EMA/21188/2023

European Medicines Agency decision

P/0031/2023

of 31 January 2023

on the acceptance of a modification of an agreed paediatric investigation plan for isoflurane (Sedaconda and associated names), (EMEA-002320-PIP01-17-M03) 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/0092/2019 issued on 22 March 2019 the decision P/0190/2020 issued on 15 May 2020 and the decision P/0086/2022 issued on 11 March 2022,

Having regard to the application submitted by Sedana Medical AB on 12 September 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 16 December 2022, 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 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, 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 isoflurane (Sedaconda and associated names), 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 Sedana Medical AB, Vendevägen 89, SE-182 32- Danderyd, Sweden.

EMA/PDCO/773923/2022
Amsterdam, 16 December 2022

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

EMEA-002320-PIP01-17-M03

Scope of the application

Active substance(s):

Isoflurane

Invented name and authorisation status:

See Annex II

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 opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sedana Medical AB submitted to the European Medicines Agency on 12 September 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/0092/2019 issued on 22 March 2019 the decision P/0190/2020 issued on 15 May 2020 and the decision P/0086/2022 issued on 11 March 2022.

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

The procedure started on 17 October 2022.

Scope of the modification

Some measures and timelines 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 and to the deferral in the scope set out in the Annex I of this opinion.

   The Paediatric Committee members of Liechtenstein and Norway agree 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:

Sedation of mechanically ventilated patients

The waiver applies to:

- the paediatric population from birth to less than 3 years of age;
- inhalation vapour, liquid, inhalation use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Sedation of mechanically ventilated patients

2.1.1. Indication(s) targeted by the PIP

Sedation of mechanically ventilated patients

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

From 3 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Inhalation vapour, liquid

2.1.4. Measures

Area	Description
Quality-related studies	**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	Not applicable
Clinical studies	**Study 2 (SED002)** Randomized 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, modelling and simulation studies	Not applicable

Other studies	Not applicable
Other measures	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By August 2023
Deferral for one or more measures 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. Sedation of mechanically ventilated patients

Authorised indication(s):

- Sedation of mechanically ventilated adult patients during intensive care
  - Invented name(s): Sedaconda and associated names
  - Authorised pharmaceutical form(s): Inhalation vapour, liquid
  - Authorised route(s) of administration: Inhalation use
  - Authorised via decentralised procedure