



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1859737

European Medicines Agency decision

EMA/PE/0000222938

of 28 January 2025

on the acceptance of a modification of an agreed paediatric investigation plan for Neisseria Meningitidis Group A Polysaccharide Conjugated to Tetanus Toxoid Carrier Protein, Neisseria Meningitidis Group C Polysaccharide Conjugated to Tetanus Toxoid Carrier Protein, Neisseria Meningitidis Group W-135 Polysaccharide Conjugated to Tetanus Toxoid Carrier Protein, Neisseria Meningitidis Group Y Polysaccharide Conjugated to Tetanus Toxoid Carrier Protein, NmBPbAS1, RNmB1, RNmB2, RNmB3 (MenPenta vaccine) 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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/0445/2023 issued on 27 October 2023,

Having regard to the application submitted by Sanofi Pasteur on 30 August 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 December 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 and to the waiver.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan including changes to the waiver.

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 Neisseria Meningitidis Group A Polysaccharide Conjugated to Tetanus Toxoid Carrier Protein, Neisseria Meningitidis Group C Polysaccharide Conjugated to Tetanus Toxoid Carrier Protein, Neisseria Meningitidis Group W-135 Polysaccharide Conjugated to Tetanus Toxoid Carrier Protein, Neisseria Meningitidis Group Y Polysaccharide Conjugated to Tetanus Toxoid Carrier Protein, NmBPbAS1, RNmB1, RNmB2, RNmB3 (MenPenta vaccine), including changes to the waiver, 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 Vallee, 69007 Lyon, France.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1704213 Corr¹
Amsterdam, 13 December 2024

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA/PE/0000222938

Scope of the application

Active substance(s):

Neisseria Meningitidis Group A Polysaccharide Conjugated to Tetanus Toxoid Carrier Protein, Neisseria Meningitidis Group C Polysaccharide Conjugated to Tetanus Toxoid Carrier Protein, Neisseria Meningitidis Group W-135 Polysaccharide Conjugated to Tetanus Toxoid Carrier Protein, Neisseria Meningitidis Group Y Polysaccharide Conjugated to Tetanus Toxoid Carrier Protein, NmBPbAS1, RNmB1, RNmB2, RNmB3 (MenPenta vaccine)

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of meningococcal disease (serogroups A, B, C, W and Y)

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Intramuscular 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 30 August 2024 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0445/2023 issued on 27 October 2023.

¹ Correction 20 January 2025



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

The procedure started on 14 October 2024.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. A waiver for a new paediatric subset has been added.

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 and to the waiver in the scope set out in the Annex I of this opinion.

The Paediatric Committee members of Liechtenstein and Norway agree 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)

Waiver

1.1. Condition:

Prevention of meningococcal disease

The waiver applies to:

- the paediatric population from birth to less than 2 months of age;
- suspension for injection, intramuscular use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition:

Prevention of meningococcal disease

2.1.1. Indication(s) targeted by the PIP

Active immunization of individuals from 2 months of age against invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, B, C, W and Y

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

From 2 months to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Suspension for injection

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	Study 1 VAN00010 Dose finding study to evaluate safety and immunogenicity of MenPenta vaccine in children and adolescents from 10 years to less than 18 years of age (and adults) Study 2 VAN00011 Double-blind randomised trial to evaluate safety and immunogenicity of MenPenta vaccine compared to a licensed alternative administered concomitantly with routine vaccines

	<p>in children and adolescents from 10 years to less than 18 years of age (and adults)</p> <p>Study 3 VAN00013</p> <p>Partially blinded study to evaluate the safety and immunogenicity of the MenPenta vaccine in children from 2 months to less than 10 years of age</p> <p>Study 4 VAN00014</p> <p>Double-blind randomised placebo-controlled trial to evaluate safety and immunogenicity of MenPenta vaccine compared to a licensed alternative administered concomitantly with routine paediatric vaccines to healthy children from 2 months to less than 24 months of age</p> <p>Study 5 VAN00018</p> <p>Open-label follow-up trial of study VAN00010 (PIP study 1) to evaluate antibody persistence safety and immunogenicity of a booster dose of MenPenta vaccine in adolescents 3-4 years post-priming</p>
Modelling and simulation studies	Not applicable
Other studies	Not applicable
Extrapolation plan	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 2031
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.