EMA/757977/2016

European Medicines Agency decision

P/0364/2016

of 21 December 2016

on the acceptance of a modification of an agreed paediatric investigation plan for KEOC liquid extract ethanolic 30 per cent (w/w) of Allium cepa L. (fresh bulb) and Citrus lemon (L.) Burm. (fresh fruit) / Paullinia cupana Kunth / Theobroma cacao L. (EMEA-001835-PIP01-15-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/0145/2016 issued on 23 May 2016,

Having regard to the application submitted by Legacy Healthcare on 5 August 2016 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 11 November 2016, 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 and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

[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 KEOC liquid extract ethanolic 30 per cent (w/w) of Allium cepa L. (fresh bulb) and Citrus lemon (L.) Burm. (fresh fruit) / Paullinia cupana Kunth / Theobroma cacao L., cutaneous solution, cutaneous use, including changes to the deferral, 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 Legacy Healthcare, 27 avenue de l'Opera, 75001 - Paris, France.

EMA/PDCO/548225/2016
London, 11 November 2016

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

EMEA-001835-PIP01-15-M01

Scope of the application

Active substance(s):

KEOC liquid extract ethanolic 30 per cent (w/w) of Allium cepa L. (fresh bulb) and Citrus lemon (L.) Burm. (fresh fruit) / Paullinia cupana Kunth / Theobroma cacao L.

Condition(s):

Treatment of alopecia

Pharmaceutical form(s):

Cutaneous solution

Route(s) of administration:

Cutaneous use

Name/corporate name of the PIP applicant:

Legacy Healthcare

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Legacy Healthcare submitted to the European Medicines Agency on 5 August 2016 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/0145/2016 issued on 23 May 2016.

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

The procedure started on 13 September 2016.

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 and to the deferral 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 alopecia

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- cutaneous solution, cutaneous use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition

Treatment of alopecia

2.1.1. Indication(s) targeted by the PIP

Treatment of alopecia areata in children and adolescents

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)

Cutaneous solution

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of a container (bottle) with child-proof closure.
Non-clinical studies	0	Not applicable.
Clinical studies	1	**Study 2** Double-blind, vehicle controlled, randomized, multi-centre study to evaluate the efficacy and safety of KEOC liquid extract ethanolic 30 per cent (w/w) of Allium cepa L. (fresh bulb) and Citrus lemon (L.) Burm. (fresh fruit) / Paullinia cupana Kunth / Theobroma cacao L. (CG210) cutaneous solution in children and adolescents with moderate to severe scalp alopecia areata.

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 February 2018
Deferral for one or more measures contained in the paediatric investigation plan:	No