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 and to the deferral

MHRA-100916-PIP01-23-M01

Scope of the Application

Active Substance(s)

ELUXADOLINE

Condition(s)

Treatment of diarrhoea irritable bowel syndrome.

Pharmaceutical Form(s)

Film coated tablet

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 16/08/2023 13:07 BST an application for a Modification

The procedure started on 12/01/2024 09:50 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-100916-PIP01-23-M01

Of 26/01/2024 09:39 GMT

On the adopted decision for ELUXADOLINE (MHRA-100916-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 Modification for ELUXADOLINE, Film-coated tablet , 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 diarrhoea-predominant irritable bowel syndrome The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age. Pharmaceutical form(s): Film-coated tablet 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 diarrhoea-predominant irritable bowel syndrome

2.2 Indication(s) targeted by the PIP:

Treatment of diarrhoea-predominant irritable bowel syndrome

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):

Film-coated tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Study 5 This study was deleted during procedure MHRA-100916-PIP01-23-M01.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 1 This study was deleted during procedure MHRA-100916-PIP01-23-M01. Study 2 Double-blind, placebo-controlled study to evaluate safety and efficacy of eluxadoline in children and adolescents from 6 years to less than 18 years of age with diarrhoea-predominant irritable bowel syndrome (IBS-d). Study 3 Randomised, double-blind, placebo-controlled, parallel-group, dose-ranging study to evaluate dose-response, efficacy and safety of eluxadoline in paediatric patients (age 6 years to less than 18 years) with irritable bowel syndrome with diarrhoea (IBS-d). Study 4 This study was deleted during procedure MHA-100916-PIP01-23-M01.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
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:	31/12/2037
Deferral of one or more studies contained in the paediatric investigation plan:	Yes