

EMA/493084/2013

European Medicines Agency decision

P/0228/2013

of 23 September 2013

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for iron as iron maltol (iron(III)-maltol complex), (EMEA-001195-PIP01-11) 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 application submitted by Iron Therapeutics (UK) Ltd. on 29 June 2012 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 9 August 2013, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting a deferral.
- (4) It is therefore appropriate to adopt a decision granting a 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

A paediatric investigation plan for iron as iron maltol (iron(III)-maltol complex), capsule, hard, powder for oral suspension, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for iron maltol (iron(III)-maltol complex), capsule, hard, powder for oral suspension, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for iron maltol (iron(III)-maltol complex), capsule, hard, powder for oral suspension, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Iron Therapeutics (UK) Ltd., Rotterdam House, 116 Quayside, NE1 3DY - Newcastle-Upon-Tyne, United Kingdom.

Done at London, 23 September 2013

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

EMA/PDCO/305912/2013

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMA-001195-PIP01-11

Scope of the application

Active substance(s):

Iron as iron maltol (iron(III)-maltol complex)

Condition(s):

Treatment of iron deficiency anaemia (IDA)

Pharmaceutical form(s):

Capsule, hard

Powder for oral suspension

Route(s) of administration:

Oral use

Name / corporate name of the PIP applicant:

Iron Therapeutics (UK) Ltd.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Iron Therapeutics (UK) Ltd. submitted for agreement to the European Medicines Agency on 29 June 2012 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 10 October 2012.

Supplementary information was provided by the applicant on 17 May 2013. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report :

- to agree the paediatric investigation plan in accordance with Article 18 of said Regulation;
- to grant a deferral in accordance with Article 21 of said Regulation;
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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, 9 August 2013

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 (IDA)

The waiver applies to:

- All paediatric patients from birth to less than 6 months of age;
- for capsules, hard, for oral use, and for powder for oral suspension, for oral 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 (IDA)

2.1.1. Indication(s) targeted by the PIP

Treatment of iron deficiency anaemia (IDA).

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

From 6 months to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Capsule, hard.

Powder for oral suspension.

2.1.4. Measures

Area	Number of measures	Description
Quality	1	Measure 1 Development of an age-appropriate powder for oral suspension formulation, supplied with a dosing device.
Non-clinical	0	Not applicable.

Area	Number of measures	Description
Clinical	2	Measure 2 (ST10-01-102) Open-label, randomised, multiple-dose, parallel assignment trial to evaluate pharmacokinetics and tolerability in children and adolescents with iron deficiency from 10 to less than 18 years of age. Measure 3 (ST10-01-303) Randomised, open-label, active-controlled, randomised, multicentre, comparative trial to evaluate safety and efficacy of Iron as iron maltol (iron(III)-maltol complex) (ST10) compared to oral ferrous sulphate in children from 6 months to less than 18 years of age with iron-deficiency anaemia.

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 January 2019
Deferral for one or more measures contained in the paediatric investigation plan:	Yes