



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/206620/2013

European Medicines Agency decision

P/0087/2013

of 29 April 2013

on the acceptance of a modification of an agreed paediatric investigation plan for ceftobiprole medocaril (sodium) (EMA-000205-PIP01-08-M02) 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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/9/2009 issued on 27 January 2009, and the decision P/0212/2012 issued on 28 September 2012,

Having regard to the application submitted by Basilea Pharmaceutica International Ltd. on 6 December 2012 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 15 March 2013, 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 ceftobiprole medocartil (sodium), 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 Basilea Pharmaceutica International Ltd., 487 Grenzacherstrasse, 4005 – Basel, Switzerland.

Done at London, 29 April 2013

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/805901/2012

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

EMA-000205-PIP01-08-M02

Scope of the application

Active substance(s):

Ceftobiprole medocaril (sodium)

Condition(s):

Treatment of complicated skin and soft tissue infections

Pharmaceutical form(s):

Powder for solution for infusion

Route(s) of administration:

Intravenous use

Name / corporate name of the PIP applicant:

Basilea Pharmaceutica International Ltd.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Basilea Pharmaceutica International Ltd. submitted to the European Medicines Agency on 6 December 2012 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/9/2009 issued on 27 January 2009, and the decision P/0212/2012 issued on 28 September 2012.

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

The procedure started on 16 January 2013.

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 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, 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 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

All subsets of the paediatric population 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	1	1. Development of age appropriate infusion solutions with concentrations higher than 2 mg ceftobiprole/mL for use in term and pre-term neonates.
Non-clinical	2	2. Subcutaneous Pilot Toxicity Study with an Intravenous Comparative Phase (TOX8087) 3. Subcutaneous Toxicity Study in Neonatal and Juvenile Albino Rats (TOX8611)
Clinical	4	4. Multicentre, open-label, single-dose, pharmacokinetic and tolerability study in children 3 months to less than 18 years of age 5. Multicentre randomised, investigator-blinded, comparative safety and efficacy study in children 3 months to less than 18 years of age with complicated skin and soft tissue infections 6. Open-label study to evaluate the single-dose pharmacokinetics and safety of ceftobiprole in neonates and infants up to 3 months of age. 7. Multicentre, open label study to evaluate the safety, tolerability, pharmacokinetics and efficacy multiple doses of ceftobiprole in term and pre-term neonates and infants up to 3 months of age with late-onset sepsis.

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