



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/43439/2015

European Medicines Agency decision

P/0176/2015

of 7 August 2015

on the agreement of a paediatric investigation plan for enalapril (maleate), (EMA-001706-PIP01-14)
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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on the agreement of a paediatric investigation plan for enalapril (maleate), (EMA-001706-PIP01-14) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Ethicare GmbH on 6 November 2014 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 June 2015, in accordance with Article 18 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 agreement of a paediatric investigation plan.
- (2) It is therefore appropriate to adopt a decision agreeing a 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

A paediatric investigation plan for enalapril (maleate), age-appropriate oral solid dosage form, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

This decision is addressed to Ethicare GmbH, Am Fliederbusch 2, 45721 - Haltern am See, Germany.

Done at London, 7 August 2015

For the European Medicines Agency
Jordi Llinares Garcia
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)



EUROPEAN MEDICINES AGENCY
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EMA/PDCO/244743/2015

London, 19 June 2015

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan

EMA-001706-PIP01-14

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 16(1) of Regulation (EC) No 1901/2006 as amended, Ethicare GmbH submitted for agreement to the European Medicines Agency on 6 November 2014 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 16 December 2015.

Supplementary information was provided by the applicant on 30 March 2015. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.



Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 18 of said Regulation.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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)

Area	Number of measures	Description
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:	No
Date of completion of the paediatric investigation plan:	By October 2018
Deferral for one or more measures contained in the paediatric investigation plan:	No