GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2611
ANSWERED ON:09.12.2011
IRREGULARITIES IN CLINICAL TRIALS
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the details of regulations and procedures laid down by the Government for grant of permission to undertake clinical trials on humans in the counrty;

(b) the number of such clinical trials carried out by the Indian and foreign firms, separately indicating the area and the results of these trials during each of the last three years and the current year so far;

(c) whether cases of irregularities and malpractices in conduct of these clinical trials have been reported in the country;

(d) if so, the details thereof alongwith the action taken/proposed by the Government in each of these cases during the said period; and

(e) the corrective measures taken/ proposed by the Government for proper monitoring of clinical trials in order to stop any irregularity in their conduct?

Answer

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

(a) & (b) Clinical trials of new drugs are regulated as per the guidelines contained in Schedule Y of Drugs & Cosmetic Rules, 1945. A total number 2207 clinical trials were registered at Clinical Trial Registry, www.ctri.in, of ICMR between 21.07.2007 to 06.12.2011. The breakup of clinical trials sponsored by Indian firms / Foreign firms are available only for the period 15th March 2011 onwards after the launch of the revised version of the software on 15th March 2011, as per which the total number of clinical trials registered between 15.3.2011 to 7.12.2011 is under:

Indian Agencies = 405 Foreign Agencies = 153

The areas (States) where trials sponsored by Indian agencies are being conducted are Andhra Pradesh, Assam, Bihar, Chandigarh, Chhattisgarh, Delhi, Goa, Gujarat, Haryana, Jammu & Kashmir, Karnataka, Kerala, Madhya Pradesh, Maharashtra, Orissa, Punjab, Rajasthan, Tamil Nadu, Uttar Pradesh and West Bengal.

The areas where trials sponsored by foreign agencies are being conducted are Andhra Pradesh, Arunachal Pradesh, Assam, Bihar, Chandigarh, Chhattisgarh, Delhi, Goa, Gujarat, Haryana, Jammu & Kashmir, Karnataka, Kerala, Madhya Pradesh, Maharashtra, Orissa, Punjab, Rajasthan, Tamil Nadu, Uttar Pradesh, Uttaranchal and West Bengal.

During the last three years and current year, various new drugs have been approved based on the results of the clinical trials.

(c) & (d): Yes. A statement giving the number of cases investigated and three years and the current year is laid on action taken thereon for irregularities in conduct of clinical trials during the last three years and the current year is annexed.

(e): In order to strengthen the regulations relating to clinical trials, following proposals for amendments in Drugs and Cosmetics Rules, 1945 have been approved by Drug Technical Advisory Board (DTAB), a statutory advisory committee under the Drugs & Cosmetics Act, 1940 and a draft notification GSR 821(E) dated 18.11.2011 has also been published, by the Government therefor:

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 Ethics Committee, 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 are provided to Drugs Controller General (India) [DCG(I)].

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.

Further, the following proposals have also been approved by the DTAB for amendments in Drugs and Cosmetics Rules:

1. Incorporation of Rules to have authority for inspection by the Central Drugs Standard Control Organisation (CDSCO) assisted by the concerned state authority and to take administrative actions like suspension/cancellation of clinical trial permission, restriction of investigator, sponsor / Clinical Research Organisation (CRO) to conduct future clinical trial, in case of non-compliance.

2. Incorporation of Rules and a new schedule for registration of Ethics Committee and to amend regulatory provisions requiring that Clinical Trials should be conducted at sites which have their own Ethics Committee. However, for conduct of Bio-availability & 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 the same area where the site is located.