EMA/654063/2020

# European Medicines Agency decision

P/0511/2020

of 22 December 2020

on the acceptance of a modification of an agreed paediatric investigation plan for levofloxacin (hemihydrate) (EMEA-001211-PIP01-11-M02) 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 and the decision P/0187/2013 issued on 8 August 2013,

Having regard to the application submitted by Chiesi Farmaceutici S.p.A. on 22 July 2020 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 13 November 2020, 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 and to the deferral and to the waiver.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral and to the 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***

Changes to the agreed paediatric investigation plan for levofloxacin (hemihydrate), nebuliser solution, inhalation use, including changes to the deferral and to the waiver, 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 Chiesi Farmaceutici S.p.A., via Palermo 26/A, 43122 - Parma, Italy.

EMA/PDCO/443751/2020
Amsterdam, 13 November 2020

# Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan and on the granting of a product-specific waiver

EMEA-001211-PIP01-11-M02

## 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:**

Chiesi Farmaceutici S.p.A.

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Chiesi Farmaceutici S.p.A. submitted to the European Medicines Agency on 22 July 2020 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 and the decision P/0187/2013 issued on 8 August 2013.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral and changes to the waiver to cover the remaining subsets of the paediatric population.

The procedure started on 15 September 2020.

## Scope of the modification

The waiver has been extended to cover all subsets of the paediatric population.

## Opinion

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 and to the deferral and to amend the scope of the waiver in the scope set out in the Annex I of this opinion;
- to grant a product-specific waiver for all subsets of the paediatric population 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.

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 cystic fibrosis

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for nebuliser solution, inhalation use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

# Annex II

# Information about the authorised medicinal product

## Condition(s) and authorised indication(s):

1. Treatment of cystic fibrosis

Authorised indication(s):

- management of chronic pulmonary infections due to Pseudomonas aeruginosa in adult patients with cystic fibrosis

## Authorised pharmaceutical form(s):

Nebuliser solution

## Authorised route(s) of administration:

Inhalation use