

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
UNSTARRED QUESTION NO. 6601
TO BE ANSWERED ON 6TH APRIL, 2018**

PENTAVALENT AND DPT VACCINE

**6601. SHRI VINAYAK BHAURAO RAUT:
SHRI ANANDRAO ADSUL:
SHRI B.V. NAIK:
SHRI DHARMENDRA YADAV:
DR. SHRIKANT EKNATH SHINDE:**

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

- (a) whether Pentavalent Vaccine (PV) against Haemophilus influenza Type-B (HIB) and Hepatitis-B, has led to double the number of deaths of children compared to DPT (Diphtheria-Pertussis-Tetanus) vaccine and if so, the details thereof;
- (b) whether vaccination of 26 million children each year in India will result in 122 additional deaths within 72 hours, due to switch from DPT to PV;
- (c) if so, the details thereof and the reaction of the Government thereto;
- (d) whether there was sudden spike in deaths following immunisation in 2017 to 1,139 from 176 in 2016 and 111 in 2015;
- (e) whether the Government has conducted any study in this regard; and
- (f) if so, the details and the outcome thereof?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)**

(a): The Adverse Event Following Immunization (AEFI) surveillance system has been established to monitor any AEFI. The surveillance system encourages reporting of any death, hospitalization, clusters, disabilities, etc. following vaccination. Every AEFI case reported are investigated by trained experts of the State and National AEFI committees using a scientific, globally accepted method to do the casualty assessment to know the cause of the event including death. Mere reporting does not mean that the vaccine caused the event including death.

There has been an increase in reporting of adverse events including deaths every year. The reported rise in the number of Adverse Events Following Immunization (AEFI) is because of better reporting as part of AEFI surveillance system strengthening measure under taken, like trainings, reporting AEFI with Standard Operating Procedure, formation of District and State AEFI committees, National AEFI secretariat and strengthened with additional manpower to encourage states/UTs for AEFI reporting and analyses of such cases. This increase in reporting of adverse events trend continues even after pentavalent vaccine introduction.

(b) & (c): The assumption of additional 122 deaths within 72 hours due to switch from DPT to Pentavalent vaccine is not based on the scientific facts.

(d): As per the Adverse Event Following Immunization (AEFI) surveillance system reporting received from various States/UTs, there has been no spike in deaths following immunization in 2017 as compared to 2016 and 2015. As per reports available (as on 03 March 2018) 355 AEFI deaths were reported in 2017 compared to 345 deaths in 2016 and 311 deaths in 2015.

(e) & (f): An independent study has been conducted by INCLIN in partnership with Ministry of Health & family Welfare, Government of India and Departments of Health & family Welfare, Government of Tamil Nadu and Kerala. The study tracked 30,688 infants who received 3-primary doses of Pentavalent vaccine at 1.5 months, 2.5 months, 3.5 months and demonstrated that there is no increase in the death and hospitalization rates reported in the first week after vaccination as compared to fourth week after vaccination implying that the pentavalent vaccine is completely safe.