EMA/416185/2014

European Medicines Agency decision

P/0185/2014

of 6 August 2014

on the granting of a product specific waiver for ranibizumab (Lucentis), (EMEA-000527-PIP03-13) 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 ranibizumab (Lucentis), (EMEA-000527-PIP03-13) 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 Novartis Europharm Limited on 27 May 2013 under 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation, and to the amended application submitted on 28 March 2014 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 20 June 2014 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 ranibizumab (Lucentis), solution for injection, 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 covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/183/2009 issued on 7 September 2009, and P/291/2010 issued on 22 December 2010, including subsequent modifications thereof.

Article 3

This decision is addressed to Novartis Europharm Limited, Wimblehurst Road, RH12 5AB - Horsham, United Kingdom.

Done at London, 6 August 2014

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

EMA/PDCO/190020/2014

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

EMEA-000527-PIP03-13

Scope of the application

Active substance(s):

Ranibizumab

Invented name:

Lucentis

Condition(s):

Treatment of choroidal neovascularisation

Treatment of macular oedema

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intravitreal use

Name/corporate name of the PIP applicant:

Novartis Europharm Limited

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted for agreement to the European Medicines Agency on 27 May 2013 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 17 July 2013.

Supplementary information was provided by the applicant on 28 March 2014. The applicant withdrew its proposed paediatric investigation plan and withdrew its request for a deferral and requested a product-specific waiver in all subsets of the paediatric population.

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 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, 20 June 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of choroidal neovascularisation

The waiver applies to:

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

1.2. Condition:

Treatment of macular oedema

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for solution for injection, 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

Condition(s) and authorised indication(s):

1. Treatment of age-related macular degeneration

Authorised indication(s):

Lucentis is indicated in adults for:

- The treatment of neovascular (wet) age-related macular degeneration (AMD)

2. Treatment of macular oedema

Authorised indication(s):

Lucentis is indicated in adults for:

- The treatment of visual impairment due to diabetic macular oedema (DME)
- The treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO)

3. Treatment of choroidal neovascularisation

Authorised indication(s):

Lucentis is indicated in adults for:

- The treatment of visual impairment due to choroidal neovascularisation (CNV) secondary to pathologic myopia (PM)

Authorised pharmaceutical form(s):

Solution for injection.

Authorised route(s) of administration:

Intravitreal use