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-100218-PIP01-21-M01)

MHRA-100218-PIP01-21-M02

Scope of the Application

Active Substance(s)

DUPILUMAB

Condition(s)

Treatment of chronic spontaneous urticaria

Pharmaceutical Form(s)

Solution for injection in a pre-filled syringe

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 20/12/2024 17:15 GMT an application for a Modification

The procedure started on 13/01/2025 15:35 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-100218-PIP01-21-M02

Of 08/05/2025 07:17 BST

On the adopted decision for DUPILUMAB (MHRA-100218-PIP01-21-M02) 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 DUPILUMAB, Solution for injection in a pre-filled syringe , 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 chronic spontaneous urticaria 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 in a pre-filled syringe Route(s) of administration: SUBCUTANEOUS USE Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of chronic spontaneous urticaria

2.2 Indication(s) targeted by the PIP:

Treatment of chronic spontaneous urticaria (CSU) in patients whose disease in not adequately controlled with H1-antihistamine and anti-IgE antibody treatment

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 in a pre-filled syringe

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	3	Study 1 (EFC16461; CUPID Study A and Study B) Double-blind, randomised, placebo-controlled parallel-group trial to evaluate safety and efficacy of dupilumab in paediatric patients from 6 years to less than 18 years of age (and in adults) with chronic spontaneous urticaria (CSU) who remain symptomatic despite the use of H1-antihistamine (Study A) and in adolescents from 12 years to less than 18 years of age (and in adults) with CSU who remain symptomatic despite the use of or H1-antihistamine and an anti-IgE antibody treatment (Study B). Study 2 (PKM16982) Open-label, single-arm trial to evaluate pharmacokinetics, safety and activity of dupilumab in children from 2 years to less than 12 years of age with chronic spontaneous urticaria (CSU) who remain symptomatic despite the use of H1-antihistamine. Study 4 (EFC16461; CUPID Study C) Added during procedure MHRA-100218-PIP01-21-M02. Double-blind, randomised, placebo-controlled trial to evaluate safety and

		efficacy of dupilumab in paediatric patients from 6 years to less than 18 years of age (and in adults) with chronic spontaneous urticaria (CSU) who remain symptomatic despite the use of H1-antihistamine.
Extrapolation, Modeling & Simulation Studies	1	Study 3 Deleted during procedure MHRA-100218-PIP01-21-M01. Extrapolation Plan Added during procedure MHRA-100218-PIP01-21-M01. Dupilumab PK and response data in paediatric patients from 2 to less than 12 years from Study 2 and Studies 1 and 4 (EFC16461, CUPID) and supportive exposure-response data from adult / adolescent patients with CSU from Studies 1 and 4 (EFC16461, CUPID Studies A, B, and C) are a part of the extrapolation plan of efficacy from adults/adolescents to the paediatric population from 2 years to less than 12 years of age with chronic spontaneous urticaria.
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:	30/09/2025
Deferral of one or more studies contained in the paediatric investigation plan:	Yes