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-100815-PIP01-22-M01)

MHRA-100817-PIP01-22-M01

Scope of the Application

Active Substance(s)

SIPONIMOD

Condition(s)

Treatment of multiple sclerosis

Pharmaceutical Form(s)

Film-coated tablet

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Novartis Pharmaceuticals UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Novartis Pharmaceuticals UK Limited submitted to the licensing authority on 14/12/2022 11:13 GMT an application for a Modification

The procedure started on 02/03/2023 10:01 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

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-100817-PIP01-22-M01

Of 16/03/2023 09:07 GMT

On the adopted decision for SIPONIMOD (MHRA-100817-PIP01-22-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 SIPONIMOD, Film-coated tablet , ORAL USE .

This decision is addressed to Novartis Pharmaceuticals UK Limited, Novartis Pharmaceuticals UK Limited 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane., W12 7FQ, UNITED KINGDOM, W12 7FQ

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): Film-coated tablet 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 children/adolescent patients (10-18 years old) with relapsing forms of multiple sclerosis

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):

Film-coated tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	1	Study 1 Pre - and postnatal 6-week oral gavage study in rats.
Clinical Studies	1	Study 2 Double-blind, randomised, 3-arm, non-inferiority study comparing the efficacy and safety of ofatumumab (OMB157) and siponimod (BAF312) versus fingolimod in children from 10 years to less than 18 years of age with multiple sclerosis.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
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:	31/10/2026
Deferral of one or more studies contained in the paediatric investigation plan:	Yes