European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 30 October 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver for methoxyflurane (EMEA-000334-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 Voisin Consulting on 10 October 2008 under Article 16(1) 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 18 September 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 granting of a deferral and on the granting of a waiver,

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

(3) It is therefore appropriate to adopt a Decision granting 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 methoxyflurane, inhalation vapour, liquid, inhalation 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 methoxyflurane, inhalation vapour, liquid, inhalation 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

A waiver for methoxyflurane, inhalation vapour, liquid, inhalation 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 Voisin Consulting, 3 rue des Longs Prés, 92100- Boulogne Billancourt, France.

Done at London, 30 October 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/360823/2009
EMEA-000334-PIP01-08

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

Scope of the application

Active substance(s):
Methoxyflurane

Condition(s):
Acute pain

Pharmaceutical form(s):
Inhalation vapour, liquid

Route(s) of administration:
Inhalation use

Name/corporate name of the PIP applicant:
Voisin Consulting

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Voisin Consulting submitted for agreement to the EMEA on 10 October 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 13 November 2008.

Supplementary information was provided by the applicant on 17 April 2009.

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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 grant 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)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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 and the subset(s) of the paediatric population and condition(s) covered by the waiver 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, 18 September 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)

Acute pain

B. WAIVER

- **Condition**

Acute pain

The waiver applies to:

– Children from birth to less than 6 years of age

– for inhalation vapour, liquid for inhalation use

– on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Acute pain

- **Proposed PIP indication**

- Self administration to conscious patients with trauma and associated pain, under supervision of personnel trained in its use.
- For the management of pain associated with short surgical procedures, such as the change of dressings, dislocations and injections.

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

From 6 to less than 18 years.

- **Formulation(s)**

Inhalation vapour, liquid for inhalation use

- **Studies**

Area	Number of studies	Description
Quality		Not applicable
Non-clinical		Not applicable
Clinical	2	A randomised, double blind, multi-centre, placebo-controlled study to evaluate the safety and efficacy of methoxyflurane for the treatment of acute pain in children from 12 to less than 18 years of age. A randomised, open label, parallel group, multicentre active-controlled study to evaluate safety and efficacy of methoxyflurane compared to fentanyl for the management of acute pain in children and adolescents from 6 to less than 16 years of age.

Measures to address long term follow-up of potential safety issues or efficacy in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	**By December 2013**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**