



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/400645/2023

European Medicines Agency decision P/0404/2023

of 27 October 2023

on the agreement of a paediatric investigation plan and on the granting of a waiver for recombinant *Neisseria meningitis* group B Protein 936-741 / Meningococcal group W-135 oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / Recombinant *Neisseria meningitis* group B Protein 287-953 / Meningococcal group A oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / Recombinant *Neisseria meningitidis* group B fHbp 2-3-1.13NB fusion protein / Outer Membrane Vesicles (OMV) from *N. meningitidis* Strain NZ 98/254 / Meningococcal group C oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / Meningococcal group Y oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / Recombinant *Neisseria meningitis* group B Protein 961c (MenACWY-7B vaccine) (EMEA-003359-PIP01-22) 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 application submitted by GlaxoSmithKline Biologicals SA on 18 November 2022 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 8 September 2023, in accordance with Article 17 of Regulation (EC) No 1901/2006 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 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 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 recombinant *Neisseria meningitis* group B Protein 936-741 / Meningococcal group W-135 oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / Recombinant *Neisseria meningitis* group B Protein 287-953 / Meningococcal group A oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / Recombinant *Neisseria meningitidis* group B fHbp 2-3-1.13NB fusion protein / Outer Membrane Vesicles (OMV) from *N. meningitidis* Strain NZ 98/254 / Meningococcal group C oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / Meningococcal group Y oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / Recombinant *Neisseria meningitis* group B Protein 961c (MenACWY-7B vaccine), 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 waiver for recombinant *Neisseria meningitis* group B Protein 936-741 / Meningococcal group W-135 oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / Recombinant *Neisseria meningitis* group B Protein 287-953 / Meningococcal group A oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / Recombinant *Neisseria meningitidis* group B fHbp 2-3-1.13NB fusion protein / Outer Membrane Vesicles (OMV) from *N. meningitidis* Strain NZ 98/254 / Meningococcal group C oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / Meningococcal group Y oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / Recombinant *Neisseria meningitis* group B Protein 961c (MenACWY-7B vaccine), 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

This decision is addressed to GlaxoSmithKline Biologicals SA, Rue de l'Institut 89, 1330 – Rixensart, Belgium.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/269122/2023 Corr¹
Amsterdam, 8 September 2023

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

EMA-003359-PIP01-22

Scope of the application

Active substance(s):

Recombinant *Neisseria meningitis* group B Protein 936-741 / Meningococcal group W-135 oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / Recombinant *Neisseria meningitis* group B Protein 287-953 / Meningococcal group A oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / Recombinant *Neisseria meningitidis* group B fHbp 2-3-1.13NB fusion protein / Outer Membrane Vesicles (OMV) from *N. meningitidis* Strain NZ 98/254 / Meningococcal group C oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / Meningococcal group Y oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / Recombinant *Neisseria meningitis* group B Protein 961c (MenACWY-7B vaccine)

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of meningococcal disease

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

¹ 28 September 2023.



Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Biologicals SA submitted for agreement to the European Medicines Agency on 18 November 2022 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 3 January 2023.

Supplementary information was provided by the applicant on 23 May 2023. 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 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 Paediatric Committee member of Norway 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 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 disease

The waiver applies to:

- the paediatric population from birth to less than 2 months;
- powder and suspension for 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

Active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroups A, B, C, W and Y for use in individuals 2 months of age and above

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

From 2 months to less than 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 (MENACWY=MEN7B-001 PRI) Randomised, controlled study to assess the safety, effectiveness and immune response of MenACWY-7B vaccine when administered to healthy children and adolescents from 10 years to less than 18 years of age, aimed at selecting final dose and schedule. Study 2 (MENACWY=MEN7B-003) Randomised, controlled, dose-escalating study to assess the safety, tolerability and immunogenicity of MenACWY-7B vaccine compared to MenABCWY or MenB and MenACWY-TT vaccines in healthy infants between 55 and 89 days of age.

	Study 3 (MENACWY=MEN7B-00X) Open label, randomised, controlled study to assess the safety and immune response of meningococcal combined ABCWY vaccine in healthy children aged from 1 year to less than 4 years. Study 4 (MENACWY=MEN7B-00Y) Randomised, controlled observer-blind study to assess the safety, tolerability and immunogenicity of MenACWY-7B vaccine compared to MenACWY-TT and MenB vaccines in healthy infants aged 2 months at enrollment.
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 April 2028
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.