EMA/78577/2011

European Medicines Agency decision

P/61/2011

of 4 March 2011

on the granting of a product specific waiver for Human Papilloma Virus Type 16 E6 071-095 / Human Papilloma Virus Type 16 E7 064-098 / Human Papilloma Virus Type 16 E6 055-080 / Human Papilloma Virus Type 16 E6 001-032 / Human Papilloma Virus Type 16 E6 091-122 / Human Papilloma Virus Type 16 E6 041-065 / Human Papilloma Virus Type 16 E6 019-050 / Human Papilloma Virus Type 16 E7 022-056 / Human Papilloma Virus Type 16 E6 127-158 / Human Papilloma Virus Type 16 E6 085-109 / Human Papilloma Virus Type 16 E7 043-077 / Human Papilloma Virus Type 16 E6 109-140 / Human Papilloma Virus Type 16 E7 001-035 (EMEA-001055-PIP01-10) 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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on the granting of a product specific waiver for Human Papilloma Virus Type 16 E6 071-095 / Human Papilloma Virus Type 16 E7 064-098 / Human Papilloma Virus Type 16 E6 055-080 / Human Papilloma Virus Type 16 E6 001-032 / Human Papilloma Virus Type 16 E6 091-122 / Human Papilloma Virus Type 16 E6 041-065 / Human Papilloma Virus Type 16 E6 019-050 / Human Papilloma Virus Type 16 E7 022-056 / Human Papilloma Virus Type 16 E6 127-158 / Human Papilloma Virus Type 16 E6 085-109 / Human Papilloma Virus Type 16 E7 043-077 / Human Papilloma Virus Type 16 E6 109-140 / Human Papilloma Virus Type 16 E7 001-035 (EMEA-001055-PIP01-10) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 ISA Therapeutics BV on 7 October 2010 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 14 January 2011 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 Papilloma Virus Type 16 E6 071-095 / Human Papilloma Virus Type 16 E7 064-098 / Human Papilloma Virus Type 16 E6 055-080 / Human Papilloma Virus Type 16 E6 001-032 / Human Papilloma Virus Type 16 E6 091-122 / Human Papilloma Virus Type 16 E6 041-065 / Human Papilloma Virus Type 16 E6 019-050 / Human Papilloma Virus Type 16 E7 022-056 / Human Papilloma Virus Type 16 E6 127-158 / Human Papilloma Virus Type 16 E6 085-109 / Human Papilloma Virus Type 16 E7 043-077 / Human Papilloma Virus Type 16 E6 109-140 / Human Papilloma Virus Type 16 E7 001-035, powder for suspension for injection, subcutaneous 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 ISA Therapeutics BV, Niels Bohrweg 11-13, 2333 CA Leiden, The Netherlands.

Done at London, 4 March 2011

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

EMA/PDCO/825098/2010

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

EMEA-001055-PIP01-10

Scope of the application

Active substance(s):

Human Papilloma Virus Type 16 E6 071-095 / Human Papilloma Virus Type 16 E7 064-098 / Human Papilloma Virus Type 16 E6 055-080 / Human Papilloma Virus Type 16 E6 001-032 / Human Papilloma Virus Type 16 E6 091-122 / Human Papilloma Virus Type 16 E6 041-065 / Human Papilloma Virus Type 16 E6 019-050 / Human Papilloma Virus Type 16 E7 022-056 / Human Papilloma Virus Type 16 E6 127-158 / Human Papilloma Virus Type 16 E6 085-109 / Human Papilloma Virus Type 16 E7 043-077 / Human Papilloma Virus Type 16 E6 109-140 / Human Papilloma Virus Type 16 E7 001-035

Condition(s):

Treatment of vulvar intraepithelial neoplasia

Pharmaceutical form(s):

Powder for suspension for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

ISA Therapeutics BV

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, ISA Therapeutics BV submitted to the European Medicines Agency on 7 October 2010 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 18 November 2010.

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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 of the above mentioned condition in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations.

   The Norwegian Paediatric Committee member 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 annex and appendix.

London, 14 January 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of vulvar intraepithelial neoplasia

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age,
- for powder for suspension for injection, subcutaneous use,
- on the grounds that the disease or condition for which the specific medicinal product is intended only occurs in adults.