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 (MHRA-100114-PIP01-21) and to the deferral

MHRA-100114-PIP01-21-M01

Scope of the Application

Active Substance(s)

BARICITINIB

Condition(s)

Treatment of coronavirus disease 2019 (COVID-19)

Pharmaceutical Form(s)

Film-coated tablet Age-appropriate oral liquid dosage form

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

ELI LILLY NEDERLAND B.V.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, ELI LILLY NEDERLAND B.V. submitted to the licensing authority on 05/12/2022 14:35 GMT an application for a Modification

The procedure started on 01/03/2023 10:20 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-100114-PIP01-21-M01

Of 16/03/2023 07:28 GMT

On the adopted decision for BARICITINIB (MHRA-100114-PIP01-21-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 BARICITINIB, Film-coated tablet Age-appropriate oral liquid dosage form , ORAL USE .

This decision is addressed to ELI LILLY NEDERLAND B.V., Papendorpseweg 83, Utrecht, UNITED KINGDOM, 352

ANNEX I

1. Waiver

1.1 Condition:

Treatment of coronavirus disease 2019 (COVID-19) 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 liquid 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 coronavirus disease 2019 (COVID-19)

2.2 Indication(s) targeted by the PIP:

Treatment of coronavirus disease 2019 (COVID-19) in paediatric subjects from 1 year to less than 18 years of age requiring supplemental oxygen

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 liquid dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate oral liquid pharmaceutical form for baricitinib.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 Open label, single arm study to evaluate the pharmacokinetics and safety of baricitinib and to provide PK/PD data to support extrapolation of efficacy from adults to paediatric patients from 1 year to less than 18 years of age with confirmed COVID-19.
Extrapolation, Modeling & Simulation Studies	2	Study 3 Modelling and simulation study to determine and confirm a paediatric dose for baricitinib in paediatric patients from 1 year to less than 18 years of age with confirmed COVID-19 that should achieve an exposure equivalent to that observed in adults. Study 4 Extrapolation study to support efficacy assumptions for baricitinib in the paediatric population from 1 year to less than 18 years of age with COVId-19 from adult patients with confirmed COVID-19.
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:	31/01/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes