EMA/627452/2021

European Medicines Agency decision

P/0473/2021

of 3 December 2021

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for recombinant Neisseria meningitidis serogroup B protein 2 / recombinant Neisseria meningitidis serogroup B protein 1 / recombinant Neisseria meningitidis serogroup B protein 3 / Neisseria meningitidis serogroup B Protein-based active substance (EMEA-002954-PIP02-21) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Sanofi Pasteur on 15 February 2021 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 October 2021, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

(4) It is therefore appropriate to adopt a decision granting a waiver.

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

Has adopted this decision:

Article 1

A paediatric investigation plan for recombinant Neisseria meningitidis serogroup B protein 2 / recombinant Neisseria meningitidis serogroup B protein 1 / recombinant Neisseria meningitidis serogroup B protein 3 / Neisseria meningitidis serogroup B Protein-based active substance, suspension for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for recombinant Neisseria meningitidis serogroup B protein 2 / recombinant Neisseria meningitidis serogroup B protein 1 / recombinant Neisseria meningitidis serogroup B protein 3 / Neisseria meningitidis serogroup B Protein-based active substance, suspension for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for recombinant Neisseria meningitidis serogroup B protein 2 / recombinant Neisseria meningitidis serogroup B protein 1 / recombinant Neisseria meningitidis serogroup B protein 3 / Neisseria meningitidis serogroup B Protein-based active substance, suspension for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

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

EMA/PDCO/417915/2021
Amsterdam, 15 October 2021

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-002954-PIP02-21

Scope of the application

Active substance(s):

Recombinant Neisseria meningitidis serogroup B protein 2 /
Recombinant Neisseria meningitidis serogroup B protein 1 /
Recombinant Neisseria meningitidis serogroup B protein 3 /
Neisseria meningitidis serogroup B Protein-based active substance

Condition(s):

Prevention of meningococcal disease

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 16(1) of Regulation (EC) No 1901/2006 as amended, Sanofi Pasteur submitted for agreement to the European Medicines Agency on 15 February 2021 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 23 March 2021.

Supplementary information was provided by the applicant on 2 July 2021. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

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

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

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex 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 meningococcal disease

The waiver applies to:

- the paediatric population from birth to less than 6 weeks of age;
- suspension for injection, intramuscular use;
- on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric investigation plan

2.1. Condition:

Prevention of meningococcal disease

2.1.1. Indication(s) targeted by the PIP

Prevention of meningococcal disease (serogroup B)

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

From 6 weeks to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Suspension for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	6	Study 1 Randomised, parallel-group, active-controlled, modified double-blind (Stage 1 and Stage 2, adults and adolescents) and open-label (Stage 3 and Stage 4, toddlers and infants), stepwise age de-escalation, dose-selection, and schedule finding, descriptive study with sentinel safety cohorts and Early Safety Data Review (ESDR) to describe safety and immunogenicity of multiple meningococcal serotype B (MenB) vaccine formulations compared to the licensed MenB vaccines Bexsero

		Vaccine and Trumenba Vaccine when given alone or when co-administered with MenACWY Vaccine or routine paediatric vaccines (Stage 4) in children from 42 days to less than 18 years of age (and adults). (VAN00002) Study 2 Modified double-blind, randomised, active-controlled trial to evaluate safety and immunogenicity of a MenB vaccine candidate given alone or co-administered with MenACWY vaccine, HPV9 and Tdap vaccines compared to MenACWY vaccine, HPV9 and Tdap vaccines alone or to Bexsero vaccine in children and adolescents from 10 years to less than 18 years of age. (VAN00003) Study 3 Open-label, randomised, active-controlled, schedule finding trial to evaluate safety and immunogenicity of a MenB vaccine given alone or co-administered with routine vaccines (RV) compared to the Bexsero vaccine in healthy children from 42 days to less than 10 years of age. (VAN00005) Study 4 Open-label study to evaluate the antibody persistence following priming with the multicomponent MenB vaccine and to evaluate safety and immunogenicity of the multicomponent MenB vaccine administered as a booster dose in children and adolescents from 10 years to less than 18 years of age (and adults) who received 2 doses of the MenB vaccine from Stage 2 of Study 1 (VAN00002). (VAN00009) Study 5 Double blind, randomised, active-controlled trial to evaluate safety and immunogenicity of the multicomponent MenB vaccine administered alone or co-administered with routine paediatric vaccines compared to routine paediatric vaccines in children from 12 months to less than 24 months of age. (VAN00006) Study 6 Double-blind, randomised, active-controlled trial to evaluate safety and immunogenicity of the multicomponent MenB vaccine when administered alone or co-administered with routine paediatric vaccines compared to routine paediatric vaccines in children from 42 days to less than 90 days of age. (VAN00007)

Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	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 September 2031
Deferral for one or more measures contained in the paediatric investigation plan:	Yes