EMA/176012/2023

European Medicines Agency decision

P/0180/2023

of 15 May 2023

on the granting of a product specific waiver for recombinant humanized monoclonal antibody (immunoglobulin gamma-1 with kappa light chains, IgG1κ) directed against integrin αvβ8 produced in Chinese Hamster Ovary (CHO) cells (EMEA-003376-PIP01-22) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Only the English text is authentic.

European Medicines Agency decision

P/0180/2023

of 15 May 2023

on the granting of a product specific waiver for recombinant humanized monoclonal antibody (immunoglobulin gamma-1 with kappa light chains, IgG1κ) directed against integrin αvβ8 produced in Chinese Hamster Ovary (CHO) cells (EMEA-003376-PIP01-22) 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Pfizer Europe MA EEIG on 16 December 2022 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 31 March 2023 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 recombinant humanized monoclonal antibody (immunoglobulin gamma-1 with kappa light chains, IgG1κ) directed against integrin αvβ8 produced in Chinese Hamster Ovary (CHO) cells, solution for injection, intravenous 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 Europa MA EEIG, 17 Boulevard De La Plaine, 1050 – Brussels, Belgium.

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

EMA/PDCO/20884/2023
Amsterdam, 31 March 2023

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

EMEA-003376-PIP01-22

Scope of the application

Active substance(s):

Recombinant humanized monoclonal antibody (immunoglobulin gamma-1 with kappa light chains, IgG1κ) directed against integrin αvβ8 produced in Chinese Hamster Ovary (CHO) cells

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of renal cell carcinoma

Treatment of head and neck squamous cell carcinoma

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Pfizer Europe MA EEIG

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Pfizer Europe MA EEIG submitted to the European Medicines Agency on 16 December 2022 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 30 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 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 Paediatric Committee member of Norway 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 annexes and appendix.

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of renal cell carcinoma

The waiver applies to:

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

1.2. Condition:

Treatment of head and neck squamous cell carcinoma

The waiver applies to:

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

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.