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-100443-PIP01-22-M01) and to the deferral

MHRA-100443-PIP01-22-M02

Scope of the Application

Active Substance(s)

BARICITINIB

Condition(s)

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis and juvenile idiopathic arthritis)

Pharmaceutical Form(s)

Film-coated 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 14/04/2023 11:26 BST an application for a Modification

The procedure started on 17/07/2023 11:48 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-100443-PIP01-22-M02

Of 04/08/2023 13:38 BST

On the adopted decision for BARICITINIB (MHRA-100443-PIP01-22-M02) 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; Oral suspension , ORAL USE .

This decision is addressed to Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, Netherlands, Utrecht, NETHERLANDS, 3528

ANNEX I

1. Waiver

1.1 Condition:

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis and juvenile idiopathic arthritis). 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. Oral suspension. Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis and juvenile idiopathic arthritis).

2.2 Indication(s) targeted by the PIP:

Treatment of juvenile idiopathic arthritis. Treatment of JIA-associated uveitis.

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. 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. Study 3 Juvenile toxicology study in rats.
Clinical Studies	3	Study 4 (I4V-MC-JAHV) Double-blind, randomised, withdrawal, placebo-controlled study to evaluate safety and efficacy of baricitinib in children from 2 years to less than 18 years of age with juvenile idiopathic arthritis (JIA). Study 5 (I4V-MC-JAHU) Double-blind, randomised, withdrawal, placebo-controlled study to evaluate safety, efficacy and pharmacokinetics of baricitinib in children from 1 year to less than 18 years of age with systemic juvenile idiopathic arthritis (sJIA). Study 6 (I4V-MC-JAHW) Open-label, active controlled trial to evaluate safety and efficacy of baricitinib compared to adalimumab in children from 2 years to less than 18 years of age with active JIA-associated uveitis or chronic anterior antinuclear antibody-positive (ANA-positive) uveitis without systemic features.

Extrapolation, Modeling & Simulation Studies	0	Not appliable.
Other Studies	0	Not appliable.
Other Measures	0	Not appliable.

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:	30/09/2025
Deferral of one or more studies contained in the paediatric investigation plan:	Yes