EMA/114604/2024

European Medicines Agency decision

P/0118/2024

of 12 April 2024

on the acceptance of a modification of an agreed paediatric investigation plan for outer membrane vesicles (OMV) from N. meningitidis Strain NZ 98/254 / recombinant Neisseria meningitis group B Protein 936-741 / meningococcal group W-135 oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein / meningococcal group A oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein / meningococcal group C oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein / recombinant Neisseria meningitis group B Protein 287-953 / recombinant Neisseria meningitis group B Protein 961c / meningococcal group Y oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein (MenABCWY), (EMEA-001260-PIP01-11-M03) 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/0304/2012 issued on 20 December 2012, the decision P/0231/2020 issued on 19 June 2020 and the decision P/0437/2022 issued on 28 October 2022,

Having regard to the application submitted by GlaxoSmithKline Biologicals SA on 16 November 2023 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 23 February 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 outer membrane vesicles (OMV) from N. meningitidis Strain NZ 98/254 / recombinant Neisseria meningitis group B Protein 936-741 / meningococcal group W-135 oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein / meningococcal group A oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein / meningococcal group C oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein / recombinant Neisseria meningitis group B Protein 287-953 / recombinant Neisseria meningitis group B Protein 961c / meningococcal group Y oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein (MenABCWY), powder and suspension for suspension for injection, intramuscular 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 GlaxoSmithKline Biologicals SA, Rue de l'Institut 89, 1330 – Rixensart, Belgium.

EMA/PDCO/535264/2023 Corr[1]
Amsterdam, 23 February 2024

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

EMEA-001260-PIP01-11-M03

Scope of the application

Active substance(s):

Outer Membrane Vesicles (OMV) from N. meningitidis Strain NZ 98/254 / recombinant Neisseria meningitis group B Protein 936-741 / meningococcal group W-135 oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein / meningococcal group A oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein / meningococcal group C oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein / recombinant Neisseria meningitis group B Protein 287-953 / recombinant Neisseria meningitis group B Protein 961c / meningococcal group Y oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein (MenABCWY)

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of meningococcal meningitis

Pharmaceutical form(s):

Powder and suspension for suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

GlaxoSmithKline Biologicals SA

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Biologicals SA submitted to the European Medicines Agency on 16 November 2023 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European

[1] 27 March 2024

Medicines Agency's decision P/0304/2012 issued on 20 December 2012, the decision P/0231/2020 issued on 19 June 2020 and the decision P/0437/2022 issued on 28 October 2022.

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

The procedure started on 3 January 2024.

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 Meningococcal Meningitis

The waiver applies to:

- newborns and infants from birth to less than 2 months of age;
- powder and suspension for suspension for injection, intramuscular use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

2. Paediatric Investigation Plan

2.1. Condition:

Prevention of Meningococcal Meningitis

2.1.1. Indication(s) targeted by the PIP

Active immunization against invasive disease caused by *N. meningitides* group A, B, C, Y, and W-135 of individuals from 2 months of age and older.

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)

Powder and suspension for suspension for injection

2.1.4. Studies

Area	Description
Quality	Not applicable
Non-clinical	**Study 1 (AB04984):** Intramuscular dose range-finding developmental toxicity study in rabbit (pilot study) **Study 2 (AB20847):** Pivotal reproductive and peri/post-natal developmental toxicity study in the rabbit
Clinical	**Study 3 (V102_02):** Observer-blind, controlled, randomized study to evaluate safety, tolerability and immunogenicity of four different rMenB plus Menveo formulations in healthy adolescents. **Study 4 (V102_02E1):** Observer-blind, controlled, randomized, extension study to evaluate safety, tolerability and immunogenicity of a third dose of one of four different formulations of rMenB + Menveo in adolescents who previously received the same study vaccines in study 3.

	Study 5 (V102_03): Observer-blind, controlled, randomized study in adolescents and young adults aged 10 to 25 years to evaluate safety and immunogenicity of two different rMenB with outer membrane vesicles (OMV) + Menveo formulations. **Study 6 (V102_03E1):** Partially-blind, controlled, randomized, extension study to evaluate the safety, and immunogenicity of administration of a single dose of two MenABCWY vaccine formulations 12 months after primary series to adolescents and young adults who completed study 5. **Study 7: Study removed during EMEA-001260-PIP01-11-M02 procedure** **Study 8: Study removed during EMEA-001260-PIP01-11-M02 procedure** **Study 9: Study removed during EMEA-001260-PIP01-11-M02 procedure** **Study 10 (V102_08):** Observer-blind, randomized, controlled study to evaluate safety and immunogenicity of four rMenB containing vaccine formulations in infants 2 months of age. **Study 11 (V102_11):** Observer-blind, randomized, controlled study to evaluate immunogenicity, reactogenicity and safety of the selected MenABCWY as compared to Menveo in healthy children aged 12 to less than 24 months. **Study 12 (V102_12):** Observer-blind, randomized, controlled study to evaluate immunogenicity, reactogenicity and safety of the selected MenABCWY as compared to Menveo in healthy children aged 2 to less than 10 years. **Study 13 (V102_14):** Observer-blind, randomized, controlled study to evaluate immunogenicity and safety of MenABCWY, when given to healthy infants at 2, 3, 4 and 12 months of age. **Study 14 (V102_15) Study added during EMEA-001260-PIP01-11-M02 procedure:** Observer-blind, randomised, controlled study to assess the immunogenicity and safety of MenABCWY vaccine administered at different schedules compared to GSK meningococcal group B vaccine (Bexsero), in healthy adolescents aged 10 years to less than 18 years. **Study 15 (V102_15E1) Study added during EMEA-001260-PIP01-11-M02 procedure:** Open-Label uncontrolled study to assess the persistence of antibodies at 24 months after the last meningococcal vaccination in Study 14 (V102_15) and the response to a booster dose of MenABCWY or Bexsero, in healthy adolescents from 12 years to less than 18 years. **Study 16 (V102_16) Study added during EMEA-001260-PIP01-11-M02 procedure:** Observer-blind, randomised, controlled study to assess the effectiveness, immunogenicity and safety of MenABCWY vaccine in healthy adolescents from 10 years to less than 18 years of age. **Study 17 (V102_16E1) Study added during EMEA-001260-PIP01-11-M02 procedure:** Observer-blind, controlled study to assess the effectiveness, immunogenicity and safety of the 3rd Dose of MenABCWY administered to healthy adolescents aged from 10 years to less than 18 years.

	Study 18 (V72_72) Study added during EMEA-001260-PIP01-11-M02 procedure: Observer-blind, randomized, controlled, non-inferiority study to demonstrate effectiveness, immunogenicity and safety of Bexsero and MenABCWY when administered to healthy adolescents from 10 years to less than 18 years of age (and young adults).

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2025
Deferral for one or more studies 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.