GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:248
ANSWERED ON:08.03.2006
CLINICAL TRIALS
Rao Shri Kavuru Samba Siva

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

(a) the number of Clinical Research Organisations functioning in the country;

(b) the reasons for doing away with the requirements of phase lag in trials;

(c) the procedure followed in registering the volunteers offering them for the clinical trials and the incentives offered, if any;

(d) whether the Government proposes to put in place a regulatory apparatus as safeguard against exploitation of innocent persons and to cope with legal and ethical violations; and

(e) if so, the details thereof?

Answer

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

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 248 FOR 8TH MARCH, 2006.

A Clinical Research Organization (CRO) is an organization to which the sponsor may transfer or delegate some or all the tasks, duties and/or obligations regarding a Clinical Study.

There are about 20 Clinical Research Organizations functioning in the country. Considering India`s potential in terms of capabilities in drug discovery research of which Clinical Research is a major component, the phase lag in trials was removed so that Indian clinical investigators could participate in global multi-centric clinical trials at Phase II and Phase III stages parallel to the investigators in other countries. However, Phase I trial which involves first time use of a new molecule in human subjects has not been allowed to be conducted in India for new molecules developed abroad. The Mashelkar Committee which has examined various issues concerning Drug Regulatory System in India has highlighted `India`s potential as a global hub for Clinical Research`.

The revised Schedule Y under Drugs and Cosmetics Rules prescribes the procedures to be adopted for enrolling clinical trial study subjects. This includes taking, freely given and informed, written consent from each study subject. The investigator must provide information about the study verbally as well as using a patient information sheet, in a language that is non-technical and understandable by the study subject. Both the patient information sheet as well as the informed consent form should have been approved by the ethics committee and furnished to the licensing authority. Any changes in the informed consent documents should be approved by the ethics committee and submitted to the licensing authority before such changes are implemented.

As per the norms prescribed under Good Clinical Practices (GCP), monetary or any other inducements are not to be used to enroll the patients. Informed consent has to be obtained from every study subject as per the norms prescribed under Schedule Y, which ensures the right and safety of research subjects are adequately safeguarded.

The Government has put in place appropriate regulatory measures to ensure that clinical trials are conducted in conformance to the internationally accepted norms of GCP by amending the Rules (122A to 122E) defining the clinical trial under the Drugs and Cosmetics Rules, publication of GCP guidelines and amendment of Schedule Y under Drugs and Cosmetics Rules which prescribes the `Requirements and Guidelines to undertake clinical trials` in order to ensure that all clinical trials are conducted in a legal and ethical manner. In addition to these regulatory initiatives, a programme for audits of clinical trials by regulatory agency has also been formulated.