EMA/187330/2014

European Medicines Agency decision

P/0126/2014

of 16 May 2014

on the acceptance of a modification of an agreed paediatric investigation plan for ceftolozane / tazobactam (EMEA-001142-PIP01-11-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.

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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on the acceptance of a modification of an agreed paediatric investigation plan for ceftolozane / tazobactam (EMEA-001142-PIP01-11-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/0280/2012 issued on 21 November 2012,

Having regard to the application submitted by Cubist Pharmaceuticals (UK) Ltd on 25 March 2014 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 25 April 2014, 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 ceftolozane / tazobactam, powder 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 Cubist Pharmaceuticals (UK) Limited, 2nd Floor, Waverley House, 7-12 Noel House, W1F 8GQ - London, United Kingdom.

Done at London, 16 May 2014

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

EMA/PDCO/187333/2014

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

EMEA-001142-PIP01-11-M01

Scope of the application

Active substance(s):

Ceftolozane / tazobactam

Condition(s):

Treatment of urinary tract infections

Treatment of abdominal and gastrointestinal infections

Pharmaceutical form(s):

Powder for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Cubist Pharmaceuticals (UK) Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Cubist Pharmaceuticals (UK) Ltd submitted to the European Medicines Agency on 25 March 2014 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0280/2012 issued on 21 November 2012.

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

The procedure started on 23 April 2014.

Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified.

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E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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.

London, 25 April 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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 (PIP)

1. Waiver

Not applicable.

2. Paediatric Investigation Plan

2.1. Condition: treatment of urinary tract infections

2.1.1. Indication(s) targeted by the PIP

Treatment of complicated urinary tract infections (cUTI).

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 solution for infusion.

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	3	**Study 1** Single dose pharmacokinetic study in juvenile rats. **Study 2** 14-day dose ranging toxicity study in juvenile rats. **Study 3** 28-day toxicity study in juvenile rats.
Clinical studies	2	**Study 4** Open-label, single dose trial to evaluate pharmacokinetics of ceftolozane / tazobactam in children from birth to less than 18 years of age with proven or suspected Gram-negative infection receiving standard antibiotic therapy. **Study 5** Double blind, randomised, active controlled trial to evaluate safety, tolerability and efficacy of ceftolozane / tazobactam in children from birth to less than 18 years of age with complicated urinary tract infection (cUTI).

Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

2.2. Condition: treatment of abdominal and gastrointestinal infections

2.2.1. Indication(s) targeted by the PIP

Treatment of complicated intra-abdominal infections (cIAI).

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 solution for infusion.

2.2.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	3	**Study 1** Single dose pharmacokinetic study in juvenile rats. (Same study as for condition 'Treatment of urinary tract infections') **Study 2** 14-day dose ranging toxicity study in juvenile rats. (Same study as for condition 'Treatment of urinary tract infections') **Study 3** 28-day toxicity study in juvenile rats. (Same study as for condition 'Treatment of urinary tract infections')
Clinical studies	2	**Study 4** Open-label, single dose trial to evaluate pharmacokinetics of ceftolozane / tazobactam in children from birth to less than 18 years of age with proven or suspected Gram-negative infection receiving standard antibiotic therapy. (Same study as for condition 'Treatment of urinary tract infections')

		Study 6 Double blind, randomised, active controlled trial to evaluate safety, tolerability and efficacy of ceftolozane / tazobactam in children from birth to less than 18 years of age with complicated intra-abdominal infection (cIAI).
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No.
Date of completion of the paediatric investigation plan:	By June 2021.
Deferral for one or more studies contained in the paediatric investigation plan:	Yes.