EMA/391891/2014

European Medicines Agency decision

P/0203/2014

of 8 August 2014

on the acceptance of a modification of an agreed paediatric investigation plan for cangrelor (tetrasodium), (EMEA-001348-PIP01-12-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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on the acceptance of a modification of an agreed paediatric investigation plan for cangrelor (tetrasodium), (EMEA-001348-PIP01-12-M01) 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 European Medicines Agency's decision P/0210/2013 issued on 3 September 2013,

Having regard to the application submitted by The Medicines Company UK Ltd on 27 March 2014 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 20 June 2014, 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 cangrelor (tetrasodium), powder for concentrate for solution for infusion, intravenous 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 The Medicines Company UK Ltd, 115L Milton Park, OX14 4SA – Abingdon, United Kingdom.

Done at London, 8 August 2014

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

EMA/PDCO/204135/2014

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

EMEA-001348-PIP01-12-M01

Scope of the application

Active substance(s):

Cangrelor (tetrasodium)

Condition(s):

Prevention of non-site specific embolism and thrombosis

Pharmaceutical form(s):

Powder for concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

The Medicines Company UK Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, The Medicines Company UK Ltd submitted to the European Medicines Agency on 27 March 2014 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0210/2013 issued on 3 September 2013.

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

The procedure started on 23 April 2014.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

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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 Icelandic and the Norwegian Paediatric Committee members agree 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 annex and appendix.

London, 20 June 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 non-site specific embolism and thrombosis

2.1.1. Indication(s) targeted by the PIP

Prevention of thrombotic events in paediatric patients undergoing diagnostic and/or therapeutic percutaneous vascular procedures.

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)

Powder for concentrate for solution for infusion

2.1.4. Measures

Area	Number of measures	Description
Quality	0	Not applicable.
Non-clinical	2	**Measure 1:** Two staged study with an in vivo humanized mouse model and confirmatory in vitro study to determine a complete concentration response of cangrelor. **Measure 2:** Analysis of mechanism behind kidney toxicity in rat and dog and relevance for human in general and for children below 1 year of age in particular.
Clinical	1	**Measure 3:** A prospective, open-label, single-arm, multicentre trial to assess the pharmacokinetics/pharmacodynamics and safety of cangrelor as a procedural platelet inhibitor in the paediatric population undergoing percutaneous intravascular procedures for management of congenital heart disease.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety or efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By June 2017
Deferral for one or more measures contained in the paediatric investigation plan:	Yes