GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:35
ANSWERED ON:06.12.2013
IRREGULARITIES IN CLINICAL TRIALS
Dome Dr. Ram Chandra;Patil Shri A.T. Nana

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

(a) the mechanism put in place by the Government to monitor clinical trials on human participants and to ensure proper safeguards for trial subjects in the country;

(b) whether the Government has taken note of various reports/complaints of irregularities, violations of guidelines, unconsented conduct of clinical trials on patients and non-payment of compensation to the trial subjects in case of clinical trial related injury or death throughout the country;

(c) if so, the number of such cases reported and investigated, persons/ hospitals/pharmaceutical companies found involved and action taken against them during each of the last three years and the current year, State/UT-wise;

(d) whether the Government proposes to strengthen regulatory, monitoring and approval mechanism to curb aforesaid irregularities and non-compliance and ensure various safeguards including financial compensation for trial subjects in the country; and

(e) if so, the details thereof?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 34 FOR 6TH DECEMBER, 2013

(a): The requirements and guidelines for undertaking clinical trials are specified in Rules 122 DA, 122DAA, 122 DAB, 122 DAC, 122 DB, 122 DD and Schedule Y of Drugs & Cosmetic Rules, 1945. As per the Rule 122 DAC, clinical trial is conducted as per Good Clinical Practices (GCP) Guidelines issued by Central Drugs Standard Control Organization (CDSCO). Clinical trials can be initiated only after the approval of CDSCO and respective Ethics Committee.

(b) & (c): A Statement-I containing the details of cases of irregularities, malpractices and violation of guidelines reported and the action taken by the Government thereon IS laid on the Table of the House. As per available information, number of deaths related to clinical trials in the year 2010, 2011 and 2012 were 22, 16 and 16 respectively. The reports of Serious Adverse Events (SAEs) of injuries and deaths, received in the current year 2013 are under examination. Compensations have been paid in 21 cases of deaths related to clinical trial in 2010 and in all cases in 2011 and 2012. In one case of 2010, the compensation remained unpaid as whereabouts of the legal heir could not be traced by the investigator and his team in spite of their best efforts. A Statement-II containing the details of compensation paid in the Years 2010, 2011 and Year 2012 is laid on the Table of the House.

(d) & (e) : The following steps have been taken to strengthen the approval procedure for clinical trials, monitoring mechanism and payment of compensation to ensure that safety, rights and well-being of clinical trial subjects are protected:

i. 12 New Drug Advisory Committees (NDAC) consisting of leading experts from the Government medical colleges, institutes from all over the country have been constituted to advise CDSCO in matters related to approval of clinical trials and new drugs.

ii. Applications of Investigational New Drugs (IND), i.e. new drug Substances which have never earlier been used in human beings, are evaluated by the IND committee, chaired by the Director General, Indian Council of Medical Research.

iii. Registration of clinical trial in ICMR registry at www.ctri.in has been made mandatory.

iv. Guidelines for conducting inspection of Clinical Trial sites and sponsor/Clinical Research Organizations (CROs) have been prepared and posted on CDSCO website.

v. In light of Hon'ble Supreme Court Order dated 21.10.2013, it has been decided that for all clinical trial, in addition to the requirement of obtaining written informed consent, audio- visual recording of the informed consent process of each trial subject, including the procedure of providing information to the subject and his/her understanding on such consent, is also required to be done while adhering to the principle of confidentiality. This is applicable to the new subjects to be enrolled in all clinical trials including Global

Clinical Trials.

vi. The Drugs and Cosmetics Rules, 1945 have been amended vide Gazette Notification G.S.R. 53 (E) dated 30-01-2013 specifying procedures to analyze the reports of Serious Adverse Events occurring during clinical trials and procedures for payment of compensation in case of trial related injury or death as per prescribed timelines.

vii. The Drugs and Cosmetics Rules, 1945 have been amended vide Gazette Notification G.S.R. 63 (E) dated 01-02-2013 specifying various conditions for conduct of clinical trials, authority for conducting clinical trial inspections and actions in case of non-compliance.

viii. The Drugs and Cosmetics Rules, 1945 have been amended vide Gazette Notification G.S.R No. 72(E) Dated 08.02.13 making registration of the Ethics Committees mandatory and specifying requirements and guidelines for registration of Ethics Committee.