

EMA/31839/2021

European Medicines Agency decision P/0028/2021

of 29 January 2021

on the acceptance of a modification of an agreed paediatric investigation plan for aztreonam (ATM)/avibactam (AVI) (EMA-002283-PIP01-17-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004¹,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency²,

Having regard to the European Medicines Agency's decision P/0022/2020 issued on 6 January 2020,

Having regard to the application submitted by Pfizer Europe MA EEIG on 8 September 2020 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 December 2020, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

- (1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for aztreonam (ATM)/ avibactam (AVI), powder for concentrate for solution for infusion, intravenous use, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 - Bruxelles, Belgium.

EMA/PDCO/514762/2020
Amsterdam, 11 December 2020

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-002283-PIP01-17-M01

Scope of the application

Active substance(s):

Aztreonam (ATM)/ avibactam (AVI)

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 Europe MA EEIG

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Pfizer Europe MA EEIG submitted to the European Medicines Agency on 8 September 2020 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0022/2020 issued on 6 January 2020.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 13 October 2020.

Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:
 - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

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

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

Not applicable

1. Paediatric investigation plan

1.1. Condition:

Treatment of infections caused by aerobic gram-negative bacteria

1.1.1. Indication(s) targeted by the PIP

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

1.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age

1.1.3. Pharmaceutical form(s)

Powder for concentrate for solution for infusion

1.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1 Development of age-appropriate formulation(s) for parenteral use of 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	Not applicable	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)

Area	Number of measures	Description
		An open-label, single arm, two-part (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, modelling and 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 of age 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	Not applicable	Not applicable
Other measures	Not applicable	Not applicable

2. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By February 2028
Deferral for one or more measures contained in the paediatric investigation plan:	Yes