GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4615
ANSWERED ON:21.02.2014
COMPENSATION FOR CLINICAL TRIAL SUBJECTS
Biju Shri P. K.;Jindal Shri Naveen;Kalmadi Shri Suresh;Meghe Shri Datta Raghobaji;Rajbhar Shri Ramashankar;Sampath Shri Anirudhan;Thamaraiselvan Shri R.;Venugopal Shri P.

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

(a) whether clinical trial subjects/their families have been adequately compensated by the pharmaceutical companies in cases of Serious Adverse Events of deaths and injuries and if so, the details thereof and if not, the reasons therefor;

(b) whether an expert panel has recently made certain recommendations including a minimum compensation of Rs. 2 lakh for the clinical trial related injuries/deaths in the country;

(c) if so, the details of the recommendations of the expert panel and the follow up action taken/proposed by the Government thereon to ensure adequate compensation for clinical trial related injuries/deaths in the country;

(d) whether the Supreme Court has recently directed the Government to provide the details of the approval mechanism for clinical trials keeping in view its laxity in dealing with unethical clinical trials; and

(e) if so, the details thereof and the reaction of the Government thereto?

Answer

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

(a): A Statement containing the details of the compensation paid in respect of Serious Adverse Events (SAEs) of death attributable to clinical trials reported during the years 2010, 2011, 2012 and 2013 is annexed.

(b) & (c): The independent expert committee constituted in accordance with the requirements of Rule 122 DAB and Appendix XII of the Drugs & Cosmetic Rules, 1945 for examination of SAEs of death occurring during the clinical trials after detailed deliberations prepared a compensation formula taking intoconsideration a base amount, age and risk factor of the subject. The risk factor, in a scale of 0.5 to 4 is based on the seriousness and severity of the disease, presence of co-morbidities and duration of disease of the trial participant at the time of enrolment in the clinical trial. However in case of patients/ trial participant whose expected mortality is 90% or more (within 30 days), the committee has recommended that a fixed amount of Rs. 2 lakh may be given for clinical trial related death.

(d) & (e): In the Writ Petition (Civil) No. 33 of 2012 - Swathya Adhikar Manch vs. Union of India & others, the Hon'ble Supreme Court, on 30.9.2013, while taking note of various measures taken by the Government, asked for the report of Prof. Ranjit Roy Chaudhury Committee and also the details of the existing regime which ensures the safety of the subjects of clinical trials.

Accordingly, the Government submitted the report of Prof. Ranjit Roy Chaudhury Committee before the Hon'ble Supreme Court, actions proposed to be taken on the recommendations of the committee and details about the regulatory provisions, guidelinesand requirements for conduct of clinical trials in the country. The Hon`ble Court was informed about the various recent measures taken by the Government in this regard, as follows:

1. Amendments to Drugs & Cosmetics Rules, 1945 vide
(i) G.S.R. 53 (E) dated 30.1.2013 specifying the procedures for payment of compensation to the subjects of thetrial in case of injury or death
(ii) G.S.R. 63 (E) dated 1.2.2013 specifying various conditions for inspection of clinical trial and
(iii) G.S.R. 72 (E) dated 8.2.2013 specifying the detailed guidelines for registration of ethics committee.

2. The Drugs & Cosmetics (Amendment) Bill, 2013, introduced in the Parliament on 29.8.2013, contains a separate chapter containing penal provisions for violation and non-compliance of the provisions relating to the conduct of the clinical trials.

3. In light of the order dated 3.1.2013 of the Hon`ble Supreme Court, a system of supervision of clinical trials of new chemical entities through a Technical Committee under the chairmanship of DGHS and an Apex Committee chaired by the Secretary, Ministry of Health and Family Welfare has been put in place.

4. Further, in light of Hon'ble Supreme Court's Order dated 21.10.2013, it has been decided that for all clinical trials, in addition to the requirement of obtaining written informed consent, audio-visual recording of the informed consent process of each trial subject,

including the procedure of providing information to the subject and his/her understanding on such consent is required to be done while adhering to the principle of confidentiality.