

**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 (MHRA-100517-PIP01-22-M04) and to the deferral

MHRA-100517-PIP01-22-M06

### **Scope of the Application**

#### **Active Substance(s)**

APREMILAST

#### **Condition(s)**

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis)

#### **Pharmaceutical Form(s)**

Tablet Oral liquid

#### **Route(s) of Administration**

ORAL USE

#### **Name / Corporate name of the PIP applicant**

Amgen Limited

#### **Basis for the Decision**

Pursuant to the Human Medicines Regulations 2012, Amgen Limited submitted to the licensing authority on 20/11/2025 15:48 GMT an application for a Modification

The procedure started on 02/12/2025 14:01 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-100517-PIP01-22-M06

Of 24/02/2026 09:27 GMT

On the adopted decision for APREMILAST (MHRA-100517-PIP01-22-M06) 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 APREMILAST, Tablet Oral liquid , ORAL USE .

This decision is addressed to Amgen Limited, 216 Cambridge Science Park, Milton Road, Cambridge, UNITED KINGDOM, CB4 0WA

## ANNEX I

### 1. Waiver

#### 1.1 Condition:

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 5 years of age. Pharmaceutical form(s): Tablet. Oral liquid. Route(s) of administration: ORAL USE Reason for granting waiver: • For the paediatric population from birth to less than 1 year of age: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s). • For the paediatric population from 1 year to less than 2 years of age: on the grounds that the specific medicinal product is likely to be unsafe. • For the paediatric population from 2 years to less than 5 years of age: on the grounds that the specific medicinal product is likely to be ineffective.

### 2. Paediatric Investigation Plan:

#### 2.1 Condition(s):

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis)

## 2.2 Indication(s) targeted by the PIP:

Treatment of juvenile psoriatic arthritis (JPsA)

## 2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 5 years to less than 18 years of age.

## 2.4 Pharmaceutical Form(s):

Tablet Oral liquid

## 2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of oral liquid for paediatric use.
Non-Clinical Studies	1	Study 2 (CC-10004-TOX-1125) Toxicity study in mice during the entire developmental phase from weaning to adulthood.
Clinical Studies	1	Study 3 deleted during EMEA-000715-PIP02-11-M03. Study 4 deleted during EMEA-000715-PIP02-11-M03. Study 5 deleted during EMEA-000715-PIP02-11-M03. Study 6 (CC-10004-PSA-016; PEAPOD) (Added during procedure EMEA-000715-PIP02-11-M03) Double-blind, randomised, placebo-controlled trial to evaluate the efficacy, safety and pharmacokinetics of apremilast in children from 5 years to less than 18 years of age with active juvenile psoriatic arthritis (JPsA).
Extrapolation, Modeling & Simulation Studies	1	Study 7 (Added during procedure EMEA-000715-PIP02-11-M03) Extrapolation study to demonstrate/confirm the magnitude of effect of

		apremilast on efficacy outcomes in children from 5 years to less than 18 years of age with juvenile psoriatic arthritis (JPsA).
<b>Other Studies</b>	0	Not applicable
<b>Other Measures</b>	0	Not applicable

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

<b>Concerns on potential long term safety and efficacy issues in relation to paediatric use:</b>	Yes
<b>Date of completion of the paediatric investigation plan:</b>	31/01/2032
<b>Deferral of one or more studies contained in the paediatric investigation plan:</b>	No