EMA/227151/2019

European Medicines Agency decision

P/0170/2019

of 15 May 2019

on the agreement of a paediatric investigation plan and on the granting of a waiver for mometasone (furoate monohydrate) / olopatadine (hydrochloride) (gsp 301 ns) (EMEA-002514-PIP01-18) 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 Glenmark Pharmaceuticals Europe Ltd. on 19 December 2018 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 29 March 2019, in accordance with Article 17 of Regulation (EC) No 1901/2006 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 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 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 mometasone (furoate monohydrate) / olopatadine (hydrochloride) (gsp 301 ns), nasal spray, suspension, intranasal 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 waiver for mometasone (furoate monohydrate) / olopatadine (hydrochloride) (gsp 301 ns), nasal spray, suspension, intranasal 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

This decision is addressed to Glenmark Pharmaceuticals Europe Ltd., Building 2, Croxley Park, WD18 8YA – Watford, United Kingdom.

EMA/PDCO/181362/2019
Amsterdam, 29 March 2019

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

EMEA-002514-PIP01-18

Scope of the application

Active substance(s):

Mometasone (furoate monohydrate) / olopatadine (hydrochloride) (GSP 301 NS)

Condition(s):

Treatment of allergic rhinitis / rhino-conjunctivitis

Pharmaceutical form(s):

Nasal spray, suspension

Route(s) of administration:

Intranasal use

Name/corporate name of the PIP applicant:

Glenmark Pharmaceuticals Europe Ltd.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Glenmark Pharmaceuticals Europe Ltd. submitted for agreement to the European Medicines Agency on 19 December 2018 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 29 January 2019.

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 17(1) 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)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population and with 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.

   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 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.

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 allergic rhinitis / rhino-conjunctivitis

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- nasal spray, suspension, intranasal 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).

The waiver applies to:

- the paediatric population from 2 to less than 12 years of age;
- nasal spray, suspension, intranasal use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition:

Treatment of allergic rhinitis / rhino-conjunctivitis

2.1.1. Indication(s) targeted by the PIP

Treatment of symptoms associated with allergic rhinitis in children 12 years of age and older

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

From 12 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Nasal spray, suspension

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.

Area	Number of measures	Description
Clinical studies	3	**Study 1** Double-blind, randomised, active and placebo-controlled trial to evaluate efficacy and safety of GSP 301 NS (665 µg olopatadine HCl and 25 µg mometasone furoate) in children and adolescents from 12 to less than 18 years of age (and in adults) with seasonal allergic rhinitis (SAR) **Study 2** Double-blind, randomised, active and placebo-controlled trial to evaluate efficacy and safety of GSP 301 NS (665 µg olopatadine HCl and 25 µg mometasone furoate) in children and adolescents from 12 to less than 18 years of age (and in adults) with seasonal allergic rhinitis (SAR) **Study 3** Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of GSP 301 NS in children and adolescents from 12 to less than 18 years of age (and in adults) with perennial allergic rhinitis (PAR)
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 July 2017
Deferral for one or more measures contained in the paediatric investigation plan:	No