



European Medicines Agency

Doc. Ref. EMEA/525904/2009
P/186/2009

EUROPEAN MEDICINES AGENCY DECISION

of 8 September 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver 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 (EMEA-000429-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency²,

Having regard to the application submitted by GlaxoSmithKline Biologicals s.a on 4 December 2009 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 24 July 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation and Article 21 of said Regulation,

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

WHEREAS:

- (1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver,
- (2) It is therefore appropriate to adopt a Decision agreeing a Paediatric Investigation Plan.
- (3) It is therefore appropriate to adopt a Decision granting a deferral.
- (4) It is therefore appropriate to adopt a Decision granting a waiver.

¹ OJ L 378, 27.12.2006, p.1

² OJ L 136, 30.4.2004, p. 1

HAS ADOPTED THIS DECISION:

Article 1

A 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, powder and solvent for 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 agreed.

Article 2

A deferral 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, powder and solvent for 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 3

A waiver 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, powder and solvent for 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 4

This decision is addressed to GlaxoSmithKline Biologicals s.a, Rue de l'Institut, 89, 1330-Rixensart, Belgium.

Done at London, 8 September 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)



European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDCO/440764/2009
EMEA-000429-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL AND A WAIVER

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

Condition(s):

Meningococcal infection

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

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Biologicals s.a submitted for agreement to the EMEA on 4 December 2008 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 08/01/2009.

Supplementary information was provided by the applicant on 15 May 2009.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report :

- to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
- to grant a deferral in accordance with Article 21 of said Regulation
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded 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 Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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 Agency, together with its annex and appendix.

London, 24 July 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

THE MEASURES AND TIMELINES OF THE AGREED PAEDIATRIC INVESTIGATION PLAN AND THE SUBSET(S) OF THE PAEDIATRIC POPULATION AND CONDITION(S) COVERED BY THE WAIVER

A. CONDITION(S)

Meningococcal infection.

B. WAIVER

- **Condition**

Meningococcal infection.

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, and
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.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Meningococcal infection.

- **Proposed PIP indication**

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

- **Subset(s) of the paediatric population concerned by the paediatric development**

From 2 months to less than 18 years.

- **Formulation(s)**

Powder and solvent for solution for injection, intramuscular use

- **Studies**

Area	Sub area	Description
Clinical	Safety, immunogenicity	MenACWY-TT-036 Safety and immunogenicity in subjects from 11 to less than 18 years of age versus plain polysaccharide vaccine.
Clinical	Safety, immunogenicity	MenACWY-TT-038 Safety and immunogenicity in subjects from 2 to less than 11 years of age versus plain polysaccharide vaccine.
Clinical	Safety, immunogenicity	MenACWY-TT-039 Safety, immunogenicity and concomitant vaccine in subjects from 12 to less than 24 months versus Men C conjugate vaccine.
Clinical	Safety, immunogenicity, boosting	MenACWY-TT-048 Safety, immunogenicity, persistence at 2, 3, and 4 years, boosting in subjects from 12 to less than 24-months.
Clinical	Safety, immunogenicity	MenACWY-TT-081 Safety, immunogenicity in subjects from 2 to less than 11 years versus Men C conjugate vaccine.
Clinical	Safety, immunogenicity	MenACWY-TT-083 Safety, immunogenicity, schedule finding in infants versus Men C conjugate vaccine.
Clinical	Safety, immunogenicity	MenACWY-TT-084 Safety and immunogenicity in asplenic subjects from 6 to less than 18 years of age.

Measures to address long term follow-up of potential safety or efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2013
Deferral for some or all studies contained in the paediatric investigation plan:	Yes