EMA/627576/2017

European Medicines Agency decision

P/0276/2017

of 4 October 2017

on the acceptance of a modification of an agreed paediatric investigation plan for human fibrinogen / human thrombin (Raplixa), (EMEA-001340-PIP01-12-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/0157/2013 issued on 5 July 2013, the decision P/0043/2015 issued on 6 March 2015 and the decision P/0295/2016 issued on 4 November 2016,

Having regard to the application submitted by Mallinckrodt Pharmaceuticals Ireland Ltd on 26 May 2017 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 18 August 2017, 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 (Raplixa), sealant powder, 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 Mallinckrodt Pharmaceuticals Ireland Ltd, College Business & Technology Park, Cruiserath, Dublin 15 – Blanchardstown, Ireland.

EMA/PDCO/377883/2017
London, 18 August 2017

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

EMEA-001340-PIP01-12-M03

Scope of the application

Active substance(s):

Human fibrinogen / human thrombin

Invented name:

Raplixa

Condition(s):

Treatment of haemorrhage resulting from a surgical procedure

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Sealant powder

Route(s) of administration:

Epilesional use

Name/corporate name of the PIP applicant:

Mallinckrodt Pharmaceuticals Ireland Ltd

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, Mallinckrodt Pharmaceuticals Ireland Ltd submitted to the European Medicines Agency on 26 May 2017 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0157/2013 issued on 5 July 2013, the decision P/0043/2015 issued on 6 March 2015 and the decision P/0295/2016 issued on 4 November 2016.

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

The procedure started on 20 June 2017.

Scope of the modification

Some measures 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 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

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)

Sealant powder

2.1.4. Measures

Area	Number of measures	Description
Quality	0	Not applicable
Non-clinical	0	Not applicable
Clinical	1	**Measure 1** Randomized, single-blind (patient), controlled trial to evaluate the efficacy and safety of Raplixa in combination with an absorbable gelatin sponge, compared to gelatin sponge alone

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 December 2018
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):

- Supportive treatment where standard surgical techniques are insufficient for improvement of haemostasis.

  Raplixa must be used in combination with an approved gelatin sponge (see section 5.1). Raplixa is indicated in adults over 18 years of age.

Authorised pharmaceutical form(s):

Sealant powder

Authorised route(s) of administration:

Epilesional use