

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

UNSTARRED QUESTION NO:2158  
ANSWERED ON:24.08.2012  
CLINICAL TRIALS  
Shekhar Shri Neeraj;Singh Shri Yashvir

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

- (a) whether the Government is aware that pharmaceutical companies are targeting small towns for phase-III clinical trials;
- (b) if so, the details thereof;
- (c) whether the Government has taken note of a recent report which has observed that pharma companies have claimed over last few years that most of their drugs trials were taking place in cosmopolitan cities which has a heterogenous population but their submission has been found incorrect and basic purpose of phase-III trials is not being served;
- (d) if so, the details thereof along with the response and reaction of the Government to the findings of the Committee; and
- (e) the details of fresh action, the Government proposes to take to regulate conduct of clinical trials in the country by drugs companies in view of the above report?

**Answer**

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABIAZAD)

(a) to (d): Clinical trials of new drugs are regulated under the provisions of the Drugs and Cosmetic Rules, 1945. The requirements and guidelines for undertaking clinical trials are specified in Schedule Y of these rules. Schedule Y also mandates that clinical trial is conducted as per the Good Clinical Practices (GCP) guidelines issued by the Central Drugs Standard Control Organisation (CDSCO). As per the GCP guidelines, the Sponsor of the clinical trial is responsible for selecting the Investigator(s) / Institutions taking into account the appropriateness and availability of the study site and facilities. Clinical trial proposals are examined in consultation with New Drug Advisory Committees consisting of eminent experts. During the evaluation of these proposals, the committee also examines the proposed sites of the clinical trials.

(e) The regulatory provisions for clinical trials in the Drugs & Cosmetics Rules, 1945 are continuously being revised and strengthened, which is an ongoing process.