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-101858-PIP01-25

Scope of the Application

Active Substance(s)

atogepant

Condition(s)

Treatment of migraine headaches

Pharmaceutical Form(s)

Tablet Age-appropriate oral solid dosage 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 13/05/2025 17:24 BST an application for a Paediatric Investigation Plan

The procedure started on 20/08/2025 11:44 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 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-101858-PIP01-25

Of 10/09/2025 11:57 BST

On the adopted decision for atogepant (MHRA-101858-PIP01-25) 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 atogepant, Tablet Age-appropriate oral solid dosage form , ORAL USE .

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

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): Tablet 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 migraine headaches.

2.2 Indication(s) targeted by the PIP:

Treatment of migraine attacks

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 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 solid formulation for the paediatric population from 6 years to less than 18 years of age.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 Randomised, double-blind placebo controlled study in paediatric patients from 6 years to less than 18 years of age to evaluate safety, efficacy and tolerability of atogepant for the acute treatment of migraine.
Extrapolation, Modeling & Simulation Studies	2	Study 3 Population pharmacokinetic (PK) modelling of data from paediatric subjects with a history of migraine treated in prevention studies with atogepant. Study 4 Population PK and exposure-response modelling of data from acute treatment of migraine in adults.
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:	31/03/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes