



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/43446/2014

European Medicines Agency decision

P/0069/2014

of 17 March 2014

on the agreement of a paediatric investigation plan and on the granting of a deferral for idarucizumab (EMA-001438-PIP01-13) 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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on the agreement of a paediatric investigation plan and on the granting of a deferral for idarucizumab (EMA-001438-PIP01-13) 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 726/2004¹,

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 Boehringer Ingelheim International GmbH on 12 April 2013 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 30 January 2014, 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 idarucizumab, solution for injection/infusion, intravenous 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 idarucizumab, solution for injection/infusion, intravenous 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 Boehringer Ingelheim International GmbH, Binger Straße 173, 55216 – Ingelheim, Germany.

Done at London, 17 March 2014

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



EUROPEAN MEDICINES AGENCY
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EMA/PDCO/442878/2013 Rev Corr

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

EMA-001438-PIP01-13

Scope of the application

Active substance(s):

Idarucizumab

Condition(s):

Prevention of dabigatran associated haemorrhage

Treatment of dabigatran associated haemorrhage

Pharmaceutical form(s):

Solution for injection/infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Boehringer Ingelheim International GmbH

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Boehringer Ingelheim International GmbH submitted for agreement to the European Medicines Agency on 12 April 2013 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 22 May 2013.

Supplementary information was provided by the applicant on 26 September 2013. The applicant proposed modifications to the paediatric investigation plan.



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 and appendix.

London, 30 January 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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: prevention of dabigatran associated haemorrhage

2.1.1. Indication(s) targeted by the PIP

Prevention of haemorrhage in patients who require emergency surgery/procedures when rapid reversal of the anticoagulant effects of dabigatran is needed.

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

Children from birth to less than 18 years.

2.1.3. Pharmaceutical form(s)

Solution for injection/infusion.

2.1.4. Measures

Area	Number of measures	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	2	Measure 1: Single dose, open label study of administration of idarucizumab as rescue medication to patients in paediatric dabigatran trials to assess safety in children from birth to less than 18 years. Measure 2: Establishment of a registry of all paediatric patients treated with idarucizumab.

2.2. Condition: treatment of dabigatran associated haemorrhage

2.2.1. Indication(s) targeted by the PIP

Treatment of uncontrolled or life-threatening bleeding which requires urgent intervention in patients treated with dabigatran.

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

Children from birth to less than 18 years.

2.2.3. Pharmaceutical form(s)

Solution for injection/infusion.

2.2.4. Measures

Area	Number of measures	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	2	Measure 1: Single dose, open label study of administration of idarucizumab as rescue medication to patients in paediatric dabigatran trials to assess safety in children from birth to less than 18 years. Measure 2: Establishment of a registry of all paediatric patients treated with idarucizumab.

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 June 2018
Deferral for one or more measures contained in the paediatric investigation plan:	Yes