EMA/19486/2023

# European Medicines Agency decision

P/0020/2023

of 31 January 2023

on the acceptance of a modification of an agreed paediatric investigation plan for mometasone (furoate) / azelastine (hydrochloride) (EMEA-003122-PIP01-21-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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0347/2022 issued on 10 August 2022,

Having regard to the application submitted by Lek Pharmaceuticals d.d. on 12 September 2022 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 December 2022, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

***Article 1***

Changes to the agreed paediatric investigation plan for mometasone (furoate) / azelastine (hydrochloride), nasal spray, suspension, nasal 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 Lek Pharmaceuticals d.d., 57 Verovškova ulica, 1526 – Ljubljana, Slovenia.

EMA/PDCO/769375/2022
Amsterdam, 16 December 2022

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

EMEA-003122-PIP01-21-M01

## Scope of the application

**Active substance(s):**

Mometasone (furoate) / azelastine (hydrochloride)

**Invented name and authorisation status:**

See Annex II

**Condition(s):**

Treatment of seasonal allergic rhinitis

**Pharmaceutical form(s):**

Nasal spray, suspension

**Route(s) of administration:**

Nasal use

**Name/corporate name of the PIP applicant:**

Lek Pharmaceuticals d.d.

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Lek Pharmaceuticals d.d. submitted to the European Medicines Agency on 12 September 2022 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0347/2022 issued on 10 August 2022.

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

The procedure started on 17 October 2022.

## Scope of the modification

Some measures and 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 Paediatric Committee members of Liechtenstein and Norway agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the 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 annexes 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 seasonal allergic rhinitis

The waiver applies to:

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

  and

- the paediatric population from 2 years to less than 12 years of age;
- nasal spray, suspension, nasal use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

# 2. Paediatric investigation plan

## *2.1. Condition:*

Treatment of seasonal allergic rhinitis

### 2.1.1. Indication(s) targeted by the PIP

Treatment of the symptoms of seasonal allergic rhinitis in adolescents of 12 years of age and over

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

From 12 years to less than 18 years of age

### 2.1.3. Pharmaceutical form(s)

Nasal spray, suspension

### 2.1.4. Measures

| **Area** | **Description** |
|---|---|
| Quality-related studies | Not applicable |
| Non-clinical studies | Not applicable |
| Clinical studies | **Study 1**<br><br>Double-blind, randomised, placebo and active controlled trial to evaluate safety and efficacy of mometasone furoate / azelastine hydrochloride in adolescents from 12 years to less than 18 years of |

| | |
|---|---|
| | age (and adults) with seasonal allergic rhinitis (SAN-0677; CLK21001; 2021-004050-31)<br><br>**Study 2**<br><br>*Added during procedure EMEA-003122-PIP01-21-M01*<br><br>Open-label, single-dose, three-way crossover study to compare the fixed-dose combination of mometasone + azelastine nasal spray versus mometasone and azelastine nasal sprays in adolescents from 12 years to less than 18 years of age (and adults) with seasonal allergic rhinitis |
| Extrapolation, modelling and simulation studies | Not applicable |
| Other studies | Not applicable |
| Other measures | 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 2023 |
| Deferral for one or more measures contained in the paediatric investigation plan: | No |

# Annex II

# Information about the authorised medicinal product

***Information provided by the applicant:***

**The product is not authorised anywhere in the European Community.**