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 (MHRA-100167-PIP01-21-M01) and to the deferral

MHRA-100167-PIP01-21-M02

Scope of the Application

Active Substance(s)

SODIUM ZIRCONIUM CYCLOSILICATE

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

AstraZeneca UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AstraZeneca UK Limited submitted to the licensing authority on 16/10/2023 14:22 BST an application for a Modification

The procedure started on 24/01/2024 13:14 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 - a corrigendum to this decision was issued on 24/04/2024.

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-100167-PIP01-21-M02

Of 05/03/2024 10:25 GMT

On the adopted decision for SODIUM ZIRCONIUM CYCLOSILICATE (MHRA-100167-PIP01-21-M02) 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 SODIUM ZIRCONIUM CYCLOSILICATE, Powder for oral suspension , ORAL USE .

This decision is addressed to AstraZeneca UK Limited, 2 Pancras Square , London, UNITED KINGDOM, N1C 4AG

ANNEX I

1. Waiver

1.1 Condition:

Treatment of hyperkalaemia The waiver applies / applied to: Paediatric Subset(s): Newborn infants less than 37 weeks gestation or under 2500 g birth weight Pharmaceutical form(s): Powder for oral suspension Route(s) of administration: Oral use Nasogastric 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 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:

The paediatric population from birth (excluding newborn infants less than 37 weeks gestation or under 2500 g birth weight) 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	1	Study 1 Development of an age-appropriate oral formulation. Study 2 Deleted during procedure EMEA-001539-PIP01-13-M02.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 3 Deleted during procedure EMEA-001539-PIP01-13-M01. Study 4 Open-label correction phase followed by open label, dose titration phase, study in children less than 18 years of age with hyperkalaemia.
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:	30/06/2026
Deferral of one or more studies contained in the paediatric investigation plan:	Yes