EMA/640003/2008

European Medicines Agency decision

P/0404/2022

of 9 September 2022

on the acceptance of a modification of an agreed paediatric investigation plan for adrenaline (epinephrine) (EMEA-002749-PIP01-19-M02) 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/0431/2020 issued on 5 November 2020 and the decision P/0054/2022 issued on 11 March 2022.

Having regard to the application submitted by ARS Pharmaceuticals IRL, Limited on 25 April 2022 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 22 July 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 adrenaline (epinephrine), nasal spray, solution, 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 ARS Pharmaceuticals IRL, Limited, The Black Church St Mary's Place, D07 P4AX - Dublin, Ireland.

EMA/PDCO/244628/2022
Amsterdam, 22 July 2022

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

EMEA-002749-PIP01-19-M02

Scope of the application

Active substance(s):

Adrenaline (epinephrine)

Condition(s):

Treatment of allergic reactions

Pharmaceutical form(s):

Nasal spray, solution

Route(s) of administration:

Nasal use

Name/corporate name of the PIP applicant:

ARS Pharmaceuticals IRL, Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, ARS Pharmaceuticals IRL, Limited submitted to the European Medicines Agency on 25 April 2022 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0431/2020 issued on 5 November 2020 and the decision P/0054/2022 issued on 11 March 2022.

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

The procedure started on 23 May 2022.

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 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 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 reactions

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- nasal spray, solution, 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 allergic reactions

2.1.1. Indication(s) targeted by the PIP

The emergency treatment of allergic reactions, including anaphylaxis

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

From 1 year to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Nasal spray, solution

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of an age-appropriate device for intranasal use in children from 1 year to less than 4 years of age
Non-clinical studies	Not applicable.
Clinical studies	**Study 2** *(EPI 010)* Open-label, uncontrolled trial to evaluate pharmacokinetics, bioavailability and haemodynamic response of intranasal adrenaline in children from 4 years to less than 18 years of age with history of Type 1 hypersensitivity reactions

	Study 3 *(EPI 014)* Open-label, uncontrolled trial to evaluate pharmacokinetics, bioavailability and haemodynamic response of intranasal adrenaline in children from 1 year to less than 4 years of age with history of Type 1 hypersensitivity reactions
Extrapolation, modelling and simulation studies	**Study 4** Modelling and simulation study to evaluate the use of intranasal adrenaline in in children from 1 year to less than 18 years of age with history of Type 1 hypersensitivity reactions
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 January 2024
Deferral for one or more measures contained in the paediatric investigation plan:	Yes