World Health Organization

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Verorab Pre-filled syringe

In January 2017, Sanofi Pasteur announced its decision to discontinue the manufacturing of the diluent used to reconstitute the prequalified rabies vaccine Verorab in glass ampoule. Verorab was left with the pre-filled syringe (PFS) diluent presentation which does not meet WHO prequalification criteria.

However, rabies vaccines are life-saving medicinal products and currently there are limited number of manufacturers with Prequalified rabies vaccines. WHO has expressed its openness to find a solution to offer countries and procuring agencies (e.g., UNICEF) the option to accept the PFS if they have the relevant infrastructure to deal with the programmatic disadvantages and ensure the safe disposal of used PFS).

Considering the public health needs, WHO issued in 2019, the letter enclosed.

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In reply please refer to: I8-370-43 General PQT-CL/rs (2019-126)

Your reference:

TO WHOM IT MAY CONCERN

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VERORAB produced by Sanofi Pasteur SA was prequalified on 22 June 2005. At the time the World Health Organization (WHO) reviewed the Product Summary File of VERORAB, there were two presentations offered to United Nations (UN) agencies:

- One-dose vial freeze dried vaccine + one prefilled syringe of 0.4% NACL diluent;
- Five-dose vial freeze dried vaccine + five ampoules containing one dose of 0.4% NaCL diluent.

During the evaluation of VERORAB for prequalification, data of the diluent in a prefilled syringe (PFS) presentation was also reviewed. These data were considered satisfactory from a quality perspective.

However, PFS containing one dose of diluent was not prequalified as it does not comply with the WHO-UNICEF-UNFPA joint statement on the use of auto-disable syringes in immunization services [http://whqlibdoc.who.int/hq/1999/WHO_V&B_99.25.pdf].

The presentation has some programmatic disadvantages in developing country settings:

- It does not have an auto-disable (AD) feature to prevent reuse of the device and thus reduce the possible spread of blood borne diseases.
- Safe disposal of the used syringes (containing glass, rubber and metal) is more difficult than disposal of the AD plastic syringes used to deliver vaccines from a vial presentation and countries may not have the required infrastructure (e. g. high temperature incineration).
- It has a larger cold chain volume per dose than a single-dose vial presentation which could challenge a country's cold chain capacity.

In a letter of 9 January of 2017 from Sanofi Pasteur SA, WHO was informed that the diluent of VERORAB in ampoules (Five one-dose vials of freeze dried vaccine + five ampoules of 0.4% NaCl diluent), manufactured by the company would be discontinued by Q3 2019 and the latest batch would be expired on April 2021. The second letter was received on 21 December 2018 from Sanofi Pasteur indicating that the decision of discontinuation of the ampoule diluent will be effective in the due date.

Therefore, the diluent of VERORAB in a glass PFS will be the only presentation available in the international market.

It is recommended that a recipient country's ability to satisfactorily deal with these issues be considered should they wish to issue a request for tender for supply of this presentation.

Mr Deus Mubangizi
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Prequalification Team

VERORAB®

Poudre et solvant pour suspension injectable en seringue préremplie
Powder and solvent for suspension for injection in prefilled syringe
Polvo y disolvente para suspensión inyectable en jeringa precargada

Vaccin rabique, inactivé
Rabies vaccine, inactivated
Vacuna antirrábica, inactivada

Poudre en flacon + 0,5 mL de solvant en seringue préremplie - Boîte de 10
Powder in vial + 0.5 mL solvent in pre-filled syringe - Box of 10
Polvo en frasco + 0,5 mL de disolvente en jeringa precargada – Caja de 10

Voie intramusculaire (IM - 0,5 mL) ou intradermique (ID - 0,1 mL)
Après reconstitution avec 0,5 mL de solvant : prélever 0,5 mL pour un schéma IM ou 0,1 mL pour un schéma ID

Intramuscular (IM - 0.5 mL) or intradermal (ID - 0.1 mL) use
After reconstitution with 0.5 mL solvent: withdraw 0.5 mL for an IM regimen or 0.1 mL for an ID regimen

Vía intramuscular (IM - 0,5 mL) o intradérmica (ID - 0,1 mL)
Después de la reconstitución con 0,5 mL de disolvente: retire 0,5 mL para un esquema IM o 0,1 mL para un esquema ID

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