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

**gov.uk/mhra**

# Decision Cover Letter

## Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-100446-PIP01-22

# Scope of the Application

## Active Substance(s)

Derivative of 3#phenyl#3H,4H,6H,7H#pyrano[3,4#d]imidazol#4#one

## Condition(s)

Treatment of chronic kidney disease

## 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 21/11/2022 13:45 GMT an application for a Paediatric Investigation Plan

The procedure started on 12/04/2023 16:42 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-100446-PIP01-22

Of 06/10/2023 10:43 BST

On the adopted decision for Derivative of 3#phenyl#3H,4H,6H,7H#pyrano[3,4#d]imidazol#4#one (MHRA-100446-PIP01-22) 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 Derivative of 3#phenyl#3H,4H,6H,7H#pyrano[3,4#d]imidazol#4#one, 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 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 oral solid dosage form Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s). |

### 2. Paediatric Investigation Plan:

### 2.1 Condition(s):

| |
|---|
| Treatment of chronic kidney disease |

## 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):

Film-coated tablet Age-appropriate oral solid dosage form

## 2.5 Studies:

| Study Type | Number of Studies | Study Description |
|---|---|---|
| **Quality Measures** | 1 | Study 1 Development of film-coated mini tablets. |
| **Non-Clinical Studies** | 0 | Not applicable. |
| **Clinical Studies** | 2 | Study 2 Randomised double blind trial to evaluate dose-exposure-response and safety of BI 690517 in paediatric patients with proteinuric chronic kidney disease (CKD) and to explore efficacy endpoints. Study 3 Open label safety extension study in paediatric patients with proteinuric CKD from 6 months to less than 18 years of age. |
| **Extrapolation, Modeling & Simulation Studies** | 2 | Study 4 Population pharmacokinetic (PK) model to support the dose selection. PK sampling requirements and sample size for the clinical studies in infants, children and adolescents with CKD. Study 5 Population PK model and exposure-response investigation to support the definition of the paediatric dosing regimen and characterise the exposure-response relationship for selected efficacy endpoints and the main safety limiting endpoint. |
| **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:** | 31/12/2036 |
| **Deferral of one or more studies contained in the paediatric investigation plan:** | Yes |