EMA/617366/2015

European Medicines Agency decision

P/0241/2015

of 30 October 2015

on the acceptance of a modification of an agreed paediatric investigation plan for darbepoetin alfa (Aranesp), (EMEA-000329-PIP02-09-M04) 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, the decision P/0009/2012 issued on 24 January 2012, and the decision P/0042/2014 issued on 5 March 2014,

Having regard to the application submitted by Amgen Europe B.V. on 18 June 2015 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 September 2015, 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 waiver.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the 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

Changes to the agreed paediatric investigation plan for darbepoetin alfa (Aranesp), solution for injection, subcutaneous use, intravenous use, including changes to the waiver, 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, 30 October 2015

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/434888/2015
London, 11 September 2015

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

EMEA-000329-PIP02-09-M04

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 18 June 2015 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, the decision P/0009/2012 issued on 24 January 2012, and the decision P/0042/2014 issued on 5 March 2014.

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

The procedure started on 14 July 2015.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified. A waiver for a paediatric subset has been removed.

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 waiver 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 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 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of a single-use vial or single-use graduated prefilled syringe containing 25 µg/mL of darbepoetin alfa.
Non-clinical studies	0	Not applicable.
Clinical studies	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).

Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/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 form(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