EMA/77586/2018

European Medicines Agency decision

P/0040/2018

of 16 February 2018

on the acceptance of a modification of an agreed paediatric investigation plan for recombinant *Neisseria meningitidis* group B NHBA fusion protein / recombinant *Neisseria meningitides* group B NadA protein / recombinant *Neisseria meningitidis* group B fHbp fusion protein / Outer Membrane Vesicles (OMV) from *Neisseria meningitidis* group B strain NZ98/254 measured as amount of total protein containing the PorA P1.4 (EMEA-000139-PIP01-07-M02) 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Contact EMA www.ema.europa.eu/contact

European Medicines Agency decision

P/0040/2018

of 16 February 2018

on the acceptance of a modification of an agreed paediatric investigation plan for recombinant *Neisseria meningitidis* group B NHBA fusion protein / recombinant *Neisseria meningitides* group B NadA protein / recombinant *Neisseria meningitidis* group B fHbp fusion protein / Outer Membrane Vesicles (OMV) from *Neisseria meningitidis* group B strain NZ98/254 measured as amount of total protein containing the PorA P1.4 (EMEA-000139-PIP01-07-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/112/2010 issued on 7 July 2010 and the decision P/38/2011 issued on 17 January 2011,

Having regard to the application submitted by GSK Vaccines S.r.l. on 25 September 2017 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 15 December 2017, 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 recombinant *Neisseria meningitidis* group B NHBA fusion protein / recombinant *Neisseria meningitides* group B NadA protein / recombinant *Neisseria meningitidis* group B fHbp fusion protein / Outer Membrane Vesicles (OMV) from *Neisseria meningitidis* group B strain NZ98/254 measured as amount of total protein containing the PorA P1.4, 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, GSK Vaccines S.r.l., via Fiorentina, 1, 53100 – Siena, Italy.

EMA/PDCO/652771/2017 Corr
London, 15 December 2017

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

EMEA-000139-PIP01-07-M02

Scope of the application

Active substance(s):

Recombinant *Neisseria meningitidis* group B NHBA fusion protein / recombinant *Neisseria meningitidis* group B NadA protein / recombinant *Neisseria meningitidis* group B fHbp fusion protein / Outer Membrane Vesicles (OMV) from *Neisseria meningitidis* group B strain NZ98/254 measured as amount of total protein containing the PorA P1.4

Invented name:

Bexsero

Condition(s):

Prevention of meningococcal meningitis

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

GSK Vaccines S.r.l.

Information about the authorised medicinal product:

See Annex II

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 25 September 2017 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/112/2010 issued on 7 July 2010 and the decision P/38/2011 issued on 17 January 2011.

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

The procedure started on 17 October 2017.

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 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 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

Prevention of meningococcal meningitis

1.1. Condition: Prevention of meningococcal meningitis

The waiver applies to:

- Neonates and infants, from birth to less than 8 weeks of age;
- suspension for injection, intramuscular use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan

2.1. Condition: Meningococcal meningitis

2.1.1. Indication(s) targeted by the PIP

Prevention of infection due to *Neisseria meningitidis* serogroups B

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

From 8 weeks to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Suspension for injection

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable
Non-clinical	1	**Study 1** Embryofoetal and reproductive toxicity study
Clinical	12	**Study 2** V72P6: Open-label, multicentre, controlled, randomized safety, tolerability, and immunogenicity study of Novartis rMenB+/- OMV NZ administered to healthy infants at 2, 4, 6, and/or 12 months of age **Study 3** V72P6E1: Open-label, single centre, extension study evaluating antibody persistence compared to naïve children, safety, tolerability, and immunogenicity of booster doses of Novartis rMenB+/-OMV NZ vaccine in healthy children previously primed with one or 4 doses in study V72P6

		Study 4 V72P9: Single-blind, single centre, randomized safety, tolerability, and immunogenicity study of Novartis rMenB+/- OMV NZ in healthy infants 6-8 months of age **Study 5** V72P9E1: Open-label, single centre, extension study evaluating antibody persistence compared to naïve children, safety, tolerability, and immunogenicity of a booster dose of rMenB+/-OMV NZ in healthy children previously primed with 3 doses in study V72P9 **Study 6** V72P10: Multicentre, observer-blind, controlled safety, tolerability, and immunogenicity study of different vaccination schedules of rMenB+/-OMV NZ in healthy adolescent 11-17 years of age **Study 7** V72P12: Open-label, randomized, parallel-group, multicentre study to evaluate safety, tolerability, and immunogenicity of different immunization schedules of rMenB+OMV NZ administered with or without routine infant vaccination to healthy infants 2 months of age **Study 8** V72P12E1: Open-label, multicentre, extension study to evaluate safety, tolerability, and immunogenicity of a booster dose of rMenB+OMV NZ administered at 12, 18, or 24 months of age in infants previously primed in study V72P12 **Study 9** V72P13: Partially blinded, randomized, multicentre, controlled study to evaluate immunogenicity, safety, and lot to lot consistency of rMenB+OMV NZ when administered with routine infants vaccinations to healthy infants **Study 10** V72P13E1: Open-label, multicentre, extension study to evaluate the safety, tolerability, and immunogenicity of rMenB+OMV NZ as a booster dose at 12 months of age or as a 2-dose catch-up to healthy infants who participated in study V72P13 **Study 11** V72P13E2: Open-label, multicentre, extension study to assess antibody persistence at one year after a 4th dose booster or a 2-dose catch-up of rMenB+OMV NZ in infants who participated in V72P13E1 **Study 12** V72_28: Open-label, multicentre study to evaluate the safety, tolerability, and immunogenicity of rMenB+OMV NZ administered alone to healthy infants according to different immunization schedules and to healthy children 2 to 10 years of age **Study 13** V72_62: Open-label, multicentre study to evaluate the safety, tolerability, and immunogenicity of 2 doses of rMenB+OMV NZ in at risk children

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By March 2015
Deferral for one or more studies contained in the paediatric investigation plan:	Yes