EMA/519929/2014

European Medicines Agency decision

P/0255/2014

of 30 September 2014

on the agreement of a paediatric investigation plan and on the granting of a waiver for ibuprofen (sodium dihydrate), (EMEA-001599-PIP01-13) 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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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 17 January 2014 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 15 August 2014, 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 ibuprofen (sodium dihydrate), solution for injection/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 ibuprofen (sodium dihydrate), solution for injection/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 Proveca Limited, Daresbury Innovation Centre, Keckwick Lane, Daresbury, Halton, Cheshire, WA4 4FS – Halton, United Kingdom.

Done at London, 30 September 2014

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

EMA/PDCO/341854/2014 Corr

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

EMEA-001599-PIP01-13

Scope of the application

Active substance(s):

Ibuprofen (sodium dihydrate)

Condition(s):

Treatment of pain

Treatment of febrile disorders

Pharmaceutical form(s):

Solution for injection/infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Proveca Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Proveca Limited submitted for agreement to the European Medicines Agency on 17 January 2014 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 26 February 2014.

Supplementary information was provided by the applicant on 22 May 2014. 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)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   The Norwegian Paediatric Committee member agrees 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, 15 August 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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 (PIP)

1. Waiver

1.1. Condition:

Treatment of pain

The waiver applies to:

- The paediatric population from birth to less than 3 months of age;
- for solution for injection/infusion for intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.2. Condition:

Treatment of febrile disorders

The waiver applies to:

- The paediatric population from birth to less than 3 months of age;
- for solution for injection/infusion for intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition:

Treatment of pain

2.1.1. Indication(s) targeted by the PIP

Short term relief of mild to moderate pain

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

From 3 months to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection/infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1:** Development of an age-appropriate (40 mg/ml) ibuprofen sodium dihydrate solution for intravenous use (PRO/IBU/003).
Non-clinical studies	0	Not applicable.
Clinical studies	2	**Study 2:** Comparative bioavailability study of the new IV ibuprofen formulation developed in Study 1 with a commercially available ibuprofen tablet (PRO/IBU/001). **Study 3:** Open label, single dose, population PK study of the new IV ibuprofen formulation developed in Study 1 in otherwise healthy children requiring routine elective surgery (PRO/IBU/002).
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

2.2. Condition:

Treatment of febrile disorders

2.2.1. Indication(s) targeted by the PIP

Treatment of fever

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

From 3 months to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Solution for injection/infusion

2.2.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1:** Development of an age-appropriate (40 mg/ml) ibuprofen sodium dihydrate solution for intravenous use (PRO/IBU/003) (same as for the condition Treatment of pain).
Non-clinical studies	0	Not applicable.
Clinical studies	2	**Study 2:** Comparative bioavailability study of the new IV ibuprofen formulation developed in Study 1 with a commercially available ibuprofen tablet (PRO/IBU/001) (same as for the condition Treatment of pain). **Study 3:** Open label, single dose, population PK study of the new IV ibuprofen formulation developed in Study 1 in otherwise healthy children requiring routine elective surgery (PRO/IBU/002) (same as for the condition Treatment of pain).
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By July 2016
Deferral for one or more measures contained in the paediatric investigation plan:	No