EMA/3827/2021

European Medicines Agency decision

P/0052/2021

of 27 January 2021

on the acceptance of a modification of an agreed paediatric investigation plan for human fibrinogen/ human thrombin (VeraSeal), (EMEA-001598-PIP01-13-M03) 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/0289/2014 issued on 24 October 2014, and the decision P/0270/2016 issued on 7 October 2016,

Having regard to the application submitted by Instituto Grifols, S.A. on 10 September 2020 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 11 December 2020, 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 human fibrinogen/human thrombin (VeraSeal), solution 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 Instituto Grifols, S.A., Can Guasc, 2 Parets del Vallès, 08150 – Barcelona, Spain.

EMA/PDCO/517852/2020
Amsterdam, 11 December 2020

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

EMEA-001598-PIP01-13-M03

Scope of the application

Active substance(s):

Human fibrinogen/human thrombin

Invented name:

VeraSeal

Condition(s):

Treatment of haemorrhage resulting from a surgical procedure

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for sealant

Route(s) of administration:

Epilesional use

Name/corporate name of the PIP applicant:

Instituto Grifols, S.A.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Instituto Grifols, S.A. submitted to the European Medicines Agency on 10 September 2020 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0289/2014 issued on 24 October 2014, and the decision P/0270/2016 issued on 7 October 2016.

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

The procedure started on 13 October 2020.

Scope of the modification

Some 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 Norwegian Paediatric Committee member agrees 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 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

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

Supportive treatment in surgery where standard surgical techniques are insufficient for improvement of haemostasis and as a suture support in vascular surgery.

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.

2.1.4. Measures

Area	**Number of measures**	**Description**
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	1	**Study 1** Single-blind, randomised, active controlled trial to evaluate safety and efficacy of active substance(s) as an adjunct to control bleeding compared to Evicel in children from birth to less than 18 years of age during parenchyma and soft tissue open surgical procedures.
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:	No
Date of completion of the paediatric investigation plan:	By June 2023
Deferral for one or more measures 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 indication(s):

- for improvement of haemostasis;
- as suture support: in vascular surgery.

Authorised pharmaceutical form(s):

Solutions for sealant

Authorised route(s) of administration:

Epilesional use