EMA/344600/2014

European Medicines Agency decision

P/0167/2014

of 8 July 2014

on the acceptance of a modification of an agreed paediatric investigation plan for ozenoxacin (EMEA-000981-PIP01-10-M04) 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 acceptance of a modification of an agreed paediatric investigation plan for ozenoxacin (EMEA-000981-PIP01-10-M04) 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 726/2004[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 decision P/35/2011 issued on 28 January 2011, the decision P/229/2011 issued on 28 September 2011, the decision P/0113/2012 issued on 29 June 2012, and the decision P/0267/2013 issued on 30 October 2013,

Having regard to the application submitted by Ferrer Internacional S.A. on 28 February 2014 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 23 May 2014, 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.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed 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

Changes to the agreed paediatric investigation plan for ozenoxacin, cream, cutaneous use, 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 Ferrer Internacional S.A., Avenida Diagonal 549, 5ª planta, 08029 - Barcelona,Spain.

Done at London, 8 July 2014

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

EMA/PDCO/128820/2014

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

EMEA-000981-PIP01-10-M04

Scope of the application

Active substance(s):

Ozenoxacin

Condition(s):

Treatment of impetigo

Pharmaceutical form(s):

Cream

Route(s) of administration:

Cutaneous use

Name/corporate name of the PIP applicant:

Ferrer Internacional S.A.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Ferrer Internacional S.A. submitted to the European Medicines Agency on 28 February 2014 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/35/2011 issued on 28 January 2011, the decision P/229/2011 issued on 28 September 2011, the decision P/0113/2012 issued on 29 June 2012, and the decision P/0267/2013 issued on 30 October 2013.

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

The procedure started on 25 March 2014.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

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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 in the scope set out in the Annex I of this opinion.

   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 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.

London, 23 May 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

1.1. Condition: treatment of impetigo

The waiver applies to:

- children from birth to less than 2 months of age;
- for cream, cutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

2. Paediatric Investigation Plan

2.1. Condition: treatment of impetigo

2.1.1. Indication(s) targeted by the PIP

Treatment of impetigo

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

From 2 months to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Cream

2.1.4. Measures

Area	Number of studies	Description
Quality related studies	1	1. Development of a cream with strength of 10mg/g (1%) cream.
Non-clinical studies	3	2. Study of the in vitro percutaneous absorption through juvenile minipig skin. 3. 2-week oral study to evaluate articular toxicity and general toxicity in juvenile dogs followed by a 2-week recovery period. 4. In vitro activity study of ozenoxacin and comparative antimicrobial agents used to treat uncomplicated and/or complicated skin and soft tissue infections (SSTI) caused by Gram-positive organisms.

Clinical studies	4	5. Multicentre, randomised, double-blind, parallel group, placebo-controlled dose-finding study comparing 3 different doses of ozenoxacin cream (0.25%, 1% or 2%) in adults. 6. Multiple dose, open label study to assess the systemic absorption of ozenoxacin 1% cream following repeated topical applications in children from 2 months to less than 18 years of age and adults with impetigo. 7. Multicentre, randomised, three-arm, evaluator blinded trial to evaluate the efficacy, safety and tolerability study of repeated applications of ozenoxacin 1% cream versus placebo in children from 2 years to less than 18 years and adults with impetigo, using retapamulin to asses internal validity. 8. Multicenter, randomized, placebo controlled, parallel, double blind, superiority clinical trial to evaluate the efficacy and evaluate the safety and tolerability of a twice daily topical application of ozenoxacin 1% cream for 5 days versus placebo in patients with impetigo.
Extrapolation, modelling & simulation studies		Not applicable.
Other studies		Not applicable.
Other measures		Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2015
Deferral for one or more studies contained in the paediatric investigation plan:	No