

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

UNSTARRED QUESTION NO:3476
ANSWERED ON:16.04.2010
HUMAN PAPILLOMA VIRUS ANTI VACCINE
Sudhakaran Shri K.

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

- (a) whether the Government has approved the vaccination of Human Papilloma Virus (HPV) anti vaccine through the Non-Governmental Organisations;
- (b) if so, the details thereof and the benefits accrued thereby;
- (c) whether any deaths caused by the improper application of the vaccine have been reported in the country;
- (d) if so, the details thereof;
- (e) whether clinical trials of the vaccine have been conducted in the country; and
- (f) if so, the details thereof and if not, the reasons therefor?

Answer

THE MINISTER OF STATE FOR HEALTH & FAMILY WELFARE(SHRI S. GANDHISELVAN)

(a) to (f) Two imported brands of Human Papilloma Virus (HPV) vaccines namely "Gardasil" (imported by M/s MSD Pharmaceuticals, Gurgaon) and "Cervarix" (imported by M/s GSK Pharmaceuticals, Mumbai), were allowed to undergo clinical trial (Phase III) in India, before granting permission to import and Market Authorization. For assessing the health services needs and preparedness for introducing Human Papilloma Virus (HPV) vaccines into the health services in future, PATH, an international NGO, was given permission for a post licensure observational study of HPV vaccination in Khammam district (Andhra Pradesh) and Vadodara district (Gujarat). The study by PATH, was recommended by the Ethical Committee and Advisory Groups at State and Central level. Indian Council of Medical Research, an autonomous body under the Ministry has provided technical support for the development of protocols, and advised on ethical issues as per Govt. of India guidelines. Four deaths in the target of 14019 in Andhra and two in the target of 10,686 in Gujarat have been reported from among the children who were administered these vaccines. The cause of deaths was determined as viral fever, drowning, suicide, severe anaemia with malaria and suspected snake bite. Based on the concerns on these deaths, States have been advised not to carry out any further vaccinations at present.