

EMA/523782/2018

European Medicines Agency decision

P/0266/2018

of 14 August 2018

on the agreement of a paediatric investigation plan and on the granting of a deferral for cefiderocol (EMEA-002133-PIP01-17) 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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on the agreement of a paediatric investigation plan and on the granting of a deferral for cefiderocol (EMA-002133-PIP01-17) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Shionogi Limited on 20 March 2017 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 29 June 2018, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 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.
- (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.

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 cefiderocol, powder for solution for infusion, intravenous 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 cefiderocol, powder for solution for infusion, intravenous 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

This decision is addressed to Shionogi Limited, 5th floor, 33 Kingsway, Holborn, WC2B 6UF - London, United Kingdom.

EMA/PDCO/247009/2018

London, 29 June 2018

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

EMA-002133-PIP01-17

Scope of the application

Active substance(s):

Cefiderocol

Condition(s):

Treatment of infections due to aerobic Gram-negative bacteria

Pharmaceutical form(s):

Powder for solution for infusion

Route(s) of administration:

Intravenous use

Name / corporate name of the PIP applicant:

Shionogi Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Shionogi Limited submitted for agreement to the European Medicines Agency on 20 March 2017 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 25 April 2017.

Supplementary information was provided by the applicant on 6 April 2018. The applicant proposed modifications to the paediatric investigation plan.

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 17(1) of said Regulation;
- to grant a deferral in accordance with Article 21 of said Regulation.

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 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

Not applicable.

2. Paediatric investigation plan

2.1. Condition:

Treatment of infections due to aerobic Gram-negative bacteria

2.1.1. Indication(s) targeted by the PIP

Treatment of infections due to aerobic Gram-negative bacteria in children with limited therapeutic options

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder for solution for infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1: Generation of in-use stability data using water for injection, 5% dextrose and 0.45% sodium chloride injection as diluents for the powder for solution for infusion.
Non-clinical studies	1	Study 2: 3-week subcutaneous and intravenous toxicity study of cefiderocol in juvenile rats. (S-649266-TF-274-L)
Clinical studies	2	Study 3: Open-label, single-arm, uncontrolled trial to evaluate safety, tolerability and pharmacokinetics of single and multiple doses of cefiderocol in hospitalised paediatric patients from 3 months to less than 18 years of age with suspected or confirmed infections due to aerobic Gram-negative bacteria. Study 4: Open-label, single-arm, uncontrolled trial to evaluate safety, tolerability and pharmacokinetics of single and multiple doses of cefiderocol in hospitalised paediatric patients from birth to less than 3 months of age with suspected or confirmed infections due to aerobic Gram-negative bacteria.
Extrapolation, modelling and simulation studies	2	Study 5: Modelling and simulation study to evaluate the use of cefiderocol for the treatment of children from birth to less than 18 years of age with suspected or confirmed infections due to aerobic Gram-negative bacteria.

		Study 6: Extrapolation study to evaluate the use of cefiderocol for the treatment of children from birth to less than 18 years of age with suspected or confirmed infections due to aerobic Gram-negative bacteria.
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 March 2024
Deferral for one or more measures contained in the paediatric investigation plan:	Yes