EMA/793136/2014

European Medicines Agency decision

P/0008/2015

of 30 January 2015

on the granting of a product specific waiver for human papillomavirus type 18 L1 protein / human papillomavirus type 16 L1 protein (Cervarix), (EMEA-000234-PIP02-14) 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 726/2004[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 SA on 4 September 2014 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 12 December 2014 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A waiver for human papillomavirus type 18 L1 protein / human papillomavirus type 16 L1 protein (Cervarix), suspension 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 SA, 89, rue de l'Institut, 1330 – Rixensart, Belgium.

Done at London, 30 January 2015

For the European Medicines Agency
Zaide Frias
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/604329/2014

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

EMEA-000234-PIP02-14

Scope of the application

Active substance(s):

Human Papillomavirus type 18 L1 protein / Human Papillomavirus type 16 L1 protein

Invented name:

Cervarix

Condition(s):

Prevention of infection by human papillomavirus

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

GlaxoSmithKline Biologicals SA

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Biologicals SA submitted to the European Medicines Agency on 4 September 2014 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

Having considered the waiver as agreed in the decision P/11/2009 issued on 27 January 2009.

The procedure started on 14 October 2014.

Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended and having considered the waiver as agreed in the decision, 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(s) 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 members agree 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.

London, 12 December 2014

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

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Prevention of infection by human papillomavirus.

The waiver applies to:

- All subsets of the paediatric male population from birth to less than 18 years of age;
- for suspension 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.

The waiver applies to:

- All subsets of the paediatric female population from birth to less than 18 years of age;
- for suspension for injection, intramuscular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Prevention of infection by human papillomavirus

Authorised indication(s):

- Cervarix is a vaccine for use from the age of 9 years for the prevention of premalignant genital (cervical, vulvar and vaginal) lesions and cervical cancer causally related to certain oncogenic Human Papillomavirus (HPV) types.

Authorised pharmaceutical form(s):

Suspension for injection.

Authorised route(s) of administration:

Intramuscular use.