EMA/151864/2018

European Medicines Agency decision

P/0108/2018

of 11 April 2018

on the acceptance of a modification of an agreed paediatric investigation plan for dopamine (EMEA-001105-PIP01-10-M04) 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 (EMEA-001105-PIP01-10-M04) 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/291/2011 issued on 2 December 2011, the decision P/0213/2015 issued on 2 October 2015 and the decision P/0123/2017 issued on 5 May 2017,

Having regard to the application submitted by BrePco Biopharma Limited on 6 December 2017 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan and proposing a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 23 February 2018, in accordance with Article 22 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 acceptance of changes to the agreed paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision on the granting of 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

Changes to the agreed paediatric investigation plan for dopamine, 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

A deferral for dopamine, solution for injection, intravenous use, the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to BrePco Biopharma Limited, Suite One, The Avenue, Beacon Court, Sandyford, 18 – Dublin, Ireland.

EMA/PDCO/818619/2017
London, 23 February 2018

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

EMEA-001105-PIP01-10-M04

Scope of the application

Active substance(s):

Dopamine

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 6 December 2017 an application for modification of the agreed paediatric investigation plan 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 and the decision P/0123/2017 issued on 5 May 2017.

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

The procedure started on 3 January 2017.

Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified and a deferral has been added.

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;
   - to grant a deferral, the details of which are 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 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. Studies

Area	Number of studies	Description
Quality	1	**Study 1** Development solution for intravenous use, 1500 micrograms/ml and 4500 micrograms/ml
Non-clinical	0	Not applicable
Clinical	1	**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	0	Not applicable
Other studies	1	**Study 2** A systematic literature review of dopamine for the treatment of vascular hypotensive disorders in Childhood
Other measures	0	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