MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral.

MHRA-100678-PIP01-22-M03

Scope of the Application

Active Substance(s)

Vamikibart

Condition(s)

Treatment of uveitic macular oedema

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

INTRAVITREAL USE

Name / Corporate name of the PIP applicant

F HOFFMANN-LA ROCHE LIMITED

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, F HOFFMANN-LA ROCHE LIMITED submitted to the licensing authority on 11/09/2026 15:59 BST an application for a Modification

The procedure started on 15/09/2026 10:42 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 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-100678-PIP01-22-M03

Of 21/09/2026 11:16 BST

On the adopted decision for Vamikibart (MHRA-100678-PIP01-22-M03) 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 Vamikibart, Solution for injection , INTRAVITREAL USE .

This decision is addressed to F HOFFMANN-LA ROCHE LIMITED, 6 Falcon Way, Shire Park, Welwyn Garden City, UNITED KINGDOM, AL7 1TW

ANNEX I

1. Waiver

1.1 Condition:

Treatment of uveitic macular oedema 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 Route(s) of administration: INTRAVITREAL USE Reason for granting waiver: 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).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of uveitic macular oedema.

2.2 Indication(s) targeted by the PIP:

Treatment of uveitic macular oedema.

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

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, deleted during MHRA-100678-PIP01-22-M03. Study 2, deleted during MHRA-100678-PIP01-22-M03. Study 4 Open label, 52-week single arm, externally controlled study to evaluate efficacy and safety of vamikibart in paediatric patients from 2 years to less than 18 years of age with macular oedema (UME) associated with non-infectious uveitis (NIU). (Added during MHRA-100678-PIP01-22-M03.)
Extrapolation, Modeling & Simulation Studies	0	Study 3, deleted during MHRA-100678-PIP01-22-M03.
Other Studies	0	Not applicable.
Other Measures	1	Extrapolation plan Study 4 is part of the extrapolation plan of efficacy data from adults to the paediatric population from 2 years to less than 18 years of age with non-infectious uveitis (NIU) and associated uveitic macular oedema (UME).

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:	30/04/2032

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