EMA/710668/2018

European Medicines Agency decision

P/0357/2018

of 7 December 2018

on the acceptance of a modification of an agreed paediatric investigation plan for enalapril (maleate) (EMEA-001706-PIP01-14-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/0176/2015 issued on 7 August 2015, and the decision P/0140/2017 issued on 7 June 2017,

Having regard to the application submitted by Ethicare GmbH on 10 July 2018 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 October 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.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for enalapril (maleate), age-appropriate oral solid dosage form, 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 Ethicare GmbH, Wiechertstrasse 3, 45721 - Haltern am See, Germany.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

EMA/PDCO/505407/2018
London, 19 October 2018

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

EMEA-001706-PIP01-14-M02

Scope of the application

Active substance(s):

Enalapril (maleate)

Condition(s):

Treatment of heart failure

Pharmaceutical form(s):

Age-appropriate oral solid dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Ethicare GmbH

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Ethicare GmbH submitted to the European Medicines Agency on 10 July 2018 an application for modification of the agreed paediatric investigation plan as set out in the European Medicines Agency's decision P/0176/2015 issued on 7 August 2015, and the decision P/0140/2017 issued on 7 June 2017.

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

The procedure started on 21 August 2018.

Scope of the modification

Some measures and timelines 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 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

Not applicable.

2. Paediatric investigation plan

2.1. Condition

Treatment of heart failure

2.1.1. Indication(s) targeted by the PIP

Treatment of heart failure

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Age-appropriate oral solid dosage form

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of an age-appropriate oral solid dosage form
Non-clinical studies	0	Not applicable.
Clinical studies	3	**Study 2** Prospective, open-label single and multiple dose pharmacokinetic bridging study with exploratory pharmacodynamic assessments in patients aged from 1 month to less than 12 years (WP08) **Study 3** Prospective, open-label single and multiple dose pharmacokinetic bridging study with exploratory pharmacodynamic assessments in patients from birth to less than 6 years of age (WP09) **Study 4** Prospective open-label multi-centre extension safety study in infants and children (WP10)

Extrapolation, modelling and simulation studies	1	**Study 5** Systematic literature review, data extrapolation and modeling
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:	Yes
Date of completion of the paediatric investigation plan:	By April 2019
Deferral for one or more measures contained in the paediatric investigation plan:	No