Application of WHO Multi-Dose Vial Policy for Inactivated Polio Vaccine

**Multi-dose vials of IPV produced by Sanofi Pasteur and Bilthoven Biologicals are approved for use for up to 28 days after opening**

New preservative efficacy data from studies conducted by Bilthoven Biologicals and Sanofi Pasteur on their Inactivated Polio Vaccines (IPV) presented in 5 and 10 dose-vials has shown that both multi-dose vaccine presentations may be used up to 28 days after opening, provided that the product is appropriately handled and stored.

The [WHO Policy Statement: Multi-dose Vial Policy (MDVP), Revision 2014](https://www.who.int/immunization_monitoring/policy/mdvp_2014/en/), on the use of opened multi-dose vaccine vials specifies the criteria under which opened multi-dose vials can be kept and used for up to 28 days after opening. If the criteria are not met, the multi-dose vials must be discarded at the end of the immunization session, or within six hours of opening, whichever comes first.

Based on the data submitted by the manufacturers and validated by their national regulatory authorities, and in line with the European pharmacopeia guidelines ¹, the WHO Prequalification team has confirmed that the data supports the use of opened multi-dose vials of IPV in subsequent immunisation sessions (up to 28 days), in accordance with the [WHO Policy Statement: Multi-dose vial Policy (MDVP), Revision 2014](https://www.who.int/immunization_monitoring/policy/mdvp_2014/en/).

**Placement of Vaccine Vial Monitors (VVMs) on IPV vials**

The VVM is an important visual trigger for the implementation of the multi-dose vial policy.

Presently, the multi-dose vials of IPV are manufactured with the VVM on the flip-off cap, signalling that the vial must be discarded at the end of the immunization session, or within 6 hours, whichever comes first.

With the new approval of use for up to 28 days after opening, the VVM placement will now be changed. Future production of vials will ensure VVM placement on the label of the vaccine vial, so that after opening, the exposure of the vial to temperature over time can be monitored by the VVM, to help ensure that the vaccine has not been damaged by excessive heat exposure.

Availability of IPV multi-dose vials with VVMs on the vaccine label will start from Q2 2015.

WHO strongly recommends that countries start using the IPV multi-dose vials for up to 28 days only after the VVM placement appears on the vaccine labels, expected from May 2015.

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¹ European Pharmacopoeia, Supplement 7.6 (reference 01/2013:0153)
Programmatic implications
The delay of shifting the VVM placement from the flip-off cap to the vaccine label, which is anticipated to appear on vaccine shipments around May 2015, suggests two pathways for EPI programmes. Specifically:

| For countries with plans to introduce IPV before May 2015 | Countries will receive IPV shipments with the VVM on the cap, indicating that the opened multi-dose vial must be discarded at the end of the session or after 6 hours, whichever comes first. It is recommended that health workers are trained on handling multi-dose vials under both conditions (a 6 hour discard and 28 day discard), and are also informed of what to expect in the future in terms of vaccine presentation changes and anticipated timeline. Once supplies of IPV vials with the VVM on the label are received in-country, a memo should be sent to health workers with information on when to implement the 28 day discard to multi-dose vials of IPV and to reinforce the training health workers have received previously. The timing of this transition will be agreed per country, based on their preferences and supply availabilities. |
| For countries with plans to introduce IPV after May 2015 | Countries will receive IPV vials with the VVM on the label, indicating that the vaccine must be discarded within 28 days after opening. Generic health worker training materials will be adapted soon and available for customization per country. |

Projected vaccine wastage
A proper application of the MDVP can decrease wastage while ensuring safety. Taking advantage of using a 28-day discard on opened multi-dose vials, the indicative maximum wastage rate of **20% for 10-dose vials, and 15% for 5-dose vials**, can be used in forecasting the estimated vaccine needs.

Supply allocation principles during this transition
To support countries to successfully introduce IPV, WHO and UNICEF Supply Division are working closely with regions and countries to understand national policies related to the application of the MDVP, and to allocate the available supplies to best support the programmatic objectives.

For further information on IPV introduction as related to the Polio Endgame Plan: http://www.who.int/immunization/diseases/poliomyelitis/inactivated_polio_vaccine/en/