GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2190
ANSWERED ON:12.08.2011
CLINICAL TRIALS
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether an increase in the number of deaths of people who were part of the clinical trials of drugs/vaccines has been reported from various parts of the country including Andhra Pradesh;

(b) if so, the number of such deaths reported and the pharmaceutical companies involved in these cases during each of the last three years and the current year, State/UT-wise;

(c) the number of these death cases in which compensation was paid by the pharmaceutical companies indicating the amount paid alongwith the steps taken/ proposed to direct the erring companies to pay up compensation in other death cases;

(d) whether the Government has taken note of the instances of approval of clinical trials by so called Independent Ethics Committees (IECs);

(e) if so, the details thereof alongwith the norms and guidelines under which functioning of these IECS is being regulated; and

(f) the measures taken/proposed by the Government for the proper regulation, registration and monitoring of clinical trials and having a compensatory mechanism for the victims of such trials?

Answer

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

(a) & (b): The death of a subject enrolled in the clinical trials may occur during the trial due to various reasons. These could be disease related deaths like cancer or other serious diseases, administration to critical, and terminally ill patients, side-effects or other unrelated causes. Such deaths are investigated for causal relationship to the study trial. A Statement containing the detailed information in respect of deaths reported during trials during the last three years and in the current year up to June, 2011 along with the names of pharmaceutical companies involved is at annexed.

(c): 22 cases of trial related deaths were reported in the year 2010. A Statement containing the details of the amounts paid as compansation in each case by the sponsor is at Annexure. The Sponsors / Clinical Research Organisations (CROs) involved in the clinical trials in 2010 were directed by the Drugs Controller General (India) [DCG(I)] in April, 2011 to provide compensation to the dependents of the deceased. The concerned Ethics Committees were also requested to review the above death cases and recommend payment of compensation. The concerned sponsor CRO has been asked to provide of the requisite information in respect of compensation paid and other details relating to deaths occurred due to clinical trials in 2011 (up to June 2011).

(d) & (e): 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. the Drugs Controller General (India) and the approval obtained from the respective ethics committee. The trial site may accept the approval granted to the protocol by the Ethics Committee of another trial site or the approval granted by an Independent Ethics Committee (constituted as per provisions under Schedule Y to the said Rules), provided that the approving Ethics Committee is willing to accept their responsibilities for the study at such trial site and the trial site is willing to accept such an arrangement and that the protocol version is the same at all trial sites.

Further, it is the responsibility of the Ethics Committee that reviews and accords its approval to a trial protocol, to safeguard the rights, safety and well-being of all trial subjects. The Ethics committee should get documented 'standard operating procedures' and should maintain a record of its proceedings. The Ethics Committee should make, at appropriate intervals, an on-going review of the trials for which they review the protocols.

(f): In order to further strengthen the monitoring of clinical trials, various measures have been taken as follows:-

it has been made mandatory to register all clinical trials, permissions for which have been granted by the office of DCG(I) on or after 15th June 2009, in the ICMR clinical trial registry at www.ctri.in

Guidelines for conducting inspection of clinical trial sites and clinical research organizations / sponsors have been prepared.

It is proposed to further strengthen the regulations relating to clinical trials by making specific provisions under the Drugs and Cosmetics Rules for providing financial compensation to trial subjects in case of trial related injury or death. The responsibilities of Ethics Committee, Sponsor & Investigator are also proposed to be enhanced to ensure that financial compensation as well as medical care are provided to trial subjects who suffer trial related injuries or deaths and such information is provided to DCG (I). The format for obtaining informed consent of trial subjects is also proposed to be amended to include the details of address, occupation, annual income of the subject so as to have information regarding socio-economic status of trial subjects.

A schedule Y, draft notification has also been published in 19.1.2011 for regulisation of clinical research organisations (CROs).