

EMA/103738/2023

European Medicines Agency decision P/0116/2023

of 13 April 2023

on the granting of a product specific waiver for meningococcal group A oligosaccharide conjugated to *Corynebacterium diptheriae* CRM197 protein (MenA-CRM) / meningococcal group C oligosaccharide conjugated to *Corynebacterium diptheriae* CRM197 protein (MenC-CRM) / meningococcal group W-135 oligosaccharide conjugated to *Corynebacterium diptheriae* CRM197 protein (MenW-CRM) / meningococcal group Y oligosaccharide conjugated to *Corynebacterium diptheriae* CRM197 protein (MenY-CRM) (Menveo), (EMEA-000032-PIP02-22) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 726/2004¹,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency²,

Having regard to the application submitted by GlaxoSmithKline Biologicals Srl on 17 November 2022 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 24 February 2023 in accordance with Article 13 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

- (1) The Paediatric Committee has given an opinion on the granting of a product specific waiver.
- (2) It is therefore appropriate to adopt a decision granting a waiver.

¹ OJ L 378, 27.12.2006, p.1, as amended.

² OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

A waiver for meningococcal group A oligosaccharide conjugated to *Corynebacterium diptheriae* CRM197 protein (MenA-CRM) / meningococcal group C oligosaccharide conjugated to *Corynebacterium diptheriae* CRM197 protein (MenC-CRM) / meningococcal group W-135 oligosaccharide conjugated to *Corynebacterium diptheriae* CRM197 protein (MenW-CRM) / meningococcal group Y oligosaccharide conjugated to *Corynebacterium diptheriae* CRM197 protein (MenY-CRM) (Menveo), solution for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 2

This decision is addressed to GlaxoSmithKline Biologicals Srl, Via Fiorentina 1, 53100 - Siena, Italy.

EMA/PDCO/915236/2022
Amsterdam, 24 February 2023

Opinion of the Paediatric Committee on the granting of a product-specific waiver

EMA-000032-PIP02-22

Scope of the application

Active substance(s):

Meningococcal group A oligosaccharide conjugated to Corynebacterium diphtheriae CRM197 protein (MenA-CRM) / Meningococcal group C oligosaccharide conjugated to Corynebacterium diphtheriae CRM197 protein (MenC-CRM) / Meningococcal group W-135 oligosaccharide conjugated to Corynebacterium diphtheriae CRM197 protein (MenW-CRM) / Meningococcal group Y oligosaccharide conjugated to Corynebacterium diphtheriae CRM197 protein (MenY-CRM)

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of meningococcal meningitis

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

GlaxoSmithKline Biologicals Srl

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Biologicals Srl submitted to the European Medicines Agency on 17 November 2022 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 3 January 2023.

Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:
 - to grant a product-specific waiver for all subsets of the paediatric population and the above mentioned condition in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population and Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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

2. The grounds for the granting of the waiver are set out in 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

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Prevention of meningococcal meningitis

The waiver applies to:

- the paediatric population from birth to less than 6 weeks of age;
- solution for injection, intramuscular use;
- on the grounds that the specific medicinal product is likely to be ineffective;

and

- the paediatric population from 6 weeks to less than 18 years of age;
- solution for injection, intramuscular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Prevention of meningococcal meningitis

Authorised indication(s):

- active immunization of children (from 2 years of age), adolescents and adults at risk of exposure to *Neisseria meningitidis* groups A, C, W-135 and Y, to prevent invasive disease.
 - Invented name(s): Menveo
 - Authorised pharmaceutical form(s): Powder and solution for solution for injection
 - Authorised route(s) of administration: Intramuscular use
 - Authorised via centralised procedure