EMA/207939/2022

# European Medicines Agency decision

P/0163/2022

of 13 May 2022

on the acceptance of a modification of an agreed paediatric investigation plan for cefiderocol (Fetcroja), (EMEA-002133-PIP01-17-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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0266/2018 issued on 14 August 2018 and the decision P/0382/2020 issued on 18 September 2020,

Having regard to the application submitted by Shionogi B.V. on 17 December 2021 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 25 March 2022, 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.

(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.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

***Article 1***

Changes to the agreed paediatric investigation plan for cefiderocol (Fetcroja), powder for concentrate for solution for infusion, intravenous use, including changes to the deferral, 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 Shionogi B.V., 33 Kingsway, Holborn, WC2B 6UF – London, United Kingdom.

EMA/PDCO/8222/2022
Amsterdam, 25 March 2022

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

EMEA-002133-PIP01-17-M02

## Scope of the application

**Active substance(s):**

Cefiderocol

**Invented name:**

Fetcroja

**Condition(s):**

Treatment of infections due to aerobic Gram-negative bacteria

**Authorised indication(s):**

See Annex II

**Pharmaceutical form(s):**

Powder for concentrate for solution for infusion

**Route(s) of administration:**

Intravenous use

**Name/corporate name of the PIP applicant:**

Shionogi B.V.

**Information about the authorised medicinal product:**

See Annex II

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Shionogi B.V. submitted to the European Medicines Agency on 17 December 2021 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0266/2018 issued on 14 August 2018 and the decision P/0382/2020 issued on 18 September 2020.

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

The procedure started on 31 January 2022.

## Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified. The term for the pharmaceutical form has been updated.

## 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 and to the deferral in the scope set out in the Annex I of this opinion.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the 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 annexes 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 concentrate for solution for infusion

### 2.1.4. Measures

| Area | Description |
|---|---|
| Quality-related studies | **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 concentrate for solution for infusion. |
| Non-clinical studies | **Study 2:** 3-week subcutaneous and intravenous toxicity study of cefiderocol in juvenile rats. (S-649266-TF-274-L) |
| Clinical studies | **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.<br><br>**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 | **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 | Not applicable. |
| Other measures | 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 |

# Annex II

# Information about the authorised medicinal product

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

1. Treatment of infections due to aerobic Gram-negative bacteria

Authorised indication(s):

- Fetcroja is indicated for the treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment options.

## Authorised pharmaceutical form(s):

Powder for concentrate for solution for infusion

## Authorised route(s) of administration:

Intravenous use