GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:14
ANSWERED ON:22.02.2013
CLINICAL TRIALS
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the number of applications received and approved by the Central Drugs Standard Control Organisation (CDSCO) for conducting clinical trials of new drugs/vaccines on human beings during each of the last three years;

(b) the details of the irregularities and malpractices including unconsented conduct of trials of certain drugs/vaccines on tribals reported and the action taken by the Government thereon during the said period;

(c) the number of trial related deaths and injuries reported including the compensation paid to them during the said period, company-wise;

(d) the number of complaints for nonpayment of compensation received along with the action taken/proposed by the Government thereon during the said period; and

(e) the corrective measures taken/proposed by the Government to strengthen regulatory and monitoring mechanism to ensure proper conduct of clinical trials and safety/rights of trial subjects in the country?

Answer

THE MINISTER 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.14 FOR 22.2.2013

(a) The number of applications received for conducting clinical trials of new drugs/vaccines on human beings and those approved by CDSCO during each of the last three years and the current year is as under:

Year	New Drugs/ Vaccines	
	number of applications received	number of clinical trial permissions granted
2010	546	529
2011	306	283
2012	480	253

(b) During the last three years, there were alleged irregularities in nine cases of clinical trials. Tribal persons were included in one case of Phase-IV post licensure clinical trial of Human Papilloma Virus Vaccine, granted to an NGO, PATH (Program for Appropriate Technology in Health) on 22nd April, 2009, to conduct trials in Khammam district, Andhra Pradesh and Vadodara district, Gujarat. The Indian Council of Medical Research (ICMR) and the State Governments of Andhra Pradesh and Gujarat were the collaborating partners. In all, 14,091 girls received the vaccine in Andhra Pradesh and 10,686 girls received the vaccine in Gujarat. There were reports of deaths of 7 girls during the trial. The trial was suspended by ICMR on 7 April 2010. A committee constituted by the Ministry of Health & Family Welfare to enquire into the alleged irregularities in the conduct of studies using Human Papilloma Virus Vaccine by PATH in India reported irregularities in the following areas:

1. Consent forms and the actual implementation of the consent process during the study.

2. Method of monitoring the adverse events and the serious adverse events and remedial measures for such events.

3. Inclusion of vulnerable tribal population group.

4. Blurring of distinction between National Immunization Programme and PATH study.

5. Insurance coverage for the study participants.

6. Free supply of vaccine by the manufacturer and the statement in the consent forms that "you will not be charged for your daughter to receive the vaccine" that could be considered to be convert inducement and indirect coercion.

After investigation, the committee reported that the deaths were most probably unrelated to the vaccine, as there was no characteristic and uniform pattern of illness preceding the death, or temporal/spatial clustering.

Based on the findings of the report, a warning letter was issued to M/s. PATH on 3rd July, 2012, asking them to be careful while conducting clinical trial so as to ensure that such discrepancies are not repeated in future. M/s. PATH was also directed to comply with Schedule-Y and GCP guidelines in ongoing and future research studies.

(c) The Serious Adverse Events (SAEs) of deaths may occur during clinical trials due to various reasons. These deaths could be due to life-threatening diseases like cancer, cardio-vascular conditions like congestive heart failure / stroke and other serious diseases. They could also be due to the side-effects of the drugs or their administration to critically or terminally ill patients. Such deaths are investigated to arrive at the causal relationship, if any. Details about SAEs of death due to clinical trials and compensation paid

Year	SAEs of death clinical trials	Death due to compensation paid	Number of cases:
2010	668	22	21
2011	438	16	16
2012	436		

Note: "The cases of 2012 are under examination. - the details of compensations paid are at Annexures A and B

(d): The office of DCGI has received two requests from subjects or their relatives who have requested for payment of compensation. The matter is under examination.

(e) The following steps have been taken to strengthen the approval procedures, monitoring mechanism for clinical trials as well to ensure that safety, rights and well-being of clinical trial subjects are protected:

(1) 12 New Drug Advisory Committees (NDAC) consisting of leading experts from the government medical colleges, institutes from all over the country have been constituted to advise CDSCO in matters related to approval of clinical trials and new drugs.

(2) Applications of Investigational New Drugs (IND) ; i.e, New Drug Substances which have never earlier been used in human beings, are evaluated by the IND committee, chaired by the Director General, Indian Council of Medical Research.

(3) Registration of clinical trial in ICMR registry at www.ctri.in has been made mandatory.

(4) Guidelines for conducting inspection of Clinical Trial sites and sponsor/Clinical Research Organizations (CROs) have been prepared and posted on CDSCO website.

Further, Drugs and Cosmetics Rules, 1945, have been amended vide notifications of 30/01/2013, 01/02/2013 and 08/02/2013 to incorporate additional provisions to strengthen regulatory provisions and the monitoring mechanism in the country.