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 (MHRA-100355-PIP02-22) and to the deferral.

MHRA-100355-PIP02-22-M01

Scope of the Application

Active Substance(s)

fenebrutinib

Condition(s)

Treatment of multiple sclerosis

Pharmaceutical Form(s)

Tablet, Age appropriate oral solid dosage form

Route(s) of Administration

ORAL 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 10/10/2025 17:44 BST an application for a Modification

The procedure started on 04/11/2025 17:47 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-100355-PIP02-22-M01

Of 28/11/2025 12:06 GMT

On the adopted decision for fenebrutinib (MHRA-100355-PIP02-22-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 fenebrutinib, Tablet, Age appropriate oral solid dosage form , ORAL 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 multiple sclerosis. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 10 years of age. Pharmaceutical form(s): Tablet Age-appropriate oral solid dosage form Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of multiple sclerosis.

2.2 Indication(s) targeted by the PIP:

Treatment of relapsing multiple sclerosis (RMS) in patients 10 years of age and older.

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

The paediatric population from 10 years to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Tablet Age-appropriate oral solid dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate formulation for use in children 10 years of age and older.
Non-Clinical Studies	0	Not applicable
Clinical Studies	1	Study 2 Randomised, double-blind, active-controlled, double-dummy, non-inferiority trial to evaluate the pharmacokinetics, efficacy and safety of fenebrutinib as compared to fingolimod in children from 10 years to less than 18 years of age with relapsing multiple sclerosis (RMS).
Extrapolation, Modeling & Simulation Studies	1	Study 3 Population pharmacokinetic modelling and exposure-response modelling to establish the dose of fenebrutinib in children from 10 years to less than 18 years of age with relapsing multiple sclerosis (RMS).
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:	31/12/2029
Deferral of one or more studies contained in the paediatric investigation plan:	Yes