EMA/202883/2012

# European Medicines Agency decision

P/0071/2012

of 24 April 2012

on the acceptance of a modification of an agreed paediatric investigation plan for doripenem (monohydrate) (Doribax), (EMEA-000015-PIP01-07-M04) 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 European Medicines Agency's decision P/14/2008 issued on 31 March 2008, the decision P/151/2009 issued on 7 August 2009, the decision P/192/2010 issued on 26 October 2010 and the decision P/261/2011 issued on 28 October 2011,

Having regard to the application submitted by Janssen-Cilag International NV on 15 December 2011 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 9 March 2012, 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 doripenem (monohydrate) (Doribax), 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 Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 - Beerse, Belgium.

Done at London, 24 April 2012

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

EMA/PDCO/982132/2011

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

EMEA-000015-PIP01-07-M04

## Scope of the application

**Active substance(s):**

Doripenem (monohydrate)

**Invented name:**

Doribax

**Condition(s):**

Treatment of bacterial infections

**Authorised indication(s):**

See Annex II

**Pharmaceutical form(s):**

Powder for solution for infusion

**Route(s) of administration:**

Intravenous use

**Name/corporate name of the PIP applicant:**

Janssen-Cilag International NV

**Information about the authorised medicinal product:**

See Annex II

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## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Janssen-Cilag International NV submitted to the European Medicines Agency on 15 December 2011 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/14/2008 issued on 31 March 2008, the decision P/151/2009 issued on 7 August 2009, the decision P/192/2010 issued on 26 October 2010 and the decision P/261/2011 issued on 28 October 2011.

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

The procedure started on 12 January 2012.

## Scope of the modification

The timeline and details of studies 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 annexes and appendix.

London, 9 March 2012

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 bacterial infections.

### 2.1.1. Indication(s) targeted by the PIP

- Treatment of nosocomial pneumonia, including ventilator-associated pneumonia.
- Treatment of complicated intra-abdominal infections.
- Treatment of complicated urinary tract infections, including complicated and uncomplicated pyelonephritis and cases with concurrent bacteraemia.

### 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. Studies

| Area | Number | Description |
|---|---|---|
| Quality | 1 | Study 1: Development of a 10 mg/ml infusion solution |
| Non-clinical | 0 | Not applicable |
| Clinical | 6 | Study 2: Multi-centre, open-label, study to evaluate the PK, safety/ tolerability and to identify the appropriate dose for children from 3 months to less than 18 years.<br><br>Study 3: Randomized double-blind, multicenter, comparative study in hospitalized children 3 months to less than 18 years of age with complicated intra abdominal infections (cIAI) requiring intravenous antibiotic therapy.<br><br>Study 4: Randomized, double-blind, multicenter, comparative study in hospitalized children 3 months to less than 18 years of age with complicated urinary tract infections (cUTI) requiring intravenous antibiotic therapy.<br><br>Study 5: Randomized, double-blind, multicenter, comparative study in hospitalized children 3 months to less than 18 years of age with pneumonia requiring intravenous antibiotic therapy. |

| Area | Number | Description |
|---|---|---|
| | | Study 6: Multi-centre, open-label, study to evaluate PK, safety and tolerability in neonates including preterm infants with GA below 28 weeks and in infants less than 3 months old.<br><br>Study 7: Multi-centre, open-label, descriptive safety, tolerability and efficacy study in neonates including preterm infants with GA below 28 weeks, and in infants less than 3 months of age. |

# 3. Follow-up, completion and deferral of PIP

| | |
|---|---|
| Measures to address long term follow-up of potential safety issues in relation to paediatric use: | Yes |
| Date of completion of the paediatric investigation plan: | By December 2015 |
| Deferral for one or more studies contained in the paediatric investigation plan: | Yes |

# Annex II

# Information about the authorised medicinal product

**Condition(s) and authorised indication(s):**

1. Treatment of bacterial infections

   Authorised indications:

   Doribax is indicated for the treatment of the following infections in adults:

   - Nosocomial pneumonia (including ventilator–associated pneumonia)
   - Complicated intra-abdominal infections
   - Complicated urinary tract infections

| EU Number | Invented name | Strength | Pharmaceutical form | Route of administration | Packaging | Content (concentration) | Package size |
|---|---|---|---|---|---|---|---|
| EU/1/08/467/001 | Doribax | 500 mg | Powder for solution for infusion | Intravenous use | vial (glass) | | 10 vials |
| EU/1/08/467/002 | Doribax | 250 mg | Powder for solution for infusion | Intravenous use | vial (glass) | | 10 vials |