EMA/559070/2010

European Medicines Agency decision

P/158/2010

of 6 September 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral for ceftaroline fosamil, (EMEA-000769-PIP01-09) 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 application submitted by AstraZeneca AB on 16 November 2009 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 July 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a 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

A paediatric investigation plan for ceftaroline fosamil, powder for concentrate for solution for infusion, intravenous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for ceftaroline fosamil, powder for concentrate for solution for infusion, intravenous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to AstraZeneca AB, SE-151 85 Sodertalje, Sweden.

Done at London, 6 September 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/309589/2010

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMEA-000769-PIP01-09

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 16(1) of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted for agreement to the European Medicines Agency on 16 November 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 23 December 2009.

Supplementary information was provided by the applicant on 21 April 2010.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
   - to grant a deferral in accordance with Article 21 of said Regulation,

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

2. The measures and timelines of the agreed 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, 16 July 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

The measures and timelines of the agreed Paediatric Investigation Plan

1. Condition(s)

Treatment of complicated skin and soft tissues infections

Treatment of community-acquired pneumonia

2. Waiver

Not applicable

3. Paediatric Investigation Plan

3.1. Condition 1- Complicated skin and soft tissue infections

3.1.1. Indication targeted by the PIP

Treatment of complicated skin and soft tissue infections.

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

From birth to less than 18 years of age.

3.1.3. Pharmaceutical form(s)

Powder for concentrate for solution for infusion (intravenous use).

3.1.4. 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 systemic 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

3.2. Condition 2 – Community-acquired pneumonia

3.2.1. Indication targeted by the PIP

Treatment of community- acquired pneumonia.

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

From birth to less than 18 years of age.

3.2.3. Pharmaceutical form(s)

Powder for concentrate for solution for infusion (intravenous use).

3.2.4. 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 systemic 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, pharmacokintics and efficacy of ceftaroline versus ceftriaxone in paediatric patients from 28 days to less than 18 years of age with community acquired pneumonia

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues, efficacy 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