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-100907-PIP01-23-M01

Scope of the Application

Active Substance(s)

CEFTOLOZANE; TAZOBACTAM

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

Merck Sharp & Dohme (UK) Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Merck Sharp & Dohme (UK) Limited submitted to the licensing authority on 25/02/2023 15:17 GMT an application for a Modification

The procedure started on 21/06/2023 09:40 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-100907-PIP01-23-M01

Of 21/07/2023 08:24 BST

On the adopted decision for CEFTOLOZANE; TAZOBACTAM (MHRA-100907-PIP01-23-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 CEFTOLOZANE; TAZOBACTAM, Powder for concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to Merck Sharp & Dohme (UK) Limited , 120 Moorgate , London, UNITED KINGDOM, EC2M 6UR

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

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	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 1 (P036) Open-label, multiple-dose, non-comparative trial to evaluate safety, tolerability and pharmacokinetics of ceftolozane / tazobactam in children from birth to less than 18 years of age with nosocomial pneumonia.
Extrapolation, Modeling & Simulation Studies	2	Study 2 Modelling and simulation study to derive dosing of ceftolozane / tazobactam for use in children from birth to less than 18 years of age with nosocomial pneumonia. Study 3 Extrapolation study to evaluate ceftolozane / tazobactam for use in children from birth to less than 18 years of age with nosocomial pneumonia.
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