EMA/878709/2011

European Medicines Agency decision

P/281/2011

of 28 November 2011

on the granting of a product specific waiver for icosapent (EMEA-001117-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 icosapent (EMEA-001117-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 S.L.A. Pharma (UK) Limited on 11 April 2011 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 October 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 icosapent, gastro-resistant capsule, soft, oral 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 S.L.A. Pharma (UK) Limited, Elite House, Hill Farm Industrial Estate, Leavesden, WD25 7SA – Watford, United Kingdom.

Done at London, 28 November 2011

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/757324/2011

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

EMEA-001117-PIP01-10

Scope of the application

Active substance(s):

Icosapent

Condition(s):

Treatment of Familial Adenomatous Polyposis

Pharmaceutical form(s):

Gastro-resistant capsule, soft

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

S.L.A. Pharma (UK) Limited

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, S.L.A. Pharma (UK) Limited submitted to the European Medicines Agency on 11 April 2011 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 18 May 2011.

Supplementary information was provided by the applicant on 12 August 2011. The applicant withdrew its proposed paediatric investigation plan and requested a waiver.

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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 in 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 annex and appendix.

London, 14 October 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 Familial Adenomatous Polyposis

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- for soft gastro-resistant capsule, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.