GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:124
ANSWERED ON:17.08.2012
CLINICAL TRIALS
Naik Dr. Sanjeev Ganesh;Owaisi Shri Asaduddin

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

(a) Whether the Government has taken note of the recent data released by the World Health Organisation (WHO) which shows consistently high mortality rates in clinical trials in India;

(b) if so, the details thereof indicating the number of deaths reported in clinical trials due to Serious Adverse Events (SAEs) during each of the last three years and the current year so far;

(c) whether compensation has been paid to all the trial subjects for trial related injury or deaths;

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

(e) the corrective measures taken/proposed by the Government to ensure proper verification/examination of socio-economic profile of trial participants, safety of volunteers involved therein and compensation to the victims, particularly in view of the concerns recently expressed by the Supreme Court and the National Human Rights Commission (NHRC)?

Answer

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

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 124 FOR 17TH AUGUST, 2012

(a)&(b): The WHO has denied existence of any WHO report regarding the deaths in clinical trials in India in the past few years. However, the Serious Adverse Events (SAE) of death may occur during clinical trials due to various reasons. These could be deaths relating to diseases like cancer or administration of drug which is subject matter of clinical trial on critical or terminally ill patients or side-effects or unrelated causes. Such deaths are investigated for causal relationship. As per available data, the number of Serious Adverse Events of deaths in clinical trials reported during the last three years and current year viz. 2009, 2010, 2011 and 2012 (upto June, 2012) were 637, 668, 438 and 211 respectively. However, SAE of Death attributed to clinical trials in 2010 and 2011 were 22 and 16 only respectively. The scrutiny of cases pertaining to the year 2012 is in process.

(c)&(d): Compensation has been paid in all cases pertaining to 2010, except in one case where whereabouts of the legal heir could not be ascertained. Similarly, in respect of cases pertaining to 2011, compensation has been paid in 15 cases and in the remaining one case, issue of payment has been taken.

(e) Following steps have been taken to strengthen the provisions for regulating the conduct of clinical trials in the country:

(i) Registration of clinical trials in the Clinical Trial Registry of the Indian Council of Medical Research (ICMR) has been made mandatory since 15.6.2009.

(ii) A Committee / Core Panel of experts has been constituted to advise on matters relating to regulatory approval of clinical trials for Investigational New Drugs (IND).

(iii) A Core Investigational New Drugs (IND) panel of experts, namely, the Cellular Biology Bases Therapeutic Drugs Evaluation Committee (CBTDEC) has been constituted to advise on matters pertaining to regulatory pathways leading to the approval of clinical trials and merket authorization for the `therapeutic products derived from Stem Cell, Human Gene Manipulations and Xenotransplant Technology`.

(iv) Twelve New Drugs Advisory Committees (NDACs) have been formed to advise on matters related to review and regulatory approval of clinical trials and new drugs (except for Investigational New Drugs).

(v) Six Medical Device Advisory Committees (MDACs) have been formed to advise on matters related to review and regulatory approval of new medical devices and clinical trials (except for Investigational New Medical Devices)

(vi) A General Experts Pool for Medical device Advisory Committees has been formed on matters related to review and regulatory

approval of new medical devices and clinical trials (except for Investigational New Medical Devices).

(vii) Every approval / permission for conducting clinical trials now includes a condition that in case of study related injury or death, applicant will provide complete medical care as well as compensation for the injury or death and statement to this effect should be incorporated in the informed consent form. Further, in case of such injury or death the details of compensation provided should be intimated to the office of the Drugs Controller General (India) [DCG(I)].

(viii) Guidelines for conducting Clinical Trial inspection of site and sponsor / Clinical Research Organisations (CROs) have been prepared and posted on CDSCO website.

(ix) Draft Rules containing the guidelines and requirement for registration of CRO have been notified.

(x) Draft rules containing provisions for payment of compensation by the sponsor or his representative for injury or death of the trial subjects, expanding the responsibilities of Ethics Committees, Investigators and Sponsors therefor, amendment of the informed consent format, etc have been notified.

(xi) Draft rules containing provisions for authorising clinical trial inspection by CDSCO assisted by concerned state authority and to take administrative actions like restriction of investigator, sponsor/CRO to conduct future clinical trial in case of non-compliance have been notified.

(xii) Draft rules containing provisions specifying requirements and guidelines for registration of Ethics Committee have been notified.