EMA/646979/2012

European Medicines Agency decision

P/0265/2012

of 20 November 2012

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for levofloxacin (hemihydrate), (EMEA-001211-PIP01-11) 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 Mpex London Limited on 5 December 2011 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 5 October 2012, 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 levofloxacin (hemihydrate), inhalation solution, inhalation 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 levofloxacin (hemihydrate), inhalation solution, inhalation 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 levofloxacin (hemihydrate), inhalation solution, inhalation 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 Mpex London Limited, The Broadgate Tower, Third Floor, 20 Primrose Street, EC2A 2RS – London, United Kingdom.

Done at London, 20 November 2012

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

EMA/PDCO/491019/2012

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

EMEA-001211-PIP01-11

Scope of the application

Active substance(s):

Levofloxacin (hemihydrate)

Condition(s):

Treatment of cystic fibrosis

Pharmaceutical form(s):

Inhalation solution

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Mpex London Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Mpex London Limited submitted for agreement to the European Medicines Agency on 5 December 2011 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 12 January 2012.

Supplementary information was provided by the applicant on 2 July 2012. The applicant proposed modifications to the paediatric investigation plan.

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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 Norwegian Paediatric Committee member agrees 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, 5 October 2012

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 cystic fibrosis

The waiver applies to:

- infants from birth to less than 28 days of age;
- for inhalation solution, inhalation use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of cystic fibrosis

2.1.1. Indication(s) targeted by the PIP

Treatment of infection/colonisation with Pseudomonas aeruginosa and other bacteria in cystic fibrosis patients from 28 days and above.

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

From 28 days to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Inhalation solution.

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.

Area	Number of studies	Description
Clinical	6	**Study 1** Double-blind, randomised, multicentre, placebo-controlled trial to evaluate safety, tolerability and efficacy of 3 dosage regimens of levofloxacin (hemihydrate) in children from 16 to less than 18 years of age with cystic fibrosis (and in adults). **Study 2** Open-label, multicentre, uncontrolled trial to evaluate safety, tolerability and PK profile of levofloxacin (hemihydrate) administered in children from 6 to less than 17 years of age with cystic fibrosis. **Study 3** Double-blind, randomised, multicentre, placebo-controlled trial to evaluate efficacy and safety of levofloxacin (hemihydrate) in children from 12 to less than 18 years of age with cystic fibrosis (and in adults). **Study 4** Open-label, randomised, multicentre, active-controlled trial to evaluate efficacy and safety of levofloxacin (hemihydrate), administered over multiple cycles, in children from 12 to less than 18 years of age with cystic fibrosis (and in adults). **Study 5** Open-label, randomised, multicentre, active-controlled trial to evaluate efficacy and safety of levofloxacin (hemihydrate), administered over multiple cycles, in children from 5 to less than 12 years of age with cystic fibrosis. **Study 6** Open-label, multicentre, uncontrolled trial to evaluate activity and safety of levofloxacin (hemihydrate) in cystic fibrosis patients from 28 days to less than 18 years of age with early P. aeruginosa infections.

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 January 2019
Deferral for one or more studies contained in the paediatric investigation plan:	Yes