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 and to the deferral

MHRA-100078-PIP01-21-M01

Scope of the Application

Active Substance(s)

AZTREONAM; AVIBACTAM

Condition(s)

Treatment of infections caused by 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

Pfizer Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Pfizer Limited submitted to the licensing authority on 22/04/2021 13:34 BST an application for a Modification

The procedure started on 06/12/2021 16:16 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 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-100078-PIP01-21-M01

Of 08/12/2021 10:23 GMT

On the adopted decision for AZTREONAM; AVIBACTAM (MHRA-100078-PIP01-21-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 AZTREONAM; AVIBACTAM, Powder for concentrate for solution for infusion , Intravenous use .

This decision is addressed to Pfizer Limited, Ramsgate Road, Sandwich, Kent, United Kingdom, CT139NJ

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of infections caused by aerobic gram-negative bacteria

2.2 Indication(s) targeted by the PIP:

Treatment of infections caused by aerobic gram-negative bacteria in patients with limited therapeutic options

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

All subsets of 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 formulation(s) for parental use or fixed-dosed combination (FDC) of ATM/AVI at a ratio to be determined based on study 4 and study 5 in paediatric patients from birth to less than 18 years of age.
Non-Clinical Studies	0	Not applicable
Clinical Studies	2	Study 2 (C3601008) A randomised, open-label (with a blinded observer), active-comparator study of IV ATM/AVI in patients from 9 months of age to less than 18 years of age who are hospitalised due to complicated urinary tract infection (cUTI), complicated intra-abdominal infection (cIAI), hospital-acquired bacterial pneumonia (HABP)/ ventilator associated bacterial pneumonia (VABP), blood stream infections (BSI), or sepsis caused (confirmed or suspected) by gram-negative organisms Study 3 (C3601010) An open-label, single arm, two-part study (Part A – single dose PK and Part B – multiple dose) study of IV ATM/AVI in patients from birth to less than 9 months of age who are hospitalised due to cUTI, cIAI, HABP/VABP, BSI, or sepsis caused (confirmed or suspected) by gram-negative organisms.
Extrapolation, Modeling & Simulation Studies	2	Study 4 Population PK-PD modelling and simulation study to evaluate the PK-PD relationship of IV ATM/AVI in paediatric patients from 9 months

		to less than 18 years of age. Study 5 Population PK-PD modelling and simulation study to evaluate the PK-PD relationship of IV ATM/AVI in paediatric patients from birth to less than 9 months of age.
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:	Yes
Date of completion of the paediatric investigation plan:	29/02/2028
Deferral of one or more studies contained in the paediatric investigation plan:	Yes