European Medicines Agency

Doc. Ref. EMA/118879/2010
P/50/2010

EUROPEAN MEDICINES AGENCY DECISION

of 7 April 2010

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral for recombinant coagulation Factor VIII (N8) (EMEA-000428-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 70
E-mail: mail@ema.europa.eu http://www.ema.europa.eu

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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 as amended 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 Novo Nordisk A/S on 4 November 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a deferral under Article 20 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 February 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 21 of said Regulation,

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

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a Paediatric Investigation Plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a Decision agreeing a Paediatric Investigation Plan.

(3) It is therefore appropriate to adopt a Decision granting a 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

A Paediatric Investigation Plan for recombinant coagulation Factor VIII (N8), powder and solvent for solution for injection, 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 agreed.

Article 2

A deferral for recombinant coagulation Factor VIII (N8), powder and solvent for solution for injection, 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 granted.

Article 3

This decision is addressed to Novo Nordisk A/S, Novo Allé, DK-2880, Bagsværd, Denmark.

Done at London, 7 April 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 February 2010
EMA/PDCO/74817/2010

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMEA-000428-PIP01-08

Scope of the application

Active substance(s):

Recombinant coagulation Factor VIII (N8)

Condition(s):

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 16(1) of Regulation (EC) No 1901/2006 as amended, Novo Nordisk A/S submitted for agreement to the European Medicines Agency on 4 November 2008 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 5 March 2009.

Supplementary information was provided by the applicant on 4 December 2009.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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 agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
   - to grant a deferral in accordance with Article 21 of said Regulation,

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

2. The measures and timelines of the agreed 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.

London, 19 February 2010

On behalf of the Paediatric Committee

Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

THE MEASURES AND TIMELINES OF THE AGREED PAEDIATRIC INVESTIGATION PLAN

1. Condition(s)

Hereditary Factor VIII Deficiency

2. Waiver

Not applicable

3. Paediatric Investigation Plan

3.1 Condition to be investigated

Hereditary Factor VIII Deficiency

3.2 Indication targeted by the pip

Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency)

3.3 Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age.

3.4 Pharmaceutical form(s)

Powder and solvent for solution for injection

3.5 Studies

Area	**Number of studies**	**Description**
Quality	Total number of quality studies: 1	**Study 1** Development of age-appropriate vials
Non-clinical	Total number of studies: 0	Not applicable
Clinical	Total number of studies: 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

Area	Number of studies	Description
		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.

4. Follow-up, completion and deferral of pip

Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	By May 2012
Deferral for one or more studies contained in the paediatric investigation plan:	Yes