MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-101310-PIP01-23

Scope of the Application

Active Substance(s)

apraglutide

Condition(s)

Treatment of short bowel syndrome

Pharmaceutical Form(s)

Powder for solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

SFL Pharmaceuticals Deutschland GmbH

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, SFL Pharmaceuticals Deutschland GmbH submitted to the licensing authority on 24/02/2024 01:46 GMT an application for a Paediatric Investigation Plan

The procedure started on 03/02/2025 20:08 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 agree a paediatric investigation plan and grant a deferral and grant a waiver

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-101310-PIP01-23

Of 18/02/2026 08:38 GMT

On the adopted decision for apraglutide (MHRA-101310-PIP01-23) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for apraglutide, Powder for solution for injection , SUBCUTANEOUS USE .

This decision is addressed to SFL Pharmaceuticals Deutschland GmbH, Marie-Curie-Strasse 8, Loerrach, GERMANY, 79539

ANNEX I

1. Waiver

1.1 Condition:

Treatment of short bowel syndrome The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 4 months of age Pharmaceutical form(s): Powder for solution for injection Route(s) of administration: SUBCUTANEOUS 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 short bowel syndrome

2.2 Indication(s) targeted by the PIP:

Treatment of short bowel syndrome and intestinal failure

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

The paediatric population from birth to less than 4 months of age

2.4 Pharmaceutical Form(s):

Powder for solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	2	Study 1 Pre- and post-natal developmental toxicity study in the rat. Study 2 Definitive juvenile toxicity study in the rat.
Clinical Studies	2	Study 3 24-week open-label, safety, pharmacokinetic (PK), and pharmacodynamic study of apraglutide in children from 1 year to less than 18 years of age with short bowel syndrome who are dependent on parenteral support. Study 4 24-week open-label, safety, efficacy and pharmacokinetic (PK) controlled study of apraglutide in infants from 4 months to 12 months of age with short bowel syndrome who are dependent on parenteral support.
Extrapolation, Modeling & Simulation Studies	1	Study 5 Population pharmacokinetic model to select appropriate paediatric dose.
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:	Yes
Date of completion of the paediatric investigation plan:	30/06/2031
Deferral of one or more studies contained in the paediatric investigation plan:	Yes