EMA/757939/2016

European Medicines Agency decision

P/0320/2016

of 21 December 2016

on the acceptance of a modification of an agreed paediatric investigation plan for methoxyflurane (Penthrox), (EMEA-000334-PIP01-08-M05) 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/210/2009 issued on 30 October 2009, and the decision P/0264/2012 issued on 20 November 2012,

Having regard to the application submitted by Medical Developments UK Ltd on 25 July 2016 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 14 October 2016, 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, following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) Regulation (EC) No 1901/2006, an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

[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 (Penthrox), inhalation vapour, liquid, inhalation use, including changes to the deferral, 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 Medical Developments UK Ltd, Causeway House, 1 Dane Street, CM23 BT - Bishop's Stortford, United Kingdom.

EMA/PDCO/786432/2016
London, 16 December 2016

Final opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000334-PIP01-08-M05

Scope of the application

Active substance(s):

Methoxyflurane

Invented name:

Penthrox

Condition(s):

Treatment of acute pain

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Inhalation vapour, liquid

Route(s) of administration:

Inhalation use

Name/corporate name of the PIP applicant:

Medical Developments UK Ltd

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, Medical Developments UK Ltd submitted to the European Medicines Agency on 25 July 2016 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, and the decision P/0264/2012 issued on 20 November 2012.

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

An Opinion was adopted by the Paediatric Committee on 14 October 2016. Medical Developments UK Ltd received the Paediatric Committee Opinion on 24 October 2016.

On 22 November 2016 Medical Developments UK Ltd submitted to the European Medicines Agency a written request including detailed grounds for a re-examination of the Opinion.

The re-examination procedure started on 23 November 2016.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Final Opinion

1. The Paediatric Committee, having assessed the detailed grounds for re-examination, in accordance with Article 25(3) of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

1.1. to revise its opinion and

- to agree to changes to the paediatric investigation plan and to the deferral 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 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 and appendix.

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:

- the paediatric population 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.
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) presenting to an Emergency Department with minor trauma (MEOF-001).

		Study 2 A randomised, double-blind, multi-centre, placebo controlled study to evaluate safety and efficacy of methoxyflurane for the treatment of acute pain in children and adolescents from 6 to less than 18 years of age presenting to an Emergency Department with minor trauma (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 July 2019
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 acute pain

Authorised indication(s):

- emergency relief of moderate to severe pain in conscious adult patients with trauma and associated pain.

Authorised pharmaceutical form(s)

Inhalation vapour, liquid

Authorised route(s) of administration

Inhalation use