European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 7 September 2009

on the granting of a product specific waiver for ranibizumab (Lucentis), (EMEA-000527-PIP01-08) 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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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 Novartis Europharm Limited on 26 February 2009 under Article 13 of Regulation (EC) No 1901/2006 as amended,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 24 July 2009 in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended,

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

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 ranibizumab (Lucentis), solution for injection – single-use vial, solution for injection – single-use pre-filled syringe, intravitreal 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 Novartis Europharm Limited, Wimblehurst Road, Horsham, RH12 5AB, United Kingdom.

Done at London, 7 September 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

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

Doc. Ref. EMEA/PDCO/413075/2009
EMEA-000527-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE GRANTING OF A PRODUCT-SPECIFIC WAIVER

Scope of the application

Active substance(s):
Ranibizumab

(Invented) name:
Lucentis

Condition(s):
Visual impairment due to diabetic macular edema
Visual impairment due to macular edema associated with central retinal vein occlusion
Visual impairment due to macular edema associated with branch retinal vein occlusion

Pharmaceutical form(s):
Solution for injection – single-use vial
Solution for injection – single-use pre-filled syringe

Route(s) of administration:
Intravitreal use

Name/corporate name of the waiver applicant:
Novartis Europharm 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, Novartis Europharm Limited submitted to the EMEA on 26 February 2009 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 02 April 2009.

Supplementary information was provided by the applicant on 9 July 2009.

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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 and all the above mentioned conditions 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 occurs only in adult populations and Articles 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 Agency, together with its annexes and appendix.

London, 24 July 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

GROUNDS FOR THE GRANTING OF THE WAIVER

GROUNDS FOR THE GRANTING OF THE WAIVER

- **Condition**

Visual impairment due to diabetic macular edema

The waiver applies to:

– newborns, infants and toddlers and children (from birth to less than 12 years of age) for solution for injection - single-use vial and for solution for injection - single-use pre-filled syringe, intravitreal 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).

– adolescents (from 12 to less than 18 years) for solution for injection - single-use vial and for solution for injection - single-use pre-filled syringe, intravitreal use on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

- **Condition**

Visual impairment due to macular edema associated with central retinal vein occlusion

The waiver applies to:

– all subsets of the paediatric population from birth to less than 18 years of age for solution for injection - single-use vial and for solution for injection - single-use pre-filled syringe, intravitreal 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).

- **Condition**

Visual impairment due to macular edema associated with branch retinal vein occlusion

The waiver applies to:

– all subsets of the paediatric population from birth to less than 18 years of age for solution for injection - single-use vial and for solution for injection - single-use pre-filled syringe, intravitreal use on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented name Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/06/374/001	Lucentis	10 mg/ml	Solution for injection	Intravitreal use	Vial (glass)		1 vial