MHRA
10 South Colonnade
Canary Wharf
London
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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-101647-PIP01-24-M01

Scope of the Application

Active Substance(s)

IXEKIZUMAB

Condition(s)

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

Pharmaceutical Form(s)

solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Eli Lilly and Co. Ireland Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Eli Lilly and Co. Ireland Limited submitted to the licensing authority on 02/10/2024 12:59 BST an application for a Modification

The procedure started on 04/11/2024 17:21 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-101647-PIP01-24-M01

Of 19/11/2024 12:34 GMT

On the adopted decision for IXEKIZUMAB (MHRA-101647-PIP01-24-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 IXEKIZUMAB, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Eli Lilly and Co. Ireland Limited, Dunderrow, Kinsale, IRELAND, P17 NY71

ANNEX I

1. Waiver

1.1 Condition:

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis). The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age. Pharmaceutical form(s): Solution for injection Route(s) of administration: SUBCUTANEOUS 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, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis).

2.2 Indication(s) targeted by the PIP:

Treatment of juvenile idiopathic arthritis (JIA) subsets of Juvenile enthesitis-related arthritis (ERA) including juvenile onset ankylosing spondylitis (JoAS) and juvenile psoriatic arthritis JPsA in paediatric patients from the age of 2 years of age.

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

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

2.4 Pharmaceutical Form(s):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of prefilled syringe presentations to accommodate weight strata subcutaneous (SC) dosing in children
Non-Clinical Studies	2	Study 2 Repeat-Dose Fertility Study to investigate the potential effects of ixekizumab. Study 3 PPND Toxicity Study to evaluate development of the F1 offspring, including the immune system, following in utero exposure to ixekizumab.
Clinical Studies	1	Study 4 Open label, efficacy, safety, tolerability, pharmacokinetic study of subcutaneous ixekizumab with adalimumab reference arm in children with juvenile idiopathic arthritis subtypes of enthesitis-related arthritis (including juvenile-onset ankylosing spondylitis) and juvenile psoriatic arthritis.
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:	31/07/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes