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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-102542-PIP01-26-M01

Scope of the Application

Active Substance(s)

CEFTOBIPROLE MEDOCARIL SODIUM

Condition(s)

Treatment of pneumonia

Pharmaceutical Form(s)

Powder for concentrate for solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

MERCURY PHARMACEUTICALS LIMITED

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, MERCURY PHARMACEUTICALS LIMITED submitted to the licensing authority on 01/07/2026 08:58 BST an application for a Modification

The procedure started on 07/07/2026 18:08 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-102542-PIP01-26-M01

Of 16/07/2026 09:28 BST

On the adopted decision for CEFTOBIPROLE MEDOCARIL SODIUM (MHRA-102542-PIP01-26-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 CEFTOBIPROLE MEDOCARIL SODIUM, Powder for concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to MERCURY PHARMACEUTICALS LIMITED, DASHWOOD HOUSE 69 OLD BROAD STREET, LONDON, UNITED KINGDOM, EC2M 1QS

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of pneumonia

2.2 Indication(s) targeted by the PIP:

Treatment of nosocomial pneumonia. Treatment of community-acquired pneumonia.

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 Development of age appropriate infusion solutions with concentrations higher than 2 mg ceftobiprole/mL for use in term and pre-term neonates.
Non-Clinical Studies	2	Study 2, TOX8087 Subcutaneous Pilot Toxicity Study with an Intravenous Comparative Phase. Study 3, TOX8611 Subcutaneous Toxicity Study in Neonatal and Juvenile Albino Rats.
Clinical Studies	4	Study 4 Multicentre, open-label, single-dose, pharmacokinetic and tolerability study in children 3 months to less than 18 years of age. Study 5, BPR-PIP-002 Multicentre, randomised, investigator-blind, active controlled study to evaluate the safety, tolerability, pharmacokinetics and efficacy of ceftobiprole versus intravenous standard of care cephalosporin treatment in paediatric patients aged from 3 months to less than 18 years with nosocomial pneumonia or community-acquired pneumonia. Study 6, BPR-PIP-001 Open-label study to evaluate the single-dose pharmacokinetics and safety of ceftobiprole in neonates and infants up to 3 months of age. Study 7, BPR-PIP-003 Multicentre, open label study to evaluate the safety, tolerability, pharmacokinetics and efficacy multiple doses of

		ceftobiprole in term and pre-term neonates and infants up to 3 months of age with late-onset sepsis.
Extrapolation, Modeling & Simulation Studies	0	Not applicable
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:	31/12/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes