GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2954
ANSWERED ON:30.03.2012
CLINICAL TRIALS
Angadi Shri Suresh Chanabasappa;Baitha Shri Kameshwar ;Bauri Smt. Susmita;Bhagora Shri Tarachand;Jindal Shri Naveen;Karunakaran Shri P.;Kumar Shri P.;Patel Shri Devji;Rajesh Shri M. B.;Rajukhedi Shri Gajendra Singh;Rao Shri Sambasiva Rayapati;Saha Shri Anup Kumar;Siricilla Shri Rajaiah;Sudhakaran Shri K.;Tanwar Shri Ashok;Virendra Kumar Shri

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

(a) the mechanism to monitor clinical trials and bio-medical research on human participants alongwith the total number of clinical trials registered in the country during each of the last three years and the current year so far, State/UT-wise;

(b) whether the Government has taken note of various irregularities, violations of guidelines, deaths of clinical trial participants and unconsented conduct of trials on patients throughout the country including Madhya Pradesh;

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

(d) whether the Government proposes to strengthen various clinical trials regulations including insurance and compensatory provisions for clinical trial participants and enforce their strict compliance across the country; and

(e) if so, the details thereof alongwith the steps so far taken for the purpose?

Answer

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

(a): Clinical trials of new drugs are regulated under the Drugs and Cosmetic Act and Rules made there under. Clinical trials are conducted after the approval of Drugs Controller General (India) {DCG(I)} and in accordance to the approved protocols and requirements specified under the said Rules. The number of clinical trials registered with the Clinical Trials Registry India (CTRI) at Indian Council of Medical Research (ICMR) site during the last three years viz. 2009, 2010 and 2011 and the current year so far is 548, 806, 815 and 207 respectively. The State / UT-wise data is not available as the permissions for clinical trials are granted to the applicants which may be a sponsor or Clinical Research Organizaion (CRO) and the trials in majority of cases are multicentric.

(b)&(c): A statement giving the number of cases investigated and action taken thereon for irregularities, violations of guidelines throughout the country including Madhya Pradesh during the last three years is annexed.

Serious Adverse Events (SAEs) of death may occur during clinical trial due to various reasons. These could be disease related deaths like cancer etc., or administration to critical or terminally ill patients or side-effects or unrelated causes apart from clinical trial related deaths. As per available data, the total number of Serious Adverse Events of deaths in clinical trials reported during the last three years viz. 2009, 2010 & 2011 were 637, 668 & 438 respectively. As per information made available by the Sponsor / CRO, compensations were paid in 22 cases of clinical trial related deaths in the year 2010.

(d)&(e): Government has taken various measures to strengthen the monitoring mechanisms for the conduct of clinical trials in the country, as follows:

i) Registration of clinical trial in ICMR registry has been made mandatory since 15.6.2009.

ii) Every approval/permission for conducting clinical trials now includes a conditions that in case of study related inury or deth, applicant will provide complete4 medical care as well as compensation for the injury or death and statement to this effect should be incorporated in the informed consent form. Further, in case of such injury or death, the details of compensation provided are to be intimated to the office of Drugs Controller General (India) DCG (I).

iii) Guidelines for conducting Clinical Trial inspection of sites and sponsors/Clinical Research Organizations (CROs) have been prepared.

The manpower and infrastructure of CDSCO is being strengthened for strict compliance of the provisions of the said Rules. Draft Rules for making specific provisions for providing financial compensation to the trial subjects in the case of trial related injury or death have already been published for comments from public vide Gazette Notification G.S.R No.821(E) dated 18.11.2011.