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

RAJYA SABHA
UNSTARRED QUESTION NO. 2332
TO BE ANSWERED ON 7TH AUGUST, 2018

REVIVAL OF CLINICAL TRIALS

2332. SHRI BINOY VISWAM:

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

(a) whether it is a fact that there is a gradual revival in the number of clinical trials being done in India since it was at an all time low of 17 clinical trials approved by Drug Controller General of India (DCGI) in 2013;

(b) if so, the details thereof and the reasons therefor; and

(c) whether it is a fact that the guidelines for conducting the clinical trials have been liberalised recently in favour of the pharmaceutical companies and Government lacks a water tight system for monitoring the trials in the country?

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, 122DAB, 122DAC, 122DD, 122E and Schedule-Y of the Drugs and Cosmetics Rules, 1945.

The number of clinical trials permissions, including for Global Clinical trials, granted by Central Drugs Standard Control Organization since 2012 are as under:-

Year	**Total CT Issued**
2012	253
2013	73
2014	198
2015	216
2016	129
2017	213
2018 (As on 31-July-2018)	106

Contd…….

Gradual increase in number of clinical trial permission may be due to various measures taken to strengthen and streamline the regulation of clinical trials in more predictable and transparent manner.

(c): Streamlining and strengthening regulatory provisions is a continuous process. This is done keeping in view the interest of all stakeholders. 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).

……..