EMA/473134/2013

European Medicines Agency decision

P/0187/2013

of 8 August 2013

on the acceptance of a modification of an agreed paediatric investigation plan for Levofloxacin (hemihydrate) (EMEA-001211-PIP01-11-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/0265/2012 issued on 20 November 2012,

Having regard to the application submitted by Aptalis Pharma SAS on 29 April 2013 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 19 July 2013, 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 levofloxacin (hemihydrate), inhalation use, nebuliser solution, 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 Aptalis Pharma SAS, Route de Bû, 78550 – Houdan, France.

Done at London, 8 August 2013

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

EMA/PDCO/283527/2013

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

EMEA-001211-PIP01-11-M01

Scope of the application

Active substance(s):

Levofloxacin (hemihydrate)

Condition(s):

Treatment of cystic fibrosis

Pharmaceutical form(s):

Nebuliser solution

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Aptalis Pharma SAS

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Aptalis Pharma SAS submitted to the European Medicines Agency on 29 April 2013 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/0265/2012 issued on 20 November 2012.

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

The procedure started on 22 May 2013.

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 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 annex and appendix.

London, 19 July 2013

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

Waiver

1.1. Condition: treatment of cystic fibrosis

The waiver applies to:

- The paediatric population from birth to less than 28 days of age;
- for nebuliser solution, inhalation use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

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)

Nebuliser solution

2.1.4. Measures

Area	Number of measures	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	6	**Measure 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). **Measure 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.

Area	Number of measures	Description
		Measure 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). **Measure 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). **Measure 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. **Measure 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 measures contained in the paediatric investigation plan:	Yes