MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (EMEA-002133-PIP01-17-M01) and to the deferral

MHRA-101587-PIP01-24-M01

Scope of the Application

Active Substance(s)

CEFIDEROCOL SULFATE TOSYLATE

Condition(s)

Treatment of infections due to aerobic Gram-negative bacteria

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.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, SHIONOGI B.V. submitted to the licensing authority on 04/09/2024 16:54 BST an application for a Modification

The procedure started on 25/10/2024 09:26 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-101587-PIP01-24-M01

Of 22/11/2024 07:41 GMT

On the adopted decision for CEFIDEROCOL SULFATE TOSYLATE (MHRA-101587-PIP01-24-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for CEFIDEROCOL SULFATE TOSYLATE, Powder for concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to SHIONOGI B.V., Herengracht 464, Amsterdam, NETHERLANDS, 1017 CA

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of infections due to aerobic Gram-negative bacteria

2.2 Indication(s) targeted by the PIP:

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

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Powder for concentrate for solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	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 concentrate for solution for infusion.
Non-Clinical Studies	1	Study 2 (S-649266-TF-274-L) 3-week subcutaneous and intravenous toxicity study of cefiderocol in juvenile rats.
Clinical Studies	2	Study 3 (1802R2135) 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 (1904R2136) 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, Modeling & 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 a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	31/05/2026
Deferral of one or more studies contained in the paediatric investigation plan:	Yes