EMA/472033/2018

European Medicines Agency decision

P/0253/2018

of 15 August 2018

on the acceptance of a modification of an agreed paediatric investigation plan for ciprofloxacin (hydrochloride) (EMEA-001563-PIP02-15-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/0023/2017 issued on 13 February 2017,

Having regard to the application submitted by Aradigm Limited on 9 April 2018 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 29 June 2018, 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 ciprofloxacin (hydrochloride), nebuliser solution, inhalation 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 Aradigm Limited, 12 New Fetter Lane, EC4A 1JP - London, United Kingdom.

EMA/PDCO/237324/2018
London, 29 June 2018

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

EMEA-001563-PIP02-15-M01

Scope of the application

Active substance(s):

Ciprofloxacin (hydrochloride)

Condition(s):

Treatment of chronic pulmonary infections caused by *Pseudomonas aeruginosa*

Pharmaceutical form(s):

Nebuliser solution

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Aradigm Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Aradigm Limited submitted to the European Medicines Agency on 9 April 2018 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/0023/2017 issued on 13 February 2017.

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

The procedure started on 2 May 2018.

Scope of the modification

Some measures 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.

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 chronic pulmonary infections caused by *Pseudomonas aeruginosa*

The waiver applies to:

- the paediatric population from birth to less than 4 years;
- nebuliser solution, inhalation use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric investigation plan

2.1. Condition

Treatment of chronic pulmonary infections caused by *Pseudomonas aeruginosa*

2.1.1. Indication(s) targeted by the PIP

Treatment of cystic fibrosis related bronchiectasis associated with *Pseudomonas aeruginosa* infection

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

From 4 years 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-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	3	**Study 1** Safety, tolerability and PK study of Ciprofloxacin (hydrochloride) nebuliser solution in cystic fibrosis children from 4 to less than 18 years with chronic lung infections due to *Pseudomonas aeruginosa*

		Study 2 Randomised, active controlled, multicentre study to assess the efficacy, safety and tolerability of Ciprofloxacin (hydrochloride) nebuliser solution in cystic fibrosis (CF) patients from 4 to less than 18 years of age with chronic lung infection due to *Pseudomonas aeruginosa* **Study 3** Extension study of Ciprofloxacin (hydrochloride) nebuliser solution in CF patients with chronic *Pseudomonas aeruginosa* infection previously enrolled in Study 2
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:	No
Date of completion of the paediatric investigation plan:	By December 2024
Deferral for one or more measures contained in the paediatric investigation plan:	Yes