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-100722-PIP01-22) and to the deferral

MHRA-100722-PIP01-22-M01

Scope of the Application

Active Substance(s)

Ritlecitinib

Condition(s)

Treatment of vitiligo

Pharmaceutical Form(s)

Tablet Capsule, hard Age appropriate oral solid dosage form

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Pfizer Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Pfizer Limited submitted to the licensing authority on 12/03/2025 15:58 GMT an application for a Modification

The procedure started on 10/04/2025 16:35 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-100722-PIP01-22-M01

Of 20/06/2025 15:48 BST

On the adopted decision for Ritlecitinib (MHRA-100722-PIP01-22-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 Ritlecitinib, Tablet Capsule, hard Age appropriate oral solid dosage form , ORAL USE .

This decision is addressed to Pfizer Limited, Ramsgate Road, Sandwich, UNITED KINGDOM, CT13 9NJ

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): Tablet Capsule, hard Age-appropriate oral solid dosage form Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of vitiligo

2.2 Indication(s) targeted by the PIP:

Treatment of patients with nonsegmental vitiligo who are candidates for systemic treatment

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):

Tablet Capsule, hard Age-appropriate oral solid dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age appropriate oral formulation suitable for children less than 12 years of age.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	3	Study 2 (B7981040) Randomised, double-blind 52-week placebo controlled multicentre study investigating the efficacy , safety and tolerability of ritlecitinib in adolescents from 12 years to less than 18 years of age (and adults) with nonsegmental vitiligo. Study 3 (B7981038) Randomised, double-blind, placebo-controlled study to investigate the efficacy and safety of ritlecitinib in paediatric participants from 6 years to less than 18 years of age with nonsegmental vitiligo. Study 4 (B7981039) Long term, extension study to evaluate the safety and efficacy of ritlecitinib in paediatric participants 6 years to less than 18 years of age with nonsegmental vitiligo.
Extrapolation, Modeling & Simulation Studies	1	Study 5 Population pharmacokinetic (PK) modelling and simulation analysis.
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:	31/03/2034
Deferral of one or more studies contained in the paediatric investigation plan:	Yes