

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
RAJYA SABHA
QUESTION NO 09.11.2010
ANSWERED ON

DRUG TRIALS AT BHOPAL MEMORIAL HOSPITAL AND RESEARCH CENTRE .

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SHRI MOINUL HASSAN

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

- (a) the details of all drug trials including the names of sponsors, drugs, objectives, number of subjects for which permission was given by the Drugs Controller General India (DCGI) from 1 January, 2004 to 31 December, 2008 conducted at Bhopal Memorial Hospital and Research Centre;
- (b) the names and affiliations of the members of the Ethics Committee of the hospitals during the said period;
- (c) the amount of money that was received either by the Hospital and/or investigators for each of the trials from sponsors;
- (d) whether any of the trials were inspected or monitored on-site by the DCGI; and
- (e) if so, the details thereof?

ANSWER

THE MINSITER OF STATE FOR HEALTH AND FAMILY WELFARE

(SHRI DINESH TRIVEDI)

(a) to (c): Statement-I containing the information in respect of clinical trials for which permission was given by the Drugs Controller General India [DCG(I)] from 1 January, 2004 to 31 December, 2008 and the amount of money received by the Hospital for each of the trials is enclosed. Further, Statement-II containing the information provided by the Director, Bhopal Memorial Hospital and Research Center, Bhopal about the details of the Ethics Committee of Bhopal Memorial Hospital and Research Centre during the period 1 January, 2004 to 31 December, 2008 is also enclosed.

(d) and (e): The inspection of Bhopal Memorial Hospital and Research Centre was carried out from 10-08-2010 to 12-08-2010 by a team constituted by the Central Drugs Standard Control Organisation (CDSCO) for a clinical trial titled "A Phase 3, Randomized, Double-Blind, Parellel-Group, Multinational Trial of Intravenous Telavancin Pneumonia with a Focus on Patients with Infections Due to Methicillin Resistant Staphylococcus aureus (Protocol No. 0015). Findings of the inspection show some deficiencies for which Dr. Pradeep Bhattacharya (Principal Investigator) and M/s Quintiles Ltd., Bangalore (CRO) were asked to explain their position vide letter Dt. 28-9-2010. M/s Quintiles Ltd., Bangalore (CRO) has already submitted its reply.