



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/129779/2012

European Medicines Agency decision P/0047/2012

of 29 February 2012

on the agreement of a paediatric investigation plan and on the granting of a deferral for fibrinogen concentrate / thrombin preparation / aprotinin / calcium chloride (EMA-001079-PIP01-10) 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 application submitted by Kedrion S.p.A. on 10 December 2010 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 January 2012, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 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 agreement of a paediatric investigation plan and on the granting of a deferral.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting a 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

A paediatric investigation plan for fibrinogen concentrate / thrombin preparation / aprotinin / calcium chloride, powder and solvent for sealant, epilesional use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for fibrinogen concentrate / thrombin preparation / aprotinin / calcium chloride, powder and solvent for sealant, epilesional use, the details of which are set out in the opinion of the Paediatric Committee of 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, frazione Castelveccchio Pascoli, 55051 Barga – Lucca, Italy.

Done at London, 29 February 2012

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/896313/2011

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMA-001079-PIP01-10

Scope of the application

Active substance(s):

Fibrinogen concentrate / thrombin preparation / 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 16(1) of Regulation (EC) No 1901/2006 as amended, Kedrion S.p.A. submitted for agreement to the European Medicines Agency on 10 December 2010 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 19 January 2011.

Supplementary information was provided by the applicant on 24 October 2011.



Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
- to grant a deferral in accordance with Article 21 of said Regulation.

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 agreed 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(es) and appendix.

London, 13 January 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, 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

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. Studies

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

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. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	1	Same as for Condition 2.1
Clinical	2	Study 2: Same as for Condition 2.1 Study 3: Same as for Condition 2.1

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2014.
Deferral for one or more studies contained in the paediatric investigation plan:	Yes