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Government to ensure safety of vaccines

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There have been reports that bivalent oral polio vaccine supplied by Ghaziabad based Biomed Pvt Ltd had some quality issues.

As the vaccine is part of the government's universal immunisation programme, the ministry has issued directions for the immediate withdrawal of this particular manufacturer's vaccine.

It may be remembered that the decision to switch to inactivated poliovirus vaccine (IPV) and bivalent Oral Polio Vaccine (bOPV) from trivalent Oral Polio Vaccine (tOPV) in all polio campaigns and routine immunization in India and elsewhere from April 2016 was taken following certification of global eradication of type 2 wild poliovirus. In India, the last Type 2 wild polio virus case was detected in the year 1999. The tOPV that was used till April 2016 contained three types of poliovirus vaccines (P1, P2 and P3) and protected against all three types of wild polioviruses – type 1, type 2 and type 3, while bOPV contains two types of poliovirus vaccines (P1 and P3) and protects against type 1 and type 3 wild polioviruses. Type 2 component from oral polio vaccine was removed as a part of global polio end game strategy.

Recently, type 2 polio vaccine virus was found in some sewage and stool samples. The detection of type 2 vaccine virus indicates that a very robust polio surveillance jointly managed by MoHFW and WHO is still maintained even after 7 years have elapsed since last wild poliovirus case in the country was reported. This detection indicated the use of a type 2 poliovirus containing vaccine, despite the fact that tOPV that contained type 2 poliovirus vaccine had been phased out globally, and in India, in April 2016, as a part of the Polio End Game strategy.

On investigation, it was found that in a few vials of bOPV supplied by Biomed, there were traces of P2 vaccine. The Ministry of Health and Family Welfare taking WHO on board took immediate and comprehensive action. Following the report, the use of all the vaccine supplied by this manufacturer was immediately stopped in the country till investigation was completed. Additional legal samples of bOPV were immediately sent for testing to the Central Drug Laboratory in Kasauli, which confirmed the previous report of presence of traces of P2 polio vaccine virus. The Drugs Controller General of India immediately filed an FIR and issued notice to the company asking it to stop manufacturing and supplying till further orders. The MD of the company was immediately arrested.

Type 2 polio vaccine virus traces which have been found in bOPV vials is the attenuated (weakened) poliovirus and does not cause paralysis and was also earlier used in tOPV till April 2016. The recipients of such vaccine will usually shed the vaccine virus through fecal route for about 4-6 weeks after which it will die down. In small areas where such vials were used, polio surveillance in environment and through stool collection has been significantly enhanced by MoHFW, with support from WHO and partners to keep constant vigil on the shedding of the polio vaccine virus. To enhance immunity against type 2 poliovirus further, special mop up rounds for administering IPV are being conducted in the specified areas to reach out to such children who may have missed IPV. This would provide immunity to all the children against all the three types of polio virus including Type 2.

In view of high routine immunization coverage being achieved in India and administration of tOPV till 2016, our population level immunity against all three types of virus is very high. This fact was acknowledged and appreciated in recently conducted India Expert Advisory Group on Polio which comprises of international and national experts. India has also made remarkable progress under Swachh Bharat Abhiyaan

In light of all the above facts and measures taken, the risk of any child getting vaccine derived polio disease is practically nil.

Sufficient polio vaccine from alternate sources is available in the programme to implement Routine Immunization (RI) and Pulse Polio Immunization (PPI) and maintain the immunity against polio-viruses.

No sample has tested positive for wild poliovirus in sewage or AFP cases since 2011. The country remains polio-free and this status has been maintained for more than seven years since the last wild poliovirus case in the country was reported in January 2011. No child has been infected with wild poliovirus as reported in some sections of the media.

A team of MoHFW, DCGI, ICMR and WHO is continuously monitoring the situation. Government of India is committed as always to ensure that all vaccines used in the programme are safe and effective.