GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:330
ANSWERED ON:16.12.2011
DRUG TESTING/CLINICAL TRIALS
Baitha Shri Kameshwar ;Mani Shri Jose K.

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

(a) the details of the drugs testing laboratories operating in the country, State/UT-wisePRESCRIBED ABN;

(b) whether some of the above drugs testing laboratories are non- functional or are under-performing;

(c) if so, the details thereof, the reasons for their under performance along with the corrective measures taken in this regard, State/UT-wise including Jharkhand;

(d) whether deaths have been reported on account of administration of un-tested drugs and also during clinical trials of drugs;

(e) if so, the details of the socio-economic profile of the deceased both for terminally ill cases and those died due to clinical trials alongwith the amount of compensation paid to the victims; and

(f) the details of code of ethics followed by the investigating teams, institutions, drug companies and patients for clinical trials alongwith the measures taken/proposed to ensure that poor and vulnerable sections of the society are not subjected to drug trials?

Answer

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

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 330 FOR 16TH DECEMBER, 2011

(a) The requisite information on the Central Government Drugs Testing Laboratories and the drug testing laboratories of the State/Union Territory Governments are enclosed at Annexure-1 & II respectively.

(b)&(c): The Central Government is aware that some of the drug testing laboratories of the State / UT Governments are not functioning properly. For example in the States of Jharkhand and Chhattisgarh, the drugs testing laboratories are not functional at present because of manpower shortage.The State Governments are responsible for their functioning.

(d)&(e): There are no reports of death on account of administration of un-tested drugs as it is mandatory for the manufacturers to test each batch of the drug before release for sale. However, death may occur during clinical trials due to various reasons. These could be disease related deaths as in case of cancer or administration of the drug to critically ill patients or side- effects or unrelated causes, etc. Such deaths are investigated for causal relationship by the investigator and by the medical experts of the sponsor. 22 cases of trial related deaths were reported in clinical trials in the year 2010 and compensations have been paid in all these cases. Details of the compensation paid in these cases are at Annexure-III.

So far the socioeconomic profiles of the trial subjects have not been included in the format for Informed Consent taken at the time of their enrollment.

(f) The clinical trials on a new drug are initiated only after the permission has been granted by the Licensing Authority under Rule 21(b) i.e. Drugs Controller General (India) {DCG(I)} and the approval obtained from the respective Ethics Committee. The responsibilities of sponsor, investigator and ethics committee have been prescribed in the Schedule "Y" of Drugs and Cosmetics Rules and Good Clinical Practice (GCP) guidelines for clinical trials in India recognized under Schedule "Y". The Investigator is responsible for the conduct of the trial according to the protocol and the GCP Guidelines. The Sponsor of the clinical trial is responsible for implementing and maintaining quality assurance systems to ensure that the clinical trial is conducted and data generated, documented and reported in compliance with the protocol and Good Clinical Practice (GCP) Guidelines for clinical trials in India.

It is the responsibility of the Ethics Committee (EC), which reviews and accords its approval to a trial protocol, to safeguard the rights, safety and well-being of all trial subjects. The Ethics Committee is required to exercise particular care to protect the rights, safety and well being of all subjects participating in the trial.

In order to strengthen the regulations relating to clinical trials, a Draft Notification GSR 821(E) dated 18-11-2011 for amendments in Drugs and Cosmetics Rules has been published. This Notification contains the following provisions:-

1. Incorporation of provisions for providing financial compensation to the trial subjects in case of trial related injury or death.

2. Enhancement of responsibilities of 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.

3. 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.