EMA/739090/2012

European Medicines Agency decision

P/0282/2012

of 23 November 2012

on the granting of a product specific waiver for icatibant (Firazyr), (EMEA-000408-PIP02-12) 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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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 Shire Orphan Therapies GmbH on 2 July 2012 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 5 October 2012 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 icatibant (Firazyr), solution for injection, subcutaneous 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 Shire Orphan Therapies GmbH, Friedrichstrasse 149, D-10117 – Berlin, Germany.

Done at London, 23 November 2012

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

EMA/PDCO/601514/2012

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

EMEA-000408-PIP02-12

Scope of the application

Active substance(s):

Icatibant

Invented name:

Firazyr

Condition(s):

Treatment of ACE inhibitor-induced angioedema

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Shire Orphan Therapies GmbH

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, Shire Orphan Therapies GmbH submitted to the European Medicines Agency on 2 July 2012 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 9 August 2012.

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.

London, 5 October 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition: Treatment of ACE inhibitor-induced angioedema

The waiver applies to:

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

Authorised indications:

Firazyr is indicated for symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults (with C1-esterase-inhibitor deficiency).

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/08/461/001	Firazyr	30 mg	Solution for injection	Subcutaneous use	pre-filled syringe (glass)	3 ml (10 mg/ml)	1 pre-filled syringe + 1 needle
EU/1/08/461/002	Firazyr	30 mg	Solution for injection	Subcutaneous use	pre-filled syringe (glass)	3 ml (10 mg/ml)	3 pre-filled syringes + 3 needles