EMA/710628/2018

European Medicines Agency decision

P/0362/2018

of 7 December 2018

on the acceptance of a modification of an agreed paediatric investigation plan for phenylephrine hydrochloride / ketorolac trometamol (OMS302) (EMEA-001256-PIP02-12-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/0136/2013 issued on 14 June 2013,

Having regard to the application submitted by Omeros Corporation on 16 July 2018 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 October 2018, 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 and to the deferral and to the waiver.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral and to the 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

Changes to the agreed paediatric investigation plan for phenylephrine hydrochloride / ketorolac trometamol (OMS302), concentrate for solution for injection, irrigation solution, intraocular use, ocular use, including changes to the deferral, and to the waiver, 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 Omeros Corporation, 201 Elliot Ave West, 98119 - Seattle, Washington, USA.

EMA/PDCO/505282/2018
London, 19 October 2018

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan and on the granting of a product-specific waiver

EMEA-001256-PIP02-12-M02

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 22 of Regulation (EC) No 1901/2006 as amended, Omeros Corporation submitted to the European Medicines Agency on 16 July 2018 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0136/2013 issued on 14 June 2013.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral and changes to the waiver to cover the remaining subsets of the paediatric population.

The procedure started on 21 August 2018.

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Scope of the modification

The waiver has been extended to cover all subsets of the paediatric population.

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 and to the deferral and to amend the scope of the waiver 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 and 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, as set out in Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex and appendix.

Annex I

Grounds for granting of the waiver

1. Waiver

1.1. Condition: lens therapeutic procedures

The waiver applies to:

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

And to:

- the paediatric population from 13 to less than 18 years of age;
- concentrate for solution for injection, irrigation solution;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.