GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3579
ANSWERED ON:29.07.2009
CLINICAL TRIALS OF MEDICINES BY MNCS
Rao Shri Kavuri Samba Siva

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

(a) whether certain clinical trials of experimental drugs and the laboratories producing data in this regard were found fake;

(b) if so, the details thereof;

(c) whether the existing guidelines suffer from any infirmities to regulate experimental drugs on human beings by Multi National Companies (MNCs) in the country;

(d) if so, the details thereof; and

(e) the action taken by the Government in this regard?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a)&(b): The office of Drugs Controller General(India) has received reports that certain clinical trials of experimental drugs were conducted by one investigator at one hospital in Jamnagar, Gujarat by creating false documents. In reply to query made by Central Drugs Standard Control Organisation (CDSCO), Medical Superintendent of the hospital has informed that the investigator created false Ethics Committee and fabricated various letters with false signature and stamps/seals and submitted the same to various companies to start drug trials. Medical Superintendent of the hospital has also informed that a police complaint with city B Division Police Station, Jamnagar has been filed on 02.04.09.

(c) to (e): There exists adequate provisions under the Drugs and Cosmetics Rules to regulate Clinical trials in the country effectively. Clinical trials are required to be carried out in accordance with requirements and guidelines specified in Rule 122DA, 122DAA, 122 DB, 122E and Schedule Y of Drugs and Cosmetics Rules. Schedule Y also mandates that clinical trial is conducted as per Good Clinical Practices (GCP) Guidelines issued by CDSCO, Directorate General of Health Services,Government of India. Clinical trial can be initiated in the country only after approval from DCG(I) and respective ethics committee.

Further, the following steps have been taken to tighten the regulations for clinical trials in the country:

(1) 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 state holders involved in clinical trials.

(2) The Drugs & Cosmetics (Amendment) Bill 2007 introduced in the Rajya Sabha on 21.8.2007 contains separate regulatory provisions for clinical trial.

(3) For registration of Clinical Research Organisation (CRO) draft guidelines have been prepared and posted on CDSCO website for public comments.