EMA/573797/2014

European Medicines Agency decision

P/0240/2014

of 26 September 2014

on the acceptance of a modification of an agreed paediatric investigation plan for glycopyrronium (bromide) (EMEA-001366-PIP01-12-M02) 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 European Medicines Agency's decision P/0158/2013 issued on 5 July 2013 and decision P/0052/2014 issued on 7 March 2014,

Having regard to the application submitted by Proveca Limited on 20 June 2014 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 September 2014, in accordance with Article 22 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 acceptance of changes to the agreed paediatric investigation plan.

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

Changes to the agreed paediatric investigation plan for glycopyrronium (bromide), oral liquid, oral 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

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

Done at London, 26 September 2014

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

EMA/PDCO/387731/2014

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

EMEA-001366-PIP01-12-M02

Scope of the application

Active substance(s):

Glycopyrronium (bromide)

Condition(s):

Treatment of sialorrhoea

Pharmaceutical form(s):

Oral liquid

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Proveca Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Proveca Limited submitted to the European Medicines Agency on 20 June 2014 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0158/2013 issued on 5 July 2013 and decision P/0052/2014 issued on 7 March 2014.

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

The procedure started on 16 July 2014.

Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified.

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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.

   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 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, 12 September 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 sialorrhoea

The waiver applies to:

- The paediatric population from birth to less than 2 years;
- for oral liquid, oral 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 sialorrhoea

2.1.1. Indication(s) targeted by the PIP

Treatment of sialorrhoea.

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

From 2 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Oral liquid.

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	1	Study 1: Development of an age-appropriate oral liquid formulation
Non-clinical studies	0	Not applicable.
Clinical studies	2	Study 2: Open label, single dose, two way crossover study to compare the bioavailability of 2 mg glycopyrronium bromide from a new oral solution (2 mg/5 ml) (test product) with that of 2 mg glycopyrronium bromide from Cuvposa 1 mg/5 ml solution (reference product) in healthy adults Study 3: Systematic literature review of glycopyrronium bromide use in children for the treatment of sialorrhoea to support its safe and effective use

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By October 2014
Deferral for one or more measures contained in the paediatric investigation plan:	No