EMA/922736/2011

European Medicines Agency decision

P/291/2011

of 2 December 2011

on the agreement of a paediatric investigation plan for dopamine (hydrochloride) (EMEA-001105-PIP01-10) 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 for dopamine (hydrochloride) (EMEA-001105-PIP01-10) 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 application submitted by BrePco Biopharma Limited on 17 January 2011 under Article 16(1) of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 14 October 2011, in accordance with Article 18 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 agreement of a paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

[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 dopamine (hydrochloride), solution for injection, 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

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

Done at London, 2 December 2011

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

EMA/PDCO/695881/2011

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

EMEA-001105-PIP01-10

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 16(1) of Regulation (EC) No 1901/2006 as amended, BrePco Biopharma Limited submitted for agreement to the European Medicines Agency on 17 January 2011 an application for a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 23 February 2011.

Supplementary information was provided by the applicant on 25 July 2011.

A meeting with the Paediatric Committee took place on 13 October 2011.

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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.

   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, 14 October 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, 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: Treatment of vascular hypotensive disorders

2.1.1. Indication(s) targeted by the PIP

Treatment of hypotension in the extremely low gestational age newborn.

Treatment of hypotension in 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, 1500 micrograms/mL.

2.1.4. Studies

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

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 February 2017
Deferral for one or more studies contained in the paediatric investigation plan:	No