MHRA
10 South Colonnade
Canary Wharf
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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-102304-PIP01-26

Scope of the Application

Active Substance(s)

VICADROSTAT; EMPAGLIFLOZIN

Condition(s)

Treatment of chronic kidney disease

Pharmaceutical Form(s)

Tablet, AGE-APPROPRIATE ORAL SOLID DOSAGE FORM

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Boehringer Ingelheim International GmbH

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Boehringer Ingelheim International GmbH submitted to the licensing authority on 29/01/2026 11:43 GMT an application for a Paediatric Investigation Plan

The procedure started on 03/02/2026 14:00 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 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-102304-PIP01-26

Of 23/10/2026 08:34 BST

On the adopted decision for VICADROSTAT; EMPAGLIFLOZIN (MHRA-102304-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 VICADROSTAT; EMPAGLIFLOZIN, Tablet Age-appropriate oral solid dosage form , ORAL USE .

This decision is addressed to Boehringer Ingelheim International GmbH, Binger Strasse 173, Ingelheim am Rhein, GERMANY, 55216

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): 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 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):

Tablet Age-appropriate oral solid dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of age-appropriate solid oral formulations as separate minitablets or granules for vicadrostat and empagliflozin for children from 2 years to less than 18 years of age.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 (EASi-KIDNEY Kids; 1378-0022) Open-label, single-arm study with integrated PK assessment to evaluate the long-term safety and confirm dose exposure-response of the combination of vicadrostat and empagliflozin in paediatric patients from 2 years to less than 18 years of age with chronic kidney disease.
Extrapolation, Modeling & Simulation Studies	3	Study 3 Modelling in drug development (MIDD) analyses to support dose selection for vicadrostat, PK sampling requirements and sample size for the paediatric clinical study (Study 2). Study 4 Modelling in drug development (MIDD) analyses to confirm exposure and dose for the different subsets of the paediatric population including exposure-response investigations. Extrapolation Plan Studies 2, 3 and the EMPA-KIDNEY Kids study (1245-0256) are part of the extrapolation plan of efficacy data from adult patients to the paediatric population from 2 years to less

		than 18 years of age with condition chronic kidney disease.
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:	30/11/2034
Deferral of one or more studies contained in the paediatric investigation plan:	Yes