GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:358
ANSWERED ON:01.08.2014
COMPENSATION FOR CLINICAL TRIAL SUBJECTS
Gaddigoudar Shri Parvatagouda Chandanagouda;Jaiswal Dr. Sanjay

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

(a) Whether the Government has taken note of a large number of deaths of women during the course of clinical trial for cervical cancer screening method in Maharashtra and Tamil Nadu, if so, the details thereof and the steps taken/proposed to be taken by the Government to inquire into the matter;

(b) Whether adequate compensation has been paid for the aforesaid trial-related deaths, if so, the details thereof along with the norms adopted for determining the quantum of compensation and if not, the reasons therefor;

(c) Whether the draft guidelines brought out by the Central Drugs Standard Control Organisation (CDSCO) for determining the quantum of financial compensation to be paid in cases of clinical trial related injury or death have been opposed by health activists, if so, the details thereof and the reasons therefor; and

(d) The steps taken/proposed to be taken by the Government to address their concerns and to work out a compensation formula in the interest of trial subjects?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. HARSH VARDHAN)

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 358 FOR 1st`AUGUST, 2014

(a) and (b): There have been reports of deaths of women during a study to assess efficacy of cervical cancer screening and breast cancer screening strategies in reducing mortality from cervical and breast cancers among women. The study has compared the cancer death rates among women offered screening to those offered no screening. However, those offered no screening were counselled to report to health facilities. This was part of the studies funded by US National Cancer Institute and Bill & Melinda Gates Foundation and conducted by Tata Memorial Hospital, Mumbai and International Agency for Research on Cancer, WHO. The said study, however, does not fall within the purview of clinical trials and hence these were not clinical trial related deaths. Since these deaths are not attributable to clinical trials, the question of compensation, therefore, does not arise.

(c) and (d): The Drugs & Cosmetics Rules, 1945, were amended vide Gazette Notification G.S.R. 53(E) dated 30-01-2013 for inter alia specifying procedures to examine the reports of Serious Adverse Events (SAEs) occurring during clinical trials and procedures for payment of compensation in case of trial related injury or death as per the prescribed timelines. As per the amended Rules, in case of death, an independent Expert Committee is required to examine the cases of deaths and give recommendations to DCG(I) to determine the cause of death and also to decide the quantum of compensation in cases of clinical trial related death. The Committee after detailed deliberations prepared a compensation formula which is being followed to determine the quantum of compensation in case of trial related deaths. For serious adverse events of injury (other than death), draft formulae to determine the quantum of compensation have been prepared by another Committee which were uploaded on the website of the CDSCO for seeking comments of stakeholders before finalizing the same. Some comments/suggestions/objections have been received from various stakeholders including NGOs/civil society.