

EMA/587540/2014

European Medicines Agency decision

P/0280/2014

of 30 October 2014

on the acceptance of a modification of an agreed paediatric investigation plan for fibrinogen / thrombin / aprotinin / calcium chloride (EMEA-001079-PIP01-10-M02) 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 726/2004¹,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency²,

Having regard to the European Medicines Agency's decision P/0047/2012 issued on 29 February 2012, and the decision P/0206/2013 issued on 3 September 2013,

Having regard to the application submitted by Kedrion S.p.A. on 23 June 2014 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 September 2014, 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.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for fibrinogen / thrombin / aprotinin / calcium chloride, 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

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

Done at London, 30 October 2014

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/398382/2014 **Corr**

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

EMA-001079-PIP01-10-M02

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

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 23 June 2014 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, and the decision P/0206/2013 issued on 3 September 2013.

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

The procedure started on 16 July 2014.

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 Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan 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 annex and appendix.

London, 12 September 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

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

Not applicable.

2. Paediatric investigation plan

2.1. Condition

Treatment of haemorrhage resulting from a surgical procedure

2.1.1. Indication(s) targeted by the PIP

Treatment of haemorrhage resulting from a surgical procedure

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder and solvent for sealant

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	1	Study 1 Local tolerability and thrombogenicity induced by Fibrin Sealant (Fibrinogen / Thrombin / Aprotinin / Calcium Chloride) in epigastric free-flap surgical model in the child-adolescent rat.
Clinical studies	2	Study 2 Open-label, randomised, multicentre, controlled trial to evaluate the efficacy and safety of Fibrin Sealant (Fibrinogen / Thrombin / Aprotinin / Calcium Chloride) as an adjuvant for haemostasis control, in paediatric patients from birth to 18 years of age requiring open-heart surgery. Study 3 Open-label, randomised, multicentre, controlled trial to evaluate the efficacy and safety of Fibrin Sealant (Fibrinogen / Thrombin / Aprotinin / Calcium Chloride) as an adjuvant for haemostasis control, in paediatric patients from birth to 18 years of age requiring abdominal or orthopaedic surgery.

Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

2.2. Condition

Prevention of haemorrhage resulting from a surgical procedure

2.2.1. Indication(s) targeted by the PIP

Prevention of haemorrhage resulting from a surgical procedure

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

From birth to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Powder and solvent for sealant

2.2.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	1	Same as for Condition 2.1.
Clinical studies	2	Study 2 Same as for Condition 2.1. Study 3 Same as for Condition 2.1.
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By March 2016
Deferral for one or more measures contained in the paediatric investigation plan:	Yes