GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:32
ANSWERED ON:23.11.2012
CLINICAL TRIALS
Meghwal Shri Arjun Ram ;Thamaraiselvan Shri R.

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

(a) the number of applications received for conducting clinical trials of new drugs/vaccines on human beings and those approved by the Central Drugs Standard Control Organisation (CDSCO) during each of the last three years and the current year;

(b) the number of sponsors/Clinical Research Organisations (CROs) operating and offering clinical research and services indicating the provisions made to regulate them;

(c) the number of inspections of clinical trial sites and sponsors/Clinical Research Organisations (CROs) carried out along with the instances of non-compliance of Good Clinical Practices (GCP) noticed and the action taken/proposed against the offenders during the said period;

(d) the number of trial subjects participated and clinical trial related injury or death of trial subjects reported indicating the number of such cases in which financial compensation has been paid during the said period, company-wise; and

(e) the steps taken/proposed by the Government to strengthen the approval and monitoring mechanism for clinical trials as well to ensure safety and rights of trial subjects?

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.32 FOR 23.11.2012

(a) The number of applications received for conducting clinical trials of new drugs/vaccines on human beings and those approved by Central Drugs Standard Control Organisation (CDSCO) during each of the last three years and the current year is as under:

Year	New Drugs/ Vaccines number of applications received	number of clinical trial permissions granted
2009	492	488
2010	546	529
2011	306	283
2012 (upto October)	390	244

(b): There is no requirement for the registration of Clinical Research Organisation. However, all the clinical trials are required to be registered in the Clinical Trial Registry of India (CTRI) of the Indian Council of Medical Research (ICMR) at www.ctri.in Registration of clinical trials at this registry has been made mandatory since 15.6.2009. As per CTRI database, 79 Indian Pharmaceutical Companies, 47 Multi-national Pharmaceutical Companies and 71 Clinical Research Organisations have been so registered. Clinical trials of new drugs are regulated under the provisions of the Drugs and Cosmetic Rules, 1945 and the requirements and guidelines for undertaking clinical trials are specified in Schedule Y of these Rules. Schedule Y also mandates that clinical trials are conducted as per Good Clinical Practices (GCP) Guidelines issued by Central Drugs Standard Control Organisation (CDSCO). Schedule Y / GCP Guidelines specify the responsibilities of sponsors/Clinical Research Organisations in clinical trials.

(c): During the last three years and the current year, there are nine inspections / investigations conducted in cases of alleged irregularities in clinical trials. Details of these cases and action taken there on are at Annexure - A. In addition to above, 14 cases of routine inspections of clinical trial sites / company were conducted out of which so far in 3 cases, warning letters have been issued to the companies concerned.

(d): As per the data obtained from CTRI, ICMR, the number of trial subjects in clinical trials during the last three years and current year viz. 2009, 2010, 2011 & Up to November, 2012, were 99417, 116033, 70352 and 66673 respectively. Serious Adverse Events (SAEs) resulting of deaths may occur during clinical trials due to various reasons. These deaths could be due to life-threatening diseases like cancer, cardio-vascular conditions like congestive heart failure / stroke and other serious diseases. They could also be due to the side-effects of the drugs administered to critically or terminally ill patients. Such deaths are investigated to ascertain at the causal relationship, if any. As per available data, the number of Serious Adverse Events of deaths in clinical trials reported during the last three years and current year viz.2009, 2010, 2011 & Up to June 2012 were 637, 668, 438 & 211 respectively. However, SAEs of death due to clinical trials were 16, 22 & 16 in 2009, 2010 and 2011 respectively. Compensations have been paid in 21 cases of deaths related to clinical trial in 2010 and in all cases in 2011. 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. The details of compensation paid in the Year 2010 and Year 2011 are attached as Annexure 'B & C'.

(e): Following concrete steps have been taken to strengthen the approval procedures, monitoring mechanism for clinical trials as well to ensure that safety, rights and well-being of clinical trial subjects are protected:

(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 since 15.6.2009.

(4) Every approval / permission for conducting clinical trials now includes a condition that in case of study related injury or death, applicant will provide complete medical care as well as compensation for the injury or death and statement to this effect would be incorporated in the informed consent form.

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

(6) Draft rules have been notified to provide for the following:

(i) Medical treatment and financial compensation to the trial subjects in case of trial related injury or death;

(ii) Procedure for payment of financial compensation;

(iii) Enhancement of responsibilities of Ethics Committee (EC), Sponsor & Investigator to ensure that financial compensation as well as medical care is provided to the trial subjects who suffer trial related injury or deaths and such information is provided to the Drugs Controller General (India) [DCG(I)].

(iv) Amendment of the format for obtaining informed consent of trial subjects to include the details of address, occupation, annual income of the subject so as to have information regarding socio-economic status of the trial subjects.

(7) Draft rules have been notified to incorporate Rules to have authority for clinical trials inspections by CDSCO and to take administrative actions like restriction on investigators/ sponsors / CROs from conducting future clinical trials in case of non-compliance.

(8) Draft rules have been notified to incorporate Rules and Schedule Y-1 specifying requirements and guidelines for registration of Ethics Committee.