GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1429
ANSWERED ON:05.03.2010
CLINICAL TRIALS OF DRUGS
Tewari Shri Manish

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

(a) the details of the regulatory framework for authorising clinical trials of untested pharmaceutical drugs from Phase I to Phase IV on human beings;

(b) the Agency/Department entrusted with the work of administrative superintendence of these regulations;

(c) the number of such clinical trials conducted in government/public hospitals between January 2004 till date;

(d) the number of clinical trials of imported pharmaceutical formulations conducted from Phase I to Phase IV during the said period in private hospitals across the country;

(e) the names of the pharmaceutical companies who conducted clinical trials of their drugs on human beings in the hospitals owned by their subsidiaries or related group companies; and

(f) the number of fatalities reported during the said period as a consequence of these clinical trials?

Answer

THE MINISTER OF STATE FOR HEALTH & FAMILY WELFARE(SHRI DINESH TRIVEDI)

(a) & (b) Clinical trials are regulated under the Drugs & Cosmetic Act, 1940 and the Drugs & Cosmetic Rules, 1945 made there under. Clinical trials on 'New Drugs' from Phase I to Phase IV are required to be carried out in accordance with the requirements and guidelines specified in Rule 122DA, 122DAA, 122DB, 122E and Schedule Y of the Drugs & Cosmetic Rules. Schedule Y also mandates that clinical trial is conducted as per Good Clinical Practices (GCP) Guidelines issued by Central Drugs Standard Control Organisation (CDSCO). Clinical trial can be initiated in the country only after approval from the Drugs Controller General (India) {DCG(I)} and respective Ethics Committees. Prior to the 17th November, 2008, registration of clinical trial was voluntary. From 15th June, 2009, it has been made mandatory to register all clinical trials permitted on or after the said date at Indian Council of Medical Research (ICMR) registry at www.ctri.in before enrolling first patient in the study. Such registration will improve transparency and accountability of all stake holders involved in clinical trials.

(c) to (e): Number of clinical trials actually conducted in government/private hospitals are not available with the CDSCO as prior to the 17th November, 2008, registration of clinical trial was voluntary. The number of clinical trial permissions granted by CDSCO to firms/sponsors/government hospitals/private hospitals between January, 2004 to December, 2009 is approximately 2000.

(f): Death may occur during clinical trials due to various reasons.These could be disease related deaths like cancer etc or administration to critical or terminally ill patients or side effects or unrelated causes. Such deaths are investigated for causal relationship by investigator and by medical experts of sponsor. The information collated revealed that there were 132 deaths in the year 2007, 288 in the year 2008 and 308 upto August,2009.