EMA/421237/2011

European Medicines Agency decision

P/126/2011

of 7 June 2011

on the agreement of a paediatric investigation plan and on the granting of a deferral for octocog alfa (EMEA-001064-PIP01-10) 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 application submitted by Bayer Schering Pharma AG on 6 September 2010 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 20 April 2011, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 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 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 octocog alfa, 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 octocog alfa, 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 Bayer Schering Pharma AG, Müllerstrasse 178, 13342, Berlin, Germany.

Done at London, 7 June 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/176694/2011

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

EMEA-001064-PIP01-10

Scope of the application

Active substance(s):

Octocog alfa

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 Schering Pharma AG

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Bayer Schering Pharma AG submitted for agreement to the European Medicines Agency on 6 September 2010 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 13 October 2010.

Supplementary information was provided by the applicant on 7 February 2011. The applicant proposed modifications to the paediatric investigation plan, requested a deferral and withdrew its request for a waiver.

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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 Norwegian Paediatric Committee member agrees 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, 20 April 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

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.

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. Studies

Area	Number of studies	Description
Quality	0	Not applicable
Non-clinical	0	Not applicable
Clinical	5	Study 1: Open-label, multicentre, cross-over, single dose trial to evaluate pharmacokinetics of new Octocog alfa (BAY 81-8973) as compared to already authorised Octocog alfa (KOGENATE Bayer), in previously treated adult and adolescent patients at least 12 years of age, with hereditary factor VIII deficiency. Study 2: Open-label, multicentre, uncontrolled, cross-over comparing two different methods (assays) for measuring the amount of study drug, multiple dose trial to evaluate safety and efficacy of new Octocog alfa (BAY 81-8973), in previously treated adult and adolescent patients at least 12 years of age, with hereditary factor VIII deficiency. Study 3: Open-label, multicentre, uncontrolled, multiple dose trial to evaluate safety, efficacy and pharmacokinetics of new Octocog alfa (BAY 81-8973) for prophylaxis and treatment of bleeding, in previously treated patients less than 12 years of age, with hereditary factor VIII deficiency. Study 4: Open-label, multicentre, uncontrolled, multiple dose trial to evaluate efficacy and safety of new Octocog alfa (BAY 81-8973) for prophylaxis and treatment of bleeding in previously untreated children with hereditary factor VIII deficiency.

		Study 5: Open-label, multicentre, uncontrolled, multiple dose trial to monitor the safety of new Octocog alfa (BAY 81-8973), including immunogenicity, in patients less than 12 years of age with hereditary factor VIII deficiency.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By February 2015
Deferral for one or more studies contained in the paediatric investigation plan:	Yes