PUBLIC ASSESSMENT SUMMARY REPORT

IMOVAX POLIO - SANOFI PASTEUR

What is Imovax Polio?

Imovax Polio is a Poliomyelitis Vaccine (Inactivated) trivalent produced by Sanofi Pasteur (SP) 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 Medium without Phenol red	2.5 µl 12.5 µl Up to 0.5 mL

The vaccine is supplied in Type I glass vial of 7 mL capacity for 10 doses.

VVM type 7 is accepted, in principle, as suitable for use with this product for which the 3 year-shelf life claimed by SP 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 Imovax Polio used for?

Imovax Polio is indicated for the prevention of poliomyelitis in infants, children and adults for primary vaccination and as a booster.
This vaccine may also be indicated for subjects for whom the oral polio vaccine is contraindicated and as a booster for subjects who has been previously vaccinated with oral vaccine.

How is Imovax Polio used?

One dose consists of 0.5 ml for both children and adults.
The preferred route of administration is intramuscular, although the vaccine may also be given subcutaneously.
Poliomyelitis vaccine can simultaneously be administered with other vaccines on different injection locations.

The vaccine can be given as a sequential dose(s) 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.

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 WHO multi-dose open vial policy is applied to IMOVAX 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 the vaccine 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?

Imovax Polio 10 dose vial was first licensed in France under number NL 12835-2 in July 1982. The last renewal is dated 24 July 2013.
The National Regulatory Authority is the Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM) - www. ansm.sante.fr/

How has Imovax Polio been studied from the clinical point of view?

Imovax Polio is licensed in France since 1982 and licensed in approximately 60 countries worldwide as standalone vaccine or as part of a combination.
Since its first licensure, the formulation has been incorporated and evaluated in a wide variety of new combination vaccines, including the recently WHO prequalified Hexaxim, hexavalent vaccine.
These trials within different clinical developmental programs all indicated an adequate immune responsiveness of the 3 polio serotypes, that showed to be highly immunogenic after finalising the primary 2 dose or 3 dose series using the presence of neutralising antibodies as correlate for protection.

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 Imovax Polio, the Product Summary File and the responses provided by SP 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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