European Medicines Agency

Doc. Ref. EMEA/604653/2009
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# EUROPEAN MEDICINES AGENCY DECISION

**of 7 October 2009**

**on the granting of a product specific waiver for pegaptanib sodium, Macugen (EMEA-000611-PIP01-09) 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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**on the granting of a product specific waiver for pegaptanib sodium, Macugen (EMEA-000611-PIP01-09) 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 Pfizer Global Research & Development on 22 May 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 21 August 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 pegaptanib sodium, Macugen, 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 Pfizer Global Research & Development, Ramsgate Road, Sandwich, CT13 9NJ, United Kingdom.

Done at London, 7 October 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/408943/2009
EMEA-000611-PIP01-09

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

## Scope of the application

Active substance(s):
Pegaptanib sodium

(Invented) name:
Macugen

Condition(s):
Diabetic retinopathy

Pharmaceutical form(s):
Solution for injection

Route(s) of administration:
Intravitreal use

Name/corporate name of the waiver applicant:
Pfizer Global Research & Development

Information about the authorised medicinal product: see Annex II

## Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Pfizer Global Research & Development submitted to the EMEA on 22 May 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 25 June 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 annex and appendix.

London, 21 August 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**

**Diabetic retinopathy**

The waiver applies to:

– newborns, infants and toddlers and children (from birth to less than 12 years of age)

– for solution for injection, 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).

The waiver applies to:

– adolescents (from 12 to less than 18 years)

– for solution for injection - single-use vial and

– 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**

| EU Number | Invented Name | Strength | Pharmaceutical form | Route of administration | Packaging | Content (concentration) | Package size |
|---|---|---|---|---|---|---|---|
| EU/1/05/325/002 | Macugen | 0.3 mg | Solution for Injection | Intravitreal Injection | Pre-filled syringe | Leur-lock prefilled syringe | |