GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:185
ANSWERED ON:24.08.2012
RIGHTS/SAFETY OF CLINICAL TRIAL SUBJECTS
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government has scientifically analysed the high number of deaths of subjects in clinical trials including Serious Adverse Events (SAE) in order to find out their causes in the country;

(b) if so, the details thereof and if not, the reasons therefor;

(c) the details of the provisions made in respect of the rights and safety of subjects participating in clinical trials along with the steps taken/proposed to make them aware of their rights;

(d) the details of inquiry conducted in the cases of illegal and unethical clinical trials along with the action taken/proposed by the Government against the offenders during the last three years and the current year; and

(e) whether the Government proposes to review/examine present guidelines, legal provisions, approval procedure and monitoring mechanism for clinical trials in view of deaths of subjects and also reported irregularities in giving approval to conduct these trials in the country, and if so, the details thereof and if not, the reasons therefor?

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. 185 FOR 24TH AUGUST, 2012

(a) & (b): Yes, Madam. The Serious Adverse Events (SAEs) 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 or their administration to critically or terminally ill patients. Such deaths are investigated to arrive 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 viz. 2010, 2011 & Up to June 2012 were 668, 438 & 211 respectively. However, SAEs of death due to clinical trials were 22 & 16 in 2010 and 2011 respectively.

Analysis of deaths during clinical trials has shown that they have occurred in following categories:

S.No.	Categories	No.of Deaths in 2010	No.of Deaths in 2011	No.of Deaths in 2012
1	Anticancer	226	139	66
2	Cardiovascular	368	229	82
3	Cerebrovascular	28	11	5
4	Antidiabetic	11	31	12
5	Antiviral/Antifungal	5	12	8
6	Others	30	16	38
	Total	668	438	211

(c): Clinical trials of new drugs are regulated under the Drugs and Cosmetics Act and the Rules made there under. The requirements and guidelines for undertaking clinical trials are specified in Schedule Y of Drugs & Cosmetics Rules. Schedule Y also mandates the clinical trials to be conducted as per Good Clinical Practices (GCP) Guidelines issued by Central Drugs Standard Control Organisation (CDSCO). Schedule-Y and GCP guidelines provide detailed provisions / safety measures to ensure that the rights, safety and well-being of trial subjects are protected. Clinical trial can be initiated only after the approval of CDSCO and the respective Ethics Committee. In all trials, a freely given informed written consent is required to be obtained from the people participating in the trials. During this process, the details of the trial, risks / benefits involved and the subject`s rights are explained to the trial subjects.

(d): A statement indicating the details of inquiries and action taken thereon during the last three years and the current year is enclosed at Annexure.

(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) A draft notification has been issued for incorporation of a new rule in the Drugs & Cosmetics Rules, 1945, which provides 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 on 17.07.2012 vide G.S.R No. 572(E) 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 on 17.07.2012 vide G.S.R No. 573(E) to incorporate Rules and Schedule Y-1 specifying requirements and guidelines for registration of Ethics Committee.