EMA/35658/2011

European Medicines Agency decision

P/35/2011

of 28 January 2011

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for ozenoxacin (EMA-000981-PIP01-10) 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 Ferrer Internacional, S.A on 12 April 2010 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 10 December 2010, 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 ozenoxacin, cream, cutaneous 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 ozenoxacin, cream, cutaneous 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 ozenoxacin, cream, cutaneous 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 Ferrer Internacional, S.A, Juan de Sada 32, 08028 Barcelona, Spain.

Done at London, 28 January 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director

(Signature on file)

EMA/PDCO/677632/2010

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

EMA-000981-PIP01-10

Scope of the application

Active substance(s):

Ozenoxacin

Condition(s):

Treatment of secondarily infected traumatic lesions (SITL)

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 16(1) of Regulation (EC) No 1901/2006 as amended, Ferrer Internacional, S.A submitted for agreement to the European Medicines Agency on 12 April 2010 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 20 May 2010.

Supplementary information was provided by the applicant on 4 October 2010.

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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,
   - 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 Icelandic and the Norwegian Paediatric Committee members do 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(es) and appendix.

London, 10 December 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, 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

1. Waiver

1.1. Condition: Treatment of secondarily infected traumatic lesions

The waiver applies to:

- children from birth to less than 1 year 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.

1.2. 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 secondarily infected traumatic lesions

2.1.1. Indication(s) targeted by the PIP

Treatment of secondarily infected traumatic lesions (SITL)

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

From 1 year to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Cream

2.1.4. Studies

Area	Number of studies	Description
Quality	Total number of quality studies	Choice of the final strength of the cream: between 2,5 mg/ml and 20 mg/ml
Non-clinical	Total number of studies	**Study 1:** In vitro percutaneous absorption study through excised skin from paediatric subjects. **Study 2:** 2-week oral study to evaluate articular toxicity and general toxicity in juvenile dogs followed by a 2-week recovery period. **Study 3:** 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	Total number of studies	**Study 4:** 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. **Study 5:** Multicentre, randomised, placebo controlled, parallel, blinded two-arm clinical study to assess the efficacy, safety and tolerability study of repeated applications of ozenoxacin cream, as compared to placebo in adults and children from 2 years to less than 18 years with secondarily infected traumatic lesions (SITL). **Study 6:** Multicentre, randomised, placebo-controlled, parallel, double-blind, clinical trial to assess the efficacy of a repeated application (twice daily for a week) of an ozenoxacin cream as compared to placebo in adults and children from 2 years to less than 18 years with secondarily infected traumatic lesions (SITL) **Study 7:** Multiple dose, open-label study to assess the systemic exposure of oxenoxacin 2% applied twice daily during 7 days in children from 1 year to less than 2 years of age with secondarily infected traumatic lesions (SITL)

2.2. Condition: Treatment of impetigo

2.2.1. Indication(s) targeted by the PIP

Treatment of impetigo

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

From 2 months to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Cream

2.2.4. Studies

Area	Number of studies	Description
Quality	Total number of quality studies	Choice of the final strength of the cream: between 2,5 mg/ml and 20 mg/ml
Non-clinical	Total number of studies	**Study 1:** In vitro percutaneous absorption study through excised skin from paediatric subjects. (same as for condition 2.1) **Study 2:** 2-week oral study to evaluate articular toxicity and general toxicity in juvenile dogs followed by a 2-week recovery period. (same as for condition 2.1) **Study 3:** 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 (same as for condition 2.1)
Study Clinical	Total number of studies	**Study 4:** 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.(same as for condition 2.1) **Study 8:** Multiple dose, open label study to assess the systemic absorption of ozenoxacin 2% cream following repeated topical applications in children from 2 to less than 18 years of age and adults with impetigo. **Study 9:** Multicentre, randomised, three-arm, evaluator blinded trial to evaluate the efficacy, safety and tolerability study of repeated applications of ozenoxacin cream (0.25%, 1% or 2%) versus retapamulin ointment 1% and placebo in children from 2 years to less than 18 years and adults with impetigo. **Study 10:** Open label, multiple dose study to assess the systemic exposure of ozenoxacin 2% following repeated topical applications in children from 2 months to less than 2 years of age with impetigo.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By February 2015
Deferral for one or more studies contained in the paediatric investigation plan:	Yes