EMA/547580/2012

European Medicines Agency decision

P/0193/2012

of 24 August 2012

on the acceptance of a modification of an agreed paediatric investigation plan for human fibrinogen / human thrombin (Evicel) (EMEA-001149-PIP01-11-M01) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0025/2012 issued on 27 January 2012,

Having regard to the application submitted by Omrix Biopharmaceuticals NV on 23 April 2012 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 6 July 2012, 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.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[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 human fibrinogen / human thrombin (Evicel), solution for sealant, medicated sponge, epilesional use, 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 Omrix Biopharmaceuticals NV/SA, Leonardo Da Vincilaan 15, 1831 Diegem, Belgium.

Done at London, 24 August 2012

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

EMA/PDCO/292452/2012

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

EMEA-001149-PIP01-11-M01

Scope of the application

Active substance(s):

Human fibrinogen / human thrombin

Invented name:

Evicel

Condition(s):

Treatment of haemorrhage resulting from a surgical procedure

Treatment of cerebrospinal fluid leakage resulting from a neurosurgical procedure

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for sealant

Medicated sponge

Route(s) of administration:

Epilesional use

Name/corporate name of the PIP applicant:

Omrix Biopharmaceuticals NV

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Omrix Biopharmaceuticals NV submitted to the European Medicines Agency on 23 April 2012 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/0025/2012 issued on 27 January 2012.

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

The procedure started on 15 May 2012.

Scope of the modification

Amendment of the scope of the Paediatric Investigation Plan to include another condition.

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 in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees 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 annex(es) and appendix.

Langen, Germany, 6 July 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

1.1. Condition: Treatment of haemorrhage resulting from a surgical procedure

The waiver applies to:

- from birth to less than 28 days;
- for medicated sponge, epilesional use;
- on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of haemorrhage resulting from a surgical procedure

2.1.1. Indication(s) targeted by the PIP

Indicated as supportive treatment in surgery, for improvement of haemostasis where standard surgical techniques are ineffective and impractical.

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)

Solution for sealant.

Medicated sponge.

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1. Development of Medicated sponge.
Non-clinical	0	Not applicable.
Clinical	3	Study 2. Open-label, randomised, multicentre, active-controlled, trial to evaluate safety and efficacy of Medicated sponge Human Fibrinogen / Human Thrombin as an adjunct to control mild to moderate bleeding in children from 1 month to less than 18 years of age requiring surgery. Study 3. Open-label, randomised, multicentre, controlled trial to evaluate safety and efficacy of Medicated sponge Human Fibrinogen / Human Thrombin as an adjunct to control severe soft tissue bleeding in children from 1 month to less than 18 years of age requiring surgery.

Area	Number of studies	Description
		Study 4. Open-label randomised, multicentre, active -controlled trial to evaluate safety and efficacy of Human Fibrinogen / Human Thrombin Solution for sealant as an adjunct to control bleeding in children from birth to less than 18 years of age requiring surgery.

2.2 Condition: Treatment of cerebrospinal fluid leakage resulting from a neurosurgical procedure

2.1.5. 2.2.1 Indication(s) targeted by the PIP

Indicated as supportive treatment in surgery, cerebrospinal leakage resulting from neurosurgical procedure

2.1.6. 2.2.2 Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age.

2.1.7. 2.2.3 Pharmaceutical form(s)

Solution for sealant.

2.1.8. 2.2.4 Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	1	Study 5: A randomized, controlled clinical study evaluating the safety and efficacy of EVICEL when used as an adjunct to dural sutures during neurosurgical procedures.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By August 2020
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of haemorrhage resulting from a surgical procedure.

   Authorised indications: Supportive treatment in surgery where standard surgical techniques are insufficient, for improvement of haemostasis.

2. Treatment of haemorrhage resulting from a surgical procedure.

   Authorised indication: Suture support for haemostasis in vascular surgery.

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/08/473/001	Evicel	50-90 mg/ml 800-1200 IU/ml	Solutions for sealant	Epilesional use	vial (glass)	1 ml	2 vials
EU/1/08/473/002	Evicel	50-90 mg/ml 800-1200 IU/ml	Solutions for sealant	Epilesional use	vial (glass)	2 ml	2 vials
EU/1/08/473/003	Evicel	50-90 mg/ml 800-1200 IU/ml	Solutions for sealant	Epilesional use	vial (glass)	5 ml	2 vials