20 October 2022

Re: Verorab (Rabies vaccine ≥ 2.5IU) powder and solvent for suspension for injection under Section 19A of the Therapeutic Goods Act 1989

Dear Healthcare Professional,

The Australian registered Merieux Inactivated Rabies Vaccine 2.5 IU powder for injection vial with diluent syringe (AUST R: 26675) is anticipated to be in higher than usual demand due to low availability of other Australian registered rabies vaccines from other suppliers.

Sanofi has been able to arrange supply of an alternative product, **Verorab (Rabies vaccine ≥ 2.5IU) powder and solvent for suspension for injection** on a temporary basis. This product is NOT registered in Australia and supply is authorised under an approval granted by the Therapeutic Goods Administration (TGA) under section 19A of the Therapeutic Goods Act 1989 until 28 February 2023 for the following indication:

> *Verorab is indicated for pre-exposure immunisation in persons at special risk of contracting rabies as well as post exposure immunisation against rabies.*

Verorab (Rabies vaccine ≥ 2.5IU) powder and solvent for suspension for injection is registered and marketed in France and many other countries.

Please note the following information regarding differences between Verorab (Rabies vaccine ≥ 2.5IU) powder and solvent for suspension for injection and the Australian registered rabies vaccines.

	RABIPUR rabies virus vaccine (Inactivated) 2.5 IU powder for injection vial with diluent pre-filled syringe **(AUST R: 298194)**	**MERIEUX INACTIVATED RABIES VACCINE (MIRV) 2.5IU powder for injection vial with diluent syringe** **(AUST R: 26675)**	**Section 19A product - VERORAB (Rabies vaccine ≥ 2.5IU) powder and solvent for suspension for injection in prefilled syringe**
Strain	Fixed-virus strain, Flury LEP ≥ 2.5 IU	Inactivated Wistar rabies virus strain PM/W138 15033M ≥ 2.5 IU	Inactivated Wistar rabies virus strain PM/WI38 1503-3M ≥ 2.5 IU
Dose	**1.0 mL** of reconstituted vaccine	**1.0 mL** of reconstituted vaccine	**0.5 mL** of reconstituted vaccine
Excipients	Trometamol (3.5 mg), sodium chloride (4.5 mg), disodium edetate (0.25 mg), monopotassium glutamate (0.9 mg), polygeline (10.5 mg), sucrose (60 mg), water for injections (1.0 mL).	Neomycin (100-150 micrograms), Human serum albumin (up to 70 mg), Water for injections	**Powder*:** Maltose, 20% human albumin solution, Basal Medium Eagle (mixture of mineral salts including potassium, vitamins, dextrose and amino-acids including L-Phenylalanine), water for injections and traces of Polymyxin, Streptomycin, Neomycin.

Solvent: sodium chloride, water for injections.
* Composition of the powder before the freeze-drying step.

The current Australian Immunisation Handbook recommends that a pre-exposure prophylaxis (PrEP) or postexposure prophylaxis (PEP) course can be completed with an alternative rabies cell culture- derived vaccine if necessary, providing the vaccine is endorsed by the World Health Organization (also known as 'pre-qualified'). **Verorab (Rabies vaccine ≥ 2.5IU) powder and solvent for suspension for injection** is a WHO pre-qualified vaccine and hence it can be used to complete the PrEP or PEP course started with MIRV or Rabipur.

The VERORAB package contains a vial of lyophilized vaccine and a pre-filled syringe with a fixed needle that contains 0.5 mL of diluent. **The supplied prefilled syringe with fixed needle should be used only for vaccine reconstitution. Once the vaccine is reconstituted, a new sterile syringe and needle, which are not contained in the VERORAB package, must be used to withdraw the reconstituted vaccine and administer the vaccine to the patient.** The size and the length of the needle used for intramuscular vaccine administration should be chosen in accordance with the current national immunisation guidelines.

Further information on **Verorab (Rabies vaccine ≥ 2.5IU) powder and solvent for suspension for injection** can be found in the Package Insert provided in each pack of VERORAB.

Adverse Event Reporting
Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **Verorab (Rabies vaccine ≥ 2.5IU) powder and solvent for suspension for injection** should be reported by healthcare professionals and patients to Sanofi on 1800 818 806 or ae@sanofi.com. Alternatively, this information can be reported to the TGA at www.tga.gov.au/reportingproblems.

Please forward this information to relevant staff members in your organisation.

If you would like further information regarding **Verorab (Rabies vaccine ≥ 2.5IU) powder and solvent for suspension for injection** please contact:

- For medical enquiries contact Sanofi Medical Information 1800 818 806
- For enquiries relating to supply contact Sanofi Customer Service 1800 829 468

Thank you for your understanding.

Regards,

Dr Iris Depaz
Head of Medical Sanofi Pasteur and Sanofi ANZ Medical Country Lead

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