EMA/21391/2023

European Medicines Agency decision

P/0055/2023

of 30 January 2023

on the acceptance of a modification of an agreed 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), (EMEA-002814-PIP02-21-M01) 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/0080/2022 issued on 11 March 2022.

Having regard to the application submitted by Pfizer Europe MA EEIG on 12 September 2022 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 16 December 2022, 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 deferral 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 deferral and 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 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, including changes to the deferral and 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 Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 - Brussels, Belgium.

EMA/PDCO/798601/2022
Amsterdam, 16 December 2022

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

EMEA-002814-PIP02-21-M01

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)

Invented name and authorisation status:

See Annex II

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 22 of Regulation (EC) No 1901/2006 as amended, Pfizer Europe MA EEIG submitted to the European Medicines Agency on 12 September 2022 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/0080/2022 issued on 11 March 2022.

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

The procedure started on 17 October 2022.

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 deferral 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)

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 6 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 6 months of age.

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

From 6 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	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**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)** *This study was deleted with procedure EMEA-002814-PIP02-21-M01* **Study 4 (C351100X)** *This study was deleted with procedure EMEA-002814-PIP02-21-M01* **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. **Study 6 (C351100Z)** *This study was introduced with procedure EMEA-002814-PIP02-21-M01* Randomized, controlled, immunogenicity, safety and tolerability study of MenABCWY in infants 6 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.
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 2027
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