EMA/247674/2011

European Medicines Agency decision

P/95/2011

of 4 April 2011

on the granting of a product specific waiver for ezetimibe/simvastatin (Inegy and associated names) (EMEA-000006-PIP02-10) 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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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 MSD-SP Limited on 13 December 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 18 March 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 ezetimibe/simvastatin (Inegy and associated names), tablet, 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 MSD-SP Limited, Hertford Road, Hoddesdon, Hertfordshire, EN11 9BU Hoddesdon, United Kingdom.

Done at London, 4 April 2011

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

EMA/PDCO/214314/2011

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

EMEA-000006-PIP02-10

Scope of the application

Active substance(s):

Ezetimibe/simvastatin

Invented name:

Inegy and associated names

Condition(s):

Prevention of cardiovascular events in chronic kidney disease

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

MSD-SP Limited

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, MSD-SP Limited submitted to the European Medicines Agency on 13 December 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 19 January 2011.

A meeting with the Paediatric Committee took place on 17 March 2011.

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)(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, 18 March 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: prevention of cardiovascular events in chronic kidney disease

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age,
- for tablet for oral use,
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of hypercholesterolaemia

   Authorised indications:

   Inegy is indicated as adjunctive therapy to diet for use in patients with primary (heterozygous familial and non-familial) hypercholesterolaemia or mixed hyperlipidaemia where use of a combination product is appropriate:

- patients not appropriately controlled with a statin alone,
- patients already treated with a statin and ezetimibe.

2. Treatment of homozygous familial hypercholesterolaemia (HoFH)

   Authorised indications:

   Inegy is indicated as adjunctive therapy to diet for use in patients with HoFH. Patients may also receive adjunctive treatments (e.g., low-density lipoprotein [LDL] apheresis).

Invented name	**Strength**	**Pharmaceutical form**	**Route of administration**
INEGY and associated names	10/10, 10/20, 10/40 and 10/80 mg/mg	Tablets	Oral use