EMA/532591/2021 Corr[1]

European Medicines Agency decision

P/0437/2021

of 29 October 2021

on the granting of a product specific waiver for humanized monoclonal antibody of IgG1 sub-type targeting the human SEMA3A polypeptide (EMEA-002957-PIP02-21) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Only the English text is authentic.

[1] 26 January 2023

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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 726/2004[2],

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[3],

Having regard to the application submitted by Boehringer Ingelheim International GmbH on 1 June 2021 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 10 September 2021 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.

Has adopted this decision:

Article 1

A waiver for humanized monoclonal antibody of IgG1 sub-type targeting the human SEMA3A polypeptide, powder and solvent for 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 Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 - Ingelheim am Rhein, Germany.

[2] OJ L 378, 27.12.2006, p.1.
[3] OJ L 136, 30.4.2004, p. 1.

EMA/PDCO/344899/2021 Corr[1]
Amsterdam, 10 September 2021

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

EMEA-002957-PIP02-21

Scope of the application

Active substance(s):

Humanized monoclonal antibody of IgG1 sub-type targeting the human SEMA3A polypeptide

Condition(s):

Treatment of diabetic retinopathy

Pharmaceutical form(s):

Powder and solvent for solution for injection

Route(s) of administration:

Intravitreal use

Name/corporate name of the PIP applicant:

Boehringer Ingelheim International GmbH

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Boehringer Ingelheim International GmbH submitted to the European Medicines Agency on 1 June 2021 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 12 July 2021.

[1] 26 January 2023

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 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 European Medicines Agency, together with its annex and appendix.

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of diabetic retinopathy

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- powder and solvent for solution for injection, intravitreal use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).