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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-100355-PIP02-22

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 20/06/2022 13:32 BST an application for a Paediatric Investigation Plan

The procedure started on 20/06/2022 15:07 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-100355-PIP02-22

Of 07/07/2022 10:40 BST

On the adopted decision for Fenebrutinib (MHRA-100355-PIP02-22) 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 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	0	Not applicable
Non-Clinical Studies	1	Study 1 Development of an age-appropriate formulation for use in children 10 years of age and older.
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