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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral.

MHRA-100807-PIP01-22-M02

Scope of the Application

Active Substance(s)

RIMEGEPANT SULFATE

Condition(s)

Treatment of migraine headaches

Pharmaceutical Form(s)

Oral lyophilisate

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 10/10/2023 10:02 BST an application for a Modification

The procedure started on 01/02/2024 09:58 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-100807-PIP01-22-M02

Of 08/02/2024 09:03 GMT

On the adopted decision for RIMEGEPANT SULFATE (MHRA-100807-PIP01-22-M02) 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 RIMEGEPANT SULFATE, Oral lyophilisate , ORAL USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Treatment of migraine headaches The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age. Pharmaceutical form(s): Oral lyophilisate Route(s) of administration: ORAL USE Reason for granting waiver: On the grounds the specific medicinal product does not represent a significant therapeutic benefit over existing treatments

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of migraine headaches

2.2 Indication(s) targeted by the PIP:

Treatment of migraine attacks in children and adolescents.

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):

Oral lyophilisate

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age appropriate oral lyophilisate.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	3	Study 2 Open-label, single dose pharmacokinetic and tolerability study of rimegepant in paediatric subjects from 6 years to less than 12 years of age with a history of migraine headache including assessment of palatability of the formulation. Study 3 Double-blind, placebo-controlled, group sequential placebo-controlled study to assess the efficacy and safety of rimegepant for the acute treatment of migraine (with or without aura) in children and adolescents from 6 to less than 18 years of age. Study 4 Open-label study to assess the safety and tolerability of long term use of rimegepant taken up to once per day by children and adolescents (from 6 to less than 18 years of age) with migraine.
Extrapolation, Modeling & Simulation Studies	1	Study 5 Population PK model based on adult data to establish paediatric doses to be used in paediatric studies 1, 2 and 3 and confirmation of appropriateness of these doses.
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:	31/10/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes