GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:886
ANSWERED ON:25.02.2011
CLINICAL TRIALS
Mohan Shri P. C.

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

(a) the total number of clinical trials registered in the country during each of the last three years and the current year so far, State/UT-wise;

(b) whether the Committee appointed by the Government to investigate ethical violations in conducting such clinical trials in the country has since submitted its report;

(c) if so, the details thereof alongwith the action taken thereon;

(d) whether the Government proposes to frame a comprehensive policy in order to strengthen the regulation of clinical trials and compensate the victims of the harmful affects of such trials; and

(e) if so, the details thereof and if not, the reasons therefor?

Answer

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

(a): As per the information made available by the National Institute of Medical Statistics (NIMS),ICMR, New Delhi, the total number of clinical trials registered in the country at the ICMR clinical trial registry (CTRI) during the last three years and current year is as follows:

July 2007 - December 200711

Jan 2008 - Dec.2008137

Jan.2009 - Dec. 2009546

Jan. 2010 - Dec. 2010806

Jan. 2011 - 21 Feb. 2011122

(b) & (c): The ICMR had decided to investigate allegations of ethical violations in connection with the clinical trials of Human Papillomavirus (HPV) Vaccines conducted by PATH-India in collaboration with the State Governments of Andhra Pradesh and Gujarat. Pending the report of the investigations. The vaccination under the project undertaken by the organisation remains suspended since 8th April,2010.

(d) & (e): Schedule Y of Drugs & Cosmetics Rules, 1945 mandates that clinical trials are required to be conducted as per Good Clinical Practice (GCP) guidelines issued by the Central Drugs Standard Control Organisation (CDSCO). Clinical trials can be initiated in the country only after approval from the Drugs Controller General (India) and the respective ethics committees which should exercise particular care to protect the rights, safety and well-being of all trial subjects. GCP guidelines further specify that the research subjects who suffer physical injury as a result of their participation in the clinical trial are entitled to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability subject to confirmation from the Ethics

Committee. These also stipulate that the sponsors are obliged to pay such compensation in these cases. The Drugs and Cosmetics (Amendment) Bill, 2007 also contains provisions for regulating clinical trials in the country.