EMA/137334/2015

European Medicines Agency decision

P/0060/2015

of 1 April 2015

on the acceptance of a modification of an agreed paediatric investigation plan for ferumoxytol, (Rienso) (EMEA-000373-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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on the acceptance of a modification of an agreed paediatric investigation plan for ferumoxytol, (Rienso) (EMEA-000373-PIP02-09-M04) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/248/2009 issued on 10 December 2009, the decision P/38/2010 issued on 31 March 2010, the decision P/0086/2012 issued on 25 May 2012, and the decision P/0014/2013 issued on 23 January 2013,

Having regard to the application submitted by AMAG Pharmaceuticals, Inc. on 24 November 2014 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 February 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 deferral.

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

Changes to the agreed paediatric investigation plan for ferumoxytol, (Rienso), solution for infusion, intravenous use, including changes to the deferral, 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 AMAG Pharmaceuticals, Inc., 1100 Winter Street, 02451 – Waltham, USA.

Done at London, 1 April 2015

For the European Medicines Agency
Jordi Llinares Garcia
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/732011/2014

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

EMEA-000373-PIP02-09-M04

Scope of the application

Active substance(s):

Ferumoxytol

Invented name:

Rienso

Condition(s):

Treatment of iron deficiency anaemia

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

AMAG Pharmaceuticals, Inc.

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, AMAG Pharmaceuticals, Inc. submitted to the European Medicines Agency on 24 November 2014 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/248/2009 issued on 10 December 2009, the decision P/38/2010 issued on 31 March 2010, the decision P/0086/2012 issued on 25 May 2012, and the decision P/0014/2013 issued on 23 January 2013.

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

The procedure started on 16 December 2014.

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 and to the deferral 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 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, 13 February 2015

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 (PIP)

1. Waiver

1.1. Condition:

Treatment of iron deficiency anaemia

The waiver applies to:

- Children from birth to less than 6 months;
- for solution for infusion / intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of iron deficiency anaemia

2.1.1. Indication(s) targeted by the PIP

Treatment of iron deficiency anaemia

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

From 6 months to less than 18 years.

2.1.3. Pharmaceutical form(s)

Solution for infusion, intravenous use

2.1.4. Studies

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of age-appropriate vial size.
Non-clinical studies	0	Not applicable.
Clinical studies	3	**Study 2** Open-label, randomised, active-controlled trial to evaluate safety, efficacy, and pharmacokinetics of ferumoxytol compared with oral iron for the treatment of iron deficiency anaemia in paediatric subjects with chronic kidney disease in children from 6 months to less than 18 years.

		Study 3 *(Study 3 was deleted in procedure EMEA-000373-PIP02-09-M03)* **Study 4** Open-label extension trial to evaluate safety and efficacy of ferumoxytol for the episodic treatment of iron deficiency anaemia in paediatric subjects with chronic kidney disease in children from 6 months to less than 18 years. **Study 5** Open-label, randomised, active-controlled trial to evaluate safety, efficacy, and pharmacokinetics of ferumoxytol compared with oral iron for the treatment of iron deficiency anaemia in paediatric subjects in children from 6 months to less than 18 years.
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:	Yes
Date of completion of the paediatric investigation plan:	By April 2019
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of iron deficiency anaemia

Authorised indication(s):

- Treatment of iron deficiency anaemia in adult patients with chronic kidney disease (CKD)

Authorised pharmaceutical form(s):

Solution for infusion

Authorised route(s) of administration:

Intravenous use