EMA/392193/2014

European Medicines Agency decision

P/0206/2014

of 8 August 2014

on the agreement of a paediatric investigation plan for captopril (EMEA-001544-PIP01-13) 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 application submitted by Proveca Limited on 9 October 2013 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 20 June 2014, 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 captopril, age-appropriate oral liquid 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 Proveca Limited, Daresbury Innovation Centre, Keckwick Lane, Daresbury, WA4 4FS – Halton, United Kingdom.

Done at London, 8 August 2014

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/200310/2014 Corr

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

EMEA-001544-PIP01-13

Scope of the application

Active substance(s):

Captopril

Condition(s):

Treatment of heart failure

Pharmaceutical form(s):

Age-appropriate oral liquid dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Proveca Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Proveca Limited submitted for agreement to the European Medicines Agency on 9 October 2013 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 19 November 2013.

Supplementary information was provided by the applicant on 28 March 2014. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.

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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 Icelandic and the Norwegian Paediatric Committee members agree 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.

London, 20 June 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

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 liquid dosage form

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	2	**Study 1:** Development of an age-appropriate captopril oral solution (PRO/CAP/003). **Study 2:** In vitro stability study of the developed age-appropriate captopril oral solution (PRO/CAP/004).
Non-clinical studies	0	Not applicable.
Clinical studies	4	**Study 3:** Study to investigate the palatability of the developed (in Study 1) age-appropriate captopril oral solution in an adult population (PRO/CAP/005). **Study 4:** Bioequivalence study in adult healthy volunteers to compare the developed (in Study 1) age-appropriate captopril oral solution with a licensed captopril tablet (PRO/CAP/006).

Area	Number of measures	Description
		Study 5: Open-label, single dose population PK study of oral captopril administered to children from birth to less than 12 years of age, diagnosed with heart failure (PRO/CAP/001). **Study 6:** Long term safety study of oral captopril administered to children from birth to less than 12 months of age (PRO/CAP/007).
Extrapolation, modelling and simulation studies	1	**Study 7:** Systematic literature review of the available evidence in adolescents and extrapolation/modelling to support a paediatric application for captopril in the treatment of heart failure (PRO/CAP/002).
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 September 2018
Deferral for one or more measures contained in the paediatric investigation plan:	No