EMA/441051/2016

European Medicines Agency decision

P/0207/2016

of 12 August 2016

on the acceptance of a modification of an agreed paediatric investigation plan for turoctocog alfa (NovoEight) (EMEA-000428-PIP01-08-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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Contact EMA www.ema.europa.eu/contact

European Medicines Agency decision

P/0207/2016

of 12 August 2016

on the acceptance of a modification of an agreed paediatric investigation plan for turoctocog alfa (NovoEight) (EMEA-000428-PIP01-08-M03) 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 European Medicines Agency's decision P/50/2010 issued on 7 April 2010, the decision P/0150/2012 issued on 16 July 2012 and the decision P/0091/2013 issued on 29 April 2013,

Having regard to the application submitted by Novo Nordisk A/S on 4 April 2016 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 24 June 2016, 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 turoctocog alfa (NovoEight), 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 Novo Nordisk A/S, Novo Allé, 2880 – Bagsvaerd, Denmark.

EMA/PDCO/268058/2016
London, 24 June 2016

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

EMEA-000428-PIP01-08-M03

Scope of the application

Active substance(s):

Turoctocog alfa

Invented name:

NovoEight

Condition(s):

Treatment of hereditary factor VIII deficiency

Authorised indication(s):

See Annex II

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

Information about the authorised medicinal product:

See Annex II

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5510
Send a question via our website www.ema.europa.eu/contact

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 4 April 2016 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/50/2010 issued on 7 April 2010, the decision P/0150/2012 issued on 16 July 2012 and the decision P/0091/2013 issued on 29 April 2013.

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

The procedure started on 26 April 2016.

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 annexes 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 (congenital 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 measures	Description
Quality	1	**Measure 1** Development of age-appropriate vials
Non-clinical	0	Not applicable
Clinical	3	**Study 2** Open-label, multicentre, multiple dose trial to evaluate pharmacokinetics, safety, immunogenicity of Recombinant coagulation Factor VIII (N8) in previously treated children from 12 to less than 18 years of age with severe haemophilia A. **Study 3** Open-label, multicentre, multiple dose, trial to evaluate pharmacokinetics, safety, immunogenicity of Recombinant coagulation Factor VIII (N8) in previously treated children from birth to less than 12 years of age with severe haemophilia A. **Study 4** open-label, multicentre trial to evaluate safety and immunogenicity of Recombinant coagulation Factor VIII (N8) in previously untreated children from birth to less than 18 years of age with haemophilia A.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2018
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of hereditary factor VIII deficiency

Authorised indication(s):

- Treatment of haemophilia A (congenital factor VIII deficiency).

Authorised pharmaceutical form(s):

Powder and solvent for solution for injection.

Authorised route(s) of administration:

Intravenous use.