GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:71
ANSWERED ON:22.10.2008
CLINICAL TRIALS
Shukla Smt. Karuna;Singh Shri Manik

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

(a) whether cases of death due to clinical trials have been reported from different parts of the country during the last three years and the current year;

(b) if so, the details thereof;

(c) whether a number of babies/infants have died during clinical trials at the All India Institute of Medical Sciences (AIIMS) during the said period;

(d) if so, the details thereof;

(e) whether the drugs tested during clinical trials were manufactured by the multinational companies;

(f) if so, the details of such companies and the drugs manufactured by them for clinical trials;

(g) the action taken by the Government against the guilty doctors/companies responsible for the death of babies/infants and to check such incidents;

(h) whether the Government has paid any compensation to the families of the deceased children; and

(i) if so, the details thereof?

Answer

THE MINISTER OF HEALTH & FAMILY WELFARE (DR. ANBUMANI RAMADOSS)

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 71 FOR 22ND OCTOBER, 2008

(a)&(b): Some deaths have been reported due to clinical trials from different parts of the country during the last three years. Detailed information in this regard is being collected and will be laid on the table of the House.

(c)&(d): The All India Institute of Medical Sciences, New Delhi (AIIMS) has informed the Government about some cases of deaths of children at AIIMS, New Delhi during clinical trials. A total of 49 deaths of children have occurred out of 4142 children enrolled in 42 clinical studies at AIIMS, New Delhi. AIIMS has, however, stated that these deaths have occurred mainly due to serious/life threatening disease conditions. A Committee was constituted by Director, AIIMS to examine the issue following media reports regarding deaths among children in clinical trials. The key findings of the report are as follows:

(1) All studies had scientific rationale and had undergone necessary scientific review. All the study protocol were approved by the Ethics Committee of AIIMS.

(2) None of the deaths reported during clinical studies could be attributed to treatment modality under trial and they were due to the underlying high risk illness and serious co-morbid disease conditions that the children suffered from. The deaths occurred despite institutions of standard therapy for all subjects irrespective of whether they belonged to study or the control group. None of the mortality rates reported under these trials is higher than that reported in patients with similar illness. Further, the committee noted that rather additional lives were being saved because of intensive monitoring required for trial per se.

(e) There were no deaths in the trials in which the drugs manufactured by the multinational companies were used.

(f)to(i): Do not arise.