EMA/72070/2012

European Medicines Agency decision

P/035/2012

of 3 February 2012

on the agreement of a paediatric investigation plan and on the granting of a waiver for 2-Iminobiotin (EMEA-001070-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.

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8670
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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on the agreement of a paediatric investigation plan and on the granting of a waiver for 2-Iminobiotin (EMEA-001070-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 Neurophyxia B.V. on 10 May 2011 under Article 16(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 13 January 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 2-Iminobiotin, solution for infusion, 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 2-Iminobiotin, solution for infusion, 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 Neurophyxia B.V., Onderwijsboulevard 219, 5223DE –'s Hertogenbosch, The Netherlands.

Done at London, 3 February 2012

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

EMA/72070/2012

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

EMEA-001070-PIP01-10

Scope of the application

Active substance(s):

2-Iminobiotin

Condition(s):

Treatment of perinatal asphyxia

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Neurophyxia B.V.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Neurophyxia B.V. submitted for agreement to the European Medicines Agency on 10 May 2011 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 15 June 2011.

Supplementary information was provided by the applicant on 24 October 2010. The applicant proposed modifications to the paediatric investigation plan.

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E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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 Articles 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(es) and appendix.

London, 13 January 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

Waiver

1.1. Condition: Treatment of perinatal asphyxia

The waiver applies to:

- All subsets of the paediatric population from 44 weeks of gestational age to less than 18 years of age;
- for solution for infusion, 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 perinatal asphyxia

2.1.1. Indication(s) targeted by the PIP

2.1.2. Prevention of perinatal asphyxia

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

Newborns from 33 weeks to less than 44 weeks of gestational age.

2.1.4. Pharmaceutical form(s)

Solution for infusion

2.1.5. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	2	Study 1 Randomised, placebo controlled dose range finding study of 2-Iminobiotin after moderate to severe perinatal hypoxia-ischemia in the newborn piglet. Study 2 Randomised, placebo controlled study of combination treatment of 2-Iminobiotin with hypothermia after moderate to severe perinatal hypoxia-ischemia in the newborn piglet.
Clinical	6	Study 3 Double blind, randomised, placebo-controlled multicentre study with an open label pilot phase to evaluate safety, efficacy and pharmacokinetics of 2-Iminobiotin for the treatment of moderate to severe perinatal asphyxia in neonates with a gestational age from 36 to less than 44 weeks. Study 4 Pilot open-label study to evaluate safety, tolerability and pharmacokinetics of 2-Iminobiotin for the treatment of moderate to severe perinatal asphyxia in neonates of from 33 to less than 36 weeks of gestational age. Study 5 Double blind, randomised, placebo-controlled multicentre study with an open label pilot phase to evaluate safety, efficacy and pharmacokinetics of 2-Iminobiotin for the treatment of moderate to severe perinatal asphyxia in neonates with a gestational age from 36 to less than 44 weeks receiving

Area	Number of studies	Description
		hypothermia treatment. Study 6 Open-label study to evaluate safety, tolerability and pharmacokinetics of 2-Iminobiotin for the treatment of moderate to severe perinatal asphyxia in neonates from 33 to less than 36 weeks of gestation receiving hypothermia treatment. Study 7 Double blind, randomised, placebo-controlled multicentre study to evaluate efficacy at 24 months of age, safety and tolerability of 2-Iminobiotin for the treatment of moderate to severe perinatal asphyxia in neonates from 33 weeks gestational age. Study 8 Double blind, randomised, placebo-controlled multicentre study to evaluate efficacy at 24 months of age, safety and tolerability of 2-Iminobiotin for treatment of moderate to severe perinatal asphyxia in neonates from 33 weeks gestational age receiving hypothermia treatment.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2018
Deferral for one or more studies contained in the paediatric investigation plan:	No