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-102407-PIP01-26

Scope of the Application

Active Substance(s)

Nurandociguat

Condition(s)

Treatment of chronic kidney disease

Pharmaceutical Form(s)

Age-appropriate oral dosage form Film-coated tablet

Route(s) of Administration

Oral use

Name / Corporate name of the PIP applicant

Bayer plc

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Bayer plc submitted to the licensing authority on 24/07/2026 09:17 BST an application for a Paediatric Investigation Plan

The procedure started on 04/08/2026 15:57 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-102407-PIP01-26

Of 22/10/2026 08:22 BST

On the adopted decision for Nurandociguat (MHRA-102407-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 Nurandociguat, Age-appropriate oral dosage form Film-coated tablet , Oral use .

This decision is addressed to Bayer plc, 400 South Oak Way, Reading, UNITED KINGDOM, RG2 6AD

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): Age-appropriate oral dosage form Film-coated tablet 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 as clinical studies(s) are not feasible.

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):

Age-appropriate oral dosage form Film-coated tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate oral dosage form suitable for use in the paediatric population from 2 years to under 18 years of age.
Non-Clinical Studies	2	Study 2 Dose range-finding juvenile animal study to evaluate the toxicokinetic and general toxicity profile of nurandociguat in juvenile rats and to define suitable dose levels for the definitive juvenile animal study. Study 3 Definitive juvenile animal study to evaluate the toxicokinetic and general toxicity profile of nurandociguat in juvenile rats.
Clinical Studies	1	Study 4 Double-blind, randomised, placebo-controlled trial to evaluate efficacy, safety and pharmacokinetics of nurandociguat as add-on to standard of renin-angiotensin-aldosterone-system inhibitors (RAASi) therapy in children from 2 years to less than 18 years of age with chronic kidney disease stages of 2-3 and proteinuria.
Extrapolation, Modeling & Simulation Studies	3	Study 5 Modelling and simulation analyses to predict pharmacokinetics of nurandociguat in the paediatric population for selection of initial doses to be used in paediatric clinical trials. Study 6 Modelling and simulation analyses to confirm initial pharmacokinetics predictions

		of nurandociguat. Extrapolation Plan Studies 4 to 6 form part of the paediatric extrapolation plan to support extrapolation of efficacy from the adult reference population to the paediatric target population from 2 years to less than 18 years of age with 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:	31/12/2037
Deferral of one or more studies contained in the paediatric investigation plan:	Yes