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-101549-PIP01-24

Scope of the Application

Active Substance(s)

RO7790121; Afimkibart

Condition(s)

Treatment of ulcerative colitis

Pharmaceutical Form(s)

Solution for injection/infusion

Route(s) of Administration

INTRAVENOUS USE; SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Roche Products Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Roche Products Limited submitted to the licensing authority on 06/08/2024 10:59 BST an application for a Paediatric Investigation Plan

The procedure started on 06/09/2024 11:24 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-101549-PIP01-24

Of 08/08/2025 14:04 BST

On the adopted decision for Afimkibart (MHRA-101549-PIP01-24) 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 Afimkibart, Solution for injection/infusion , INTRAVENOUS USE SUBCUTANEOUS USE .

This decision is addressed to Roche Products Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, UNITED KINGDOM, AL7 1TW

ANNEX I

1. Waiver

1.1 Condition:

Treatment of ulcerative Colitis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Solution for injection/ infusion Route(s) of administration: INTRAVENOUS USE SUBCUTANEOUS 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 ulcerative colitis

2.2 Indication(s) targeted by the PIP:

Treatment of paediatric patients from 2 years to less than 18 years of age with moderately to severely active ulcerative colitis

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

The paediatric population from 2 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for injection/infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 1 Double-blind, randomised, multi-centre induction and maintenance trial to evaluate the pharmacokinetics, pharmacodynamics, immunogenicity, safety, and activity of intravenous and subcutaneous afimkibart (for up to 52 weeks of administration) in children from 2 years to less than 18 years of age with moderately to severely active ulcerative colitis.
Extrapolation, Modeling & Simulation Studies	2	Study 2 Population pharmacokinetic/ pharmacodynamic modelling study of intravenous and subcutaneous afimkibart in paediatric (and adult) patients with ulcerative colitis. Extrapolation plan Studies 1 and 2 are part of an extrapolation plan covering the paediatric population from 2 years to less than 18 years of age.
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:	31/12/2030

Deferral of one or more studies contained in the paediatric investigation plan:	Yes