EMA/365809/2022

European Medicines Agency decision

P/0209/2022

of 10 June 2022

on the acceptance of a modification of an agreed paediatric investigation plan for dopamine (hydrochloride), (EMEA-001105-PIP01-10-M06) 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 dopamine (hydrochloride), (EMEA-001105-PIP01-10-M06) 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 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/291/2011 issued on 2 December 2011, the decision P/0213/2015 issued on 2 October 2015, the decision P/0123/2017 issued on 5 May 2017 and the decision P/0108/2018 issued on 11 April 2018,

Having regard to the application submitted by Brepco Biopharma Limited on 25 January 2022 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 22 April 2022, 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, 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 dopamine (hydrochloride), solution for injection, intravenous 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 Brepco Biopharma Limited, The Avenue, Beacon Court, Sandyford, 18 – Dublin, Ireland.

EMA/PDCO/60832/2022
Amsterdam, 22 April 2022

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

EMEA-001105-PIP01-10-M06

Scope of the application

Active substance(s):

Dopamine (hydrochloride)

Condition(s):

Treatment of vascular hypotensive disorders

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Brepco Biopharma Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Brepco Biopharma Limited submitted to the European Medicines Agency on 25 January 2022 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/291/2011 issued on 2 December 2011, the decision P/0213/2015 issued on 2 October 2015, the decision P/0123/2017 issued on 5 May 2017 and the decision P/0108/2018 issued on 11 April 2018.

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

The procedure started on 21 February 2022.

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 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 annex 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 vascular hypotensive disorders

2.1.1. Indication(s) targeted by the PIP

Treatment of hypotension in neonates including the extremely low gestational age newborn

Treatment of hypotension in infants and children

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 injection

2.1.4. Measures

Area	**Description**
Quality	**Study 1** Development solution for intravenous use, 1500 micrograms/ml and 4500 micrograms/ml
Non-clinical	Not applicable
Clinical	**Study 3** Double-blinded, randomised, multi-centre, placebo controlled trial to evaluate safety and efficacy of dopamine in neonates with a gestational age at birth less than 28 completed weeks
Extrapolation, modelling and simulation studies	Not applicable
Other studies	**Study 2** A systematic literature review of dopamine for the treatment of vascular hypotensive disorders in Childhood
Other measures	Not applicable

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 April 2021
Deferral for one or more studies contained in the paediatric investigation plan:	Yes