European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 24 March 2009

on the agreement of a Paediatric Investigation Plan and on the refusal of a deferral and on the granting of a waiver for glucose monohydrate (EMEA-000221-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.

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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 Cblaya & Mhuguet S.L. on 4 April 2008 under Article 15 of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and 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 13 of said Regulation 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 refusal of a deferral and on the granting of a waiver,

(2) It is therefore appropriate to adopt a Decision granting a Paediatric Investigation Plan,

(3) It is therefore appropriate to adopt a Decision refusing a deferral,

(4) It is therefore appropriate to adopt a Decision granting a waiver.

[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 glucose monohydrate, oral solution, oral 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 glucose monohydrate, oral solution, oral 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 refused.

Article 3

A waiver for glucose monohydrate, oral solution, oral 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 4

This decision is addressed to Cblaya & Mhuguet S.L., c/ Bruc 59, ppal 2ª, 08009 Barcelona, Spain.

Done at London, 24 March 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/22873/2009
EMEA-000221-PIP01-08

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

Scope of the application

Active substance:
Glucose monohydrate

Condition(s):
Pain

Pharmaceutical form(s):
Oral solution

Route(s) of administration:
Oral use

Name/corporate name of the PIP applicant:
Cblaya & Mhuguet S.L.

Basis for opinion

Pursuant to Article 15 of Regulation (EC) No 1901/2006 as amended, Cblaya & Mhuguet S.L. 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 and a waiver under Article 13 of said Regulation.

The procedure started on 8 May 2008.

Supplementary information was provided by the applicant on 28 November 2008.

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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 refuse a deferral in accordance with Article 21 of said Regulation.
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population

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 AND THE SUBSET(S) OF THE PAEDIATRIC POPULATION AND CONDITION(S) COVERED BY THE WAIVER

A. CONDITION(S)
Pain

B. WAIVER
Pain

- **Condition**

The waiver applies to: Infants and children from 12 months to less than 18 years for oral solution and oral use on the grounds that the specific medicinal product is likely to be ineffective.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Pain

Proposed PIP indication

Procedural Pain from heel lancing, venipuncture and vaccination

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

From birth to less than 12 months.

- **Formulation(s)**

Oral solution for Oral use

- **Studies**

Area	Number of studies	Description
Quality	0	Not applicable
Non-clinical	0	Not applicable.
Clinical	5	Single centre, randomised, single dose, parallel group, double blind, placebo controlled dose finding study, following heel lancing. Multi-centre, randomised, single-dose, parallel group, double-blind, placebo controlled confirmatory study to assess the efficacy and safety of identified concentration for the prevention of pain during to heel lancing puncture in pre-term and neonates up to 28 days Multi-centre, randomised, single-dose, parallel group, double-blind, placebo controlled confirmatory study to assess the efficacy and safety of identified concentration for the prevention of pain during vaccination in all age groups up to 12 months old Multi-centre, randomised, single-dose, parallel group, double-blind, placebo controlled confirmatory study to assess the efficacy and safety of identified concentration for the prevention of pain during venipuncture in pre-term and neonates up to 28 days Multi-centre, randomised, single-dose, parallel group, double-blind, double-dummy, active control (Ametop) confirmatory study to assess the efficacy and safety of identified concentration for the prevention of pain during venipuncture in infants from 28 days to 12 months

Measures to address long term follow-up of potential safety issues /efficacy in relation to paediatric use: **No**

Date of completion of the paediatric investigation plan: **By Dec 2011**

Deferral for some or all studies contained in the paediatric investigation plan: **No**