



European Medicines Agency

Doc. Ref. EMEA/96585/2009  
P/37/2009

**EUROPEAN MEDICINES AGENCY DECISION**

**of 23 February 2009**

**on the agreement of a Paediatric Investigation Plan and on the granting of a deferral for  
clevidipine butyrate (EMEA-000282-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.*

## EUROPEAN MEDICINES AGENCY DECISION

of 23 February 2009

**on the agreement of a Paediatric Investigation Plan and on the granting of a deferral for clevudipine butyrate (EMEA-000282-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<sup>1</sup>,

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<sup>2</sup>,

Having regard to the application submitted by The Medicines Company on 28 May 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 6 February 2009, 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.

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<sup>1</sup> OJ L 378, 27.12.2006, p.1

<sup>2</sup> OJ L 136, 30.4.2004, p. 1

HAS ADOPTED THIS DECISION:

*Article 1*

A Paediatric Investigation Plan for clevidipine butyrate, emulsion 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 clevidipine butyrate , emulsion for intravenous injection, 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 The Medicines Company, 6 The Shrubbery, Barham, Kent, CT4 6NU.

Done at London, 23 February 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/56599/2008  
EMEA-000282-PIP01-08

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

### **Scope of the application**

Active substance:  
Clevipidine butyrate

Condition(s):  
Hypertensive disease

Pharmaceutical form(s):  
Emulsion for infusion

Route(s) of administration:  
Intravenous use

Name/corporate name of the PIP applicant:  
The Medicines Company

### **Basis for opinion**

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, The Medicines Company submitted for agreement to the EMA on 28 May 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 1 July 2008.

Supplementary information was provided by the applicant on 27 November 2008.

## 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 Agency, together with its annex(es) and appendix.

London, 6 February 2009

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**

## PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Hypertensive disease

- **Proposed PIP indication**

Blood pressure management in the perioperative period.

- **Subset(s) of the paediatric population concerned by the paediatric development**

From 0 to less than 18 years.

- **Formulation(s)**

Emulsion for infusion 0.5 mg/ml for intravenous use.

- **Studies**

| Area         | Number of studies | Description                                                                                                                                                                                                                                                                                  |
|--------------|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Quality      | 0                 | Not applicable.                                                                                                                                                                                                                                                                              |
| Non-clinical | 0                 | Not applicable.                                                                                                                                                                                                                                                                              |
| Clinical     | 1                 | Open-label study to assess in a stepwise approach per age group, the safety and pharmacodynamics of clevidipine in paediatric patients undergoing a surgical procedure requiring anaesthesia, and for whom parenteral IV antihypertensive therapy for blood pressure management is expected. |

|                                                                                                                      |                      |
|----------------------------------------------------------------------------------------------------------------------|----------------------|
| <b>Measures to address long term follow-up of potential safety issues or efficacy in relation to paediatric use:</b> | <b>No</b>            |
| <b>Date of completion of the paediatric investigation plan:</b>                                                      | <b>By March 2012</b> |
| <b>Deferral for some or all studies contained in the paediatric investigation plan:</b>                              | <b>Yes</b>           |