

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

**RAJYA SABHA
UNSTARRED QUESTION NO. 108
TO BE ANSWERED ON 11TH DECEMBER, 2018**

SAFETY OF POLIO VACCINES

108. DR. BANDA PRAKASH:

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

- (a) whether Government is aware of reports in a section of the print media mentioning that bivalent oral polio vaccine supplied by a particular manufacturer has some quality issues; and
- (b) if so, the details thereof along with the measures taken by Government thereon?

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

(a) & (b): Yes, the Government is aware of the reports in print media regarding quality issues in bivalent oral polio vaccine (bOPV) supplied by a particular manufacturer.

Several samples of Poliomyelitis Vaccine, Live, Oral Indian Pharmacopoeia (I.P) Bivalent (Bivalent/bOPV) manufactured by M/s BioMed Pvt. Ltd, Ghaziabad were drawn by Drugs inspectors of CDSCO and sent for test/analysis at Central Drugs Laboratory (CDL) Kasauli. Two samples of a batch of Poliomyelitis Vaccine, Live, Oral Indian Pharmacopoeia (I.P) Bivalent (Bivalent/bOPV) were declared as not of standard quality and deemed to be adulterated by the Government analyst, CDL as per the provisions of the Drugs and Cosmetics Act, 1940 as the samples were found to contain Polio Virus Type 2.

Pursuant to above, CDSCO had issued a show cause notice and stop production order to the firm to stop production of all Human vaccines manufactured at the said facility, till further order on 27.09.2018. Simultaneously, as a part of further investigation, the Drugs Inspector of CDSCO had filed a complaint with Station House Officer (SHO), Kavi Nagar, Ghaziabad.

In addition to above mentioned steps, Ministry of Health & Family Welfare has issued instructions to all the States/UTs to stop use of bOPV supplied by M/s BioMed Pvt. Ltd. Further, in the identified districts of Telangana and Uttar Pradesh, where the suspected batch of OPV that was not of standard quality was used, special vaccination campaigns with Inactivated Polio Vaccine (IPV) have been carried out to boost immunity against Type 2 Polio Virus.