EMA/381903/2018

European Medicines Agency decision

P/0176/2018

of 15 June 2018

on the acceptance of a modification of an agreed paediatric investigation plan for ceftaroline fosamil (Zinforo), (EMEA-000769-PIP01-09-M08) 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 726/2004[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/158/2010 issued on 6 September 2010, the decision P/256/2011 issued on 26 October 2011, the decision P/0072/2012 issued on 24 April 2012, the decision P/0006/2013 issued on 21 January 2013, the decision P/0074/2014 issued on 2 April 2014, P/0301/2015 issued on 21 December 2015, the decision P/0355/2016 issued on 21 December 2016 and the decision P/0013/2018 issued on 30 January 2018,

Having regard to the application submitted by Pfizer Limited on 5 February 2018 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 27 April 2018, 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 ceftaroline fosamil (Zinforo), 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 Limitedm Ramsgate Road, Sandwich, Kent, CT13 9NJ – Sandwich, United Kingdom.

EMA/PDCO/85912/2018
London, 27 April 2018

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

EMEA-000769-PIP01-09-M08

Scope of the application

Active substance(s):

Ceftaroline fosamil

Invented name:

Zinforo

Condition(s):

Treatment of complicated skin and soft tissue infections

Treatment of community acquired pneumonia

Authorised indication(s):

See Annex II

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

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Pfizer Limited submitted to the European Medicines Agency on 5 February 2018 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/158/2010 issued on 6 September 2010, the decision P/256/2011 issued on 26 October 2011, the decision P/0072/2012 issued on 24 April 2012, the decision P/0006/2013 issued on 21 January 2013, the decision P/0074/2014 issued on 2 April 2014, P/0301/2015 issued on 21 December 2015, the decision P/0355/2016 issued on 21 December 2016 and the decision P/0013/2018 issued on 30 January 2018.

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

The procedure started on 27 February 2018.

Scope of the modification

Some measures and 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 annexes 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 complicated skin and soft tissue infections

2.1.1. Indication(s) targeted by the PIP

Treatment of complicated skin and soft tissue infections

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 studies	Description
Quality	0	Not applicable
Non-clinical	1	**Study 1** Repeated dose toxicity study in juvenile rats.
Clinical	3	**Study 2 (P903-21 / D3720C00006)** Multicentre, open-label, sequential, single-dose pharmacokinetic and tolerability study of ceftaroline in paediatric patients from birth to less than 12 years of age, with suspected or confirmed infection. **Study 3 (P903-23 / D3720C00004)** Multicentre, randomised, observer-blinded, active controlled study to evaluate the safety, tolerability, pharmacokinetics and efficacy of ceftaroline versus vancomycin or semi synthetic penicillin with or without aztreonam in paediatric patients with complicated skin and soft tissue infections from 2 months of age to less than 18 years. **Study 4 (C2661002 / D3720C00009 / P903-26)** Multicentre, open label study to evaluate the safety, tolerability, pharmacokinetics and efficacy of ceftaroline plus ampicillin plus optional aminoglycoside in term and pre-term neonates and young infants less than 2 months of age with late onset sepsis.

		Study 6 *deleted in procedure EMEA-000769-PIP01-09-M08*
Extrapolation, modelling and simulation studies	1	**Study 7** *added in procedure EMEA-000769-PIP01-09-M08* Population PK-PD modelling and extrapolation study of the pharmacokinetic (PK) exposure, clinical efficacy and safety data of high-dose ceftaroline fosamil.

2.2. Condition

Treatment of community acquired pneumonia

2.2.1. Indication(s) targeted by the PIP

Treatment of community acquired pneumonia

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

From birth to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Powder for concentrate for solution for infusion

2.2.4. Measures

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	1	**Study 1** Repeated dose toxicity study in juvenile rats (same as study 1 for condition 1).
Clinical	3	**Study 2 (P903-21 / D3720C00006)** Multicentre, open-label, sequential, single-dose pharmacokinetic and tolerability study of ceftaroline in paediatric patients from birth to less than 12 years of age with suspected or confirmed infection (same as study 2 for condition 1) **Study 4 (C2661002 / D3720C00009 / P903-26)** Multicentre, open label study to evaluate the safety, tolerability, pharmacokinetics and efficacy of ceftaroline plus ampicillin plus optional aminoglycoside in term and pre-term neonates and young infants less than 2 months of age with late onset sepsis (same as study 4 for condition 1).

		Study 5 (D3720C00007 / P903-31) Multicentre, randomised, observer-blinded, active controlled study to evaluate the safety, tolerability, pharmacokinetics and efficacy of ceftaroline versus ceftriaxone in paediatric patients from 2 months of age to less than 18 years of age with community acquired pneumonia.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By July2018
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of complicated skin and soft tissue infections

Authorised indication(s):

- Treatment of complicated skin and soft tissue infections (cSSTI) in adults and children from the age of 2 months.

2. Treatment of community acquired pneumonia

Authorised indication(s):

- Treatment of community acquired pneumonia (CAP) in adults and children from the age of 2 months

Authorised pharmaceutical form(s):

Powder for concentrate for solution for infusion

Authorised route(s) of administration:

Intravenous use