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-100167-PIP01-21-M01

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 15/07/2021 21:12 BST an application for a Modification

The procedure started on 06/12/2021 14:15 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

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-M01

Of 07/12/2021 12:31 GMT

On the adopted decision for SODIUM ZIRCONIUM CYCLOSILICATE (MHRA-100167-PIP01-21-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 SODIUM ZIRCONIUM CYCLOSILICATE, Powder for oral suspension , Oral use .

This decision is addressed to AstraZeneca UK Limited, 600 Capability Green, Luton, United Kingdom, LU1 3LU

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:	31/12/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes