European Medicines Agency

Doc. Ref. EMEA/23291/2009
P/9/2009

EUROPEAN MEDICINES AGENCY DECISION

of 27 January 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral for ceftobiprole medocaril sodium (EMEA-000205-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 70
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

EUROPEAN MEDICINES AGENCY DECISION

of 27 January 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral for ceftobiprole medocaril sodium (EMEA-000205-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 Janssen-Cilag International N.V. on 4 April 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended 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 12 December 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 21 of said Regulation**,**

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended.

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 granting 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 ceftobiprole medocaril sodium, powder 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 ceftobiprole medocaril sodium, powder 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 Janssen-Cilag International N.V., Turnhoutseweg 30, Beerse , B-2340, Belgium.

Done at London, 27 January 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDCO/638021/2008
EMEA-000205-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL

Scope of the application

Active substance:
Ceftobiprole medocaril sodium

Condition(s):
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:
Janssen-Cilag International N.V.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Janssen-Cilag International N.V. submitted for agreement to the EMEA on 4 April 2008 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 8 May 2008.

Supplementary information was provided by the applicant on 12 September 2008.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 40
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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 Icelandic and the Norwegian Paediatric Committee members agree 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 Agency, together with its annex and appendix.

London, 12 December 2008

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

A. CONDITION(S)

Complicated skin and soft tissue infections

B. WAIVER

Not applicable

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

  Complicated skin and soft tissue infections

- **Proposed PIP indication**

  Complicated skin and soft tissue infections

- **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

- **Formulation(s)**

  Powder for solution for infusion, intravenous use

- **Studies**

Area	Number of studies	Description
Non-clinical	2	Juvenile toxicity study in rats
Clinical	1	Multicentre, open-label, single-dose, pharmacokinetic and tolerability study in children 3 months to less than 18 years of age
	1	Multicentre randomised, investigator-blinded, comparative safety and efficacy study in children with complicated skin and soft tissue infections
	1	Pharmacokinetic, safety and tolerability study in neonates and infants less than 3 months

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	**By December 2012**
Deferral for initiation of some or all studies contained in the paediatric investigation plan:	**Yes**
Deferral for completion of some or all studies contained in the paediatric investigation plan:	**Yes**