EMA/693022/2013

European Medicines Agency decision

P/0289/2013

of 29 November 2013

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-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.

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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, and the decision P/278/2011 issued on 28 November 2011,

Having regard to the application submitted by GlaxoSmithKline Biologicals s.a on 18 July 2013 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 11 October 2013, 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.
[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, 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, 29 November 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/447668/2013

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

EMEA-000429-PIP01-08-M02

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 18 July 2013 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, and the decision P/278/2011 issued on 28 November 2011.

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

The procedure started on 15 August 2013.

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 Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

   The measures and timelines of the paediatric investigation plan and the subsets of the paediatric population and condition 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.

London, 11 October 2013

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

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

1. Waiver

1.1. Condition: prevention of Meningococcal Disease

The waiver applies to:

- paediatric population from birth to less than 2 months of age;
- for 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 Infection 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, intramuscular use

2.1.4. Measures

Area	Number of Measures	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	7	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. 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.

Area	Number of Measures	Description
		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. 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. 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. 6. A study evaluating a 2-dose versus a 3-dose MenACWY-TT primary vaccination schedule in infancy. 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.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term efficacy issues in relation to paediatric use:	No.
Date of completion of the paediatric investigation plan:	By April 2015.
Deferral for one or more studies 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 infection

   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