EMA/278715/2011

European Medicines Agency decision

P/101/2011

of 11 March 2011

on the agreement of a paediatric investigation plan and on the granting of a waiver for darbepoetin alfa (Aranesp) (EMEA-000329-PIP02-09) 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 Amgen Europe B.V on 19 October 2009 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 18 March 2011, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 13 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 waiver.

(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 waiver.

[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 darbepoetin alfa (Aranesp) (EMEA-000329-PIP02-09), solution for injection, subcutaneous use, 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 waiver for darbepoetin alfa (Aranesp) (EMEA-000329-PIP02-09), solution for injection, subcutaneous use, 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 Amgen Europe B.V, Minervum 7061, 4817-ZK, Breda, The Netherlands.

Done at London, 11 March 2011

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

EMA/PDCO/65739/2011

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

EMEA-000329-PIP02-09

Scope of the application

Active substance(s):

Darbepoetin alfa

Invented name:

Aranesp

Condition(s):

Treatment of anaemia due to chronic disorders

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Intravenous use

Name/corporate name of the PIP applicant:

Amgen Europe B.V

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Amgen Europe B.V submitted for agreement to the European Medicines Agency on 19 October 2009 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 19 November 2009.

Supplementary information was provided by the applicant on 10 January 2011.

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 waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   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 and the subset(s) of the paediatric population and condition(s) covered by the waiver 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(es) and appendix.

London, 18 March 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

Waiver

1.1. Condition: Treatment of anaemia due to chronic disorders

The waiver applies to:

- adolescents (from 12 to less than 18 years);
- for solution for injection, for subcutaneous or intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of anaemia due to chronic disorders

2.1.1. Indication(s) targeted by the PIP

Treatment of symptomatic anaemia associated with chronic renal failure (CRF)

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

From birth to less than 12 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1 Development of a single-use vial containing 25 µg/mL of darbepoetin alfa.
Non-clinical	0	Not applicable.
Clinical	3	Study 2 Open label, single-arm trial to evaluate safety and tolerability, pharmacokinetics and pharmacodynamics of darbepoetin alfa in children from birth to less than 1 year of age with anaemia due to chronic kidney disease (CKD). Study 3 Double blind, randomised, multicentre trial to evaluate efficacy of darbepoetin alfa at different dosage regimes in children from 1 to less than 18 years of age with anaemia due to chronic kidney disease (CKD). Study 4 Non-interventional, prospective observational registry study to evaluate safety of darbepoetin alfa in children from birth to less than 17 years of age with anaemia due to chronic kidney disease (CKD).

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:	No
Date of completion of the paediatric investigation plan:	By December 2013.
Deferral for one or more studies contained in the paediatric investigation plan:	No