PUBLIC ASSESSMENT SUMMARY REPORT – Bivalent Poliomyelitis Vaccine Type 1&3, live (oral), BIOPOLIO® B1/3, Bharat Biotech International Ltd. (BBIL), India

What is Poliomyelitis Vaccine (Oral) bivalent types 1 & 3 (bOPV)?

Poliomyelitis Vaccine (Oral) bivalent types 1 & 3 (bOPV) is a vaccine filled by BBIL from monovalent bulks supplied by Bio Farma, Indonesia with the following composition:

Name of ingredients	Unit and/or percentage formula
Active ingredients :	
Polio virus (Sabin) Type 1 Polio virus (Sabin) Type 3 Grown in Primary Monkey Kidney Cells	6.0 $CCID_{50}$/0.1ml =2drops 5.8 $CCID_{50}$/0.1ml =2drops
Excipients :	
$MgCl_2$ $6H_2O$ Polysorbate (Tween 80) Kanamycin Sulphate Neomycin Sulphate Water for Injection	20.33 mg 10.0 µg 15.0 µg 15.0 µg 0.1 ml

Source of the prequalified monovalent bulk is Bio Farma, Indonesia.

The vaccine is supplied in transparent glass vials of 3 mL capacity, in 20 doses.

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

What is Poliomyelitis Vaccine (Oral) bivalent types 1 & 3 (bOPV) used for?

Bivalent Oral Polio type 1 & type 3 vaccine is indicated for poliomyelitis routine immunization activities in children from 0 to 5 years of age, to interrupt type 1 & type 3 poliovirus transmission. Bivalent Oral Polio type 1 & type 3 vaccine is also indicated for poliomyelitis Supplementary Immunization Activities (SIAs) in all age groups, to interrupt type 1 & type 3 poliovirus transmission in remaining polio endemic areas.

How is Poliomyelitis Vaccine (Oral) bivalent used?

bOPV can be given safely and effectively at the same time as measles, rubella , mumps, inactivated poliomyelitis vaccine (IPV), DTP, DT, TT,Td, BCG, hepatitis B, Haemophilus influenzae type b, yellow fever vaccine, and vitamin A supplementation.

Precautions for use:

bOPV must be administered by oral route only, by using an oral dropper supplied with the vaccine vial.
2 drops will deliver 0.1 mL directly into the mouth from the multi dose vial by dropper. For older children it may be preferred to avoid the possible bitter taste by first placing the drops on a sugar lump or in syrup. Care should be taken not to contaminate a multi dose dropper with saliva of the vaccinee. Overdose, if any, will not result in ill-effect.

What are the vaccine characteristics?

bOPV must be stored at -20°C. Under these recommended storage conditions, the vaccine is stable for 24 months that may include exposure to 2-8°C for a maximum period of 6 months.

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

bOPV was licensed in India on 22 March 2010. The NRA of Record for this vaccine is the Central Drugs Standard Control Organization in India, www.cdsco.nic.in

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

No specific clinical data was required before licensing of BBIL bOPV and prequalification by WHO. The monovalent bulks produced by Bio Farma in Indonesia and filled by several manufacturers have been extensively used and epidemiological and clinical data have clearly demonstrated the good seroprotection acquired in the target population with those different bOPVs.

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, site audit of the manufacturing facilities 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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