

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

STARRED QUESTION NO:386

ANSWERED ON:07.09.2012

FINANCIAL COMPENSATION FOR CLINICAL TRIAL SUBJECTS

Dharmshi Shri Babar Gajanan;Yaskhi Shri Madhu Goud

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

- (a) the quantum of financial compensation paid by the pharmaceutical companies for clinical trial-related injury or death in the country along with the parameters adopted for assessing the compensation amount during each of the last three years and the current year;
- (b) the details of the provisions made by the Central Drugs Standard Control Organisation (CDSCO) in the draft guidelines on the quantum of financial compensation to be paid in case of clinical trial-related injury or death of subjects;
- (c) whether there has been opposition to these draft guidelines from various quarters;
- (d) if so, the details thereof along with the reasons therefor; and
- (e) the steps taken/proposed by the Government to address their concerns and ensure a uniform compensation formula irrespective of age, income, severity of the disease and direct short-term injury of trial subjects?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABIAZAD)

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO.386 FOR 7TH SEPTEMBER, 2012

(a) Clinical trial of new drug are regulated under Rule 122 DA, 122 E and Schedule Y of the Drugs & Cosmetics Rules. Schedule Y mandates that the clinical trials are conducted as per the Good Clinical Practice (GCP) Guidelines issued by Central Drugs Standard Control Organisation (CDSCO). At present, there is no provision under Drugs and Cosmetics Rules requiring payment of financial compensation in case of clinical trial related injury or death of trial subject or specifying parameters to be adopted for assessing the amount of compensation. However, para 2.4.7 of the Good Clinical Practice (GCP) Guidelines for Clinical Trials provides that the trial subjects who suffer physical injury as a result of their participation in clinical trials are entitled to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability, subject to confirmation from the Ethics Committee. In case of death, their dependants are entitled to compensation.

Details of payments of financial compensation made prior to 2010 by company / sponsor in cases of trial related deaths are not readily available. However, the details of compensation paid in 2010 and 2011 are attached at Annexure A & B. Payments of compensation in such cases of trial related deaths in the current year so far would be made after completion of necessary procedures.

As per information available, these payments were made by the companies based on recommendations of the respective Ethics Committees, age of the person, disease severity, annual income etc.

(b) Draft guidelines for determining the quantum of financial compensation to be paid in cases of clinical trial related injury or death have been prepared and uploaded on the CDSCO website www.cdscsco.nic.in on 03.08.2012 seeking public comments. As per the draft guidelines, the quantum of compensation is proposed to be based on :

- i) Age;
- ii) Income;
- iii) Seriousness and severity of the disease from which the subject was suffering at the time of his/her participation in the trial.
- iv) Percentage of disability in case of injury.

(c)to(e): Suggestions / comments have been received from various quarters on these draft guidelines. The Government expects to finalise these Guidelines soon keeping in view the rights and well-being of trial subjects.