MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-101618-PIP01-24-M01) and to the deferral

MHRA-101618-PIP01-24-M02

Scope of the Application

Active Substance(s)

ADRENALINE

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 the Decision

Pursuant to the Human Medicines Regulations 2012, ARS Pharmaceuticals IRL, Limited submitted to the licensing authority on 21/08/2025 20:32 BST an application for a Modification

The procedure started on 02/09/2025 22:14 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Final Decision Letter

MHRA-101618-PIP01-24-M02

Of 10/12/2025 15:28 GMT

On the adopted decision for ADRENALINE (MHRA-101618-PIP01-24-M02) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for ADRENALINE, Nasal spray, solution , NASAL USE .

This decision is addressed to ARS Pharmaceuticals IRL, Limited, The Black Church St Mary's Place, Dublin, IRELAND, D07 P4AX

ANNEX I

1. Waiver

1.1 Condition:

Treatment of allergic reactions. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 months of age. Pharmaceutical form(s): Nasal spray, solution. Route(s) of administration: NASAL USE. Reason for granting waiver: 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(s):

Treatment of allergic reactions.

2.2 Indication(s) targeted by the PIP:

The emergency treatment of allergic reactions, including anaphylaxis.

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 6 months to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Nasal spray, solution.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate device for intranasal use in children from 6 months to less than 4 years of age.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 2 (EPI 010) Open-label, uncontrolled trial to evaluate pharmacokinetics, bioavailability and haemodynamic response of intranasal adrenaline in children from 4 to less than 18 years of age with history of Type 1 hypersensitivity reactions. Study 3 (EPI 020) Open-label, uncontrolled trial to evaluate pharmacokinetics, bioavailability and haemodynamic response of intranasal adrenaline in children from 6 months to less than 4 years of age with history of Type 1 hypersensitivity reactions.
Extrapolation, Modeling & Simulation Studies	1	Study 4 Modelling and simulation study to evaluate the use of intranasal adrenaline in in children from 1 to less than 18 years of age with history of Type 1 hypersensitivity reactions.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No

Date of completion of the paediatric investigation plan:	30/04/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes