MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral;

MHRA-101293-PIP01-23-M01

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

Medical Developments UK Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Medical Developments UK Ltd submitted to the licensing authority on 13/12/2023 02:27 GMT an application for a Modification

The procedure started on 20/12/2023 18:36 GMT

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-101293-PIP01-23-M01

Of 09/01/2024 10:11 GMT

On the adopted decision for METHOXYFLURANE (MHRA-101293-PIP01-23-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for METHOXYFLURANE, Inhalation vapour, liquid , INHALATION USE .

This decision is addressed to Medical Developments UK Ltd, Causeway House, 1 Dane Street, Bishops Stortford, UNITED KINGDOM, CM23 2BT

ANNEX I

1. Waiver

1.1 Condition:

Treatment of acute pain. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age. Pharmaceutical form(s): Inhalation vapour, liquid Route(s) of administration: INHALATION USE Reason for granting waiver: 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(s):

Treatment of acute pain.

2.2 Indication(s) targeted by the PIP:

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

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 6 years of age to 18 years of age.

2.4 Pharmaceutical Form(s):

Inhalation vapour, liquid

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 1 (MEOF-001) 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. Study 2 (MEOF-002) 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.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No

Date of completion of the paediatric investigation plan:	31/12/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes