GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:211
ANSWERED ON:06.12.2006
CLINICAL TRIALS ON PATIENTS
Malhotra Prof. Vijay Kumar;Tripathi Shri Chandramani

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

(a) Whether the Government has received any complaints regarding clinical trials on patients without their consent;

(b) If so, the details thereof ;

(c) The action taken by the Government in this regard and the outcome thereof ;

(d) Whether the Government is contemplating to enact a law in regard to the trial of medicines and compensation to be given due to the harm caused as a result thereof; and

(e) If so, the details thereof ?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a)to(e) : A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 211 FOR 6TH DECEMBER, 2006

An Anonymous complaint was received in the Central Drugs Standard Control Organisation on 22.11.2006 wherein it was alleged that two Medical institutions at Salem, namely Sheron Cancer Research Institution, Yercaud Adivaram and S.K.S. Hospital, Brindavan Road, Salem, have conducted clinical trials on more than 400 healthy individuals and they were misled as if the exercise is a medical check up. These clinical trials are stated to have been done under the banner of Lotus Laboratory, a branch of Sheron Cancer Centre. It also alleged that some of the subjects for this clinical trial are suffering with problem of pain in the legs of recurrent nature and loss of sexual desire. They Deputy Drugs Controller (I), South Zone, CDSCO, Chennai, has been directed to conduct an investigation into the complaint in association with Drug Controller of Tamil Nadu and Subject Experts and submit a report to this Ministry.

The Drugs and Cosmetics Rules have a provision for monitoring the clinical trials for new drugs as defined under Rule 122 A to 122 E. Also in Schedule-Y of the Drugs and Cosmetic Act specifies the requirements and guidelines for clinical trials. One of the requirements of Schedule-Y is compliance with Good Clinical Practices (GCP). The point 2.4.7 of GCP guidelines recommends compensation for accidental injuries and makes it obligatory for the sponsors to pay compensation to the victims.

A proposal to amend the Drug and Cosmetic Act to provide that no person shall conduct clinical trials in respect of any drug or cosmetic except under, and in accordance with, the permission granted by the Central Drugs Authority and also to specify the penal action in term of imprisonment and or fine, which may extend to Twenty Lakh rupees in case of contravention by any person, is under consideration.