European Medicines Agency

Doc. Ref. EMEA/30247/2009
P/11/2009

EUROPEAN MEDICINES AGENCY DECISION

of 27 January 2009

on the refusal of a Paediatric Investigation Plan and on the refusal of a deferral and on the granting of a waiver for Human Papillomavirus type 16 L1 protein, Human Papillomavirus type 18 L1 protein (Cervarix) EMEA-000234-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 726/2004[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 application submitted by GlaxoSmithKline Biologicals, s.a. on 4 April 2008 under Article 16(1) 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 12 December 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and in accordance with Article 13 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 refusal of a Paediatric Investigation Plan and on the refusal of a deferral and on the granting of a waiver,

(2) It is therefore appropriate to adopt a Decision refusing a Paediatric Investigation Plan.

(3) It is therefore appropriate to adopt a Decision refusing 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 Human Papillomavirus type 16 L1 protein, Human Papillomavirus type 18 L1 protein (Cervarix), suspension for injection, intramuscular injection, 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 refused.

Article 2

A deferral for Human Papillomavirus type 16 L1 protein, Human Papillomavirus type 18 L1 protein (Cervarix), 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 refused.

Article 3

A product-specific waiver for Human Papillomavirus type 16 L1 protein, Human Papillomavirus type 18 L1 protein (Cervarix), suspension for injection, intramuscular injection, 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, B-1330 Rixensart, Belgium.

Done at London, 27 January 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency

Doc. Ref. EMEA/30247/2009
EMEA-000234-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE REFUSAL OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL AND ON THE GRANTING OF A PRODUCT-SPECIFIC WAIVER

Scope of the application

Active substance:
Human Papillomavirus type 16 L1 protein
Human Papillomavirus type 18 L1 protein

Invented name:
Cervarix

Condition:
Infection by Human Papillomavirus in females

Pharmaceutical form:
Suspension for injection

Route of administration:
Intramuscular injection

Name/corporate name of the PIP applicant:
GlaxoSmithKline Biologicals, s.a.

Information about the authorised medicinal product:
See Annex II

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 April 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 8 May 2008.

Supplementary information was provided by the applicant on 2 October 2008.

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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 refuse the paediatric investigation plan in accordance with Article 18 of said Regulation as the measures and the timelines are not appropriate to ensure the generation of the necessary data determining the conditions in which the medicinal product may be used to treat the paediatric population or some subsets, nor to adapt a paediatric formulation, or do not bring expected significant therapeutic benefit,

- to refuse a deferral in accordance with Article 21 of said Regulation,

- to grant a product-specific waiver for all subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with 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 Icelandic and the Norwegian Paediatric Committee member(s) agree with the above-mentioned recommendation of the Paediatric Committee.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annex and appendix.

London, 12 December 2008

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU number	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Packaging**	**Content**	**Package size**
EU/1/07/419/001	Cervarix	20 µg / 20 µg*	Suspension for injection	Intramuscular use	vial (glass)	0.5 ml	1 vial
EU/1/07/419/002	Cervarix	20 µg / 20 µg*	Suspension for injection	Intramuscular use	vial (glass)	0.5 ml	10 vials
EU/1/07/419/003	Cervarix	20 µg / 20 µg*	Suspension for injection	Intramuscular use	vial (glass)	0.5 ml	100 vials
EU/1/07/419/004	Cervarix	20 µg / 20 µg*	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe + 1 needle
EU/1/07/419/005	Cervarix	20 µg / 20 µg*	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe + 2 needles
EU/1/07/419/006	Cervarix	20 µg / 20 µg*	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes + 10 needles
EU/1/07/419/007	Cervarix	20 µg / 20 µg*	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes + 20 needles
EU/1/07/419/008	Cervarix	20 µg / 20 µg*	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe
EU/1/07/419/009	Cervarix	20 µg / 20 µg*	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes

* Human Papilloma Virus-16/ Human Papilloma Virus-18 L1 proteins