EMA/829145/2011

European Medicines Agency decision

P/256/2011

of 26 October 2011

on the acceptance of a modification of an agreed paediatric investigation plan for ceftaroline fosamil (EMEA-000769-PIP01-09-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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on the acceptance of a modification of an agreed paediatric investigation plan for ceftaroline fosamil (EMEA-000769-PIP01-09-M01) 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/158/2010 issued on 6 September 2010,

Having regard to the application submitted by AstraZeneca AB on 29 June 2011 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 9 September 2011, 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 ceftaroline fosamil, 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 AstraZeneca AB, SE-151 85 – Sodertalje, Sweden.

Done at London, 26 October 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/611170/2011

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

EMEA-000769-PIP01-09-M01

Scope of the application

Active substance(s):

Ceftaroline fosamil

Condition(s):

Treatment of complicated skin and soft tissue infections

Treatment of community acquired pneumonia

Pharmaceutical form(s):

Powder for concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

AstraZeneca AB

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted to the European Medicines Agency on 29 June 2011 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 application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 13 July 2011.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

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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 Icelandic and the Norwegian Paediatric Committee members agree 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(es) and appendix.

London, 9 September 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

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. Studies

Area	Number of studies	Description
Quality	1	Study 1: Appropriate paediatric dose vial to be developed.
Non-clinical	1	Study 2: Repeated dose toxicity study in juvenile rats.
Clinical	3	Study 3: Multicenter, 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 4: Multicenter, randomised, investigator-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 28 days of age to less than 18 years. Study 5: Multicenter, open label study to evaluate the safety, tolerability, pharmacokinetics and efficacy of ceftaroline plus ampicillin plus optional aminoglycoside in term and pre-term neonates with late onset sepsis.

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. Studies

Area	Number of studies	Description
Quality	1	Study 1: Appropriate paediatric dose vial to be developed *(same as study 1 for condition 1).*
Non-clinical	1	Study 2: Repeated dose toxicity study in juvenile rats *(same as study 2 for condition 1).*
Clinical	3	Study 3: Multicenter, 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 3 for condition 1).* Study 5: Multicenter, open label study to evaluate the safety, tolerability, pharmacokinetics and efficacy of ceftaroline plus ampicillin plus optional aminoglycoside in term and pre-term neonates with late onset sepsis *(same as study 5 for condition 1).* Study 6: Multicenter, randomised, investigator-blinded, active controlled study to evaluate the safety, tolerability, pharmacokinetics and efficacy of ceftaroline versus ceftriaxone in paediatric patients from 28 days 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 March 2017
Deferral for one or more studies contained in the paediatric investigation plan:	Yes