MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-100722-PIP01-22

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 31/10/2022 15:03 GMT an application for a Paediatric Investigation Plan

The procedure started on 20/03/2023 17:28 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 agree a paediatric investigation plan and grant a deferral and grant a waiver

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

Of 09/10/2023 11:49 BST

On the adopted decision for Ritlecitinib (MHRA-100722-PIP01-22) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan 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, CT139NJ

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 12 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 12 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:	31/07/2031
Deferral of one or more studies contained in the paediatric investigation plan:	Yes