EMA/312705/2017

European Medicines Agency decision

P/0142/2017

of 7 June 2017

on the acceptance of a modification of an agreed paediatric investigation plan for turoctocog alfa pegol (EMEA-001174-PIP02-12-M02) 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 726/2004[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 European Medicines Agency's decision P/0227/2012 issued on 3 October 2012, and the decision P/0284/2014 issued on 28 October 2014,

Having regard to the application submitted by Novo Nordisk A/S on 26 January 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 21 April 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.

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

[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 turoctocog alfa pegol, powder and solvent for solution for injection, intravenous use, 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 Novo Nordisk A/S, Novo Allé, 2880 - Bagsværd, Denmark.

EMA/PDCO/61211/2017
London, 21 April 2017

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001174-PIP02-12-M02

Scope of the application

Active substance(s):

Turoctocog 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:

Novo Nordisk A/S

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Novo Nordisk A/S submitted to the European Medicines Agency on 26 January 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/0227/2012 issued on 3 October 2012, and the decision P/0284/2014 issued on 28 October 2014.

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

The procedure started on 21 February 2017.

Scope of the modification

Some measures 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 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

2.1.4. Measures

Area	Number of studies	Description
Quality	0	**Study 1** Removed in Modification of an agreed PIP 001174-PIP02-12-M02
Non-clinical	0	Not applicable.
Clinical	4	**Study 2** Open-label trial to evaluate pharmacokinetics, safety, efficacy of Glycopegylated recombinant coagulation factor VIII (N8-GP) in previously treated children from 12 to less than 18 years of age (and adults) with severe hereditary Factor VIII deficiency **Study 3** Open-label, non-randomised trial to evaluate safety and the haemostatic effect of N8-GP during surgical procedures in children with haemophilia A from 12 years to less than 18 years of age (and adults) **Study 4** Open-label trial to evaluate pharmacokinetics, safety, efficacy of N8-GP in previously treated children less than 12 years of age with Haemophilia A

		Study 5 Open-label trial to evaluate safety, efficacy, immunogenicity of N8-GP in previously untreated children from birth to less than 6 years of age with hereditary Factor VIII deficiency.

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 December 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes