EMA/236895/2010

European Medicines Agency decision

P/65/2010

of 4 May 2010

on the granting of a product specific waiver for octocog alfa (Advate) (EMEA-000358-PIP02-09) 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 octocog alfa (Advate) (EMEA-000358-PIP02-09) 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 Baxter AG on 10 December 2009 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 19 March 2010 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 octocog alfa (Advate), powder and solvent for 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 Baxter AG, Industriestrasse 67, 1221 Vienna, Austria.

Done at London, 4 May 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/129793/2010

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

EMEA-000358-PIP02-09

Scope of the application

Active substance(s):

Octocog alfa

Invented name:

Advate

Condition(s):

Haemophilia A (congenital Factor VIII deficiency)

Pharmaceutical form(s):

Powder and solvent for solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Baxter AG

Information about the authorised medicinal product: see Annex II

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Baxter AG submitted to the European Medicines Agency on 10 December 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 21 January 2010.

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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 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, 19 March 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

Grounds for the granting of the waiver

1. GROUNDS FOR THE GRANTING OF THE WAIVER

1.1. Condition

Haemophilia A (congenital Factor VIII deficiency)

1.1.1 Indication:

Immune Tolerance Induction (ITI) in patients with haemophilia A (congenital Factor VIII deficiency) who have developed inhibitors to Factor VIII

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age.
- for Powder and solvent for solution for injection for intravenous use.
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

1.1.2 Indication:

Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency).

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age.
- for Powder and solvent for solution for injection for intravenous use.
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

Annex II

Information about the authorised medicinal product

EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content	Package size
EU/1/03/271/001	Advate	250 IU	Powder and solvent for solution for injection	Intravenous use	powder: vial (glass); solvent: vial (glass)	powder: 250 IU; solvent: 5 ml (50 IU/ml)	1 vial + 1 vial + reconstitution device
EU/1/03/271/002	Advate	500 IU	Powder and solvent for solution for injection	Intravenous use	powder: vial (glass); solvent: vial (glass)	powder: 500 IU; solvent: 5 ml (100 IU/ml)	1 vial + 1 vial + reconstitution device
EU/1/03/271/003	Advate	1000 IU	Powder and solvent for solution for injection	Intravenous use	powder: vial (glass); solvent: vial (glass)	powder: 1000 IU; solvent: 5 ml (200 IU/ml)	1 vial + 1 vial + reconstitution device
EU/1/03/271/004	Advate	1500 IU	Powder and solvent for solution for injection	Intravenous use	powder: vial (glass); solvent: vial (glass)	powder: 1500 IU; solvent: 5 ml (300 IU/ml)	1 vial + 1 vial + reconstitution device
EU/1/03/271/005	Advate	2000 IU	Powder and solvent for solution for injection	Intravenous use	powder: vial (glass); solvent: vial (glass)	powder: 2000 IU; solvent: 5 ml (400 IU/ml)	1 vial + 1 vial + reconstitution device
EU/1/03/271/006	Advate	3000 IU	Powder and solvent for solution for injection	Intravenous use	powder: vial (glass); solvent: vial (glass)	powder: 3000 IU; solvent: 5 ml (600 IU/ml)	1 vial + 1 vial + reconstitution device