EMA/471941/2021

European Medicines Agency decision

P/0350/2021

of 8 September 2021

on the acceptance of a modification of an agreed paediatric investigation plan for aztreonam (ATM)/ avibactam (AVI), (EMEA-002283-PIP01-17-M02) 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

European Medicines Agency decision

P/0350/2021

of 8 September 2021

on the acceptance of a modification of an agreed paediatric investigation plan for aztreonam (ATM)/ avibactam (AVI) , (EMEA-002283-PIP01-17-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 726/2004[1],

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 Agency[2],

Having regard to the European Medicines Agency's decision P/0022/2020 issued on 6 January 2020 and the decision P/0028/2021 issued on 29 January 2021,

Having regard to the application submitted by Pfizer Europe MA EEIG on 15 April 2021 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 23 July 2021, 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.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[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, 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/252755/2021
Amsterdam, 23 July 2021

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-002283-PIP01-17-M02

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 15 April 2021 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 and the decision P/0028/2021 issued on 29 January 2021.

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

The procedure started on 25 May 2021.

Scope of the modification

Some measures 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 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

2. Paediatric investigation plan

2.1. Condition:

Treatment of infections caused by aerobic gram-negative bacteria

2.1.1. Indication(s) targeted by the PIP

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

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder for concentrate for solution for infusion

2.1.4. 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) 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

3. 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