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 (EMEA-001741-PIP03-16-M01) and to the deferral

MHRA-101491-PIP01-24-M01

Scope of the Application

Active Substance(s)

UPADACITINIB

Condition(s)

Treatment of Crohn's disease

Pharmaceutical Form(s)

Prolonged-release tablet; Age-appropriate oral pharmaceutical form

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

AbbVie Ltd.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AbbVie Ltd. submitted to the licensing authority on 16/10/2024 10:46 BST an application for a Modification

The procedure started on 02/12/2024 08:17 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 and to link this PIP with related PIP Decisions covering all authorised indications of upadacitinib for the treatment of alopecia areata, treatment of atopic dermatitis, treatment of vasculitides, treatment of vitiligo, for treatment of ulcerative colitis, treatment of systemic lupus erythematosus, treatment of hidradenitis suppurativa and for treatment of chronic idiopathic arthritis, including all subsequent modifications thereof.

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-101491-PIP01-24-M01

Of 21/01/2025 10:09 GMT

On the adopted decision for UPADACITINIB (MHRA-101491-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 UPADACITINIB, Prolonged-release tablet; Age-appropriate oral pharmaceutical form , ORAL USE .

This decision is addressed to AbbVie Ltd., AbbVie House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, UNITED KINGDOM, SL6 4UB

ANNEX I

1. Waiver

1.1 Condition:

Treatment of Crohn's disease The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Prolonged-release tablet Age-appropriate oral pharmaceutical form 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 Crohn's disease (CD)

2.2 Indication(s) targeted by the PIP:

Treatment of paediatric patients with moderately to severely active Crohn's disease

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):

Prolonged-release tablet Age-appropriate oral pharmaceutical form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Age-appropriate oral solid dosage form (dispersible tablet or multi-particulate granules) or age-appropriate oral liquid dosage form.
Non-Clinical Studies	2	Study 2 Dose range-finding juvenile toxicity study. Study 3 Definitive juvenile toxicity study to evaluate toxicity and impact of upadacitinib on neonatal/juvenile development.
Clinical Studies	1	Study 4 (M14-671) Double-blind safety, efficacy, and pharmacokinetic study with an open label induction phase of upadacitinib in children from 2 to less than 18 years with moderately to severely active Crohn's disease, who have had an inadequate response or been intolerant to corticosteroids, immunosuppressants, and/or biologic therapy, or have medical contraindications to such therapies.
Extrapolation, Modeling & Simulation Studies	1	Study 5 Population PK modelling and simulation study to determine the dose of upadacitinib in children from 2 to less than 18 years of age with Crohn's disease.
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:	30/09/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes