European Medicines Agency

Doc[d1]. Ref. EMEA/467238/2008
P/73/2008

EUROPEAN MEDICINES AGENCY DECISION

of 14 September 2008

on the application for agreement of a Paediatric Investigation Plan for[d2] ezetimibe and simvastatin (fixed combination) (INEGY and associated trade names) EMEA-000006-PIP01-07 in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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EUROPEAN MEDICINES AGENCY DECISION

of 14 September 2008

on[d3] the application for agreement of a Paediatric Investigation Plan for ezetimibe and simvastatin (fixed combination) (INEGY and associated trade names) EMEA-000006-PIP01-07 in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 26 July 2007 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 31 July 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and of its own motion in accordance with Articles 6 and 12 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency, has given a negative opinion,

(2) It is therefore appropriate to adopt a Decision following the Paediatric Committee's opinion on the Paediatric Investigation Plan.

(3) 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 Paediatric Investigation Plan for Ezetimibe and simvastatin (fixed combination), (INEGY and associated trade 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 not agreed.

Article 2

A waiver for Ezetimibe and simvastatin (fixed combination), (INEGY and associated trade names), the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to MSD-SP Limited, Hertord Road, EN11 9BU Hoddesdon.

Done at London, 14 September 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director

Signature on file

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

London, 31 July 2008
Doc[d5]. Ref: EMEA/467238/2008
EMEA-000006-PIP01-07

NEGATIVE OPINION OF THE PAEDIATRIC COMMITTEE ON A REQUEST FOR AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN FOR

Scope of the application

Active substance:
Ezetimibe and simvastatin (fixed combination)

Invented name:
INEGY and associated trade names

Condition(s):
Hypercholesterolaemia
Mixed (combined) hyperlipidaemia
Sitosterolaemia

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 I

Basis for opinion

Pursuant to Article 16. of Regulation (EC) No 1901/2006 as amended, MSD-SP Limited submitted for agreement to the EMEA on 26 June 2007 a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 02 August 2007.

Supplementary information was provided by the applicant on 05 June 2008.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to refuse the paediatric investigation plan in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended,
- and pursuant to Article 12 of Regulation (EC) 1901/2006 as amended, to grant a waiver for all subsets of the paediatric population and all above-mentioned conditions in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, 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 scientific conclusions and the grounds for refusal of the paediatric investigation plan are set out in the summary report appended to this opinion.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annex and appendix(ces).

London, 31 July 2008

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

Country	Invented name	Strength	Pharmaceutical form	Route of administration
Austria	INEGY, VYTORIN	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Belgium	INEGY	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Bulgaria*	INEGY	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Cyprus	INEGY	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Czech Republic	INEGY	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Denmark	INEGY	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Estonia	INEGY	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Finland	INEGY, VYTORIN	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
France	INEGY, VYTORIN	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Germany	INEGY, VYTORIN, ZEKLEN, GOLTOR	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Greece	INEGY, VYTORIN	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Hungary	INEGY	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Ireland	INEGY, VYTORIN	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Italy	INEGY, VYTORIN, ZEKLEN, GOLTOR	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Iceland	INEGY	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Latvia	INEGY	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Lithuania	INEGY	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Luxembourg	INEGY, VYTORIN	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Malta	INEGY	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Netherlands	INEGY	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Norway	INEGY, VYTORIN	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Poland	INEGY	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Portugal	INEGY, VYTORIN	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Romania*	INEGY	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Slovak Republic	INEGY	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Slovenia	INEGY	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Spain	INEGY, VYTORIN	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
Sweden	INEGY	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral
United Kingdom	INEGY, VYTORIN	10/10, 10/20, 10/40, 10/80 mg	Tablet	Oral