MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral.

MHRA-100212-PIP01-21-M04

Scope of the Application

Active Substance(s)

FINERENONE

Condition(s)

Treatment of chronic kidney disease.

Pharmaceutical Form(s)

Film-coated tablet Granules for oral suspension

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 23/02/2026 15:19 GMT an application for a

The procedure started on 25/02/2026 10:02 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-100212-PIP01-21-M04

Of 03/03/2026 09:21 GMT

On the adopted decision for FINERENONE (MHRA-100212-PIP01-21-M04) 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 for FINERENONE, Film-coated tablet Age-appropriate oral (liquid or solid) dosage form , 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): Film-coated tablet Age-appropriate oral (liquid or solid) dosage form Route(s) of administration: ORAL USE Reason for granting waiver: For the paediatric population from birth to less than 6 months of age: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s). For the paediatric population from 6 months to 2 years of age: 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 chronic kidney disease.

2.2 Indication(s) targeted by the PIP:

Treatment of chronic kidney disease associated with proteinuria in addition to a therapy with angiotensin converting enzyme inhibitors (ACEI) or angiotensin receptor blockers (ARB).

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):

Film-coated tablet Age-appropriate oral (liquid or solid) dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of granules for oral suspension.
Non-Clinical Studies	1	Study 2 Juvenile toxicity study.
Clinical Studies	4	Study 3 Relative bioavailability and food effect study of age-appropriate oral liquid formulation in adult healthy subjects. Study 9 Relative bioavailability and food effect study of age-appropriate oral solid formulation in adult healthy subjects. Study 4 Randomized, double blind, placebo-controlled efficacy, safety and PK/PD study in children from 2 years to less than 18 years of age with chronic kidney disease (CKD) associated with proteinuria. Study 5 Open-label safety extension study in children from 2 years to less than 18 years of age with chronic kidney disease (CKD) associated with proteinuria.
Extrapolation, Modeling & Simulation Studies	3	Study 6 Physiologically based PK modelling study to predict pharmacokinetics and to define the doses of finerenone for the paediatric clinical trial in children from 2 years to less than 18 years of age with proteinuria associated with chronic

		kidney disease (CKD). Study 7 Population PK-PD modelling study to characterise the pharmacokinetics and compare the expected and observed pharmacokinetics and pharmacodynamics in children from 2 years to less than 18 years of age with proteinuria associated with CKD. Study 8 Extrapolation study to support exposure and efficacy assumptions in children from 2 years to less than 18 years of age with proteinuria associated 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:	Yes
Date of completion of the paediatric investigation plan:	31/03/2029
Deferral of one or more studies contained in the paediatric investigation plan:	Yes