GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:502
ANSWERED ON:11.05.2012
CLINICAL TRIALS
Begum Tabassum ;Rani Killi Krupa

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

(a) whether the Government has taken note of media reports regarding conduct of clinical trials by certain multinational drug companies illegally in collusion with certain hospitals/medical colleges/NGOs in the country;

(b) if so, the details thereof;

(c) the number of such complaints received alongwith the action taken/proposed by the Government thereon during the last three years and the current year so far, State/UT-wise;

(d) whether the Government proposes to tighten the approval and monitoring mechanism and provide for strict punishment to offenders in order to check illegal clinical trials in the country ; and

(e) if so, the details thereof?

Answer

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

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 502 FOR 11th MAY, 2012

(a)to(c): There have been media reports about irregularities in the conduct of clinical trials. A detail of such cases and action taken thereon during 2010, 2011 and 2012 (till date) is enclosed at Annexure-1.

(d)&(e): Yes, Madam. In order to strengthen the regulation and monitoring of clinical trials in the country, the following measures have been taken by the Government:

(i) All clinical trials, the permissions for which have been granted by the office of DCG(I) on or after 15th June 2009, have to be mandatorily registered on the clinical trial registry at www.ctri.in of Indian Council of Medical Research (ICMR).

(ii) CDSCO has issued guidelines for conducting inspection of clinical trial sites and Sponsor / Clinical Research Organisations (CROs).

(iii) Twelve New Drug Advisory Committees (NDACs) and Six Medica] Device Advisory Committees (MDACs) have been constituted to evaluate clinical trials proposals. These committees consist of leading experts from Central and State Government medical institutions.

(iv) A draft notification has been issued for incorporation of a new rule in the Drugs & Cosmetics Rules, 1945, which provides the following:

(a) medical treatment and financial compensation to the trial subjects in case of trial related injury or death;

(b) Procedure for payment of financial compensation;

(c) Enhancement of responsibilities of Ethics Committee (EC), Sponsor & Investigator to ensure that financial compensation as well as medical care is provided to the trial subjects who suffer trial related injury or deaths and such information is provided to DCG(I).

(d) Amendment of the format for obtaining informed consent of trial subjects to include the details of address, occupation, annual income of the subject so as to have information regarding socio-economic status of the trial subjects.