MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-101521-PIP01-24)

MHRA-101521-PIP01-24-M01

Scope of the Application

Active Substance(s)

Derivative of 6-(piperidine-1-carbonyl)pyridin-3-ol

Condition(s)

Treatment of glomerulonephritis and nephrotic syndrome

Pharmaceutical Form(s)

Film-coated 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 18/09/2025 19:56 BST an application for a Modification

The procedure started on 04/11/2025 13:21 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

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-101521-PIP01-24-M01

Of 22/12/2025 12:48 GMT

On the adopted decision for Derivative of 6-(piperidine-1-carbonyl)pyridin-3-ol (MHRA-101521-PIP01-24-M01) 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 Modification for Derivative of 6-(piperidine-1-carbonyl)pyridin-3-ol, Film-coated 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 glomerulonephritis and nephrotic syndrome The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 1 year of age Pharmaceutical form(s): Film-coated 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 does not represent a significant therapeutic benefit over existing treatments

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of glomerulonephritis and nephrotic syndrome

2.2 Indication(s) targeted by the PIP:

Treatment of steroid-resistant nephrotic syndrome (SRNS) due to primary focal-segmental glomerulosclerosis (FSGS), minimal-change disease (MCD), diffuse mesangial proliferative disease (DMP) or IgM-nephropathy (IgMN) in patients from 1 year to less than 18 years of age.

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

The paediatric population from 1 year to less than 18 years of age

2.4 Pharmaceutical Form(s):

Film-coated tablet Age appropriate oral solid dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	2	Study 1 Development of an age-appropriate oral solid dosage form. Study 2 Food compatibility and in-use stability study.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 3 Open-label, randomised, active-controlled trial to evaluate pharmacokinetics, safety and efficacy of BI 764198 compared to standard-of-care in children from 1 year to less than 18 years of age with steroid-resistant nephrotic syndrome due to focal-segmental glomerulosclerosis, minimal-change disease, diffuse-mesangioproliferative disease, IgM-nephropathy or C1q deposit nephropathy with or without mesangial proliferation. Study 6 (Added during procedure MHRA-101521-PIP01-24-M01) Randomised, double blind, parallel group study in patients with biopsy-proven primary focal-segmental glomerulosclerosis (FSGS) or known genetic FSGS related to mutation in the TRPC6 gene (TRPC6-related nephropathy).
Extrapolation, Modeling & Simulation Studies	2	Study 4 Modelling and simulation study to select the dose of BI 764198,

		sample size and plasma sampling schedule for PIP study 3. Study 5 Population PK/PD model and exposure-response analysis.
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:	29/02/2036
Deferral of one or more studies contained in the paediatric investigation plan:	Yes