EMA/306111/2013

European Medicines Agency decision

P/0136/2013

of 14 June 2013

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for phenylephrine hydrochloride / ketorolac trometamol (OMS302), (EMEA-001256-PIP02-12) 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.

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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 Omeros Corporation on 6 August 2012 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 17 May 2013, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation 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 deferral 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 deferral.

(4) 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 phenylephrine hydrochloride / ketorolac trometamol (OMS302), concentrate for solution for injection, irrigation solution, intraocular use, ocular 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 deferral for phenylephrine hydrochloride / ketorolac trometamol (OMS302), concentrate for solution for injection, irrigation solution, intraocular use, ocular 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

A waiver for phenylephrine hydrochloride / ketorolac trometamol (OMS302), concentrate for solution for injection, irrigation solution, intraocular use, ocular 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 4

This decision is addressed to Omeros Corporation, 1420 Fifth Avenue, Suite 2600, 98101 - Seattle, Washington, United States.

Done at London, 14 June 2013

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

EMA/PDCO/710240/2012

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

EMEA-001256-PIP02-12

Scope of the application

Active substance(s):

Phenylephrine hydrochloride / ketorolac trometamol (OMS302)

Condition(s):

Lens therapeutic procedures

Pharmaceutical form(s):

Concentrate for solution for injection

Irrigation solution

Route(s) of administration:

Intraocular use

Ocular use

Name/corporate name of the PIP applicant:

Omeros Corporation

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Omeros Corporation submitted for agreement to the European Medicines Agency on 6 August 2012 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 12 September 2012.

Supplementary information was provided by the applicant on 22 February 2013. 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 deferral in accordance with Article 21 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)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all 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, 17 May 2013

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: lens therapeutic procedures

The waiver applies to:

- The paediatric population from birth to less than 13 years of age;
- for concentrate for solution for injection, irrigation solution;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan

2.1. Condition: lens therapeutic procedures

2.1.1. Indication(s) targeted by the PIP

Prevention of intraoperative miosis and reduction of postoperative pain in the early postoperative period in lens replacement surgery with phacoemulsification.

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

From 13 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Concentrate for solution for injection.

Irrigation solution.

2.1.4. Measures

Area	Number of measures	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	1	**Measure 1:** Double-blind, randomised, placebo controlled trial to evaluate efficacy and safety of OMS302 in children from 13 to less than 18 years of age undergoing cataract extraction with lens replacement.

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 March 2017
Deferral for one or more measures contained in the paediatric investigation plan:	Yes