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

POLIO SABIN™ ONE AND THREE (ORAL)

GLAXOSMITHKLINE, BELGIUM

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 GlaxoSmithKline (GSK), Belgium with the following composition:

Name of ingredients	Unit and/or percentage formula
Active ingredients:	
Polio virus (Sabin) Type 1 LSc, 2ab (Live, attenuated)	Not less than $10^{6.0}$ $CCID_{50}$*
Polio virus (Sabin) Type 3 Leon 12a, 1b (Live, attenuated)	Not less than $10^{5.8}$ $CCID_{50}$
Grown in MRC5 human diploid cells	0.1mL=2 drops
Excipients:	
Magnesium chloride	20.33 mg
L-arginine	0.87 mg
Polysorbate 80	0.01 mg
Neomycin sulphate and Polymyxin B sulphate	Traces amount
WFI	Up to 0.1 mL

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

The vaccine is presented in glass vials (multi-dose vials containing 10 doses or 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 bivalent oral poliomyelitis vaccine types 1 and 3 (bOPV) used for?

Bivalent oral poliomyelitis vaccine types 1 and 3 (bOPV) is indicated for active immunization in all age groups against infection caused poliomyelitis viruses of Types 1 and 3.
According to WHO recommendations, bOPV types 1 and 3 vaccine is indicated for poliomyelitis Supplementary Immunization Activities (SIAs) in children from 0 to 5 years of age, to interrupt Type 1 and Type 3 polioviruses transmission in remaining polio endemic areas.

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 administered at the same time as *Haemophilus influenzae* type b vaccine, hepatitis B vaccine, diphtheria, pertussis and/or tetanus vaccine, inactivated polio vaccine (IPV), measles, rubella and/or mumps vaccine, yellow fever vaccine or BCG vaccine if this fits into the vaccination schedule.

Concomitant administration of oral poliomyelitis vaccine (OPV) and rotavirus vaccine does not affect the immune response to the polio antigens but may slightly reduce the immune response to rotavirus vaccine. A clinical trial involving more than 4200 subjects who received OPV concomitantly with GlaxoSmithKline Biologicals' rotavirus vaccine (Rotarix™) showed that clinical protection against severe rotavirus gastro-enteritis was maintained.

Warnings and precautions for use

Fever, vomiting and diarrhoea have been observed after immunization with bOPV types 1 and 3. The vaccine may not prevent or modify the course of the disease in subjects already infected with a wild Type 1 or Type 3 poliovirus.

The administration of bOPV types 1 and 3 should be postponed in subjects suffering from acute severe febrile illness, or persistent diarrhoea or vomiting. However, the presence of a minor infection, such as a cold, should not result in the deferral of vaccination.

Since diarrhoea and/or vomiting (as well as gastro-intestinal infection) may interfere with the administration of bOPV types 1 and 3, the dose received will not be counted as part of the immunization schedule and should be repeated after recovery.

Previous vaccination with IPV is not a contraindication for the use of bOPV types 1 and 3.

bOPV types 1 and 3 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. For young 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.

Once opened, multi-dose vials 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?

The vaccine is potent if stored at not higher than –20°C until the expiry date indicated on the vial. It can be stored for up to six months between +2°C and +8°C.

The vaccine may present a colour varying from yellow to pink, due to a minor variation of its 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 types 1 and 3 was licensed in Belgium on 9th October, 2009. The NRA of Record for this vaccine is the Federal Agency of Medicines and Health Products in Belgium, www.fagg-afmps.be/en/

How has bOPV types 1 and 3 been studied from the clinical point of view?

No specific clinical data was required for the licensing of GSK bOPV types 1 and 3 by AFMPS and prequalification by WHO. A randomized controlled trial study of bivalent oral polio vaccine manufactured by Indian filler using monovalent bulk procured from PT. Bio Farma (Persero) was conducted in India, in 2008.
It was assessed the superiority of bOPV types 1 and 3, monovalent type 2 OPV (mOPV2), monovalent type 3 OPV (mOPV3) 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 types 1 and 3.
The study was published by Roland W Sutter et al in Lancet, 2010; 376, 1682-88 and served the purposes of licensing and prequalification.

Other information about evaluation of bOPV types 1 and 3:

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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