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-101758-PIP01-24

Scope of the Application

Active Substance(s)

deuruxolitinib

Condition(s)

Treatment of alopecia areata

Pharmaceutical Form(s)

Tablet, Age appropriate oral formulation.

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Sun Pharma UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Sun Pharma UK Limited submitted to the licensing authority on 18/12/2024 19:27 GMT an application for a Paediatric Investigation Plan

The procedure started on 21/01/2025 07:45 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 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-101758-PIP01-24

Of 16/06/2025 07:58 BST

On the adopted decision for deuruxolitinib (MHRA-101758-PIP01-24) 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 deuruxolitinib, Tablet, Age appropriate oral formulation. , ORAL USE .

This decision is addressed to Sun Pharma UK Limited, 6-9 The Square Stockley Park, London, UNITED KINGDOM, UB11 1FW

ANNEX I

1. Waiver

1.1 Condition:

Treatment of alopecia areata The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age Pharmaceutical form(s): Tablet Age appropriate oral formulation Route(s) of administration: ORAL 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 alopecia areata

2.2 Indication(s) targeted by the PIP:

Treatment of severe alopecia areata in patients from 6 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 6 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Tablet Age-appropriate oral dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate oral formulation for children from 6 years to less than 12 years of age.
Non-Clinical Studies	1	Study 2 Definitive juvenile toxicity study in rats.
Clinical Studies	2	Study 3 (CP543.3101) Double-blind, randomised, placebo-controlled trial with an open label extension, to evaluate safety and efficacy of deuruxolitinib in adolescents from 12 years to less than 18 years of age with severe alopecia areata (AA). Study 4 (CP543.3102) Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of deuruxolitinib in children from 6 years to less than 12 years of age with severe alopecia areata (AA).
Extrapolation, Modeling & Simulation Studies	1	Study 5 Modelling and simulation study to determine an age-appropriate dosing regimen in paediatric patients from 6 years to less than 18 years of age with severe alopecia areata, achieving comparable exposures to the efficacious dose observed in adults.
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:	31/12/2033
Deferral of one or more studies contained in the paediatric investigation plan:	Yes