EMADOC-1700519818-2038135

European Medicines Agency decision

EMA/PE/0000239079

of 16 April 2025

on the acceptance of a modification of an agreed paediatric investigation plan for cangrelor (tetrasodium) (Kengrexal) 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 Union procedures for the authorisation and supervision of medicinal products for human 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, the decision P/203/2014 issued on 8 August 2014 and the decision EMA/PE/0000221485 issued on 6 December 2024,

Having regard to the application submitted by Chiesi Farmaceutici S.p.A. on 25 November 2024 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 28 February 2025, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for cangrelor (tetrasodium) (Kengrexal), 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 Chiesi Farmaceutici S.p.A., 26 A Via Palermo, 43122 – Parma, Italy.

EMADOC-1700519818-1802434Corr [1]
Amsterdam, 28 February 2025

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

EMA/PE/0000239079

Scope of the application

Active substance(s):

Cangrelor (tetrasodium)

Invented name and authorisation status:

See Annex II

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:

Chiesi Farmaceutici S.p.A.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Chiesi Farmaceutici S.p.A. submitted to the European Medicines Agency on 25 November 2024 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 decision P/203/2014 issued on 8 August 2014 and the decision EMA/PE/0000221485 issued on 6 December 2024.

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

The procedure started on 2 January 2025.

[1] 4 April 2025

Scope of the modification

Some measures and 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 Paediatric Committee member of Norway 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: 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	**Description**
Quality	Not applicable.
Non-clinical	**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	**Measure 3:** *Deleted in procedure EMA-PE-0000239079* Measure 4: *Added in procedure EMA/PE/0000239079* Prospective, open-label, single-arm, multi-centre study to assess the pharmacokinetics/pharmacodynamics and safety of different cangrelor doses in neonatal subjects at risk of thrombosis (MDCO-CAN-15-01, EudraCT Number: 2016-000134-22) Measure 5: *Added in procedure EMA/PE/0000239079* Prospective, open-label, non-randomised, multicenter trial to assess the safety

	and pharmacodynamics of cangrelor as procedural platelet inhibitor in paediatric patients undergoing percutaneous vascular procedures. (CLI-06727AA1-03)
Modelling and simulation analyses	Measure 6: *Added in procedure EMA/PE/0000239079* Population pharmacokinetic-pharmacodynamic modelling in adult subjects (ICx-B206 – M&S1 – Step 1) Measure 7: *Added in procedure EMA/PE/0000239079* Population pharmacokinetic-pharmacodynamic modelling in adult subjects (ICx-B206 – M&S1 – Step 2) Measure 8: *Added in procedure EMA/PE/0000239079* Updated PK model after integration of 2 additional datasets in adults (M&S2 Step 1 and 2) Measure 9: *Added in procedure EMA/PE/0000239079* Updated PK model after integration of 2 additional datasets in adults (M&S2 Step 3 and 4)
Other studies	Not applicable.
Extrapolation plan	*Added in procedure EMA/PE/0000239079* Studies 4-9 are part of an extrapolation plan covering the paediatric population from birth to less than 18 years of age, as agreed by the PDCO.

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 November 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Prevention of non-site specific embolism and thrombosis

Authorised indication(s):

- Kengrexal, co-administered with acetylsalicylic acid (ASA), is indicated for the reduction of thrombotic cardiovascular events in adult patients with coronary artery disease undergoing percutaneous coronary intervention (PCI) who have not received an oral P2Y12 inhibitor prior to the PCI procedure and in whom oral therapy with P2Y12 inhibitors is not feasible or desirable.
  - Invented name(s): Kengrexal
  - Authorised pharmaceutical forms: powder for concentrate for solution for infusion
  - Authorised route(s) of administration: intravenous use
  - Authorised via centralised procedure