GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:70
ANSWERED ON:01.03.2013
SERIOUS ADVERSE EVENTS IN CLINICAL TRIALS
Owaisi Shri Asaduddin;Singh Shri Ratan

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

(a) the existing procedure to ascertain any Serious Adverse Events (SAE) to the subjects during the clinical trials of drugs in the country;

(b) the number of SAE deaths attributable to the clinical trials reported during each of the last three years and the current year, year-wise;

(c) the procedure laid down by the Government to determine the quantum of financial assistance to be paid in SAE deaths in/attributed to clinical trials and the reasons for allowing arbitrary payment of compensation by pharmaceutical companies in such cases;

(d) whether the Supreme Court has recently urged the Government to put in place proper mechanisms to stop illegal clinical trials by multi-national companies; and

(e) if so, the follow up action taken/ proposed by the Government thereon and to harmonise the regulatory mechanism with international guidelines for clinical trials in India?

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.70 FOR 1ST MARCH, 2013

(a) Schedule Y of the Drugs & Cosmetics Rules specifies the procedures to ascertain and examine the Serious Adverse Events (SAEs) to the subjects during the clinical trials. The Investigator conducting the trial is mandated to ascertain the SAE and report the same to the Drugs Controller General of India, the Sponsor and the Ethics Committee within 24 hours of its occurrence. The detailed procedures in this regard have been incorporated in the Drugs & Cosmetics Rules vide Gazette Notification GSR No. 53 (E) dated 30 January, 2013.

(b) As per the available data, the number of Serious Adverse Events of deaths in clinical trials reported during the last three years viz. 2010, 2011 & 2012 were 668, 438 and 436, respectively. However, SAEs of deaths attributable to clinical trials were 22, 16 and 16, respectively.

(c) In case of Serious Adverse Events of death, an independent Expert Committee constituted by DCG (I) shall examine the case and give recommendations to DCG (I) to determine the cause of death and also to decide the quantum of compensation, in case of clinical trial related death. The Expert Committee, while examining the event may take into consideration, the reports of the Investigator, the Sponsor and the Ethics Committee. DCG (I) after considering the recommendations of the Expert Committee shall determine the cause of death and decide quantum of compensation to be paid by the Sponsor or his representative in case of trial related deaths within three months of receiving the report of SAEs of death. Detailed procedures in this regard have been incorporated in the Drugs & Cosmetics Rules vide Gazette Notification GSR No. 53 (E) dated 30 January, 2013.

(d)&(e): The Hon'ble Supreme Court in the hearing of a Public Interest Litigation Writ Petition (Civil) No. 33/2012 - Swasthya Adhikar Manch, Indore Vs. Union of India on the subject of clinical trials in the country on 3rd January, 2013, directed that the clinical trials of new chemical entity shall be conducted strictly in accordance with the procedure prescribed in Schedule 'Y' of Drugs & Cosmetics Act, 1940 under the chairmanship of the Secretary, Department of Health & Family Welfare. Accordingly, an Apex Committee under the chairmanship of the Secretary, Department of Health & Family Welfare, with Secretary, Department of Health Research−cum-Director General, Indian Council of Medical Research, and the Director General Health Services, has been constituted to monitor the approval and conduct of clinical trials. Several steps have been taken by the Government before and after the said hearing / directions of the Hon`ble Court, as follows to strengthen the clinical trial approval procedures and their monitoring mechanism 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 mostly from the Government medical colleges and

institutes from all over the country have been constituted to advise the Central Drugs Standard Control Organisation (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 an IND Committee, chaired by the Director General, Indian Council of Medical Research (ICMR).

3. Registration of clinical trial in ICMR`s registry at www.ctri.in has been made mandatory.

4. Guidelines for conducting inspection of clinical trial sites and sponsor / Clinical Research Organizations (CROs) have been prepared.

5. Proposals to amend the toxicity study data requirements for approval of clinical trial / new drugs to make it harmonized with the international guidelines has been approved by Drugs Technical Advisory Board (DTAB).

6. To further strengthen the regulatory provisions and the monitoring mechanism of clinical trials in the country, the Drugs and Cosmetics Rules, 1945, have been amended as follows:

A. Amendment vide Gazette Notification G.S.R. 53 (E) dated 30-01-2013 specifying procedures to analyse the reports of Serious Adverse Events occurring during clinical trials and procedures for payment of compensation in case of trial related injury or death as per prescribed timelines.

B. Amendment vide Gazette Notification G.S.R. 63(E) dated 01-02-2013 specifying various conditions for conduct of clinical trials, authority for conducting clinical trial inspections and actions in case of non-compliance.

C. The registration of the Ethics Committees has been made mandatory in the Drugs & Cosmetics Rules vide Gazette Notification G.S.R No. 72(E) Dated 08.02.13 specifying requirements and guidelines for registration of Ethics Committee.