

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:1507
ANSWERED ON:13.12.2013
DEATHS DUE TO HPV VACCINE
Sule Supriya

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

- (a) whether incidences of deaths due to administration of Human Papilloma Virus (HPV) Vaccine have been reported in the country;
- (b) if so, the details thereof;
- (c) whether the Indian Council of Medical Research (ICMR) has approved the said vaccine despite its adverse impact;
- (d) if so, the details thereof and the reasons therefor; and
- (e) the corrective measures taken/ proposed by the Government in this regard?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ABU HASEM KHAN CHOUDHURY)

(a) to (d): No.

(e): Office of Drugs Controller General (India), Directorate General of Health Services has informed that seven cases of incidences of death were reported in Phase IV post licensure clinical trial on Human Papilloma Virus (HPV) Vaccine, five deaths reported in Khammam Dist. in Andhra Pradesh and two deaths in Vadodara Dist. in Gujarat. These deaths were, however, not found to be related to HPV vaccine administration as investigated by Professor Agarwal Committee. However, for the strengthening of the procedures related to conduct of clinical trial in the country and also taking into consideration the suggestion of Inquiry Committee, the following rules have been introduced by Central Drugs Standards Control Organization (CDSCO) in the Drugs and Cosmetics Act:

- 1) New Rule 122 DAB vide GSR 53 (E) for the compensation in case of injury or death during the clinical trial.
- 2) New Rule 122 DAC vide GSR 63 (E) for the permission to conduct clinical trial.
- 3) New Rule 122 DD vide GSR 72 (E) for the registration of Ethics Committee.

Procedures for consent taking have been made stringent.

Further Drugs and Cosmetic (Amendment) Bill 2013 has been introduced in the Parliament which has separate chapter on clinical trials and also includes penal provisions for the misconduct in the clinical trial.