EMA/29421/2023

European Medicines Agency decision

P/0009/2023

of 31 January 2023

on the acceptance of a modification of an agreed paediatric investigation plan for fibrinogen / thrombin / aprotinin / calcium chloride (KolFib; SILKETAL), (EMEA-001079-PIP01-10-M06) 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/0047/2012 issued on 29 February 2012, the decision P/0206/2013 issued on 3 September 2013, the decision P/0280/2014 issued on 30 October 2014 and the decision P/0199/2018 issued on 19 July 2018,

Having regard to the application submitted by Kedrion S.p.A. on 8 September 2022 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and proposing 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 and Article 13 of said Regulation,

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 and on the granting of a waiver.

(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.

(3) It is therefore appropriate to adopt a decision granting a waiver.

[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 fibrinogen / thrombin / aprotinin / calcium chloride (KolFib; SILKETAL), powder and solvent for sealant, epilesional 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

A waiver for fibrinogen / thrombin / aprotinin / calcium chloride (KolFib; SILKETAL), powder and solvent for sealant, epilesional use, the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Kedrion S.p.A., Località ai Conti, 55051 - Castelvecchio Pascoli - Barga – Lucca, Italy.

EMA/PDCO/780133/2022
Amsterdam, 16 December 2022

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

EMEA-001079-PIP01-10-M06

Scope of the application

Active substance(s):

Fibrinogen / thrombin / aprotinin / calcium chloride

Condition(s):

Treatment of haemorrhage resulting from a surgical procedure

Prevention of haemorrhage resulting from a surgical procedure

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder and solvent for sealant

Route(s) of administration:

Epilesional use

Name/corporate name of the PIP applicant:

Kedrion S.p.A.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Kedrion S.p.A. submitted to the European Medicines Agency on 8 September 2022 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0047/2012 issued on 29 February 2012, the decision P/0206/2013 issued on 3 September 2013, the decision P/0280/2014 issued on 30 October 2014 and the decision P/0199/2018 issued on 19 July 2018.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral and proposed a waiver to cover the entire paediatric population.

The procedure started on 17 October 2022.

Scope of the modification

A waiver to cover all subsets of the paediatric population has been added.

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;
   - to grant a waiver for one or more subsets of the paediatric population concluded in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   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:

Treatment of haemorrhage resulting from a surgical procedure

The waiver applies to:

- the paediatric population from birth to less than 18 years of age;
- powder and solvent for sealant, epilesional use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.2. Condition:

Prevention of haemorrhage resulting from a surgical procedure

The waiver applies to:

- the paediatric population from birth to less than 18 years of age;
- powder and solvent for sealant, epilesional use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Supportive treatment where standard surgical techniques are insufficient

Authorised indication(s): Supportive treatment for improvement of haemostasis in adult patients.

Supportive treatment as an adhesive/sealant or as suture support in myringoplasty (Type I tympanoplasty) in adult patients.

- Supportive treatment for improvement of haemostasis in adult patients.
  - Invented name(s): KolFib; SILKETAL
  - Authorised pharmaceutical form(s): powder and solvent for sealant
  - Authorised route(s) of administration: epilesional use
  - Authorised via national procedure
- Supportive treatment as an adhesive/sealant or as suture support in myringoplasty (Type I tympanoplasty) in adult patients.
  - Invented name(s): KolFib; SILKETAL
  - Authorised pharmaceutical form(s): powder and solvent for sealant
  - Authorised route(s) of administration: epilesional use
  - Authorised via national procedure