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

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What is ORAL BIVALENT TYPES 1 and 3 POLIOMYELITIS VACCINE (bOPV)?

ORAL BIVALENT TYPES 1 and 3 POLIOMYELITIS VACCINE (bOPV) is a vaccine produced by Sanofi Pasteur, France with the following composition:

Name of ingredients	Unit and/or percentage formula
Active ingredients:	
Poliomyelitis virus type 1, LS - c2ab strain (live, attenuated)	At least 6.0 log* $CCID_{50}$**
Poliomyelitis virus type 3, Léon - 12a1b strain (live, attenuated)	At least 5.8 log*$CCID_{50}$**
Produced in Vero Cells	For each 0.1mL dose (2 drops)
Excipients:	
Human albumin solution	1 mg
HEPES buffer solution	q.s 0.1mL
Magnesium chloride solution containing	q.s 0.1mL
Polysorbate (Tween 80)	
Phenol red	
Polymyxin, neomycin & streptomycin	Undetectable traces

* Previously expressed as "at least 10^x $CCID_{50}$"

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

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 ORAL BIVALENT TYPES 1 and 3 POLIOMYELITIS VACCINE (bOPV) used for?

bOPV vaccine is indicated in all age groups for primary vaccination and reinforcement of the immunity against poliomyelitis caused by types 1 and 3 polioviruses.

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

How is ORAL BIVALENT TYPES 1 and 3 POLIOMYELITIS VACCINE (bOPV) used?

bOPV must be administered by oral route only, by using a multi-dose dropper.
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.

bOPV may be given concomitantly during the same vaccination session with injectable inactivated vaccines such as diphtheria, tetanus, pertussis (acellular or whole cell) vaccines, the inactivated poliomyelitis vaccine, the *Haemophilus influenzae* type b conjugate vaccine, hepatitis A vaccines and hepatitis B vaccines, pneumococcal conjugate vaccines and with some live attenuated vaccines such as measles, rubella, mumps and yellow fever vaccines.

Concomitant administration of the oral poliomyelitis vaccine decreases the immune response to the rotavirus vaccine. However, there is currently no evidence that clinical protection against severe gastroenteritis is modified.

Do not use bOPV vaccine in case of:

- Allergy (hypersensitivity)
  - to any component of the vaccine
  - to neomycin, streptomycin or polymyxin B used during manufacturing and which may be present as traces
- Severe reactions after previous administration of an oral poliomyelitis vaccine
- Close contact with patients having immune deficiency
- Primary immune deficiency or immune deficiency subsequent to treatment, leukaemia, lymphoma or advanced malignancy.

Patients with asymptomatic human deficiency virus (HIV) infection should be vaccinated according to the WHO official recommendations.

Warnings and precautions for use

In the event of vomiting after administration of a dose, a second dose may be given after the disorder has disappeared. In the event of fever or acute disease, it may be recommended to postpone vaccination according to national policy.

After vaccination, polioviruses are excreted by vaccinees during the first 4–6 weeks and may contaminate contact persons, including pregnant or breast-feeding women. The safety of the bOPV vaccine in pregnant or breast-feeding women is not known. Clinical and epidemiological studies have not revealed any congenital malformations or foetotoxic effects related to the oral poliomyelitis vaccine in exposed pregnant women.

In premature or low birth weight infants, vaccination must be performed at chronological age, without correction related to duration of pregnancy (gestational age) or birth weight.

No adverse effects have been noticed as a result of overdose and no particular actions are to be put in place in case of overdose.

bOPV vaccine contains two of the three components of the trivalent oral poliomyelitis vaccine and it is anticipated to exhibit the same reactogenicity profile than the trivalent oral poliomyelitis vaccine such as

vaccine associated paralytic poliomyelitis (VAPP) that may occur within 4 to 8 weeks following immunization. For more information, please refer to the package insert.

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 in compliance with WHO Multi-Dose Vial Policy.

What are the vaccine characteristics?

bOPV must be stored in a freezer (-20°C). Under these recommended storage conditions, the vaccine is stable for 24 months. After thawing, the product can be stored for a maximum period of 6 months in a refrigerator (between 2°C and 8°C).

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

bOPV was licensed in France on 26 July 2011. The NRA of Record for this vaccine is the Agence nationale de sécurité du médicament et des produits de santé (ANSM) in France, www.ansm.sante.fr

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

No Sanofi Pasteur sponsored clinical trials were conducted with bOPV. The approval of this vaccine has been granted based on the experience accumulated since the first development of the trivalent oral polio vaccine from Institut Mérieux (Sanofi Pasteur ancestor company) in the mid 1970's.

In 2008-2009, a clinical trial was conducted in India (in Indore, Pune and Chennai), to compare the rate of seroconversion to each serotype in the bivalent OPV with that of the respective monovalent OPV and trivalent OPV. For both types 1 and 3 polio, bivalent OPV was found to be at least 35% more effective than trivalent OPV and almost as good as the monovalent OPVs. A final trial review of results concluded that the strategic use of bOPV in Supplementary Immunization Activities could be an important additional tool in polio eradication, in those areas where both serotypes are circulating.

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/

This summary was last updated on 9 June 2016 and published on date.