



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/646936/2012

European Medicines Agency decision

P/0264/2012

of 20 November 2012

on the acceptance of a modification of an agreed paediatric investigation plan for methoxyflurane (EMEA-000334-PIP01-08-M02) 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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on the acceptance of a modification of an agreed paediatric investigation plan for methoxyflurane (EMA-000334-PIP01-08-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/210/2009 issued on 30 October 2009,

Having regard to the application submitted by ORION Clinical Services on 13 July 2012 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 5 October 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 methoxyflurane, inhalation vapour, liquid, inhalation 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 ORION Clinical Services, 7 Bath Road, SL1 3UA – Slough, United Kingdom.

Done at London, 20 November 2012

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

EMA/PDCO/486631/2012

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-000334-PIP01-08-M02

Scope of the application

Active substance(s):

Methoxyflurane

Condition(s):

Treatment of acute pain

Pharmaceutical form(s):

Inhalation vapour, liquid

Route(s) of administration:

Inhalation use

Name / corporate name of the PIP applicant:

ORION Clinical Services

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, ORION Clinical Services submitted to the European Medicines Agency on 13 July 2012 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/210/2009 issued on 30 October 2009.

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

The procedure started on 9 August 2012.

Scope of the modification

The timelines of the 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.

Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the 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 European Medicines Agency, together with its annex(es) and appendix.

London, 5 October 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

1.1. Condition: Treatment of 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.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of acute pain

2.1.1. Indication(s) targeted by the PIP

- 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.

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 6 to less than 18 years.

2.1.3. Pharmaceutical form(s)

Inhalation vapour, liquid for inhalation use.

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable
Non-clinical	0	Not applicable

Area	Number of studies	Description
Clinical	2	Study 1: 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 (and in adults) (MEOF-001). Study 2: 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 (MEOF-002).

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2013
Deferral for one or more studies contained in the paediatric investigation plan:	Yes