

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

[gov.uk/mhra](https://www.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-101439-PIP01-24-M01

Scope of the Application

Active Substance(s)

(R)-1-(1-acryloylpiperidin-3-yl)-4-amino-3-(4-phenoxyphenyl)-1H-imidazo[4,5-c]pyridin-2(3H)-one

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

Sanofi Winthrop Industrie

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Sanofi Winthrop Industrie submitted to the licensing authority on 21/06/2024 12:36 BST an application for a Modification

The procedure started on 07/08/2024 13:58 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.

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

[gov.uk/mhra](https://www.gov.uk/mhra)

Final Decision Letter

MHRA-101439-PIP01-24-M01

Of 27/08/2024 10:34 BST

On the adopted decision for (R)-1-(1-acryloylpiperidin-3-yl)-4-amino-3-(4-phenoxyphenyl)-1H-imidazo[4,5-c]pyridin-2(3H)-one (MHRA-101439-PIP01-24-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 (R)-1-(1-acryloylpiperidin-3-yl)-4-amino-3-(4-phenoxyphenyl)-1H-imidazo[4,5-c]pyridin-2(3H)-one, Film-coated tablet , ORAL USE .

This decision is addressed to Sanofi Winthrop Industrie, 82 avenue Raspail, Gentilly, FRANCE, 94250

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 the specific medicinal product does not represent a significant therapeutic benefit as clinical studies 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 remitting 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	0	Not applicable.
Clinical Studies	1	Study 1 (EFC-ped) Multi-centre randomised active controlled double-blind parallel group trial to evaluate efficacy, safety and pharmacokinetics of SAR442168 in paediatric patients from 10 years to less than 18 years of age with relapsing multiple sclerosis (MS).
Extrapolation, Modeling & Simulation Studies	4	Study 2 (PBPM-ped) Modelling and simulation study to support dose-finding for paediatric patients with MS. Study 3 (SIM-ped) Population-pharmacokinetic study to support dose-finding for paediatric patients with MS. Study 4 (POH-ped) Descriptive data analysis, pop-PK model. Study 5 (BAY study) Bayesian model using adult POP PK model with allometric scaling.
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:	31/05/2035

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