EMA/22299/2013

European Medicines Agency decision

P/0016/2013

of 25 January 2013

on the agreement of a paediatric investigation plan and on the granting of a waiver for dobutamine (hydrochloride) (EMEA-001262-PIP01-12) 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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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 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 Proveca Limited on 12 March 2012 under Article 15(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 7 December 2012, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 13 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 agreement of a paediatric investigation plan and on the granting of a waiver.

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

(3) It is therefore appropriate to adopt a decision granting a waiver.

[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 dobutamine (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

A waiver for dobutamine (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 granted.

Article 3

This decision is addressed to Proveca Limited, Daresbury Innovation Centre, Keckwick Lane, Daresbury, WA4 4FS – Halton, United Kingdom.

Done at London, 25 January 2013

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

EMA/PDCO/668644/2012

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

EMEA-001262-PIP01-12

Scope of the application

Active substance(s):

Dobutamine (hydrochloride)

Condition(s):

Treatment of neonatal circulatory failure

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Proveca Limited

Basis for opinion

Pursuant to Article 15 of Regulation (EC) No 1901/2006 as amended, Proveca Limited submitted for agreement to the European Medicines Agency on 12 March 2012 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 16 April 2012.

Supplementary information was provided by the applicant on 17 September 2012. The applicant proposed modifications to the paediatric investigation plan.

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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,
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

   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 and the subset(s) of the paediatric population and condition(s) covered by the waiver 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, 7 December 2012

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

1.1. Condition: treatment of neonatal circulatory failure

The waiver applies to:

- the paediatric population from 1 month to less than 18 years;
- for solution for injection, intravenous use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan

2.1. Condition: treatment of neonatal circulatory failure

2.1.1. Indication(s) targeted by the PIP

Treatment of neonatal circulatory failure in the first 72 hours after birth.

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 1 month of age.

2.1.3. Pharmaceutical form(s)

Solution for injection.

2.1.4. Measures

Area	Number of measures	Description
Quality	1	Measure 1 Development of a pharmaceutical form (solution for injection) with age appropriate excipients, volume, concentration and strength appropriate to the neonatal population.
Non-clinical	0	Not applicable.

Clinical	4	Measure 2 Open-label, uncontrolled, multiple centre, observational study of dobutamine in neonates of a gestational age (GA) from 24 weeks to less than 33 weeks with a postnatal age of less than 72 hours with circulatory impairment. [Neo-Circ001] Measure 3 Open-label, uncontrolled, multi-centre dose-finding study for dobutamine in premature neonates from 24 weeks GA to less than 33 weeks GA during the adaptation to birth (postnatal age less than 72 hours). [Neo-Circ002] Measure 4 Multi-centre, randomized, placebo-controlled, double blind trial to evaluate the safety and efficacy of dobutamine as a treatment for haemodynamic insufficiency in preterm neonates neonates from 24 weeks GA to less than 33 weeks GA during the adaptation to birth (postnatal age less than 72 hours). [Neo-Circ003] Measure 5 Systematic review on the use of dobutamine in patients from 33 weeks GA to less than 28 days postnatal age. [Neo-Circ004]

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 March 2016
Deferral for one or more measures contained in the paediatric investigation plan:	No