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-101509-PIP01-24

Scope of the Application

Active Substance(s)

Ferric Citrate Coordination Complex

Condition(s)

Treatment of anaemias due to chronic kidney disorders

Pharmaceutical Form(s)

Film-coated tablet; Age-appropriate oral solid dosage form.

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Averoa SAS

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Averoa SAS submitted to the licensing authority on 30/07/2024 10:46 BST an application for a Paediatric Investigation Plan

The procedure started on 06/09/2024 11:37 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 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-101509-PIP01-24

Of 15/11/2024 07:55 GMT

On the adopted decision for Ferric Citrate Coordination Complex (MHRA-101509-PIP01-24) 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 Ferric Citrate Coordination Complex, Film-coated tablet; Age-appropriate oral solid dosage form. , ORAL USE .

This decision is addressed to Averoa SAS, 11 Avenue Paul Verlaine, Grenoble, FRANCE, 38100

ANNEX I

1. Waiver

1.1 Condition:

Treatment of anaemias due to chronic kidney disorders The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 months of age Pharmaceutical form(s): Film-coated tablet Age-appropriate oral solid dosage form 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):

Treatment of anaemias due to chronic kidney disorders

2.2 Indication(s) targeted by the PIP:

Treatment of iron deficiency anaemia in chronic kidney disease (CKD) patients with elevated serum phosphorus levels

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

The paediatric population from 6 months to less than 18 years of age

2.4 Pharmaceutical Form(s):

Film-coated tablet Age-appropriate oral solid dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	2	Study 1 (FRML-0019) Development of 250 mg film coated tablet for children from 6 years to less than 18 years of age. Study 2 (AVA1014-DEV-PAED-202301) Development of an age-appropriate oral solid dosage form for children from 6 months to less than 6 years of age.
Non-Clinical Studies	1	Study 3 (CRL 20087496) Oral juvenile toxicity study in rats by repeated dietary administration, to evaluate the potential adverse effects of repeated dietary exposure to ferric citrate coordination complex (FCCC).
Clinical Studies	2	Study 4 (KRX-0502-308) 36-week, single-arm, open-label study to evaluate the safety, tolerability, and activity of ferric citrate coordination complex (FCCC) in children from 6 months to less than 18 years of age with hyperphosphatemia related to chronic kidney disease (CKD). Study 5 (KRX-0502-309) 24-week, open-label, randomised, 2-arm study to evaluate the safety, tolerability, and activity of ferric citrate coordination complex in children from 6 months to less than 18 years of age with iron deficiency anaemia (IDA) associated with non-dialysis dependent chronic kidney disease (NDD-CKD).

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:	31/12/2030
Deferral of one or more studies contained in the paediatric investigation plan:	Yes