EMA/465548/2018

European Medicines Agency decision

P/0214/2018

of 17 July 2018

on the acceptance of a modification of an agreed paediatric investigation plan for potassium citrate monohydrated / potassium hydrogen carbonate (ADV7103) (EMEA-001535-PIP01-13-M01) 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/0252/2014 issued on 30 September 2014,

Having regard to the application submitted by Advicenne on 12 March 2018 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 1 June 2018, 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 potassium citrate monohydrated / potassium hydrogen carbonate (ADV7103), prolonged-release granules, 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 Advicenne, 2 rue Briçonnet, 30000 – Nîmes, France.

EMA/PDCO/166645/2018
London, 1 June 2018

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

EMEA-001535-PIP01-13-M01

Scope of the application

Active substance(s):

Potassium citrate monohydrated / potassium hydrogen carbonate (ADV7103)

Condition(s):

Treatment of cystinuria

Pharmaceutical form(s):

Prolonged-release granules

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Advicenne

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Advicenne submitted to the European Medicines Agency on 12 March 2018 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/0252/2014 issued on 30 September 2014.

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

The procedure started on 3 April 2018.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

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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 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 cystinuria

The waiver applies to:

- the paediatric population from birth to less than 6 months of age;
- prolonged-release granules, 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 cystinuria

2.1.1. Indication(s) targeted by the PIP

Treatment of cystinuria

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)

Prolonged-release granules

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	2	**Study 1** Randomised, placebo-controlled, double-blind, 4-arm, parallel group, dose-ranging study, to assess the effect on urine pH values during 24h of ADV7103 as compared to placebo after a 7 day-treatment, in children from 6 months to less than 18 years of age with cystinuria (and in adults).

		Study 2 Open-label study to assess the safety and tolerability of ADV7103 as compared to Standard of Care after a 2-year treatment period, in children from 6 months to less than 18 years of age with cystinuria (and in adults).

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 January 2017
Deferral for one or more measures contained in the paediatric investigation plan:	Yes