EMA/150427/2021

European Medicines Agency decision

P/0134/2021

of 14 April 2021

on the acceptance of a modification of an agreed paediatric investigation plan for citric acid (as citric acid anhydrous) / sodium chloride / simeticone / macrogol 4000 / sodium citrate /sodium sulfate (as sodium sulfate anhydrous) / potassium chloride (Clensia), (EMEA-001356-PIP02-12-M04) 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/0051/2014 issued on 7 March 2014, the decision P/0019/2017 issued on 31 January 2017, the decision P/0223/2018 issued on 17 July 2018 and the decision P/0339/2020 issued on 9 September 2020,

Having regard to the application submitted by Alfasigma S.p.A. on 27 November 2020 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 26 February 2021, 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 citric acid (as citric acid anhydrous) / sodium chloride / simeticone / macrogol 4000 / sodium citrate / sodium sulfate (as sodium sulfate anhydrous) / potassium chloride (Clensia), powder for oral solution, oral 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 Alfasigma S.p.A., Via Ragazzi del '99 n.5, 40133 - Bologna, Italy.

EMA/PDCO/661102/2020
Amsterdam, 26 February 2021

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

EMEA-001356-PIP02-12-M04

Scope of the application

Active substance(s):

Citric acid (as citric acid anhydrous) / sodium chloride / simeticone / macrogol 4000 / sodium citrate / sodium sulfate (as sodium sulfate anhydrous) / potassium chloride

Invented name:

Clensia

Condition(s):

Bowel cleansing prior to clinical procedures

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for oral solution

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Alfasigma S.p.A.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Alfasigma S.p.A. submitted to the European Medicines Agency on 27 November 2020 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/0051/2014 issued on 7 March 2014, the decision P/0019/2017 issued on 31 January 2017, the decision P/0223/2018 issued on 17 July 2018 and the decision P/0339/2020 issued on 9 September 2020.

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

The procedure started on 4 January 2021.

Scope of the modification

Some measures 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 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:

Bowel cleansing prior to clinical procedures

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- powder for oral solution, 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:

Bowel cleansing prior to clinical procedures

2.1.1. Indication(s) targeted by the PIP

Bowel preparation before a diagnostic procedure concerning the colon

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

From 2 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder for oral solution

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable

Clinical studies	1	**Study 1 (PMF104 PD1-2-3/2013)** Randomised, single-blind, active controlled, multi-centre trial to evaluate efficacy, safety, tolerability, acceptability and palatability of Clensia compared to a solution containing macrogol 3350 or macrogol 4000 (58-59.5 g per litre); anhydrous sodium sulfate (5.67-5.7 g per litre); sodium bicarbonate (1.67-1.7 g per litre); sodium chloride (1.45-1.47 g per litre); potassium chloride (0.73-0.75 g per litre) in children from 2 to less than 18 years of age requiring a diagnostic procedure concerning the colon ***Study 2*** *was deleted during procedure EMEA-001356-PIP02-12-M01.* ***Study 3*** *was deleted during procedure EMEA-001356-PIP02-12-M01.*
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 December 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. Bowel cleansing prior to clinical procedures

Authorised indications:

- Bowel cleansing in adults prior to any clinical procedures requiring a clean bowel e.g. bowel endoscopy or radiology.

Authorised pharmaceutical form(s)

Powder for oral solution

Authorised route(s) of administration

Oral use