EMA/52905/2014

European Medicines Agency decision

P/0042/2014

of 5 March 2014

on the acceptance of a modification of an agreed paediatric investigation plan for darbepoetin alfa (Aranesp), (EMEA-000329-PIP02-09-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.

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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/101/2011 issued on 11 April 2011, and the decision P/0009/2012 issued on 24 January 2012,

Having regard to the application submitted by Amgen Europe B.V. on 25 October 2013 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 17 January 2014, 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 darbepoetin alfa (Aranesp), solution for injection, subcutaneous use, 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 Amgen Europe B.V., Minervum 7061, 4817-ZK - Breda, The Netherlands.

Done at London, 5 March 2014

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/52905/2014 corr

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

EMEA-000329-PIP02-09-M03

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 22 of Regulation (EC) No 1901/2006 as amended, Amgen Europe B.V. submitted to the European Medicines Agency on 25 October 2013 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/101/2011 issued on 11 April 2011, and the decision P/0009/2012 issued on 24 January 2012.

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

The procedure started on 19 November 2013.

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 in the scope set out in the Annex I of this opinion.

   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 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 annexes and appendix.

London, 17 January 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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

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. Measures

Area	Number of measures	Description
Quality	1	**Measure 1** Development of a single-use vial containing 25 µg/mL of darbepoetin alfa.
Non-clinical	0	Not applicable.
Clinical	3	**Measure 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). **Measure 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).

		Measure 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

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2016
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of anaemia due to chronic disorders

   Authorised indications:

   - Treatment of symptomatic anaemia associated with chronic renal failure (CRF) in adults and paediatric patients.
   - Treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy.

Authorised pharmaceutical formulation(s):

Solution for injection in a pre-filled syringe or pre-filled pen, Solution for injection in a vial (glass)

Authorised route(s) of administration:

Intravenous use, subcutaneous use