EMA/89818/2024

# European Medicines Agency decision

P/0078/2024

of 8 March 2024

on the acceptance of a modification of an agreed paediatric investigation plan for eluxadoline (EMEA-001579-PIP01-13-M06) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

**Disclaimer**

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

**Only the English text is authentic.**

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0021/2015 issued on 30 January 2015, the decision P/0388/2017 issued on 19 December 2017, the decision P/0107/2020 issued on 18 March 2020 and the decision P/0128/2022 issued on 13 April 2022.

Having regard to the application submitted by AbbVie Limited on 12 October 2023 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 January 2024, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

***Article 1***

Changes to the agreed paediatric investigation plan for eluxadoline, film-coated tablet, oral use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

***Article 2***

This decision is addressed to AbbVie Limited, Abbott House, Vanwall Business Park, Vanwall Road, SL6 4XE – Maidenhead, United Kingdom.

EMA/PDCO/501007/2023
Amsterdam, 19 January 2024

# Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001579-PIP01-13-M06

## Scope of the application

**Active substance(s):**

Eluxadoline

**Invented name and authorisation status:**

See Annex II

**Condition(s):**

Treatment of diarrhoea-predominant irritable bowel syndrome

**Pharmaceutical form(s):**

Film-coated tablet

**Route(s) of administration:**

Oral use

**Name/corporate name of the PIP applicant:**

AbbVie Limited

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, AbbVie Limited submitted to the European Medicines Agency on 12 October 2023 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0021/2015 issued on 30 January 2015, the decision P/0388/2017 issued on 19 December 2017, the decision P/0107/2020 issued on 18 March 2020 and the decision P/0128/2022 issued on 13 April 2022.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 20 November 2023.

## Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

## Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

# Annex I

# The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

# 1. Waiver

## *1.1. Condition*

Treatment of diarrhoea-predominant irritable bowel syndrome

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- film-coated tablet; oral use;
- 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*

Treatment of diarrhoea-predominant irritable bowel syndrome

### 2.1.1. Indication(s) targeted by the PIP

Treatment of diarrhoea-predominant irritable bowel syndrome

### 2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 6 years to less than 18 years of age

### 2.1.3. Pharmaceutical form(s)

Film-coated tablet

### 2.1.4. Measures

| **Area** | **Description** |
|---|---|
| Quality-related studies | **Study 5** (study deleted during procedure EMEA-001579-PIP01-13-M05) |
| Non-clinical studies | Not applicable |
| Clinical studies | **Study 1** (study deleted during procedure EMEA-001579-PIP01-13-M02)<br>**Study 2**<br>Double-blind, placebo-controlled study to evaluate safety and efficacy of Eluxadoline in children and adolescents 6 years to less than 18 years with diarrhoea-predominant irritable bowel syndrome (IBS-d)<br>**Study 3** (study added during procedure EMEA-001579-PIP01-13-M02) |

| | |
|---|---|
| | 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-<18 years) with irritable bowel syndrome with diarrhoea (IBS-d)<br><br>**Study 4** (study deleted during procedure EMEA-001579-PIP01-13-M05) |
| Extrapolation, modelling and simulation studies | Not applicable |
| Other studies | Not applicable |
| Other measures | Not applicable |

# 3. Follow-up, completion and deferral of PIP

| | |
|---|---|
| Concerns on potential long term safety/efficacy issues in relation to paediatric use: | Yes |
| Date of completion of the paediatric investigation plan: | By December 2037 |
| Deferral for one or more measures contained in the paediatric investigation plan: | Yes |

# Annex II

# Information about the authorised medicinal product

***Information provided by the applicant:***

**The product is not authorised anywhere in the European Community.**