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-100212-PIP01-21-M03

Scope of the Application

Active Substance(s)

FINERENONE

Condition(s)

Treatment of chronic kidney disease

Pharmaceutical Form(s)

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

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 16/04/2025 11:14 BST an application for a Modification

The procedure started on 24/04/2025 15:52 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 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-M03

Of 06/05/2025 09:45 BST

On the adopted decision for FINERENONE (MHRA-100212-PIP01-21-M03) 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 deferral included in that paediatric investigation plan).

This decision applies to a Modification for FINERENONE, Film-coated tablet Age-appropriate oral dosage (liquid or solid) 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 6 months of age. Pharmaceutical form(s): Film-coated tablet Age-appropriate dosage (liquid or solid) form Route(s) of administration: ORAL USE Reason for granting waiver: 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)..

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment 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 6 months 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 an age appropriate oral (liquid or solid) form.
Non-Clinical Studies	1	Study 2 Definitive 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 Randomised, double blind, placebo controlled study to evaluate the efficacy, safety and PK/PD in children from 6 months 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 1 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 dose of finerenone for the paediatric clinical trial in children 6 months 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 6 months to less than 18 years of age with proteinuria associated with CKD. Study 8 Extrapolation study to support exposure and efficacy assumptions in children 6 months 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