

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

UNSTARRED QUESTION NO:241
ANSWERED ON:06.12.2013
PENTAVALENT VACCINE
Sugumar Shri K.

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

- (a) the names of the States where pentavalent vaccine has been introduced so far;
- (b) whether the Government has conducted any study about the safety of 'Pentavalent vaccine' after death of some children were reported within 72 hours of vaccination;
- (c) if so, the details thereof and the outcome thereof; and
- (d) the corrective measures taken by the Government in this regard?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABIAZAD)

(a): Pentavalent vaccine has been introduced in Tamil Nadu, Kerala, Puducherry, Goa, Karnataka, Gujarat, Haryana and Jammu & Kashmir.

(b): Pentavalent vaccine is a licensed vaccine. Any drugs including vaccines are licensed by Drug Controller General of India after examining the safety profile of the product.

There is an established system of AEFI surveillance (Adverse Events Following Immunization Surveillance), which is a mechanism to track all kinds of adverse events including deaths that may occur following vaccination whether related or unrelated. It signals zero tolerance on the part of Government for missing out even single vaccine related adverse event. All these AEFI cases have been examined by the AEFI committee.

(c): AEFI Surveillance and related assessments by National AEFI Committee did not find any consistent causal relationship between the administration of pentavalent vaccine and the deaths of children following vaccination.

(d): Government is already taking several measures and initiated steps to strengthen AEFI monitoring which include revision of guidelines for AEFI in 2010, their dissemination to all the programme officers in the States and districts and training of various categories of primary health care staff with a view to improve reporting. The District/State AEFI committees have been constituted to regularly review and analyse all the reported AEFI cases. A National AEFI committee has been setup which is headed by an independent expert outside the government and regularly reviews AEFI status. Besides that, a National AEFI secretariat has been established and four Causality Assessment workshops have been conducted in 2012 & 2013 to review all the AEFI cases during 2011-13. The AEFI secretariat is also collaborating with Indian Pharmacopoeia Commission (IPC) the pharmaco-vigilance centre of CDSCO, which has network of more than 90 regional centres for reporting of adverse drug reactions including AEFIs. Special workshops have been conducted at national level and for the pentavalent using states to familiarize them with the latest WHO AEFI Causality Assessment guidelines and develop an effective AEFI monitoring system. It may also be noted that India has successfully cleared the National Regulatory Authority (NRA) Assessment conducted by WHO-Head Quarters in December 2012 which certifies that India meets the international standards for vaccine regulations. All these initiatives are part of an overall effort by the government to improve the quality of immunization programme and enhance public confidence.