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

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Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-100135-PIP03-25

Scope of the Application

Active Substance(s)

frexalimab

Condition(s)

Treatment of multiple sclerosis

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

Intravenous use; Subcutaneous 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 30/04/2025 17:13 BST an application for a Paediatric Investigation Plan

The procedure started on 28/05/2025 21:23 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-100135-PIP03-25

Of 02/02/2026 14:10 GMT

On the adopted decision for frexalimab (MHRA-100135-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 frexalimab, Solution for injection , Intravenous use; Subcutaneous 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): Solution for injection Route(s) of administration: Intravenous use 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 multiple sclerosis

2.2 Indication(s) targeted by the PIP:

Treatment of relapsing 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):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	1	Study 1 Enhanced pre- and postnatal development reproductive toxicity study in pregnant cynomolgus monkeys to assess developmental toxicity endpoints.
Clinical Studies	1	Study 2 Double-blind, randomised trial to evaluate pharmacokinetics, safety and efficacy of frexalimab compared to an active comparator in children from 10 years to less than 18 years of age with relapsing multiple sclerosis (RMS).
Extrapolation, Modeling & Simulation Studies	2	Study 3 Modelling and simulation study using a population PK (PopPK) model to support selection of initial paediatric dose for clinical study 2. Study 4 Modelling and simulation study using a physiologically based PK (PBPK) model to support selection of initial paediatric dose for clinical study 2.
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:	30/06/2035
Deferral of one or more studies contained in the paediatric investigation plan:	Yes