EMA/145472/2022

European Medicines Agency decision

P/0109/2022

of 13 April 2022

on the acceptance of a modification of an agreed paediatric investigation plan for ferumoxytol, (EMEA-000373-PIP02-09-M05) 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.

European Medicines Agency decision

P/0109/2022

of 13 April 2022

on the acceptance of a modification of an agreed paediatric investigation plan for ferumoxytol, (EMEA-000373-PIP02-09-M05) 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 Union procedures for the authorisation and supervision of medicinal products for human 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, the decision P/0014/2013 issued on 23 January 2013 and the decision P/0060/2015 issued on 1 April 2015,

Having regard to the application submitted by Covis Pharma Europe B.V. on 20 November 2021 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 25 February 2022, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for ferumoxytol, solution for infusion, intravenous 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 Covis Pharma Europe B.V., Gustav Mahlerplein 2, 1082 MA - Amsterdam, The Netherlands.

EMA/PDCO/709210/2021 Corr
Amsterdam, 25 February 2022

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

EMEA-000373-PIP02-09-M05

Scope of the application

Active substance(s):

Ferumoxytol

Condition(s):

Treatment of iron deficiency anaemia

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Covis Pharma Europe B.V.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Covis Pharma Europe B.V. submitted to the European Medicines Agency on 20 November 2021 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, the decision P/0014/2013 issued on 23 January 2013 and the decision P/0060/2015 issued on 1 April 2015.

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

The procedure started on 4 January 2022.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. The scope of the waiver has been extended to cover an additional age group.

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 annex 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

The waiver applies to:

- children from birth to less than 2 years;
- 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 2 years to less than 18 years

2.1.3. Pharmaceutical form(s)

Solution for infusion, intravenous use

2.1.4. Studies

Area	**Description**
Quality-related studies	**Study 1** *Study 1 was deleted as a result of procedure EMEA-000373-PIP02-09-M05.*
Non-clinical studies	Not applicable.
Clinical studies	**Study 2** *Study 2 was deleted as a result of procedure EMEA-000373-PIP02-09-M05.* **Study 3** *Study 3 was deleted as a result of procedure EMEA-000373-PIP02-09-M03.*

	Study 4 *Study 4 was deleted as a result of procedure EMEA-000373-PIP02-09-M05.* **Study 5** *Study 5 was deleted as a result of procedure EMEA-000373-PIP02-09-M05.* **Study 6** (**AMAG-FER-IDA-352)** Open-label, randomised, active controlled trial to evaluate safety, efficacy and pharmacokinetics of intravenous ferumoxytol in paediatric subjects from 2 years to less than 18 years of age with iron deficiency anaemia (IDA)
Extrapolation, modelling and simulation studies	Not applicable
Other studies	Not applicable
Other measures	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 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes