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

MHRA-101739-PIP01-24-M01

Scope of the Application

Active Substance(s)

ASCORBIC ACID; MACROGOL 3350; POTASSIUM CHLORIDE; SODIUM ASCORBATE; SODIUM CHLORIDE; SODIUM SULPHATE

Condition(s)

Bowel cleansing prior to clinical procedures

Pharmaceutical Form(s)

Powder for oral solution

Route(s) of Administration

ORAL USE, GASTRIC USE

Name / Corporate name of the PIP applicant

Norgine Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Norgine Limited submitted to the licensing authority on 18/12/2024 12:00 GMT an application for a Modification

The procedure started on 17/01/2025 07:49 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-101739-PIP01-24-M01

Of 04/03/2025 09:16 GMT

On the adopted decision for ASCORBIC ACID; MACROGOL 3350; POTASSIUM CHLORIDE; SODIUM ASCORBATE; SODIUM CHLORIDE; SODIUM SULPHATE (MHRA-101739-PIP01-24-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 ASCORBIC ACID; MACROGOL 3350; POTASSIUM CHLORIDE; SODIUM ASCORBATE; SODIUM CHLORIDE; SODIUM SULPHATE, Powder for oral solution , ORAL USE, GASTRIC USE .

This decision is addressed to Norgine Limited, Norgine House, Widewater Place, Moorhall Road, Harefield, UNITED KINGDOM, UB9 6NS

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 1 year of age. Pharmaceutical form(s): Powder for oral solution Route(s) of administration: ORAL USE, GASTRIC USE Reason for granting waiver: On the grounds 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 cleansing prior to any procedure requiring a clean bowel

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

The paediatric population from 1 year 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	1	Study 1 This study was deleted during procedure MHRA-101739-PIP01-24-M01. Study 2 Evaluation of physical compatibility of Plenvu with feeding tubes.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 3 Randomised, colonoscopist-blind, controlled, parallel group study, with a dose determination run-in phase, to evaluate efficacy, safety, pharmacokinetics, tolerability, acceptability and palatability of NER1006 in children from 12 to less than 18 years of age undergoing colonoscopy, using a standardised active comparator. Study 4 This study was deleted during procedure MHRA-101739-PIP01-24-M01. Study 5 This study was deleted during procedure MHRA-101739-PIP01-24-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:	30/04/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes