



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/420384/2017

European Medicines Agency decision

P/0195/2017

of 10 July 2017

on the acceptance of a modification of an agreed paediatric investigation plan for damoctocog alfa pegol (EMEA-001229-PIP01-11-M03) 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 European Medicines Agency's decision P/0216/2012 issued on 28 September 2012, the decision P/0070/2015 issued on 1 April 2015, and the decision P/0025/2016 issued on 29 January 2016,

Having regard to the application submitted by Bayer AG on 7 March 2017 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 23 June 2017, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 acceptance of changes to the agreed paediatric investigation plan and to the deferral.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for damoctocog alfa pegol, powder and solvent for solution for injection, intravenous use, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Bayer AG, Kaiser-Wilhelm-Allee 1, 51368 - Leverkusen, Germany.

EMA/PDCO/220601/2017 Corr
London, 23 June 2017

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-001229-PIP01-11-M03

Scope of the application

Active substance(s):

Damoctocog alfa pegol

Condition(s):

Treatment of hereditary 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:

Bayer AG

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Bayer AG submitted to the European Medicines Agency on 7 March 2017 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0216/2012 issued on 28 September 2012, the decision P/0070/2015 issued on 1 April 2015, and the decision P/0025/2016 issued on 29 January 2016.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 25 April 2017.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:
 - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

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

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

Not applicable.

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of hereditary factor VIII deficiency

2.1.1. Indication(s) targeted by the PIP

Treatment and prophylaxis of bleeding in patients with Haemophilia A (hereditary factor VIII deficiency)

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder and solvent for solution for injection

Measures

Area	Number of studies	Description
Quality-related studies	1	Study 1 Development of a 250 IU vial size.
Non-clinical studies	0	Not applicable.
Clinical studies	2	Study 2 Open-label, uncontrolled trial to evaluate pharmacokinetics, safety and efficacy of damoctocog alfa pegol for prophylaxis and treatment of bleeding in previously treated patients (PTP) from 12 to less than 18 years (and adults), with severe hereditary factor VIII deficiency. Study 3 Open-label, uncontrolled trial to evaluate pharmacokinetics, safety and efficacy of damoctocog alfa pegol for prophylaxis and treatment of bleeding in previously treated patients (PTP) less than 12 years of age, with severe hereditary factor VIII deficiency. Study 4 Deleted during PIP modification procedure EMA 001229-PIP01-11-M03.

Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By July 2017
Deferral for one or more studies contained in the paediatric investigation plan:	Yes