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-100221-PIP01-21-M01

Scope of the Application

Active Substance(s)

BARICITINIB

Condition(s)

Treatment of atopic dermatitis

Pharmaceutical Form(s)

Tablet, Oral suspension

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 18/08/2021 10:11 BST an application for a

The procedure started on 13/04/2022 15:24 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-100221-PIP01-21-M01

Of 28/04/2022 07:01 BST

On the adopted decision for BARICITINIB (MHRA-100221-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 for BARICITINIB, Tablet, Oral suspension , Oral use .

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

ANNEX I

1. Waiver

1.1 Condition:

Treatment of atopic dermatitis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Tablet; Oral suspension 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 atopic dermatitis

2.2 Indication(s) targeted by the PIP:

Treatment of patients with moderate to severe atopic dermatitis

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

The paediatric population from 2 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Tablet; Oral suspension

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate liquid oral formulation.
Non-Clinical Studies	2	Study 2 Pre- and postnatal development study in rats (WIL-353280). Study 3 Juvenile toxicology study in rats (9000909).
Clinical Studies	1	Study 4 Randomised, double-blind, parallel-group, placebo-controlled trial to evaluate PK, efficacy and safety of baricitinib in children from 2 to less than 18 years of age with moderate to severe atopic dermatitis (I4V-MC-JAIP).
Extrapolation, Modeling & Simulation Studies	0	Not applicable
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:	30/09/2022
Deferral of one or more studies contained in the paediatric investigation plan:	Yes