GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1365
ANSWERED ON:27.11.2009
CLINICAL TRIALS
Gandhi Shri Feroze Varun

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

(a) the details of the registered clinical trials undertaken in th country during the last three years and the current year;

(b) whether the Government has received complaints/reports of unfair inducements to participate in these clinical trials;

(c) if so, the details thereof and the steps taken or proposed to be taken to protect the rights of the trial participants;

(d) whether the Government also proposes to regulate the functioning of Contract Research Organisations (CROs)/ Sponsors undertaking clinical trials in the country and to impose penal provisions for any frauds by them; and

(e) if so, the details thereof?

Answer

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

(a): Prior to 17th November, 2008, registration of clinical trial was voluntary. For all clinical trials, permission of which were granted between 17th November, 2008 to 14th June, 2009, applicants were advised to get the trials registered at Indian Council of Medical Research (ICMR) registry at www.ctri.in. However for all clinical trials permitted on or after 15th June, 2009, it is mandatory to register the trial at the said ICMR site before enrolling first patient in the study. Clinical Trial Registry- India (CTRI) is maintained by National Institute of Medical Statistics, ICMR and was launched on 20 July, 2007. The details of the registered clinical trials as obtained from ICMR is as under:

Year	No. of registered Trials
July07 -Dec-07	11
Jan08 - Dec-08	137
Jan09 - 24th Nov.09	464
Total	612

(b) & (c): There is no such information about inducements to participate in these clinical trials.

(d) & (e): Yes. Draft guidelines and requirements for registration of organization conducting clinical trials in the country have been developed, which are proposed to be incorporated as new Schedule to Drugs and Cosmetics Rules, 1945. It is also proposed to make new provision in the Drugs and Cosmetics Rules to ensure that no organization or individual shall conduct clinical trial without prior registration of the organization with CDSCO as per the proposed guidelines. The said guideline is under approval of Drug Technical Advisory Board.

The Drugs and Cosmetics (Amendment) Bill, 2007 pending in Rajya Sabha also contains provisions to incorporate penal provision for misconduct in clinical trials.