PUBLIC ASSESSMENT SUMMARY REPORT – Poliomyelitis Vaccine (Inactivated)

Trivalent IPV - Bilthoven Biologicals BV

What is Poliomyelitis Vaccine (Inactivated) trivalent (IPV)?

Poliomyelitis Vaccine (Inactivated) trivalent is a vaccine produced by Bilthoven Biologicals BV (BBio) from wild Salk Strains that are inactivated with the following composition:

Name of ingredients	Unit and/or percentage formula
Active ingredients :	
Polio virus (Mahoney) Type 1 Polio virus (MEF-1) Type 2 Polio virus (Saukett) Type 3 Grown in continued cell line Vero	40 D-antigen units 8 D-antigen units 32 D-antigen units
Excipients :	
2-phenoxyethanol Formaldehyde Phenol red Buffer dilution fluid and Water for injection q.s.	2.5 mg 12.5 µg 0.008 mg Added to 0.5 mL

The vaccine is supplied in transparent glass vials of 3 mL and 4 mL capacity respectively for 1 & 5 doses.

VVM type 7 is accepted, in principle, as suitable for use with this product for which the 3 year-shelf life claimed by BBio has been approved by WHO. However VVM7 reaches its expiry after 2 years 8 months at 5°C and 1 year 8 months at 8°C. Therefore, there is a concern that the VVM on batches of vaccine supplied could reach its expiry point while the vaccine is still within its expiry date, leading to vaccine wastage.
Given the current need for supply, as a temporary measure, it is however accepted that the VVM 7 continue to be used for this vaccine, as it is expected that vaccine will not be stored for a significant time before use. Furthermore, the Company has indicated the VVM placement (on the label of the vial) will occur after orders are received and shortly before shipment and thus the gap between remaining shelf life of a batch and VVM expiry is minimised.

What is Poliomyelitis Vaccine (Inactivated) trivalent used for?

IPV is indicated for active immunization against poliomyelitis viruses of infants and adults.

How is Poliomyelitis Vaccine (Inactivated) trivalent used?

One dose consists of 0.5 ml for both children and adults. The vaccine is given subcutaneously or intramuscularly.
Primary immunization consists of three vaccinations, administered with a minimum interval of 4 weeks. Infants should receive the primary series within the first 6 months after birth. After completion of the first series of vaccinations, a booster dose can be administered after an interval of at least six months.
If local authorities recommend a vaccination schedule that starts before the age of 2 months and/or if the interval between doses is less than 8 weeks, a booster dose should be administered, however not before the age of 9 months.

Poliomyelitis vaccine can simultaneously be administered with other vaccines on different injection locations.

The vaccine can be used sequentially after or before the use of OPV (WER. No. 9, 2014, 89, 73–92)

This vaccine must be used in accordance with national recommendations in force and according to WHO recommendations.

Precautions for use:

The vaccine colour may range from orange-yellow to orange-red. Vaccine with a clearly yellow or violet colour cannot be used.
Under no circumstances administer Poliomyelitis vaccine intravascular.

What are the vaccine characteristics?

Real time and accelerated stability data reviewed support a shelf-life of 3 years when the vaccine is stored at 2-8°C.
IPV cannot be frozen.

The multi-dose open vial policy is applied to BBio IPV. This allows the vial to be used as long as the VVM has not reached the discard point, the vaccine has not expired and the vaccine has not been contaminated (WHO/V&B/00.14). Also it can be kept up to 28 days after opening, if it is stored at 2-8°C and the conditions mentioned above are fulfilled.

Who is the regulatory authority responsible for its oversight vis a vis WHO?

Poliomyelitis vaccine single-dose was licensed in the Netherlands under number RVG 17642 in December 1993.
Poliomyelitis vaccine multidose was licensed in the Netherlands under number RVG 114720 in November 2014.

The National Regulatory Authority is the Medicines Evaluation Board (MEB) - www.cbg-meb.nl

How has IPV been studied from the clinical point of view?

NVI Inactivated Poliomyelitis Vaccine (IPV NVI) was granted marketing authorization in 1993 (RVG 17642) and since then there has been experience with this vaccine in Europe and Israel. In all main aspects the IPV_{VERO} formulation is identical to the RIVM IPV manufactured in primary monkey kidney cells (IPV_{MKC}) that was registered in the Netherlands in 1981. The virus types and quantity of the active ingredient in each dose are the same. The volume of the preparation of the two formulations has changed, but not so that efficacy and safety should be affected.

The clinical studies with IPV_{MKC} were conducted in the late 1970s and explored a range of formulations of the active ingredients (from double to half the current formulation) in the following countries: Mali, Burkina Faso (then Upper Volta), Ivory Coast, Finland and Sweden. All these studies showed good safety and immunogenicity for the vaccine in all the populations. The final formulation was further tested for safety and immunogenicity in trials in Israel and Finland. These clinical studies formed the basis for the market authorization for the IPV_{MKC} in the Netherlands.

Post-marketing surveillance safety data are provided regularly as part of the update of the PQ vaccine annual report.

Other information about evaluation of IPV:

As part of the prequalification process for BBio IPV, the Product Summary File and the responses provided by BBio to observations made by WHO have been reviewed for quality, safety and efficacy by a team of WHO experts.

The vaccine meets the Recommendations to assure the quality, safety and efficacy of poliomyelitis vaccine (inactivated), WHO TRS 993, annex 3, that have been approved by ECBS at its 65th meeting in Oct 2014 and published at: http://www.who.int/biologicals/en/

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