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-101995-PIP01-25-M01

Scope of the Application

Active Substance(s)

ISOFLURANE

Condition(s)

Sedation of mechanically ventilated patients

Pharmaceutical Form(s)

Inhalation vapour, liquid

Route(s) of Administration

INHALATION USE

Name / Corporate name of the PIP applicant

Sedana Medical AB

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Sedana Medical AB submitted to the licensing authority on 25/06/2025 10:52 BST an application for a Modification

The procedure started on 25/06/2025 16:07 BST

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-101995-PIP01-25-M01

Of 27/06/2025 13:15 BST

On the adopted decision for ISOFLURANE (MHRA-101995-PIP01-25-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 ISOFLURANE, Inhalation vapour, liquid , INHALATION USE .

This decision is addressed to Sedana Medical AB, Svärdvägen 3A, Danderyd, SWEDEN, SE-18233

ANNEX I

1. Waiver

1.1 Condition:

Sedation of mechanically ventilated patients The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 3 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 is likely to be unsafe.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Sedation of mechanically ventilated patients.

2.2 Indication(s) targeted by the PIP:

Sedation of mechanically ventilated patients.

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

The paediatric population from 3 years to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Inhalation vapour, liquid

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate device/system to allow treatment of children from 3 years of age with isoflurane during mechanical ventilation.
Non-Clinical Studies	0	Not applicable
Clinical Studies	1	Study 2 (SED002) Randomised active controlled study to compare efficacy and safety of inhaled isoflurane delivered by the AnaConDa device to intravenous midazolam for sedation in mechanically ventilated children admitted to a paediatric intensive care unit or with a planned ICU admission, and requiring mechanical ventilation and sedation for at least 12 hours.
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:	31/08/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes