) for determining the quantum of compensation in case of clinical trial related deaths and injury (other than death).

In compliance of the order dated 03.01.2013 of the Hon'ble Supreme Court, a system of supervision of clinical trial has been put in place by constituting an Apex Committee under the chairpersonship of Secretary, Health and Family Welfare; and a Technical Committee under chairpersonship of Director General, Health Services (DGHS). Accordingly, clinical trial proposals of new chemical entities (NCEs) are evaluated through a three tier system comprising: (i) Subject Expert Committee (SEC), (ii) a Technical Committee and (iii) the Apex Committee. Other clinical trial proposals are evaluated through a two tier system of SEC and Technical Committee.

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