EMA/710340/2011

European Medicines Agency decision

P/226/2011

of 27 September 2011

on the refusal of a product specific waiver for antithrombin alfa (ATryn) (EMEA-001154-PIP01-11) 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 GTC Biotherapeutics UK Limited on 15 April 2011 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 12 August 2011 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 refusal of a product specific waiver.

(2) It is therefore appropriate to adopt a decision refusing 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 antithrombin alfa (ATryn), powder for solution for infusion, 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 refused.

Article 2

This decision is addressed to GTC Biotherapeutics UK Limited, 10 Norwich Street, EC4A 1BD - London

United Kingdom.

Done at London, 27 September 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/662464/2011

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

EMEA-001154-PIP01-11

Active substance(s):

Antithrombin alfa

Invented name:

ATryn

Condition(s):

Treatment of antithrombin deficiency

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

GTC Biotherapeutics UK Limited

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, GTC Biotherapeutics UK Limited submitted to the European Medicines Agency on 15 April 2011 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 15 June 2011.

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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 refuse the granting of a product-specific waiver for all subsets of the paediatric population and the above mentioned condition(s) as it does not meet the grounds detailed in Article 11(1) of said Regulation.

   The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The scientific conclusions and the grounds for refusal are set out in the summary report appended to this opinion.

3. The grounds for refusal are summarised in Annex I.

This opinion is forwarded to the applicant(s) and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

London, 12 August 2011

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

Annex I

Grounds for the refusal of the waiver

1. Waiver

The waiver is refused for the following:

1.1. Condition: treatment of antithrombin deficiency

The request for the waiver applied to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for powder for solution for infusion, intravenous use.

The waiver request does not provide evidence to support the following grounds set out in Article 11(1) of Regulation (EC) No 1901/2006 that:

(a) the specific medicinal product is likely to be ineffective or unsafe in the paediatric population;

(b) the disease or condition for which the specific medicinal product is intended occurs only in adult populations;

(c) the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients;

because:

the specific medicinal product may represent a significant therapeutic benefit as the needs are not met.

The waiver request is therefore refused by the PDCO.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of congenital antithrombin deficiency

   Authorised indications:

   Prophylaxis of venous thromboembolism in surgery of patients with congenital antithrombin deficiency. ATryn is normally given in association with heparin or low molecular weight heparin.

EU Number	Invented name	Strength	Pharmaceu-tical form	Route of administra-tion	Packa-ging	Content (concentration)	Package size
EU/1/06/355/001	ATryn	1750 IU	Powder for solution for infusion	Intravenous use	Vial (glass)	1750 IU (175 IU/ml)	1 vial
EU/1/06/355/002	ATryn	1750 IU	Powder for solution for infusion	Intravenous use	Vial (glass)	1750 IU (175 IU/ml)	10 vials
EU/1/06/355/003	ATryn	1750 IU	Powder for solution for infusion	Intravenous use	Vial (glass)	1750 IU (175 IU/ml)	25 vials