MHRA
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Canary Wharf
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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-100273-PIP01-21

Scope of the Application

Active Substance(s)

5-Ethoxy-1-(6-(3-methyl-2-((5-methyl-2-(tetrahydro-2Hpyran- 4-yl)-1,2,3,4-tetrahydroisoquinolin-6-yl)methoxy)phenyl)pyridin-2-yl)-1H-pyrazole-4- carboxylic acid

Condition(s)

Treatment of chronic kidney disease

Pharmaceutical Form(s)

Modified-release film-coated tablet; Modified-release granules; Age-appropriate formulation

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 08/02/2022 10:54 GMT an application for a Paediatric Investigation Plan

The procedure started on 31/08/2022 07:18 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-100273-PIP01-21

Of 14/10/2022 11:23 BST

On the adopted decision for 5-Ethoxy-1-(6-(3-methyl-2-((5-methyl-2-(tetrahydro-2Hpyran- 4-yl)-1,2,3,4-tetrahydroisoquinolin-6- yl)methoxy)phenyl)pyridin-2-yl)-1H-pyrazole-4- carboxylic acid (MHRA-100273-PIP01-21) 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 5-Ethoxy-1-(6-(3-methyl-2-((5-methyl-2-(tetrahydro-2Hpyran- 4-yl)-1,2,3,4-tetrahydroisoquinolin-6- yl)methoxy)phenyl)pyridin-2-yl)-1H-pyrazole-4- carboxylic acid, Modified-release film-coated tablet; Modified-release granules; Age-appropriate formulation , 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 (CKD) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 months of age Pharmaceutical form(s): Modified-release film-coated tablet; Modified-release granules; Age-appropriate formulation 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 (CKD)

2.2 Indication(s) targeted by the PIP:

Treatment of proteinuric chronic kidney disease

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):

Modified-release film-coated tablet; Modified-release granules; Modified-release tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate formulation.
Non-Clinical Studies	0	Not applicable
Clinical Studies	2	Study 2 Randomised double blind phase III PK trial to evaluate dose-exposure-response and safety of BI 685509 in paediatric patients with proteinuric CKD and to explore efficacy endpoints. Study 3 Open label safety extension study. Main objective is to evaluate safety of BI 685509 in paediatric patients with proteinuric chronic kidney disease (CKD) aged 6 months to less than 18 years.
Extrapolation, Modeling & Simulation Studies	2	Study 4 Population pharmacokinetic (PK) model. Study 5 Population PK model and exposure-response investigations.
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:	30/11/2031
Deferral of one or more studies contained in the paediatric investigation plan:	Yes