

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

UNSTARRED QUESTION NO:3985
ANSWERED ON:26.08.2011
SURVEILLANCE NETWORK FOR NEW VACCINES
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether the programmatic errors were the cause of child deaths after Immunization in the country;
- (b) if so, the details thereof and the reasons therefor;
- (c) whether the Government has joined the global post-marketing surveillance network for new vaccines;
- (d) if so, the details thereof; and
- (e) the steps taken/proposed by the Government to be taken for imparting training to paramedical staff undertaking immunization so as to minimize programmatic errors in the future?

Answer

THE MINISTER OF STATE FOR HEALTH & FAMILY WELFARE (SHRI SUDIP BANDYOPADHYAY)

- (a): Yes. Programme errors are one of the causes of child deaths after immunization in the country.
- (b): Fatal programmatic errors are usually associated with Measles vaccine. As per the existing guidelines measles vaccine needs to be used within 4 hours of reconstitution. Failure to observe this precaution could result in fatal Toxic Shock Syndrome due to secondary infection of the vaccine with *Staphylococcus Aureus* (Bacteria). In some situations use of wrong diluent for reconstitution has also been reported as another cause.
- (c): Yes.
- (d): Global Post Marketing Surveillance (PMS) Network is part of the World Health Organization (WHO) Programme for International Drug Monitoring, which is maintained by the Uppsala Monitoring Centre (UMC) in Sweden. Globally, 12 countries are part of the PMS network and as part of this network, the case-based Adverse Events Following Immunization (AEFI) data from the member countries are reported to the global database through web-based data management system developed by the UMC named as "VigiFlow". Currently, the VigiFlow software is used by pharmaco- vigilance centers of 32 member countries of the WHO-UMC Programme.

From India, Maharashtra state has participated in the Global Post Marketing Surveillance (PMS) Network for new vaccines, in October 2009. National AEFI Committee has approved the data flow mechanism for reporting to the PMS network in October 2010.
- (e): The paramedical staff and health workers involved in service delivery under immunization program are trained in safe immunization practices, including vaccine handling, vaccine reconstitution, injection safety, and safe waste disposal. In addition Operational Guidelines for Adverse Event Following Immunization (AEFI) have been developed and disseminated for reporting and case management of AEFI.