MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
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-102525-PIP01-26

Scope of the Application

Active Substance(s)

Balcinrenone; DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE

Condition(s)

Treatment of chronic kidney disease

Pharmaceutical Form(s)

Capsule, hard, Oral age-appropriate formulation

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 19/06/2026 23:05 BST an application for a Paediatric Investigation Plan

The procedure started on 26/06/2026 16:43 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-102525-PIP01-26

Of 01/10/2026 15:23 BST

On the adopted decision for Balcinrenone; DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE (MHRA-102525-PIP01-26) 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 Balcinrenone; DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, Capsule, hard, Oral age-appropriate formulation , ORAL USE .

This decision is addressed to AstraZeneca UK Limited, 2 Pancras Square, 8th Floor, London, UNITED KINGDOM, N1C 4AG

ANNEX I

1. Waiver

1.1 Condition:

Treatment of chronic kidney disease The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Capsule, hard Age-appropriate oral formulation Route(s) of administration: Oral use Reason for granting waiver: on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of chronic kidney disease

2.2 Indication(s) targeted by the PIP:

Treatment of chronic kidney disease

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

The paediatric population from 2 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Capsule, hard; Age-appropriate oral formulation

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate oral solid dosage form.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 Double-blind, randomised, placebo-controlled trial with an open-label extension period to evaluate efficacy, safety, pharmacokinetics and pharmacodynamics of balcinrenone/ dapagliflozin in children from 2 years to less than 18 years of age with chronic kidney disease (CKD).
Extrapolation, Modeling & Simulation Studies	1	Study 3 Population pharmacokinetic (PopPK) modelling and simulation analyses to predict initial doses of balcinrenone and dapagliflozin for children from 2 years to less than 18 years with CKD.
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:	31/03/2036
Deferral of one or more studies contained in the paediatric investigation plan:	Yes