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 agreed paediatric investigation plan and to the deferral

MHRA-101447-PIP01-24-M01

Scope of the Application

Active Substance(s)

DIFELIKEFALIN ACETATE

Condition(s)

Treatment of chronic kidney disease associated pruritus.

Pharmaceutical Form(s)

Solution for injection/infusion.

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Vifor Fresenius Medical Care Renal Pharma France

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Vifor Fresenius Medical Care Renal Pharma France submitted to the licensing authority on 31/05/2024 14:37 BST an application for a Modification

The procedure started on 16/07/2024 14:44 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.

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Final Decision Letter

MHRA-101447-PIP01-24-M01

Of 23/07/2024 16:49 BST

On the adopted decision for DIFELIKEFALIN ACETATE (MHRA-101447-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 DIFELIKEFALIN ACETATE, Solution for injection/ infusion. , INTRAVENOUS USE .

This decision is addressed to Vifor Fresenius Medical Care Renal Pharma France , 100 - 101 Terrasse Boieldieu, Tour Franklin Defense 8 , Paris, FRANCE, 92942

ANNEX I

1. Waiver

1.1 Condition:

Treatment of chronic kidney disease associated pruritus. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 12 years of age. Pharmaceutical form(s): Solution for injection. Route(s) of administration: INTRAVENOUS 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 chronic kidney disease associated pruritus.

2.2 Indication(s) targeted by the PIP:

Treatment of chronic kidney disease associated pruritus in haemodialysis patients.

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

The paediatric population from 12 years to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Solution for injection.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Open-label, non-comparative trial to evaluate pharmacokinetics, safety and activity of difelikefalin in paediatric subjects on haemodialysis from 12 years to less than 18 years of age with chronic kidney disease associated pruritus.
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:	31/03/2026
Deferral of one or more studies contained in the paediatric investigation plan:	Yes