EMA/53565/2024

European Medicines Agency decision

P/0051/2024

of 8 March 2024

on the acceptance of a modification of an agreed paediatric investigation plan for purified inactivated rabies virus (WISTAR PM/WI 38-1503-3M strain) (EMEA-002234-PIP01-17-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0219/2018 issued on 17 July 2018 and the decision P/0319/2020 issued on 12 August 2020,

Having regard to the application submitted by Sanofi Pasteur on 13 October 2023 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 January 2024, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for purified inactivated rabies virus (WISTAR PM/WI 38-1503-3M strain), powder and solvent for suspension for injection, intramuscular use, intradermal use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Sanofi Pasteur, 14 espace Henry Vallée, 69007 – Lyon, France.

EMA/PDCO/478257/2023
Amsterdam, 19 January 2024

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-002234-PIP01-17-M02

Scope of the application

Active substance(s):

Purified inactivated rabies virus (WISTAR PM/WI 38-1503-3M strain)

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of rabies viral infection

Pharmaceutical form(s):

Powder and solvent for suspension for injection

Route(s) of administration:

Intramuscular use

Intradermal use

Name/corporate name of the PIP applicant:

Sanofi Pasteur

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sanofi Pasteur submitted to the European Medicines Agency on 13 October 2023 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0219/2018 issued on 17 July 2018 and the decision P/0319/2020 issued on 12 August 2020.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 20 November 2023.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Prevention of rabies viral infection

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- powder and solvent for suspension for injection; intramuscular use and intradermal use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric investigation plan

2.1. Condition

Prevention of rabies viral infection

2.1.1. Indication(s) targeted by the PIP

Prevention of rabies in pre- and post-exposure prophylaxis

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 1 year to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder and solvent for suspension for injection

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1** Randomised, observer-blind, active-controlled trial to evaluate safety and immunogenicity of a pre-exposure regimen of an earlier formulation of purified inactivated rabies virus (WISTAR PM/WI 38-1503-3M strain) [hereafter referred to as VRVg-1] compared to Imovax rabies vaccine in healthy children and adolescents from 2 to less than 18 years of age (VRV06).

	Study 2 Randomised, observer-blind, active-controlled trial to evaluate safety and immunogenicity of a simulated post-exposure regimen of VRVg-1 compared to Verorab rabies vaccine in healthy children and adolescents from 10 to less than 18 years of age (and adults) (VRV08). **Study 3** Randomised, observer-blind, active-controlled trial to evaluate safety and immunogenicity of a pre-exposure regimen of purified inactivated rabies virus (WISTAR PM/WI 38-1503-3M strain) [hereafter referred to as VRVg-2] compared to Verorab or Imovax rabies vaccine in healthy children and adolescents from 1 year to less than 18 years of age (and adults). **Study 4** Randomised, observer-blind, active-controlled trial to evaluate safety and immunogenicity of two post-exposure regimens of VRVg-2 compared to Verorab vaccine in healthy children and adolescents from 1 year to less than 18 years of age (and adults) (VRV09).
Extrapolation, modelling and simulation studies	Not applicable
Other studies	Not applicable
Other measures	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use	No
Date of completion of the paediatric investigation plan	By December 2023
Deferral for one or more measures contained in the paediatric investigation plan	No

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.