

EMA/742001/2016

European Medicines Agency decision

P/0350/2016

of 2 December 2016

on the refusal of a paediatric investigation plan and on the refusal of a deferral and on the refusal of a waiver for antithrombin alfa (Recombinant human antithrombin), (EMA-001154-PIP02-15) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

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 726/2004¹,

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 Agency²,

Having regard to the application submitted by GTC Biotherapeutics UK Limited on 25 January 2016 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 14 October 2016, in accordance with Article 18 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

- (1) The Paediatric Committee of the European Medicines Agency has given an opinion on the refusal of a paediatric investigation plan and on the refusal of a deferral and on the refusal of a waiver.
- (2) It is therefore appropriate to adopt a decision refusing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision refusing a deferral.
- (4) 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 paediatric investigation plan for antithrombin alfa (Recombinant human antithrombin), 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

A deferral for antithrombin alfa (Recombinant human antithrombin), 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 3

A waiver for antithrombin alfa (Recombinant human antithrombin), 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 4

This decision is addressed to GTC Biotherapeutics UK Limited, 10 Norwich Street, EC4A 1BD – London, United Kingdom.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/660900/2016 **Corr**

London, 14 October 2016

Opinion of the Paediatric Committee on the refusal of a Paediatric Investigation plan and a deferral and a waiver EMA-001154-PIP02-15

Scope of the application

Active substance(s):

Antithrombin alfa

Invented name:

Recombinant human antithrombin

Condition(s):

Treatment of antithrombin deficiency

Authorised indication(s):

See Annex I

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 I



Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, GTC Biotherapeutics UK Limited submitted for agreement to the European Medicines Agency on 25 January 2016 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 1 March 2016.

Supplementary information was provided by the applicant on 22 July 2016. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:
 - to refuse the paediatric investigation plan in accordance with Article 18 of said Regulation, as the measures and the timelines are not appropriate to ensure the generation of the necessary data determining the conditions in which the medicinal product may be used to treat the paediatric population or some subsets, nor to adapt a paediatric formulation;
 - to refuse a deferral in accordance with Article 21 of said Regulation;
 - to refuse the granting of a waiver in accordance with Article 13 of said Regulation, for some of the 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 Norwegian Paediatric Committee member agrees 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.

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

Annex I

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Prevention of venous thromboembolism

Authorised indication(s):

- ATryn is indicated for the prophylaxis of venous thromboembolism in surgery of adult patients with congenital antithrombin deficiency. It is normally given in association with heparin or low molecular weight heparin.

Authorised pharmaceutical form(s):

Powder for solution for infusion

Authorised route(s) of administration:

Intravenous use