MHRA
10 South Colonnade
Canary Wharf
London
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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-101880-PIP02-25

Scope of the Application

Active Substance(s)

Duvakitug

Condition(s)

Treatment of Crohn’s disease

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

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 27/06/2025 14:34 BST an application for a Paediatric Investigation Plan

The procedure started on 28/07/2025 13:07 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-101880-PIP02-25

Of 05/03/2026 15:20 GMT

On the adopted decision for Duvakitug (MHRA-101880-PIP02-25) 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 Duvakitug, Solution for injection , 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 Crohn’s 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 over existing treatments.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of Crohn’s disease

2.2 Indication(s) targeted by the PIP:

Treatment of moderate to severe Crohn's disease

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 2 years to less than18 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 study for effects of duvakitug in cynomolgus monkeys with a six-month lactation/maturation phase.
Clinical Studies	1	Study 2 Double-blind study with an open-label induction phase, to evaluate the efficacy, safety, tolerability and pharmacokinetics of subcutaneous duvakitug in children and adolescents from 2 years to less than 18 years of age with moderate to severe Crohn's disease, who have failed or not responded to standard treatment.
Extrapolation, Modeling & Simulation Studies	2	Study 3 Population pharmacokinetic modelling and simulation analyses to predict the initial paediatric dose(s) for children and adolescents from 2 years to less than 18 years of age, to be used in the paediatric clinical study (PIP Study 2). Study 4 Population pharmacokinetic modelling and simulation analyses to support the regimen and posology to be used in paediatric patients.
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:	31/01/2036
Deferral of one or more studies contained in the paediatric investigation plan:	Yes