PUBLIC ASSESSMENT SUMMARY REPORT –BIVALENT ORAL POLIOMYELITIS VACCINE TYPES 1 AND 3

PT BIO FARMA (PERSERO), INDONESIA

What is bivalent oral poliomyelitis vaccine types 1 and 3 (bOPV)?

Bivalent oral poliomyelitis vaccine types 1 and 3 (bOPV) is a vaccine produced by PT Bio Farma (Persero), Indonesia with the following composition:

Name of ingredients	Unit and/or percentage formula
Active ingredients:	
Poliomyelitis virus type 1, Sabin strain (live, attenuated)	Not less than 6.0 log $CCID_{50}$*
Poliomyelitis virus type 3, Sabin strain (live, attenuated)	Not less than 5.8 log $CCID_{50}$
Grown in primary monkey kidney cells	For each 0.1mL dose (2 drops)
Excipients:	
Sucrose	35% v/v
Erythromycin	Not more than 2mcg
Kanamycin	Not more than 10 mcg

*$CCID_{50}$: 50% Cell Culture Infective Doses (viral infectious units)

The vaccine comes in vials of 10 and 20 doses.

Real time and accelerated stability data reviewed support the use of a VVM type 2 that is affixed on the vial label.

What is bivalent oral poliomyelitis vaccine types 1 and 3 (bOPV) used for?

Bivalent oral poliomyelitis vaccine types 1 and 3 (bOPV) is used for active immunization in all age groups against infection caused by poliomyelitis viruses of types 1 and 3.

bOPV is also indicated in the Supplementary Immunization Activities (SIAs) in children from 0 to 5 years of age to interrupt types 1 and 3 poliovirus transmission and since 2016 it is used for routine immunization program in infants.

The use of this vaccine should be in accordance with national and WHO recommendations.

How is bivalent oral poliomyelitis vaccine types 1 and 3 (bOPV) used?

bOPV can be given safely and effectively at the same time as measles, rubella, mumps, DPT, DT,TT, Td, BCG, Hepatitis B, *Haemophilus influenza* type b, yellow fever, IPV (Inactivated polio vaccine) and Vitamin A supplementation.

Warnings and precautions for use

In case of diarrhea, the dose received will not be counted as part of the immunization schedule and it should be repeated after recovery.

bOPV must be administered by oral route only, by using a multi-dose dropper supplied with the vaccine vial.
2 drops will deliver 0.1 mL directly into the mouth from the multi-dose vial by dropper. Care should be taken not to contaminate a multi dose dropper with saliva of the vaccinee.

Once opened, multi-dose vials of bOPV should be kept between +2°C and +8°C. Multi-dose vials from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions for up to a maximum of 4 weeks, in compliance with WHO Multi-Dose Vial Policy.

What are the vaccine characteristics?

bOPV must be stored in a freezer (at not higher than -20°C). Under these recommended storage conditions, the vaccine is stable for 24 months (untill the expiry date indicated on the label). After thawing, the product can be stored for a maximum period of 6 months in a refrigerator, between 2°C and 8°C (Please refer to WHO Multi-DoseVial Policy). The vaccine may present a color varying from yellow to light red, due to a slight variation of pH; however this does not affect the quality of the vaccine.

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

bOPV was licensed in Indonesia on 18 February 2010. The NRA of Record for this vaccine is the National Agency of Drug and Food Control, Indonesia, http://www.pom.go.id/

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

No specific clinical data was required before licensing of Bio Farma bOPV and prequalification by WHO. A randomized controlled trial study of bivalent Oral Polio Vaccine manufacturer by Indian filler using monovalent bulk procured by PT. Bio Farma (Persero) was conducted in India, in 2008.
It was assessed the superiority of monovalent type 2 OPV (mOPV2), monovalent type 3 OPV (mOPV3) or bOPV over trivalent OPV (tOPV) and the non-inferiority of bivalent vaccine compared with mOPV1 and mOPV3.

The findings demonstrated the superiority of bOPV compared with tOPV, and the non-inferiority of bOPV compared with mOPV1 and mOPV3.
Epidemiological and clinical data have clearly showed the good seroprotection acquired in the target population with bOPV.

Other information about evaluation of bOPV

Assessment of the product was based on appropriate review of the submitted Product Summary File, evaluation of the consistency of final product characteristics and follow up of implementation of recommendations made by WHO reviewers during the evaluation.

The vaccine meets WHO requirements of WHO TRS 980, annex 2 published at:
http://www.who.int/immunization_standards/en/

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