GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1309
ANSWERED ON:30.11.2012
CLINICAL TRIAL PARTICIPANTS
Ahir Shri Hansraj Gangaram;Alagiri Shri S. ;Bapurao Shri Khatgaonkar Patil Bhaskarrao;Bhoi Shri Sanjay;Bundela Shri Jeetendra Singh;Gaikwad Shri Eknath Mahadeo;Gandhi Smt. Maneka Sanjay;Gorakhnath Shri ;Jaiswal Shri Gorakh Prasad ;Natarajan Shri P.R.;Paranjpe Shri Anand Prakash;Ramasubbu Shri S.;Singh Alias Pappu Singh Shri Uday;Singh Rajkumari Ratna;Sinh Dr. Sanjay

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

(a) the details of the provisions made by the Government under the Drugs and Cosmetics Rules in respect of clinical trials of drugs and rights/safety of trial participants in the country;

(b) whether the said provisions are adequate to protect the interests of trial participants from becoming guinea pigs in global clinical trials;

(c) if so, the details thereof along with the lacuna noticed therein;

(d) whether the Drug Technical Advisory Board (DTAB) has recommended for amendment in the Drugs and Cosmetics Rules;and

(e) if so, the details thereof along with the follow up action taken/proposed by the Government thereon?

Answer

MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a) to (c): Clinical trials of new drugs are regulated under the Drugs and Cosmetic Act, 1940 and Rules made there under. The requirements and guidelines for undertaking clinical trials are specified in Schedule Y of Drugs & Cosmetic Rules. Schedule Y also mandates that clinical trial is conducted as per Good Clinical Practices (GCP) Guidelines issued by Central Drugs Standard Control Organisation (CDSCO). Clinical trials can be initiated only after the approval of CDSCO and respective Ethics Committee. In all trials, a freely given informed written consent is required to be obtained from the person participating in the study. Where that person is not able to give informed consent (like an unconscious person or a minor or those suffering from severe mental illness or disability), the same may be obtained from a legally acceptable representative of that person. Thus, Schedule-Y and GCP guidelines provide detailed provisions / safety measures to ensure that the rights, safety and well-being of trial subjects are protected.

(d): Yes.

(e): Based on the recommendations of Drug Technical Advisory Board (DTAB), following draft rules for amendments in the provisions of Drugs and Cosmetics Rules related to clinical trials have been published:

(1) GSR 821(E) 18.11.2011:

(i) Medical treatment and financial compensation to the trial subjects in case of trial related injury or death;

(ii) Procedure for payment of financial compensation;

(iii) Enhancement of responsibilities of Ethics Committee (EC), Sponsor & Investigator to ensure that financial compensation as well as medical care is provided to the trial subjects who suffer trial related injury or deaths and such information is provided to the Drugs Controller General (India) [DCG(I)].

(iv) Amendment of the format for obtaining informed consent of trial subjects to include the details of address, occupation, annual income of the subject so as to have information regarding socio-economic status of the trial subjects.

(2) GSR 572(E) dated 17.07.2012: To provide the authority for clinical trials inspections by CDSCO and for taking administrative actions like restriction on investigators/ sponsors / CROs from conducting future clinical trials in case of non-compliance.

(3) GSR 573(E) dated 17.07.2012: Requirements and guidelines for registration of Ethics Committee.

The DTAB has also recommended the following proposals:

Amendment in Schedule-Y specifying that clinical trials are required to be conducted at sites which have their own Ethics Committee. However, for conduct of Bio-availability and Bio-equivalence study of drug approved in the country and / or elsewhere (for

new drug approval purpose), Ethics Committee approval may be obtained from Independent Ethics Committee of same areas where the site is located.

To make it mandatory that audio-video recording of informed consent process of clinical trial subjects will be maintained along with written Informed Consent Form by the investigator.