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-101911-PIP01-25

Scope of the Application

Active Substance(s)

Lunsekimig

Condition(s)

Treatment of asthma

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 20/05/2025 15:21 BST an application for a Paediatric Investigation Plan

The procedure started on 20/08/2025 14:07 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-101911-PIP01-25

Of 29/09/2025 13:48 BST

On the adopted decision for Lunsekimig (MHRA-101911-PIP01-25) 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 Lunsekimig, 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 asthma 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 asthma

2.2 Indication(s) targeted by the PIP:

Add-on maintenance treatment of severe asthma in children from 2 years to less than 18 years of age

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	1	Study 1 Development of an age-appropriate formulation and/or presentation of lunsekimig to be performed if required.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	4	Study 2 (EFC18121) Randomised, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy, safety, and tolerability of subcutaneous lunsekimig in adolescents from 12 to less than 18 years of age (and adults) with moderate-to-severe asthma. Study 3 Open-label, single-dose study to evaluate the pharmacokinetics and safety of lunsekimig in paediatric patients from 2 years to less than 18 years of age and a body weight of less than 40 kg with mild, moderate or severe asthma requiring daily controller medications. Study 4 Multicentre, randomised, double-blind, placebo controlled, parallel-group study to evaluate the efficacy, safety, and tolerability of add-on therapy with lunsekimig in paediatric patients aged from 6 years to less than 18 years of age and a body weight of less than 40 kg with moderate-to-severe asthma. Study 5 Multicentre, randomised, double-blind, placebo controlled, parallel-group study to evaluate the efficacy, safety, and tolerability of add-on

		therapy with lunsekimig in paediatric patients aged from 2 years to less than 6 years of age with uncontrolled asthma and/or recurrent severe asthmatic wheeze.
Extrapolation, Modeling & Simulation Studies	1	Study 6 Modelling and simulation study to predict doses to be used in asthma paediatric clinical studies (PIP studies 2 to 5).
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:	31/10/2040
Deferral of one or more studies contained in the paediatric investigation plan:	Yes