EMA/202542/2013

European Medicines Agency decision

P/0083/2013

of 26 April 2013

on the agreement of a paediatric investigation plan and on the granting of a deferral for ceftazidime / avibactam (EMEA-001313-PIP01-12) 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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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 31 May 2012 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 15 March 2013, 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 ceftazidime / avibactam, 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 ceftazidime / avibactam, 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, European Regulatory Affairs, Building 411A, Floor 4,

S-151 85 – Sodertalje, Sweden.

Done at London, 26 April 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/202542/2013

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

EMEA-001313-PIP01-12

Scope of the application

Active substance(s):

Ceftazidime / Avibactam

Condition(s):

Treatment of intra-abdominal infections

Treatment of urinary tract infections

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 31 May 2012 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 11 July 2012.

Supplementary information was provided by the applicant on 14 December 2012. The applicant proposed modifications to the paediatric investigation plan.

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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, 15 March 2013

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 intra-abdominal infections

2.1.1. Indication(s) targeted by the PIP

Treatment of complicated intra-abdominal infections (cIAIs)

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	1	Measure 1 Development of an age-appropriate powder for concentrate for solution for infusion of ceftazidime and avibactam in a single vial.
Non-clinical	1	Measure 2 14-day repeat dose toxicity study in juvenile rats.
Clinical	3	Measure 3 – Study D4280C00014 Open-label, single dose trial to evaluate pharmacokinetics, safety and tolerability of ceftazidime and avibactam in children from 3 months to less than 18 years of age with suspected or confirmed bacterial infection and receiving other systemic antibiotic therapy. Measure 4 – Study D4280C00015 Single blind, randomised, multicentre, active controlled, trial to evaluate safety, tolerability and efficacy of ceftazidime and avibactam in children from 3 months to less than 18 years of age with complicated intra-abdominal infections (cIAIs). Measure 6 - Study D4280C00017 Open-label, single dose trial to evaluate pharmacokinetics, safety and tolerability of ceftazidime and avibactam in children from birth to less than 3 months of age with late onset sepsis.

2.2. Condition: Treatment of urinary tract infections

2.2.1. Indication(s) targeted by the PIP

Treatment of complicated urinary tract infections (cUTIs)

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 measures	Description
Quality	1	Measure 1 Same as Condition: Treatment of intra-abdominal infections
Non-clinical	1	Measure 2 Same as Condition: Treatment of intra-abdominal infections
Clinical	3	Measure 3 – Study D4280C00014 Same as Condition: Treatment of intra-abdominal infections Measure 5 - Study D4280C00016 Single blind, randomised, multicentre, active controlled, trial to evaluate safety, tolerability and efficacy of ceftazidime and avibactam in children from 3 months to less than 18 years of age with complicated urinary tract infections (cUTI). Measure 6 - Study D4280C00017 Same as Condition: Treatment of intra-abdominal infections

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 2019.
Deferral for one or more measures contained in the paediatric investigation plan:	Yes.