EMA/356633/2014

# European Medicines Agency decision

P/0165/2014

of 27 June 2014

on the granting of a product specific waiver for aflibercept (Eylea), (EMEA-000236-PIP04-14) 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 aflibercept (Eylea), (EMEA-000236-PIP04-14) 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 Bayer Pharma AG on 14 February 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 23 May 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 aflibercept (Eylea), 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 is addressed to Bayer Pharma AG, Müllerstrasse 178, 13353 – Berlin, Germany.

Done at London, 27 June 2014

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

EMA/PDCO/139580/2014

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

EMEA-000236-PIP04-14

## Scope of the application

**Active substance(s):**

Aflibercept

**Invented name:**

Eylea

**Condition(s):**

Treatment of branch retinal vein occlusion

Treatment of choroidal neovascularisation secondary to pathologic myopia

**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:**

Bayer Pharma AG

**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, Bayer Pharma AG submitted to the European Medicines Agency on 14 February 2014 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 25 March 2014.

## 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)(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 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, 23 May 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 branch retinal vein occlusion*

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- solution for injection, intravitreal use;
- on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations.

## *1.2. Condition: treatment of choroidal neovascularisation secondary to pathologic myopia*

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- 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):

   Eylea is indicated for adults for the treatment of

   - neovascular (wet) age-related macular degeneration (AMD)

2. Treatment of central retinal vein occlusion

   Authorised indication(s):

   Eylea is indicated for adults for the treatment of

   - visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO)

## Authorised pharmaceutical form(s):

Solution for injection, solution for injection in pre-filled syringe

## Authorised route(s) of administration:

Intravitreal use