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-101244-PIP01-23)

MHRA-101244-PIP01-23-M01

Scope of the Application

Active Substance(s)

UPADACITINIB

Condition(s)

Treatment of vitiligo

Pharmaceutical Form(s)

Prolonged-release tablet, Oral solution

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 21/08/2025 01:15 BST an application for a

The procedure started on 02/09/2025 22:10 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

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-101244-PIP01-23-M01

Of 05/12/2025 07:07 GMT

On the adopted decision for UPADACITINIB (MHRA-101244-PIP01-23-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 UPADACITINIB, Prolonged-release tablet, Oral solution , ORAL USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Treatment of vitiligo The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age Pharmaceutical form(s): Prolonged-release tablet Age-appropriate oral 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 vitiligo

2.2 Indication(s) targeted by the PIP:

Treatment of nonsegmental vitiligo

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

The paediatric population from 6 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Prolonged-release tablet Age-appropriate oral dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of age-appropriate oral dosage form.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	3	Study 2 Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of upadacitinib in children from 12 years to less than 18 years of age (and adults) with nonsegmental vitiligo. Study 3 Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of upadacitinib in children from 12 years to less than 18 years of age (and adults) with nonsegmental vitiligo. Study 4 Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of upadacitinib in children from 6 years to less than 12 years of age with nonsegmental vitiligo.
Extrapolation, Modeling & Simulation Studies	2	Study 5 Modelling and simulation study to evaluate the use of upadacitinib in children from 12 years to less than 18 years of age with nonsegmental vitiligo. Study 6 Modelling and simulation study to evaluate the use of upadacitinib in children from 6 years to less than 12 years of age with nonsegmental vitiligo.
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:	31/08/2029
Deferral of one or more studies contained in the paediatric investigation plan:	Yes