EMA/762227/2018

European Medicines Agency decision

P/0369/2018

of 7 December 2018

on the acceptance of a modification of an agreed paediatric investigation plan for complex of povidone and iodine / dexamethasone (SHP640) (EMEA-001936-PIP01-16-M01) 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/0313/2016 issued on 21 December 2016,

Having regard to the application submitted by Shire Pharmaceuticals Ireland Ltd on 12 July 2018 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan,

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.

(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 complex of povidone and iodine / dexamethasone (SHP640), eye drops, suspension, ocular 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 Shire Pharmaceuticals Ireland Ltd, Block 2 & 3 Miesian Plaza, 50 – 58 Baggot Street Lower 2 – Dublin, Ireland.

EMA/PDCO/489308/2018
London, 19 October 2018

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

EMEA-001936-PIP01-16-M01

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 22 of Regulation (EC) No 1901/2006 as amended, Shire Pharmaceuticals Ireland Ltd submitted to the European Medicines Agency on 12 July 2018 an application for modification of the agreed paediatric investigation plan as set out in the European Medicines Agency's decision P/0313/2016 issued on 21 December 2016.

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

The procedure started on 21 August 2018.

Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified.

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

2. The measures and timelines of the 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 October 2021
Deferral for one or more measures contained in the paediatric investigation plan:	No