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

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Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-102412-PIP01-26-M01

Scope of the Application

Active Substance(s)

SODIUM CITRATE; CITRIC ACID; SIMETICONE; SODIUM CHLORIDE; POTASSIUM CHLORIDE; MACROGOL 4000; SODIUM SULPHATE ANHYDROUS

Condition(s)

Bowel cleansing prior to clinical procedures

Pharmaceutical Form(s)

Powder for oral solution

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Alfasigma S.p.A.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Alfasigma S.p.A. submitted to the licensing authority on 16/03/2026 14:35 GMT an application for a Modification

The procedure started on 17/03/2026 18:14 GMT

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.

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Final Decision Letter

MHRA-102412-PIP01-26-M01

Of 20/03/2026 13:53 GMT

On the adopted decision for SODIUM CITRATE; CITRIC ACID; SIMETICONE; SODIUM CHLORIDE; POTASSIUM CHLORIDE; MACROGOL 4000; SODIUM SULPHATE ANHYDROUS (MHRA-102412-PIP01-26-M01) 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 SODIUM CITRATE; CITRIC ACID; SIMETICONE; SODIUM CHLORIDE; POTASSIUM CHLORIDE; MACROGOL 4000; SODIUM SULPHATE ANHYDROUS, Powder for oral solution , ORAL USE .

This decision is addressed to Alfasigma S.p.A., Via Ragazzi del '99 n.5, Bologna, ITALY, 40133

ANNEX I

1. Waiver

1.1 Condition:

Bowel cleansing prior to clinical procedures The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Powder for oral solution Route(s) of administration: ORAL USE Reason for granting waiver: 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(s):

Bowel cleansing prior to clinical procedures

2.2 Indication(s) targeted by the PIP:

Bowel preparation before a diagnostic procedure concerning the colon

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

The paediatric population from 2 years to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Powder for oral solution

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	1	Study 1 (PMF104 PD1-2-3/2013) Randomised, single-blind, active controlled, multi-centre trial to evaluate efficacy, safety, tolerability, acceptability and palatability of Clensia compared to a solution containing macrogol 3350 or macrogol 4000 (58-59.5 g per litre); anhydrous sodium sulphate (5.67-5.7 g per litre); sodium bicarbonate (1.67-1.7 g per litre); sodium chloride (1.45-1.47 g per litre); potassium chloride (0.73-0.75 g per litre) in children from 2 to less than 18 years of age requiring a diagnostic procedure concerning the colon. Study 2, deleted during procedure EMEA-001356-PIP02-12-M01. Study 3, deleted during procedure EMEA-001356-PIP02-12-M01.
Extrapolation, Modeling & Simulation Studies	0	Not applicable
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:	20/12/2020
Deferral of one or more studies contained in the paediatric investigation plan:	Yes