GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:160
ANSWERED ON:16.08.2013
CLINICAL TRIALS
Alagiri Shri S. ;Mandal Shri Mangani Lal

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

(a) the present regulatory framework for authorising clinical trials of drugs on human beings in the country and the number of applications received and approved for conducting such trials during each of the last three years and the current year;

(b) the details of the cases of irregularities, malpractices and violation of guidelines reported and the action taken/proposed by the Government thereon during the said period;

(c) the number of clinical trial related injuries and deaths reported and the compensation paid by the pharmaceuticals companies in each of these cases during the said period;

(d) the number of complaints for nonpayment of compensation received along with the action taken/proposed by the Government thereon during the said period; and

(e) the corrective steps being taken/proposed by the Government to strengthen regulatory and monitoring mechanism to ensure proper conduct of clinical trials and safety/rights of trial participants in the country?

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. 160 FOR 16TH AUGUST, 2013

(a): Clinical trials of new drugs are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder. The requirements and guidelines for undertaking clinical trials are specified in Rule 122 DA, 122DAA, 122 DAB, 122 DAC, 122 DB, 122 DD and Schedule Y of Drugs & Cosmetics Rules. Schedule Y also mandates that clinical trial is conducted as per Good Clinical Practices (GCP) Guidelines issued by Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Govt. Of India. Clinical trials can be initiated only after the approval of CDSCO and the respective Ethics Committee.
The number of applications received for conducting clinical trials of new drugs/ vaccines on human beings and those approved by CDSCO during each of the last three years and the current year is as under:

Year	New Drugs	
	Number of applications received	Number of clinical trials permissions granted
2010	546	529
2011	306	283
2012	480	253
2013 (upto 12th August, 2013)	155	27

(b): The details of the cases of irregularities, malpractices and violation of guidelines reported and the action taken/ proposed by the Government thereon is at Annexure −A.

(c): 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 wherea bouts of the legal heir could not be traced by the investigator and his team in spite of their best efforts. The details of compensation paid in 2010, 2011 and 2012 are at Annexure B-D.

(d): The Government has received three requests from subjects or their relatives who have requested for payment of compensation. The matter is under examination.

(e): The Government has taken the following steps to strengthen the approval procedures, monitoring mechanism for clinical trials and to ensure the safety, rights and well-being of clinical trials participants:

(1) 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.

(2) 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.

(3) Registration of clinical trial in ICMR registry at www.ctri.in has been made mandatory.

(4) Guidelines for conducting inspection of Clinical Trial sites and sponsor/Clinical Research Organizations (CROs) have been prepared and posted on CDSCO website.
Apart from the above, Drugs and Cosmetics Rules, 1945 have been amended as follows in order to strengthen the regulatory provisions and the monitoring mechanism of clinical trials in the country:

A. Amendment vide Gazette Notification G.S.R. 53 (E) dated 30-01-2013 specifying procedures to analyse 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.

B. Amendment 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.

C. The registration of the Ethics Committees has been made mandatory in the Drugs & Cosmetics Rules vide Gazette Notification G.S.R No. 72(E) Dated 08.02.13 specifying requirements and guidelines for registration of Ethics Committee