# GOVERNMENT OF INDIA
# HEALTH AND FAMILY WELFARE
# LOK SABHA

STARRED QUESTION NO:173
ANSWERED ON:02.12.2011
CLINICAL TRIALS
Abdulrahman Shri ;Dhotre Shri Sanjay Shamrao

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

(a) whether the Government has taken note of various reports and complaints regarding conduct of clinical trials on patients by hospitals, clinics and pharmaceutical companies without their consent;

(b) if so, the details thereof;

(c) the number of such cases investigated, hospitals/companies found guilty and action taken in these cases including compensation during the last three years and the current year so far;

(d) whether the Government proposes to strengthen clinical trials regulations and enforce their strict compliance in the country; and

(e) if so, the details thereof alongwith the steps so far taken for the purpose?

## Answer

MINISTER OF THE STATE IN THE MINISTRY 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. 173 FOR 2ND DECEMBER, 2011

(a)to(c): Yes, Madam. A statement giving the number of cases investigated and action taken thereon for irregularities in conduct of clinical trials during the last three years and the current year is annexed.

(d)&(e): In order to strengthen the regulations relating to clinical trials, following proposals for amendments in Drugs and Cosmetics Rules, 1945, have been approved by Drug Technical Advisory Board (DTAB), a statutory advisory committee under the Drugs & Cosmetics Act, 1940:

1. Incorporation of more specific provisions for providing financial compensation to the trial subjects in case of trial related injury or death.

2. Enhancement of responsibilities of Ethics Committee, 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).

3. 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.

4. Incorporation of Rules to have authority for inspection by CDSCO, assisted by concerned state drug control authority, and to take administrative actions like suspension/cancellation of clinical trial permission, restriction of investigator, sponsor/Clinical Research Organisation (CRO) to conduct future clinical trial, in case of non-compliance.

5. Incorporation of Rules and a new schedule for registration of Ethics Committee and to amend regulatory provisions requiring that clinical trials should be conducted at sites which have their own Ethics Committees. However, for conduct of Bio-avaiJability & Bio-equivalence studies of drugs approved in the country and/or elsewhere (for new drug approval purpose), Ethics Committee approval may be obtained from Independent Ethics Committee of same area where the site is located.

6. As per prescribed procedure, these proposals are to be further examined and finalized after obtaining and taking into account the views and suggestions of various stakeholders.