GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4025
ANSWERED ON:26.08.2011
ETHICS COMMITTEES FOR CLINICAL TRIALS
Bhagat Shri Sudarshan;Vinay Kumar Alias Vinnu Shri

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

(a) whether Ethics Committee and Independent Ethics Committees have been constituted under the Drugs and Cosmetics Rules, 1945 in the country;

(b) if so, the number of these ethics committees so far functional alongwith their functions in the country;

(c) whether the Government has laid down any well defined mechanism and norms/regulations in respect of registration, composition and monitoring of these ethics committees;

(d) if so, the details thereof;

(e) whether the Government has made certain eligibility criteria and also terms and conditions for the members of these ethics committees; and

(f) if so, the details thereof?

Answer

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

(a) & (b): Under the Drugs and Cosmetics Rules, 1945, clinical trial on a new drug shall be initiated only after the permission has been granted by the Licensing Authority under Rule 21(b) i.e. Drugs Controller General (India) and the approval obtained from the respective Ethics Committee(s). As per the Good Clinical Trial Practices (GCP) Guidelines recognised under Schedule-Y to the Rules, the sponsor who conducts clinical trial is required to ensure that Ethics Committee (EC) is organised and operates according to GCP guidelines and other applicable laws and regulations.

The responsibilities of Ethics Committee are provided under Schedule Y to the said Rules. It is the responsibility of the EC to review and consider to accord its approval to a trial protocol to safeguard the rights, safety and wellbeing of all trial subjects. EC(s) should get documented 'standard operating procedures' and maintain a record of its proceedings. EC(s) should make, at appropriate intervals, an ongoing review of the trial for which they review the protocol(s). Statistics about the number of Ethics Committees constituted by various institutes in the country are not maintained centrally.

(c) & (d): Schedule Y to the said Rules provides that an EC should have at least seven members. The Committee should appoint, from among its members, a Chairperson (who is from outside the institution) and a Member-Secretary. Other members should be a mix of medical /non-medical, scientific and non-scientific persons, including lay public.

(e) & (f): The GCP Guidelines for clinical trials in India, recognised under the said Rules, further provide criteria for basic responsibilities, compositions, terms of reference, review procedures for the Ethics Committees along with guidelines for decision making process, record keeping, selection of special groups as research subjects like pregnant women, children etc.