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-100630-PIP01-22-M01

Scope of the Application

Active Substance(s)

PATIROMER SORBITEX CALCIUM

Condition(s)

Treatment of hyperkalaemia

Pharmaceutical Form(s)

Powder for oral suspension

Route(s) of Administration

ORAL 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 27/07/2022 14:49 BST an application for a Modification

The procedure started on 08/12/2022 15:36 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 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-100630-PIP01-22-M01

Of 06/01/2023 07:09 GMT

On the adopted decision for PATIROMER SORBITEX CALCIUM (MHRA-100630-PIP01-22-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 PATIROMER SORBITEX CALCIUM, Powder for oral suspension , ORAL USE .

This decision is addressed to Vifor Fresenius Medical Care Renal Pharma France, 100-101 Terrasse Boieldieu Tour Franklin La Defense 8, Paris la Defense Cedex, FRANCE, 92042

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of hyperkalaemia

2.2 Indication(s) targeted by the PIP:

Treatment of hyperkalaemia

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

All subsets of the paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Powder for oral suspension

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	3	Study 1 (RLY5016-206P) Open-label study to evaluate dose, safety and tolerability of patiromer calcium in children from 6 years to less than 18 years of age with hyperkalaemia due to chronic kidney disease. Study 2 (RLY5016-305P) Single-blind, dose titration study to evaluate efficacy and safety of patiromer calcium in the treatment of hyperkalaemia in children from 2 years to less than 18 years with chronic kidney disease (CKD). Study 3 (RLY5016-208P) Open label, multiple dose, safety and pharmacodynamic study in children from birth to less than 6 years with hyperkalaemia.
Extrapolation, Modeling & Simulation Studies	1	Study 4 Extrapolation study to support dosing and efficacy of patiromer calcium for oral suspension to the paediatric population.
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:	30/06/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes