

Mechanism for regulating clinical trials

437. SHRIMATI RENUKA CHOWDHURY: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether Government has any proper mechanism to regulate clinical trials, if so, the details thereof;
- (b) the number of clinical trials in India registered on Clinical Trial Registry-India (CTRI) during the last three years; and
- (c) the steps taken by Government to ensure that all the companies, conducting trials in the country, disclose the outcome of their trials within a year of completing them?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY): (a) Clinical trials of new drugs are regulated under Rules 122DA, 122DAB, 122DAC, 122DD and Schedule-Y of the Drugs and Cosmetics Rules, 1945. Clinical trials are required to be conducted as per the approved protocol and Good Clinical Practices (GCP) guidelines published by the Central Drugs Standard Control Organization (CDSCO). Schedule-Y of Rules prescribes the responsibilities of the Sponsor, Investigator and Ethics Committee to protect the rights, safety and well-being of clinical trial subjects.

(b) The number of clinical studies registered in the Clinical Trials Registry- India (CTRI) from 1/1/2015 to 14/12/2017 is 5541.

(c) There is no provision under the Drugs & Cosmetics Rules, 1945 which requires disclosure of the outcome of the trial within a year of completing the same.

However, as per Schedule Y of the said Rules, in case of studies prematurely discontinued for any reason including lack of commercial interest in pursuing the new drug application, a summary report is required to be submitted within 3 months.

Further, in May 2017, the Indian Council of Medical Research (ICMR) has become signatory to the WHO joint statement regarding results disclosure within one year of trial completion. The statement commits to have in place a mechanism within one year to implement the same.

Fevers caused by bacteria and viruses

438. SHRI C.P. NARAYANAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether Government has been able to wipe out various kinds of fever caused by bacteria and viruses;