GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2830
ANSWERED ON:07.02.2014
CLINICAL TRIALS
Thamaraiselvan Shri R.

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

(a) whether the present regulatoryprovisions are adequate to sustain thegrowth of the drug trial market and alsosafeguard the interests/rights of clinical trialsubjects in the country and if so, the detailsthereof;

(b) whether there has been a decline inthe clinical trial related applications and volume of drug trial market over the lastfew months;

(c) if so, the details thereof and thereasons therefor indicating the number of clinical trials related applications receivedand the current volume of the drug trialmarket in the country in comparison toeach of the last three years; and

(d) the measures taken/proposed by theGovernment to make India an attractive destination for outsourced clinical trials ofnew drugs in compliance with the rights oftrial subjects?

Answer

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

(a):The mandate of Drugs & Cosmetics Act & Rules made there under is to provide safety, efficacy and quality drugs and to protect the rights and well being of clinical trial participants. Clinical trials of new drugs are regulated under Drugs & Cosmetics Act & Rules made there under. The requirement and the guidelines for undertaking clinical trials are specified in Rule 122 DA, 122DAA, 122DAB, 122DAC, 122DB, 122DD and schedule-Y of drugs and Cosmetics Rules. Schedule 'Y' also mandates that clinical trial is conducted as per Good Clinical Practices (GCP) Guidelines issued by Central Drugs Standard Control Organization (CDSCO).

(b) & (c): No definite pattern has been seen during the last three years about the volume of clinical trials conducted in the country. The number of clinical trial related applications received and number of permission granted during last three years is as under:

Year	No. of applications Received	No. of Permission granted
2011	306	283
2012	480	253
2013	207	73

(d): The followingmeasures have been taken by theGovernment to strengthen the regulation of clinical trials in India.

12 New Drug Advisory Committees (NDAC) consisting of experts from Government medical colleges and institutes from all over the country were constituted in March, 2011 to evaluate applications for approval of clinical trials, excluding Investigational New Drugs (INDs), and approval of new drugs.

All Investigational New Drugs (IND) applications are evaluated by the IND Committees chaired by Secretary, Department of Health Research & Director General, Indian Council of Medical Research (ICMR).

The Drugs and Cosmetics Rules, 1945 have been amended to make provisions for safeguarding the rights, safety and well being of trials subjects and registration of Ethics Committee for regulating the clinical trials in the country as follows:

Amendment vide Gazette Notification G.S.R. 53 (E) dated 30-01-2013 specifying procedures to analyze the reports of Serious Adverse Events occurring during clinical trials and procedures for payment of compensation in case of trial related injury or death as per prescribed timelines.

Amendment vide Gazette Notification G.S.R. 63(E) dated 01-02-2013 specifying various conditions for conduct of clinical trials, authority for conducting clinical trial inspections and actions in case of non-compliance.

Amendment vide Gazette Notification G.S.R. 72(E) dated 08.02.2013 specifying requirements and guidelines for registration of Ethics Committees.

The Drugs and Cosmetics (Amendment) Bill, 2013 introduced in Rajya Sabha on 29th August, 2013 contains a separate chapter on clinical trials containing penal provisions, provisions for payment of compensation, Ethics Committees etc.

An Expert Committee has been constituted to examine the reports of deaths in clinical trials. The Committee has prepared a formula for determining the quantum of compensation in case of clinical trial related deaths which is available in CDSCO website.

The Committee set up under the Chairmanship of Prof.Ranjit Roy Chaudhuryto formulate policy guidelines and SOPs for approval of New Drugs, clinical trials and banning of drugs has submitted its report. The Government has examined the recommendations and finalized the action to be taken on various recommendations, the details of which have been posted on the CDSCO website.

In compliance to the Hon'ble Supreme Court's order dated 03.01.2013, a system of supervision of clinical trial has been put in place by constituting an Apex Committee under Chairmanship of Secretary, Health and Family Welfare and a Technical Committee under Chairmanship of Director General Health Services (DGHS).

Through an administrative order dated 30.08.2013,the Drugs Controller General (India) [DCG(I)] has made it mandatory for the Sponsor or his representatives to furnish the details of the contract entered by the Sponsor with the Investigator/Institutions with regard to financial support, fees, honorarium, payments in kind etc., to be paid to the Investigator.

In light of the order of Hon'ble Supreme Court dated 21.10.2013, it has been decided that with effect from 30.11.2013, in all clinical trials, in addition to the requirement of obtaining written informed consent, audio-visual recording of the informed consent process of each trial subject, including the procedure of providing information to the subject and his/her understanding on such consent is required to be done while adhering to the principles of confidentiality.