

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-101093-PIP03-25

Scope of the Application

Active Substance(s)

SATRALIZUMAB

Condition(s)

Treatment of myelin oligodendrocyte glycoprotein antibody-associated disease

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS 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 19/06/2025 18:22 BST an application for a Paediatric Investigation Plan

The procedure started on 21/07/2025 18:26 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-101093-PIP03-25

Of 02/04/2026 17:45 BST

On the adopted decision for SATRALIZUMAB (MHRA-101093-PIP03-25) 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 SATRALIZUMAB, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Roche Products Limited , Hexagon Place, Shire Park, Falcon Way, Welwyn Garden City , Welwyn Garden City , UNITED KINGDOM, AL7 1TW

ANNEX I

1. Waiver

1.1 Condition:

Treatment of myelin oligodendrocyte glycoprotein antibody-associated disease 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: Subcutaneous 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 myelin oligodendrocyte glycoprotein antibody-associated disease

2.2 Indication(s) targeted by the PIP:

Treatment of myelin oligodendrocyte glycoprotein antibody-associated disease

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	2	Study 1 (WN43194) Double-blind, randomised, placebo-controlled study with an open-label extension to evaluate pharmacokinetics, pharmacodynamics, safety, efficacy and immunogenicity of satralizumab as monotherapy or add-on to baseline/background immunosuppressive therapies (ISTs) in children from 12 years to less than 18 years of age (and adults) with relapsing myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD). Study 2 Open-label, uncontrolled study to evaluate pharmacokinetics, pharmacodynamics, safety, and tolerability of satralizumab in children from 2 years to less than 12 years of age with myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD).
Extrapolation, Modeling & Simulation Studies	3	Study 3 Modelling and simulation study to support the dose finding of satralizumab in children from 2 years to less than 12 years of age with relapsing MOGAD. Study 4 Extrapolation study to support use of satralizumab in adolescents from 12 years to less than 18 years of age

		with MOGAD. Study 5 Extrapolation study to support use of satralizumab in children from 2 years to less than 12 years of age with MOGAD.
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:	31/03/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes