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

LOK SABHA
STARRED QUESTION NO.257
TO BE ANSWERED ON THE 3RD AUGUST, 2018
CLINICAL TRIALS

***257. SHRI SUDHEER GUPTA:**
DR. KAMBHAMPATI HARIBABU:

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

(a) the rules governing clinical trial in the country at present;

(b) whether the World Health Organisation (WHO) has expressed that strict clinical trial rules will drive away drug firms and the United Nations (UN) agency's work with India would be hampered, if so, the details thereof including the details of suggestions made by WHO in this regard and the response of the Government thereto;

(c) whether the Government has held a meeting with the stakeholders comprising pharma companies and pharma lobby groups in this regard and if so, the details and the outcome thereof;

(d) the steps taken/being taken to carry out clinical trials in a transparent manner in the country; and

(e) the number of deaths occurred during the last three years across the country by clinical trials, State/UT-wise along with the details of companies penalized for negligence in clinical trials during the said period?

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

(a) to (e) A Statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 257* FOR 3RD AUGUST, 2018

(a): 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.

(b) Yes. Draft New Drugs & Clinical Trials Rules, 2018 was published on 01-02-2018 inviting public/stakeholder comments. In the light of certain provisions of the said draft Rules, an email was received from WHO expressing apprehension that there was a possibility that sponsors would not conduct clinical trials in India and go elsewhere due to such provisions. It was also stated that it would hamper WHO's work with India as WHO considers that it is a public health priority to conduct clinical trials in India. The following three possible scenarios were mentioned in respect of compensation in case of permanent disabilities /deaths in clinical trials:

1. When the Ethics Committee (EC) and sponsor agree that the disability/death is due to clinical trial participation and the sponsor pays the compensation as EC determines.
2. When both parties agree that the disability/death is not due to participation in clinical trial, no compensation needs to be paid.
3. When the EC determines that the cause of disability/death is due to participation, but the sponsor wants the expert committee of the Central Drugs Standard Control Organisation (CDSCO) to adjudicate, and the sponsor agrees, the decision is binding.

It was also stated that under the third scenario, payment of 60% interim compensation which was not recoverable may not be acceptable to sponsors.

The purpose of publishing draft Rules is to get the comments of stakeholders. The Government appreciates and welcomes all such comments, including those from the WHO. The comments have been duly considered for preparing final draft of the Rules.

(c): Yes, meetings were held with stakeholders comprising industry representatives and experts. The issues highlighted by the industry/stakeholders were noted for due consideration in preparing the final draft of the Rules.

(d): Various measures taken by the Government for strengthening the regulatory provisions in respect of clinical trials include 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).

vii. 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 chairmanship of Director General, Health Services (DGHS).

(e): Death may occur during clinical trial due to various reasons such as the disease from which the patient may be suffering or due to the investigational product or any other reason. Clinical trials are mostly multi-centric, conducted simultaneously in many Centers/States across the country. The number of persons who died during clinical trial in the last three years, the number of such cases which are related to clinical trials and the amount of compensation paid is enclosed as **Annexure.**

Annexure

S.No.	Year	No. of Serious Adverse Event (SAE) of Death reported	No. of Serious Adverse Event (SAE) of Death related to clinical trial based on available status of examination done	Total amount of Compensation paid by the applicant companies/sponsor to Serious Adverse Event (SAE) Death cases till date (INR)
1	2015	381	18	Rs.2,05,94,866/-
2	2016	378	24	Rs.1,46,21,351/-
3	2017	345	7	Rs.29,95,055/-

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