EMA/357082/2021

European Medicines Agency decision

P/0251/2021

of 9 July 2021

on the granting of a product specific waiver for human papilloma virus type 16 E6 071-095/human papilloma virus type 16 E6 109-140/human papilloma virus type 16 E7 001-035/human papilloma virus type 16 e7 022-056/human papilloma virus type 16 e7 064-098 / human papilloma virus type 16 e6 001-032/human papilloma virus type 16 e6 019-050/human papilloma virus type 16 e6 041-065/human papilloma virus type 16 e6 055-080/human papilloma virus type 16 e6 085-109/human papilloma virus type 16 e6 091-122/human papilloma virus type 16 e6 127-158 (EMEA-001055-PIP02-21) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Only the English text is authentic.

European Medicines Agency decision

P/0251/2021

of 9 July 2021

on the granting of a product specific waiver for human papilloma virus type 16 E6 071-095/human papilloma virus type 16 E6 109-140/human papilloma virus type 16 E7 001-035/human papilloma virus type 16 e7 022-056/human papilloma virus type 16 e7 064-098 / human papilloma virus type 16 e6 001-032/human papilloma virus type 16 e6 019-050/human papilloma virus type 16 e6 041-065/human papilloma virus type 16 e6 055-080/human papilloma virus type 16 e6 085-109/human papilloma virus type 16 e6 091-122/human papilloma virus type 16 e6 127-158 (EMEA-001055-PIP02-21) 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 B.V. on 11 February 2021 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 21 May 2021 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 E6 109-140/human papilloma virus type 16 E7 001-035/human papilloma virus type 16 e7 022-056/human papilloma virus type 16 e7 064-098 / human papilloma virus type 16 e6 001-032/human papilloma virus type 16 e6 019-050/human papilloma virus type 16 e6 041-065/human papilloma virus type 16 e6 055-080/human papilloma virus type 16 e6 085-109/human papilloma virus type 16 e6 091-122/human papilloma virus type 16 e6 127-158, 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 B.V., J.H. Oortweg 19, 2333 CH - Leiden, Netherlands.

EMA/PDCO/150884/2021
Amsterdam, 21 May 2021

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

EMEA-001055-PIP02-21

Scope of the application

Active substance(s):

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

Condition(s):

Treatment of HPV16 positive malignancies

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

ISA Therapeutics B.V.

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, ISA Therapeutics B.V. submitted to the European Medicines Agency on 11 February 2021 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 23 March 2021.

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(s) 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 does not occur in the specified subset(s) 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 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.

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of HPV16 positive malignancies

The waiver applies to:

- the paediatric population from birth to less than 14 years of age
- suspension for injection, subcutaneous use.
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

The waiver applies to:

- adolescents from 14 years to less than 18 years of age
- suspension for injection, subcutaneous use.
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).