EMA/392672/2019

European Medicines Agency decision

P/0269/2019

of 14 August 2019

on the acceptance of a modification of an agreed paediatric investigation plan for octenidine (dihydrochloride) (Laryngomedin Octenidin Antisept and associated names), (EMEA-001514-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/0093/2016 issued on 23 March 2016,

Having regard to the application submitted by Cassella-med GmbH & Co. KG on 14 March 2019 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 28 June 2019, 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 and to the waiver.

(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 and to the waiver.

[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 octenidine (dihydrochloride) (Laryngomedin Octenidin Antisept and associated names), lozenge, oral use, including changes to the deferral and to the waiver, 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 Cassella-med GmbH & Co. KG, Gereonsmühlengasse 1, 50670 - Cologne Germany.

EMA/PDCO/185594/2019
Amsterdam, 28 June 2019

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

EMEA-001514-PIP01-13-M01

Scope of the application

Active substance(s):

Octenidine (dihydrochloride)

Invented name:

Laryngomedin Octenidin Antisept and associated names

Condition(s):

Treatment of upper respiratory tract infections

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Lozenge

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Cassella-med GmbH & Co. KG

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Cassella-med GmbH & Co. KG submitted to the European Medicines Agency on 14 March 2019 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/0093/2016 issued on 23 March 2016.

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

The procedure started on 30 April 2019.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. A waiver for a new paediatric subset has been added.

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 and to the waiver 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 annexes 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 upper respiratory tract infections

The waiver applies to:

- the paediatric population from birth to less than 12 years of age;
- lozenge, 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 upper respiratory tract infections

2.1.1. Indication(s) targeted by the PIP

Treatment of sore-throat due to infectious pharyngitis

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

From 12 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Lozenge

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	*Study 1 deleted in procedure EMEA-001514-PIP01-13-M01.*
Non-clinical studies	0	Not applicable.
Clinical studies	1	**Study 2** Double-blind, randomised, parallel group, placebo- and active-controlled trial to evaluate the efficacy and safety of octenidine in children from 12 years to less than 18 years of age (and adults) with acute sore throat. (MCMK0112) *Study 3 deleted in procedure EMEA-001514-PIP01-13-M01.* *Study 4 deleted in procedure EMEA-001514-PIP01-13-M01.*

Area	Number of measures	Description
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:	Yes
Date of completion of the paediatric investigation plan:	By March 2015
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of upper respiratory tract infections

Authorised indication(s):

- Laryngomedin Octenidin Antisept is indicated for short term adjuvant treatment of inflammation of the mucosa of the mouth and throat with typical symptoms like pain, reddening and swelling, in adults and in adolescents from 12 years to less than 18 years of age.

Authorised pharmaceutical form(s):

Lozenge

Authorised route(s) of administration:

Oral use