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

LOK SABHA
STARRED QUESTION NO. 204
TO BE ANSWERED ON THE 11TH MARCH, 2016
CLINICAL TRIALS FOR DRUGS

***204. SHRI VINAYAK BHAURAO RAUT:**

SHRI NAGENDRA KUMAR PRADHAN:

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

(a) whether the Supreme Court in 2013 had urged the Government to create mechanism for monitoring clinical trials for new drugs in the country, if so, the details in this regard along with follow-up action taken thereon;

(b) the details of infrastructure developed so far in the country, after the said direction of Apex Court;

(c) whether the Government has received the requests from various health experts and organizations for setting up of clinical trial facilities in public sector so as to prevent drug companies going abroad for the purpose; and

(d) if so, the details thereof and the steps taken by the Government thereon?

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

(a) to (d): A statement is laid on the Table of the House

STATEMENT REFERRED TO IN REPLY TO LOK SABHA

STARRED QUESTION NO. 204* FOR 11TH MARCH, 2016

(a): In Writ Petition (Civil) No. 33 of 2012, Swasthya Adhikar Manch, Indore & another versus Union of India & Ors., the Hon'ble Supreme Court, in its Order dated 03-01-2013, directed that clinical trials of new chemical entities be conducted strictly in accord with the procedure prescribed in Schedule 'Y' of the Drugs & Cosmetics Rules, 1945, under the direct supervision of Secretary, Ministry of Health & Family Welfare, Government of India.

(b): In compliance of the order of the Hon'ble Court, a system of supervision of clinical trial has been put in place by constituting an Apex Committee under the chairmanship of Secretary, Health and Family Welfare; and a Technical Committee under chairmanship 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. Other 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).

(c) and (d): Suggestions for improvement in the system for conduct of clinical trials have been received from time to time from various stakeholders. The suggestions received also include creation of conditions conducive for improving the ease of conducting clinical trials in the country so that such clinical trials are not shifted to other countries. The Government has examined all such suggestions and taken pro-active steps to ensure that patient safety is not compromised at any cost and the approval process is expedited. These include:

- subject experts to be on the panels of Subject Expert Committees (SECs) have been increased to 350.
- meetings of Subject Expert Committees, Technical Committee and Apex Committee are being organized frequently and at regular intervals of time.
- on-line portal for application of clinical trial has been created and its phase-I has been operationalized.

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