EMA/37951/2023

European Medicines Agency decision

P/0080/2023

of 13 March 2023

on the acceptance of a modification of an agreed paediatric investigation plan for methoxyflurane (Penthrox and associated names) (EMEA-000334-PIP01-08-M11) 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 Union procedures for the authorisation and supervision of medicinal products for human 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, decision P/264/2012 issued on 20 November 2012, decision P/320/2016 issued on 21 December 2016, decision P/0171/2017 issued on 3 July 2017, decision P/0110/2018 issued on 11 April 2018, decision P/0063/2019 issued on 22 March 2019, decision P/0178/2020 issued on 13 May 2020, and decision P/0525/2021 issued on 3 December 2021,

Having regard to the application submitted by Medical Developments UK Ltd on 13 October 2022 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 20 January 2023, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for methoxyflurane (Penthrox and associated names), 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 Medical Developments UK Ltd, Causeway House, 1 Dane Street, CM23 2BT - Bishops Stortford, United Kingdom.

EMA/PDCO/858430/2022
Amsterdam, 20 January 2023

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

EMEA-000334-PIP01-08-M11

Scope of the application

Active substance(s):

Methoxyflurane

Invented name and authorisation status:

See Annex II

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:

Medical Developments UK Ltd

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 13 October 2022 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, decision P/264/2012 issued on 20 November 2012, decision P/320/2016 issued on 21 December 2016, decision P/0171/2017 issued on 3 July 2017, decision P/0110/2018 issued on 11 April 2018, decision P/0063/2019 issued on 22 March 2019, decision P/0178/2020 issued on 13 May 2020, and decision P/0525/2021 issued on 3 December 2021.

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

The procedure started on 21 November 2022.

Scope of the modification

Some measures of the Paediatric Investigation 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.

   The Paediatric Committee member of Norway 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 annexes 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 (PIP)

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;
- 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	Description
Quality	Not applicable
Non-clinical	Not applicable
Clinical	**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 December 2023
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

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

- Invented name(s): Penthrox and associated names
- Authorised pharmaceutical form(s): Inhalation vapour, liquid
- Authorised route(s) of administration: Inhalation use
- Authorised via decentralised procedure