EMA/211923/2015

European Medicines Agency decision

P/0089/2015

of 8 May 2015

on the acceptance of a modification of an agreed paediatric investigation plan for *N. meningitidis* serogroup A polysaccharide conjugated to tetanus toxoid / *N. meningitidis* serogroup C polysaccharide conjugated to tetanus toxoid / *N. meningitidis* serogroup W polysaccharide conjugated to tetanus toxoid / *N. meningitidis* serogroup Y polysaccharide conjugated to tetanus toxoid (Nimenrix), (EMEA-000429-PIP01-08-M04) 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/186/2009 issued on 8 September 2009, the decision P/278/2011 issued on 28 November 2011, the decision P/0289/2013 issued on 29 November 2013, and the decision P/0228/2014 issued on 5 September 2014,

Having regard to the application submitted by GlaxoSmithKline Biologicals s.a. on 19 December 2014 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 20 March 2015, 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 *N. meningitidis* serogroup A polysaccharide conjugated to tetanus toxoid / *N. meningitidis* serogroup C polysaccharide conjugated to tetanus toxoid / *N. meningitidis* serogroup W polysaccharide conjugated to tetanus toxoid / *N. meningitidis* serogroup Y polysaccharide conjugated to tetanus toxoid (Nimenrix), powder and solvent for solution 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 GlaxoSmithKline Biologicals s.a, Rue de l'Institut, 89, 1330 – Rixensart, Belgium.

Done at London, 8 May 2015

For the European Medicines Agency
Jordi Llinares Garcia
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/29195/2015
London, 20 March 2015

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

EMEA-000429-PIP01-08-M04

Scope of the application

Active substance(s):

N. meningitidis serogroup A polysaccharide conjugated to tetanus toxoid / *N. meningitidis* serogroup C polysaccharide conjugated to tetanus toxoid / *N. meningitidis* serogroup W polysaccharide conjugated to tetanus toxoid / *N. meningitidis* serogroup Y polysaccharide conjugated to tetanus toxoid

Invented name:

Nimenrix

Condition(s):

Prevention of meningococcal disease

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder and solvent for solution for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

GlaxoSmithKline Biologicals s.a.

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Biologicals s.a. submitted to the European Medicines Agency on 19 December 2014 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/186/2009 issued on 8 September 2009, the decision P/278/2011 issued on 28 November 2011, the decision P/0289/2013 issued on 29 November 2013, and the decision P/0228/2014 issued on 5 September 2014.

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

The procedure started on 20 January 2015.

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 Icelandic and the Norwegian Paediatric Committee members 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

– ***Condition:***

Prevention of meningococcal disease

The waiver applies to:

- paediatric population from birth to less than 2 months of age;
- powder and solvent for solution for injection, intramuscular use;
- on the grounds that the specific medicinal product is likely to be ineffective;
- 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 disease

2.1.1. Indication(s) targeted by the PIP

Active immunisation against invasive diseases caused by *Neisseria meningitidis* group A, C, W-135 and Y

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 solvent for solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	7	**Study 1:** A randomised, open, controlled, multicenter primary vaccination study to demonstrate the non-inferiority of the immunogenicity of MenACWY-TT versus Mencevax ACWY given to healthy subjects aged from 11 to less than 18 years.

Area	Number of measures	Description
		Study 2: Open, randomised, controlled primary vaccination study to demonstrate the non-inferiority of the meningococcal serogroup ACWY conjugate vaccine MenACWY-TT given intramuscularly versus Mencevax ACWY given subcutaneously to healthy subjects from 2 to less than 11 years of age. **Study 3:** Open, randomised, controlled primary vaccination study to demonstrate the immunogenicity and safety of the meningococcal serogroup ACWY conjugate MenACWY-TT vaccine and its non-inferiority compared to Meningitec and to demonstrate the non-inferiority of the coadministration of MenACWY-TT with Priorix-Tetr compared to the administration of each of the two vaccines given separately, in healthy children from 12 to less than 24 months. **Study 4:** An open, controlled study to evaluate the longterm antibody persistence at 2, 3, and 4 years after a single dose of MenACWY-TT vaccine versus one dose of Meningitec™ administered in healthy children from 12 to less than 24-months of age who were primed in study MenACWY-TT-039 and to evaluate the immunogenicity and safety of a booster dose of the same meningococcal conjugate vaccine as given in the primary study, 4 years after priming. **Study 5:** An open, randomised, controlled, primary vaccination study to demonstrate non-inferiority of the investigational meningococcal serogroup ACWY conjugate vaccine compared to licensed MenC-CRM197 conjugate vaccine when administered to healthy subjects aged from 2 to less than 11 years. **Study 6:** A study evaluating a 2-dose versus a 3-dose MenACWY-TT primary vaccination schedule in infancy. **Study 7:** An open, controlled study to evaluate immunogenicity of MenACWY-TT conjugate vaccine administered intramuscularly to at risk subjects from 1 to less than 18 years and to an age-matched control group of healthy subjects.
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	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 2016
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Prevention of meningococcal disease

Authorised indication(s):

- Active immunisation of individuals from the age of 12 months and above against invasive meningococcal diseases caused by *Neisseria meningitidis* group A, C, W-135 and Y.

Authorised pharmaceutical form(s):

Powder and solvent for solution for injection

Authorised route(s) of administration:

Intramuscular use