EMA/65205/2022

European Medicines Agency decision

P/0080/2022

of 11 March 2022

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for neisseria meningitidis serogroup B fHbp subfamily A / Neisseria meningitidis group C polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria meningitidis serogroup B fHbp subfamily B / Neisseria meningitidis group W-135 polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria meningitidis group Y polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria meningitidis group A polysaccharide conjugated to tetanus toxoid carrier protein (MenABCWY) (EMEA-002814-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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Pfizer Europe MA EEIG on 3 June 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 21 January 2022, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

A paediatric investigation plan for neisseria meningitidis serogroup B fHbp subfamily A / Neisseria meningitidis group C polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria meningitidis serogroup B fHbp subfamily B / Neisseria meningitidis group W-135 polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria meningitidis group Y polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria meningitidis group A polysaccharide conjugated to tetanus toxoid carrier protein (MenABCWY), powder and suspension for 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 neisseria meningitidis serogroup B fHbp subfamily A / Neisseria meningitidis group C polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria meningitidis serogroup B fHbp subfamily B / Neisseria meningitidis group W-135 polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria meningitidis group Y polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria meningitidis group A polysaccharide conjugated to tetanus toxoid carrier protein (MenABCWY), powder and suspension for 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 neisseria meningitidis serogroup B fHbp subfamily A / Neisseria meningitidis group C polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria meningitidis serogroup B fHbp subfamily B / Neisseria meningitidis group W-135 polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria meningitidis group Y polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria meningitidis group A polysaccharide conjugated to tetanus toxoid carrier protein (MenABCWY), powder and suspension for 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 Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 – Brussels, Belgium.

EMA/PDCO/613413/2021
Amsterdam, 21 January 2022

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

EMEA-002814-PIP02-21

Scope of the application

Active substance(s):

Neisseria meningitidis serogroup B fHbp subfamily A / Neisseria meningitidis group C polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria meningitidis serogroup B fHbp subfamily B / Neisseria meningitidis group W-135 polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria meningitidis group Y polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria meningitidis group A polysaccharide conjugated to tetanus toxoid carrier protein (MenABCWY)

Condition(s):

Prevention of invasive disease caused by Neisseria meningitidis group A, B, C, W and Y

Pharmaceutical form(s):

Powder and suspension for suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Pfizer Europe MA EEIG

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Pfizer Europe MA EEIG submitted for agreement to the European Medicines Agency on 3 June 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 12 July 2021.

Supplementary information was provided by the applicant on 18 October 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 the 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 invasive disease caused by Neisseria meningitidis group A, B, C, W and Y

The waiver applies to:

- the paediatric population from birth to less than 2 months of age;
- powder and suspension for suspension for injection, intramuscular use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Prevention of invasive disease caused by Neisseria meningitidis group A, B, C, W and Y

2.1.1. Indication(s) targeted by the PIP

Active immunisation against invasive disease caused by Neisseria meningitidis group A, B, C, W and Y from 2 months of age.

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

From 2 months of age to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder and suspension for 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	5	**Study 1 (B1971057)** Randomized, controlled, observer-blinded study to evaluate immunogenicity, safety and tolerability of bivalent rLP2086 (Trumenba) and immunogenicity, safety and tolerability of MenABCWY compared to meningococcal groups A, C, Y and W-135 Conjugate Vaccine (MenACWY-CRM) (Menveo) and to bivalent rLP2086 (Trubmeba) for the respective meningococcal group strains

		in children from 10 years to less than 18 years of age (and adults) Stage 1: evaluation of primary vaccination responses Stage 2: evaluation of persistence of immunity and responses to a booster vaccination. **Study 2 (C3511001)** Randomized, controlled, observer-blinded immunogenicity and safety study to demonstrate that the immune response for N meningitidis group A (MenA), MenC, MenW, and MenY induced by 2 doses of MenABCWY is noninferior to the immune response induced by 1 dose of the licensed meningococcal group A, C, W-135 and Y conjugate vaccine (MenACWY-CRM) (Menveo), and that the immune response for 4 primary MenB test strains induced by 2 doses of MenABCWY is noninferior to the immune response induced by 2 doses of meningococcal group b vaccine (recombinant, adsorbed) (bivalent rLP2086) (Trumenba) **Study 3 (C3511002)** Open label, controlled, immunogenicity, safety and tolerability study of MenABCWY and meningococcal serogroup B bivalent (rLP2086) (Trumenba) vaccines when co-administered with Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated), and Haemophilus type b conjugate vaccine (adsorbed) (Vaxelis), and pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) (Prevnar13) to infants 6 months of age (sentinel stage) and 2 months of age (expanded stage): **Study 4 (C351100X)** Randomized, controlled, observer-blinded, immunogenicity, safety and tolerability study of MenABCWY in infants 2 months of age To evaluate the immune response for MenA, MenC, MenW, MenY induced by MenABCWY compared to the immune response induced by MenACWY-TT (Nimenrix) after 2 primary vaccinations and after a booster dose To evaluate the immune response for MenB induced by MenABCWY compared to the immune response induced by meningococcal group B Vaccine (rDNA, component, adsorbed) (Bexsero) after 2 primary vaccinations and after a booster dose. **Study 5 (C3511006)** Randomized, active-controlled, open-label trial to evaluate immunogenicity, safety and tolerability of 2 doses of MenABCWY in children from 12 months to less than 10 years of age.
Extrapolation, modelling and	0	Not applicable

simulation studies		
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 April 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes