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

STARRED QUESTION NO:459
ANSWERED ON:27.08.2010
CLINICAL TRIALS
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**Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:**

(a) whether cases of irregularities in the clinical trials of drugs/vaccines have been reported in various parts of the country including Madhya Pradesh;

(b) if so, the details thereof alongwith the action taken by the Government in the matter;

(c) whether the Drugs Controller General proposes to tighten the approval and monitoring mechanism of such clinical trials; and

(d) if so, the details thereof?

## Answer

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

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 459 FOR 27TH AUGUST, 2010

(a) & (b): Some cases of alleged Irregularities in clinical trials as reported recently in media are as follows:

1. Alleged Irregularities in conduct of a trial with Human Papilomavirus (HPV) vaccine in a post licensure observational study trial in Gujarat and Andhra Pradesh. Indian Council of Medical Research (ICMR) has suspended the trial and the Ministry has set up a high power enquiry committee to investigate the matter.

2. Alleged irregularities in drug trials conducted in Bhopal and Indore. A team of officials from the Central Drugs Standard Control Organisation (CDSCO) has carried out recently an inspection of one clinical trial conducted at Bhopal Memorial Hospital and Research Centre (BMHRC). The Report of the inspection team is currently being examined by the office of DCG(I).

(c) & (d): Clinical trials of drugs/vaccines are permitted to be conducted in the country in accordance with requirements and guidelines specified in the Rule 122 DA, 122DAA, 122DB, 122E and Schedule Y of Drugs & Cosmetics Rules. Schedule Y also mandates that clinical trials are conducted as per Good Clinical Practice (GCP) Guidelines issued by CDSCO, Directorate General of Health Services, Government Of India. Clinical trials can be initiated in the country only after approval from Drugs Controller General of India and respective ethics committee.

In order to strengthen the regulation of clinical trials, CDSCO has taken various initiatives as follows:

# In order to improve transparency, accountability and accessibility in clinical trials, it has been made mandatory to register all clinical trials, permission for which have been granted by office of DCG(I) on or after 15th June 2009, in ICMR clinical trial registry at www.ctri.in

# Draft guidelines and requirements for registration of CRO's in the country have been developed and already approved by Drugs Technical Advisory Board (DTAB) to be incorporated as Rule 122DAB and Schedule Y1 in Drugs and Cosmetics Rules, 1945.

Regulatory officials of CDSCO have been imparted training in clinical trial inspection through various training workshops