EMA/987057/2011

European Medicines Agency decision

P/0025/2012

of 27 January 2012

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for human fibrinogen / human thrombin (Evicel), (EMEA-001149-PIP01-11) 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8670
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

European Medicines Agency decision

P/0025/2012

of 27 January 2012

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for human fibrinogen / human thrombin (Evicel), (EMEA-001149-PIP01-11) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 application submitted by Omrix Biopharmaceuticals SA on 11 April 2011 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 9 December 2011, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation 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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(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.

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

[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 human fibrinogen / human thrombin (Evicel), solution for sealant, medicated sponge, 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 human fibrinogen / human thrombin (Evicel), solution for sealant, medicated sponge, 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

A waiver for human fibrinogen / human thrombin (Evicel), solution for sealant, medicated sponge, 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 4

This decision is addressed to Omrix Biopharmaceuticals SA, Lenneke Marelaan 6, 1932 - Sint-Stevens-Woluwe, Belgium.

Done at London, 27 January 2012

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

EMA/PDCO/880874/2011

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

EMEA-001149-PIP01-11

Scope of the application

Active substance(s):

Human fibrinogen / human thrombin

Invented name:

Evicel

Condition(s):

Treatment of haemorrhage resulting from a surgical 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 SA

Information about the authorised medicinal product:

See Annex II

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Omrix Biopharmaceuticals SA submitted for agreement to the European Medicines Agency on 11 April 2011 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 18 May 2011.

Supplementary information was provided by the applicant on 3 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,
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective in part or all of the paediatric population.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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.

London, 9 December 2011

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:

- Preterm newborn infants and Term newborn infants (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 -ontrolled 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.

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