GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1767
ANSWERED ON:19.11.2010
CLINICAL AND SCIENTIFIC RESEARCH
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the regulatory measures in force in the country for the safety and protection of rights of human subjects being used in clinical and scientific research in the country;

(b) whether the Government proposes to ban the use of human subjects for clinical and scientific research;

(c) if so, the details thereof and if not, the reasons therefor;

(d) whether the Government also proposes to tighten and strengthen the rules and approval procedures related to clinical trials and marketing licences of biotechnology drugs, medical devices and vaccines; and

(e) if so, the details thereof?

Answer

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

(a) Clinical trials are regulated under the Drugs and cosmetic Act and Rules made thereunder. Schedule Y to the Drugs and Cosmetic Rules provides requirements and guidelines for permission to undertake clinical trials. The clinical trials are required to be conducted as per Good Clinical Practices (GCPs). Clinical trials can be initiated only after the approval of Drugs Controller General of India. Before enrolment of the subjects, it is required to be registered with the registry maintained by the Indian Council of Medical Research. Informed written consent is also required to be obtained from the subjects before participation. It is the responsibility of the Ethics Committee to ensure that rights, safety and well being of the trial subjects are safeguarded. Investigators are required to ensure that adequate medical care is provided to the participants for any adverse event.

(b) & (c) There is no proposal too ban the use of human subjects for clinical and scientific research as the safety and efficacy of the drug for the specific indication is required to be tested on the human subject before this could be permitted for safe use of the patients.

(c) & (e) To strengthen the approval procedure for clinical trials, a registry has been created where all such proposals have to be mandatorily registered. Other methods include inspections and random checks. The manufacture of biotechnology drugs, vaccines and medical devices is regulated under the Drugs and Cosmetics Act, 1940 and Rules made thereunder.