EMA/777575/2022

# European Medicines Agency decision

P/0416/2022

of 28 October 2022

on the acceptance of a modification of an agreed paediatric investigation plan for atropine (sulphate) (EMEA-002545-PIP01-19-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/0237/2020 issued on 17 June 2020,

Having regard to the application submitted by Fondazione Per La Ricerca Farmacologica Gianni Benzi Onlus on 30 May 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 9 September 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 atropine (sulphate), eye drops, 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 Fondazione Per La Ricerca Farmacologica Gianni Benzi Onlus, via Abate Eustasio 30, 70010 - Valenzano (Bari), Italy.

EMA/PDCO/575662/2022
Amsterdam, 9 September 2022

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

EMEA-002545-PIP01-19-M01

## Scope of the application

**Active substance(s):**

Atropine (sulphate)

**Condition(s):**

Treatment of myopia

**Pharmaceutical form(s):**

Eye drops

**Route(s) of administration:**

Ocular use

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

Fondazione Per La Ricerca Farmacologica Gianni Benzi Onlus

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Fondazione Per La Ricerca Farmacologica Gianni Benzi Onlus submitted to the European Medicines Agency on 30 May 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/0237/2020 issued on 17 June 2020.

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

The procedure started on 11 July 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 member of Norway agrees 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 myopia

The waiver applies to:

- the paediatric population from birth to less than 3 years of age;
- eye drops, ocular 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 myopia

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

Treatment to reduce progression of simple myopia in children and adolescents

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

From 3 years to less than 18 years of age.

### 2.1.3. Pharmaceutical form(s)

Eye drops

### 2.1.4. Measures

| **Area** | **Description** |
|---|---|
| Quality-related studies | **Study 1**<br>Development and preparation of ready-to-use, sterile, preservative free atropine eye drops |
| Non-clinical studies | Not applicable |
| Clinical studies | **Study 2**<br>Randomized, double blind, multiple dose, placebo-controlled, parallel-group, two-stage adaptive study to evaluate the efficacy of atropine to treat the progression of myopia in children and adolescents from 3 to less than 18 years of age (MODERATO) |
| 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 June 2026 |
| Deferral for one or more measures contained in the paediatric investigation plan: | No |