

EMA/22310/2013

European Medicines Agency decision

P/0014/2013

of 23 January 2013

on the acceptance of a modification of an agreed paediatric investigation plan for ferumoxytol (Rienso) (EMA-000373-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 726/2004¹,

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 Agency²,

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, and the decision P/0086/2012 issued on 25 May 2012,

Having regard to the application submitted by AMAG Pharmaceuticals Inc. on 17 September 2012 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 7 December 2012, 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 ferumoxytol (Rienso), solution for injection, 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 AMAG Pharmaceuticals Inc., 100 Hayden Avenue, 02421 Lexington, MA, USA.

Done at London, 23 January 2013

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/634896/2012

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

EMA-000373-PIP02-09-M03

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 injection

Route(s) of administration:

Intravenous use

Name / corporate name of the PIP applicant:

AMAG Pharmaceuticals Inc.

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 17 September 2012 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 and the decision P/0086/2012 issued on 25 May 2012.

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



The procedure started on 10 October 2012.

A meeting with the Paediatric Committee took place on 6 December 2012.

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 annex and appendix.

London, 7 December 2012

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

1.1. Condition: Treatment of iron deficiency anaemia

The waiver applies to:

- Children from birth to less than 6 months;
- for solution for injection / 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 injection, intravenous use.

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1 Development of age-appropriate vial size.
Non-clinical		Not applicable.
Clinical	4	Study 2 Open-label, randomized, 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 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, randomized, 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.
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3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By April 2018
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 indications:

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

Authorised pharmaceutical formulation(s):

Solution for injection

Authorised route(s) of administration:

Intravenous use