

EMA/757980/2016

European Medicines Agency decision

P/0313/2016

of 21 December 2016

on the agreement of a paediatric investigation plan for complex of povidone and iodine / dexamethasone (SHP640) (EMA-001936-PIP01-16) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Shire Pharmaceuticals Ireland Ltd on 18 March 2016 under Article 16(1) of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 November 2016, in accordance with Article 18 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 agreement of a paediatric investigation plan.
- (2) It is therefore appropriate to adopt a decision agreeing a 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

A paediatric investigation plan for complex of povidone and iodine / dexamethasone (SHP640), eye drops, suspension, 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

This decision is addressed to Shire Pharmaceuticals Ireland Ltd, 5 Riverwalk, Citywest Business Campus, 24 – Dublin, Ireland.

EMA/PDCO/577204/2016 Corr
London, 11 November 2016

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

EMA-001936-PIP01-16

Scope of the application

Active substance(s):

Complex of povidone and iodine / dexamethasone (SHP640)

Condition(s):

Treatment of infectious conjunctivitis

Pharmaceutical form(s):

Eye drops, suspension

Route(s) of administration:

Ocular use

Name / corporate name of the PIP applicant:

Shire Pharmaceuticals Ireland Ltd

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Shire Pharmaceuticals Ireland Ltd submitted for agreement to the European Medicines Agency on 18 March 2016 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 April 2016.

Supplementary information was provided by the applicant on 22 August 2016. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.

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.

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 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.

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

Not applicable.

2. Paediatric investigation plan

2.1. Condition

Treatment of infectious conjunctivitis

2.1.1. Indication(s) targeted by the PIP

Treatment of infectious conjunctivitis (adenoviral and bacterial)

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Eye drops, suspension

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	5	Study 1 Double-blind, randomised, active and placebo controlled trial to evaluate efficacy and safety of SHP640 ophthalmic suspension compared to povidone-iodine (PVP-I) and to placebo in children from birth to less than 18 years of age (and adults) with adenoviral conjunctivitis. Study 2 Double-blind, randomised, placebo controlled trial to evaluate efficacy and safety of SHP640 ophthalmic suspension in children from birth to less than 18 years of age (and adults) with adenoviral conjunctivitis. Study 3 Double-blind, randomised, active and placebo controlled trial to evaluate efficacy and safety of SHP640 ophthalmic suspension compared to povidone-iodine (PVP-I) and to placebo in children from birth to less than 18 years of age (and adults) with bacterial conjunctivitis.

		Study 4 Double-blind, randomised, active and placebo controlled trial to evaluate efficacy and safety of SHP640 ophthalmic suspension compared to povidone-iodine (PVP-I) and to placebo in children from birth to less than 18 years of age (and adults) with bacterial conjunctivitis. Study 5 Double-blind, randomised, active and placebo controlled trial to evaluate efficacy and safety of SHP640 ophthalmic suspension compared to placebo and a licensed topical antibiotic in children from birth to less than 18 years of age (and adults) with bacterial conjunctivitis.
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 September 2020
Deferral for one or more measures contained in the paediatric investigation plan:	No