



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/339708/2012

European Medicines Agency decision P/0086/2012

of 25 May 2012

on the acceptance of a modification of an agreed paediatric investigation plan for ferumoxytol (EMA-000373-PIP02-09-M02) 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 (EMA-000373-PIP02-09-M02) 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 726/2004¹,

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 and the decision P/38/2010 issued on 31 March 2010,

Having regard to the application submitted by AMAG Pharmaceuticals, Inc. on 23 January 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 13 April 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 ferumoxitol, 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, United States.

Done at London, 25 May 2012

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/121170/2012

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-000373-PIP02-09-M02

Scope of the application

Active substance(s):

Ferumoxytol

Condition(s):

Treatment of Iron Deficiency Anaemia

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 23 January 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 and the decision P/38/2010 issued on 31 March 2010.

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

The procedure started on 15 February 2012.

Scope of the modification

Some measures and/or timelines of the original opinion 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(es) and appendix.

London, 13 April 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:

- Preterm newborn infants, term newborn infants (from birth to less than 28 days), infants and toddlers (from 28 days 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, 30mg/mL elemental iron

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 dialysis-dependent chronic kidney disease in children from 6 months to less than 18 years. Study 3 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 nondialysis-dependent chronic kidney disease in children from 6 months to less than 18 years. 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 February 2017.
Deferral for one or more studies contained in the paediatric investigation plan:	Yes.