EMA/202479/2017

European Medicines Agency decision

P/0102/2017

of 11 April 2017

on the acceptance of a modification of an agreed paediatric investigation plan for ferric maltol (Feraccru), (EMEA-001195-PIP01-11-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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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/0228/2013 issued on 23 September 2013 and decision P/0069/2016 issued on 18 March 2016,

Having regard to the application submitted by Shield TX (UK) Limited on 9 December 2016 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 24 February 2017, 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 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 deferral and 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 ferric maltol (Feraccru), capsule, hard, powder for oral suspension, oral use, including changes to the deferral, and 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 Shield TX (UK) Limited, Northern Design Centre, Baltic Business Quarter, NE8 3DF - Gateshead Quays, United Kingdom.

EMA/PDCO/854118/2016
London, 24 February 2017

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

EMEA-001195-PIP01-11-M02

Scope of the application

Active substance(s):

Ferric maltol

Invented name:

Feraccru

Condition(s):

Treatment of iron deficiency anaemia (IDA)

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Capsule, hard

Powder for oral suspension

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Shield TX (UK) Limited

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Shield TX (UK) Limited submitted to the European Medicines Agency on 9 December 2016 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/0228/2013 issued on 23 September 2013 and decision P/0069/2016 issued on 18 March 2016.

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

The procedure started on 3 January 2017.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. A waiver for a new paediatric subset has been added.

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 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 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.

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 (IDA)

The waiver applies to:

- all paediatric patients from birth to less than 2 years 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 is likely to be unsafe.

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 2 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-related studies	1	**Study 1** Development of an age-appropriate powder for oral suspension formulation, supplied with a dosing device.
Non-clinical studies	0	Not applicable.
Clinical studies	2	**Study 2 (ST10-01-103)** 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.

		Study 3 (ST10-01-305) 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 2 to less than 18 years of age with iron-deficiency anaemia.
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 May 2020
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 (IDA)

Authorised indication(s):

- Treatment of iron deficiency anaemia (IDA) in adult patients with inflammatory bowel disease (IBD)

Authorised pharmaceutical form(s):

Capsule, hard

Authorised route(s) of administration:

Oral use