



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/452159/2012

European Medicines Agency decision P/0135/2012

of 20 July 2012

on the granting of a product specific waiver for ezetimibe (Ezetrol and associated names) (EMA-000007-PIP04-12) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by MSD-SP Limited on 12 March 2012 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 8 June 2012 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 (Ezetrol 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, 20 July 2012

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



EUROPEAN MEDICINES AGENCY
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EMA/PDCO/225417/2012

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

EMA-000007-PIP04-12

Scope of the application

Active substance(s):

Ezetimibe

Invented name:

Ezetrol and associated names

Condition(s):

Prevention of coronary heart 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



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 12 March 2012 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 16 April 2012.

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 annex and appendix.

London, 8 June 2012

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 coronary heart disease

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- for tablet, 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 Primary hypercholesterolaemia

Authorised indications:

Ezetimibe, co-administered with an HMG-CoA reductase inhibitor (statin), is indicated as adjunctive therapy to diet for use in patients with primary (heterozygous familial and non-familial) hypercholesterolaemia who are not appropriately controlled with a statin alone.

Ezetimibe monotherapy is indicated as adjunctive therapy to diet for use in patients with primary (heterozygous familial and non-familial) hypercholesterolaemia in whom a statin is considered inappropriate or is not tolerated.

2. Treatment of Homozygous familial hypercholesterolaemia (HoFH)

Authorised indications:

Ezetimibe, co-administered with a statin, is indicated as adjunctive therapy to diet for use in patients with HoFH. Patients may also receive adjunctive treatments (e.g. LDL apheresis).

3. Treatment of Homozygous sitosterolaemia (phytosterolaemia)

Authorised indication:

Ezetimibe is indicated as adjunctive therapy to diet for use in patients with homozygous familial sitosterolaemia.

Invented name	Strength	Pharmaceutical form	Route of administration
Ezetrol and associated names	10 mg	Tablet	Oral use