



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/199478/2016

European Medicines Agency decision

P/0093/2016

of 23 March 2016

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for octenidine (dihydrochloride) (EMA-001514-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 726/2004¹,

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 Cassella-med GmbH & Co. KG on 5 August 2013 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 26 February 2016, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 of said Regulation,

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 and on the granting of a deferral and on the granting of a waiver.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting a deferral.
- (4) It is therefore appropriate to adopt a decision granting a 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

A paediatric investigation plan for octenidine (dihydrochloride), lozenge, 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

A deferral for octenidine (dihydrochloride), lozenge, 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 granted.

Article 3

A waiver for octenidine (dihydrochloride), lozenge, 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 granted.

Article 4

This decision is addressed to Cassella-med GmbH & Co. KG, Gereonsmühlengasse 1-11, 50670 – Cologne, Germany.

Done at London, 23 March 2016

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/839369/2015
London, 26 February 2016

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMA-001514-PIP01-13

Scope of the application

Active substance(s):

Octenidine (dihydrochloride)

Condition(s):

Treatment of upper respiratory tract infections

Pharmaceutical form(s):

Lozenge

Route(s) of administration:

Oral use

Name / corporate name of the PIP applicant:

Cassella-med GmbH & Co. KG

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Cassella-med GmbH & Co. KG submitted for agreement to the European Medicines Agency on 5 August 2013 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 4 January 2016.

Supplementary information was provided by the applicant on 7 December 2015. The applicant proposed modifications to the paediatric investigation plan.



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;
- to grant a deferral in accordance with Article 21 of said Regulation;
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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 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 upper respiratory tract infections

The waiver applies to:

- the paediatric population from birth to less than 6 years;
- 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 6 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	1	Study 1 Development of an age-appropriate oral solid dosage form (CAS-PAED-LOZ-01).
Non-clinical studies	0	Not applicable.
Clinical studies	3	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

Area	Number of measures	Description
		throat (MCMK0112). Study 3 Double-blind, randomised, single-dose, cross-over clinical study to assess taste and palatability of different paediatric pharmaceutical formulations of octenidine lozenge in healthy adults (CAS-TASTE-01). Study 4 Double-blind, randomised, two-arm, placebo-controlled, clinical trial to assess the efficacy and safety of octenidine in children from 6 years to less than 12 years of age with acute pharyngitis with or without indication for oral antibiotic treatment as concomitant medication (CAS-CHILD-01).
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 May 2018
Deferral for one or more measures contained in the paediatric investigation plan:	Yes