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

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-101712-PIP01-24

Scope of the Application

Active Substance(s)

Tebipenem pivoxil (as the hydrobromide salt)

Condition(s)

Treatment of urinary tract infection

Pharmaceutical Form(s)

Film-coated tablet; Age-appropriate oral dosage form

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

GLAXOSMITHKLINE UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, GLAXOSMITHKLINE UK Limited submitted to the licensing authority on 13/12/2024 17:02 GMT an application for a Paediatric Investigation Plan

The procedure started on 21/01/2025 12:40 GMT

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 agree a paediatric investigation plan and grant a deferral and grant a waiver

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-101712-PIP01-24

Of 16/10/2025 07:14 BST

On the adopted decision for Tebipenem pivoxil (as the hydrobromide salt) (MHRA-101712-PIP01-24) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for Tebipenem pivoxil (as the hydrobromide salt), Film-coated tablet; Age-appropriate oral dosage form. , ORAL USE .

This decision is addressed to GLAXOSMITHKLINE UK Limited, 79 New Oxford Street, London, UNITED KINGDOM, WC1A 1DG

ANNEX I

1. Waiver

1.1 Condition:

Treatment of urinary tract infection. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 28 days Pharmaceutical form(s): Film-coated tablet Age appropriate oral dosage form Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of urinary tract infection.

2.2 Indication(s) targeted by the PIP:

Treatment of complicated urinary tract infections including acute pyelonephritis.

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

The paediatric population from 28 days to less than 18 years of age

2.4 Pharmaceutical Form(s):

Film-coated tablet Age-appropriate oral dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of age-appropriate orally dosage form for use in children from 28 days to less than 12 years age.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 Open-label, single-arm trial to evaluate pharmacokinetics and safety and support the extrapolation of efficacy of tebipenem pivoxil from adults in children from 28 days to less than 18 years of age with complicated urinary tract infections including acute pyelonephritis.
Extrapolation, Modeling & Simulation Studies	2	Study 3 Population PK (PopPK) analysis to determine the initial paediatric doses for children from 28 days to less than 18 years of age in Study 2 that provide systemic exposures equivalent to that observed in adults to ensure adequate probability of target attainment (PTA). Extrapolation plan Studies 2 and 3 are part of the extrapolation plan supporting the extrapolation of efficacy from adults for the treatment of urinary tract infections to children 28 days to less than 18 years of age by exposure-matching.
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:	30/11/2031
Deferral of one or more studies contained in the paediatric investigation plan:	Yes