EMA/303223/2020

# European Medicines Agency decision

P/0231/2020

of 19 June 2020

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 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-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 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 European Medicines Agency's decision P/0304/2012 issued on 20 December 2012,

Having regard to the application submitted by GSK Vaccines s.r.l. on 27 January 2020 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 30 April 2020, 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.

(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.

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

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 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, including changes to the deferral, 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 GSK Vaccines s.r.l. Via Fiorentina 1 53100 – Siena, Italy.

EMA/PDCO/66805/2020
Amsterdam, 30 April 2020

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

EMEA-001260-PIP01-11-M01

## 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)

**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:**

GSK Vaccines s.r.l.

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GSK Vaccines s.r.l. submitted to the European Medicines Agency on 27 January 2020 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/0304/2012 issued on 20 December 2012.

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

The procedure started on 2 March 2020.

## Scope of the modification

Some 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 and to the deferral in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member 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 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 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 | Number of studies | Description |
|---|---|---|
| Quality | 0 | Not applicable |
| Non-clinical | 2 | **Study 1:** Intramuscular dose range-finding developmental toxicity study in rabbit (pilot study)<br><br>**Study 2:** Pivotal reproductive and peri/post-natal developmental toxicity study in the rabbit |
| Clinical | 11 | **Study 3:** Observer-blind, controlled, randomized study to evaluate safety, tolerability and immunogenicity of four different rMenB plus Menveoformulations in healthy adolescents.<br><br>**Study 4:** 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:** 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.<br><br>**Study 6:** 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.<br><br>**Study 7:** Randomized, observer-blind, controlled study to evaluate the lot-to-lot consistency of the MenABCWY vaccine, non-inferiority to single dose of Menveo, and sufficient immune response to B strains in adolescents.<br><br>**Study 8:** Randomized, observer-blind, controlled, study to compare the safety and immunogenicity of two doses of Novartis MenABCWY Vaccine with one dose of Menveo in healthy vaccine-naive subjects at least 10 years of age.<br><br>**Study 9:** Observer-blind, controlled, randomized study to evaluate the safety and immunogenicity of MenABCWY, when administered with Tetanus, Diphtheria toxoid, acellular Pertussis vaccine (Tdap, GlaxoSmithKline, Boostrix) and quadrivalent Human Papillomavirus [Types 6, 11, 16, 18] recombinant vaccine (Merck & Co., Inc., Gardasil) in healthy adolescents.<br><br>**Study 10:** Observer-blind, randomized, controlled study to evaluate safety and immunogenicity of four rMenB containing vaccine formulations in infants 2 months of age.<br><br>**Study 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.<br><br>**Study 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.<br><br>**Study 13:** 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. |

# 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. |