GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4127
ANSWERED ON:26.08.2011
NORMS FOR CLINICAL TRIALS OF DRUGS VACCINES
Antony Shri Anto;Nahata Smt. P. Jaya Prada;Shekhar Shri Neeraj;Singh Shri Yashvir

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

(a) whether the Government has laid down norms and procedures encompassing various aspects relating to the conduct of clinical trials of drugs/vaccines on human beings in the country;

(b) if so, the details thereof;

(c) whether cases of violation of these norms and procedures by certain hospitals and drug manufacturing companies have been reported in the country;

(d) if so, the details thereof during the last three years and the current year so far;

(e) the action taken by the Government in each of such cases indicating the number of persons, hospitals and drug manufacturing companies prosecuted; and

(f) the corrective measures taken/proposed to be taken by the Government to check the recurrence of unethical practices and violation of rules relating to clinical trials?

Answer

THE MINISTER OF HEALTH & FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a) & (b): Clinical trials of new drugs are regulated under the Drugs and Cosmetics Act and Rules made thereunder. The requirements and guidelines for undertaking clinical trials are specified in Schedule Y of Drugs & Cosmetics 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), Directorate General of Health Services, Government of India. Clinical trials can be initiated only after the approval of Drugs Controller General (India) and respective Ethics Committee, which is responsible for safety and wellbeing of trial subjects.

(c) to (e): A statement giving the details of the cases of violation of the provisions of Drugs & Cosmetics Rules of conduct of clinical trials and action taken in these cases during the last three years is annexed.

(f): Following initiatives have been taken for further strengthening of clinical trial regulations in the country:

1. It has been made mandatory for registration of clinical trials with the Centralized Clinical Trial Registry of Indian Council of Medical Research (ICMR) with effect from 15th June, 2009.

2. Guidelines for conducting clinical trials inspections have been posted on the website of CDSCO (cdsco.nic.in).