GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:134
ANSWERED ON:14.07.2004
CLINICAL TRIALS OF NEW DRUGS
Koya Dr. P. Pookunhi

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

(a) whether the Government is aware that the Drug companies are using the patients/poor people in the country for clinical trials of their new drugs;

(b) if so, whether any norms/rules have been laid down by the Government for conducting clinical trials of new drugs;

(c) if so, the details thereof;

(d) whether the Government has made any assessment of the clinical trials being conducted by the Drug companies in violation of the laid down norms/rules;

(e) if so, the details thereof; and

(f) the remedial action taken/proposed to be taken in this regard?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS)

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 134 FOR 14TH JULY, 2004

As per Drug regulatory norms, clinical trials involving participation of human subjects (patients) are necessary for assessing overall benefits and risks i.e. safety and efficacy of new drugs. These trials are mostly carried out in hospitals (both in public and private sector) only after approval by institutional ethics committees and regulatory approval from the competent authority as stipulated in Drugs and Cosmetics Act, 1940, and Rules made thereunder.

Under Rule 122-D of the Drugs and Cosmetics Rules, 1945, it has been made mandatory that no clinical trials for new drugs whether for clinical investigation or for any clinical experiment by any institution shall be conducted except under and in accordance with appropriate permission.

Government has prescribed appropriate norms / rules for conducting clinical trials in the country under Part XA (Rule 122-A to E) and Schedule − 'Y' of the Drugs and Cosmetics Rules. Schedule 'Y' of the Drugs and Cosmetics Rules which prescribed norms for pre-clinical and clinical studies has further been revised and is under publication. Under the revised Schedule − Y, ethical aspects concerning recruitment of patients and their safety have been incorporated. The responsibilities of ethics committees, sponsors and clinical investigators and requirement of compliance with GCP norms have also been adequately laid down.

Guidelines on Good Clinical Practices (GCP) for conducting clinical trials in India have also been published in 2001. The ethical guidelines for biomedical research on human subjects have been published and circulated by Indian Council for Medical Research (ICMR).

Phase −I clinical trial i.e. first time use of new chemical entity (NCE) on human subjects in India is not permitted for the drugs developed abroad. However, in such cases, Phase-II and Phase-III Clinical trials are permitted in the country only after strict examination of safety data generated through pre-clinical and Phase − I study in the country of origin.