EMA/241589/2011

European Medicines Agency decision

P/93/2011

of 1 April 2011

on the acceptance of a modification of an agreed paediatric investigation plan for meningococcal group A oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenA-CRM), meningococcal group C oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenC-CRM), meningococcal group W-135 oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenW-CRM), meningococcal group Y oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenY-CRM) (Menveo), (EMEA-000032-PIP01-07-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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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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/19/2008 issued on 28 April 2008, decision P/103/2008 issued on 3 November 2008, decision P/193/2010 issued on 26 October 2010, and decision P/42/2011 issued on 7 February 2011,

Having regard to the application submitted by Novartis Vaccines and Diagnostics S.r.L on 7 February 2011 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 18 March 2011, 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 meningococcal group A oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenA-CRM), meningococcal group C oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenC-CRM), meningococcal group W-135 oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenW-CRM), meningococcal group Y oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenY-CRM) (Menveo), powder and solution 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 Novartis Vaccines and Diagnostics S.r.L, Via Fiorentina 1, Siena, 53100, Italy.

Done at London, 1 April 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/119763/2011

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

EMEA-000032-PIP01-07-M04

Scope of the application

Active substance(s):

Meningococcal group A oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenA-CRM)

Meningococcal group C oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenC-CRM)

Meningococcal group W-135 oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenW-CRM)

Meningococcal group Y oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenY-CRM)

Invented name:

Menveo

Condition(s):

Meningococcal meningitis

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder and solution for solution for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Novartis Vaccines and Diagnostics S.r.L

Information about the authorised medicinal product:

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Novartis Vaccines and Diagnostics S.r.L submitted to the European Medicines Agency on 7 February 2011 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/19/2008 issued on 28 April 2008, decision P/103/2008 issued on 3 November 2008, decision P/193/2010 issued on 26 October 2010, and decision P/42/2011 issued on 7 February 2011.
The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 23 February 2011.

Scope of the modification

Some measures 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 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.

London, 18 March 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, 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:

Meningococcal meningitis

The waiver applies to:

- preterm newborn infant, term newborn infants (0-27 d), infants & toddlers (28 d-2 months);
- for powder and solution for solution for injection, intramuscular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition:

Meningococcal meningitis

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

From 2 months to less than 18 years of age.

2.1.2. Pharmaceutical form(s)

Powder and solvent for solution for injection.

2.1.3. Studies

Area	Sub area	Description
Clinical	Safety, immunogenicity boosting	V59P5 Safety, Immunogenicity, Schedule Finding, Persistence at 6 or 8 mo, Boosting, Memory 2 months
Clinical	Safety, immunogenicity boosting	V59P7 Safety, Immunogenicity, Formulation Finding, Persistence at 6 and 12 mo, Boosting 1-5 years
Clinical	Safety, immunogenicity	V59P8 Comparative safety and immunogenicity in 2-10 yo (Non-inferiority MenACWY versus Menomune)

Clinical	Safety, immunogenicity	V59P9 Safety, Immunogenicity, Schedule Finding, Persistence, Boosting Infants up to 12 months
Clinical	Safety, immunogenicity	V59P10 Comparative safety and immunogenicity (subset) in 2-10 years (Non-inferiority MenACWY versus Menomune)
Clinical	Safety immunogenicity	V59P13 Comparative safety and immunogenicity in 11-55 years (Non-inferiority MenACWY versus Menactra) Lot-to-lot consistency in 11-18 years (safety and immunogenicity)
Clinical	Safety, immunogenicity	V59P14 Safety, Immunogenicity, Concomitant Vaccines Infants 2 months
Clinical	Safety, immunogenicity	V59P16 Safety and Immunogenicity Infants 2 months
Clinical	Comparative	V59P18 Comparative for Concomitant Tdap (Boostrix US formulation) and Gardasil use 11-18 years
Clinical	Safety, immunogenicity	V59P20 Comparative Safety and Immunogenicity, 2-10 years
Clinical	Safety, immunogenicity	V59P21 Safety, Immunogenicity, Concomitant Vaccines Toddlers
Clinical	Safety, immunogenicity	V59P22 Safety, Immunogenicity, Concomitant Vaccines Infants/Toddlers

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 June 2011
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)

Meningococcal meningitis

Authorised indication:

Menveo is indicated for active immunization of adolescents (from 11 years of age) and adults at risk of exposure to Neisseria meningitidis groups A, C, W135 and Y, to prevent invasive disease.

The use of this vaccine should be in accordance with official recommendations.

EU Number	Invented name	Strength	Pharmaceu-tical form	Route of administra-tion	Packaging	Package size
EU/1/10/614/001	Menveo	Meningococcal group A oligosaccharide 10 micrograms conjugated to Corynebacterium diphtheriae CRM197 protein 16.7 to 33.3 micrograms/0.5 ml Meningococcal group C oligosaccharide 5 micrograms conjugated to Corynebacterium diphtheriae CRM197 protein 7.1 to 12.5 micrograms/0.5 ml Meningococcal group W135 oligosaccharide 5 micrograms conjugated to Corynebacterium diphtheriae CRM197 protein 3.3 to 8.3 micrograms/0.5 ml Meningococcal group Y oligosaccharide 5 micrograms conjugated to Corynebacterium diphtheriae CRM197 protein 5.6 to 10.0 micrograms/0.5 ml	Powder and solution for solution for injection	Intra-muscular use	MenA lyophilised conjugate component: vial (glass); MenCWY liquid conjugate component: syringe (glass)	1 vial + 1 pre-filled syringe