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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100469-PIP01-22) and to the deferral

MHRA-100469-PIP01-22-M01

Scope of the Application

Active Substance(s)

delgocitinib

Condition(s)

Treatment of chronic hand eczema

Pharmaceutical Form(s)

Cream

Route(s) of Administration

CUTANEOUS USE

Name / Corporate name of the PIP applicant

LEO Pharma A/S

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, LEO Pharma A/S submitted to the licensing authority on 29/03/2023 16:58 BST an application for a Modification

The procedure started on 03/08/2023 07:10 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 accept change(s) to the agreed paediatric investigation plan and to the deferral

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-100469-PIP01-22-M01

Of 14/08/2023 16:39 BST

On the adopted decision for delgocitinib (MHRA-100469-PIP01-22-M01) 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 delgocitinib , Cream , CUTANEOUS USE .

This decision is addressed to LEO Pharma A/S, Industriparken 55, Ballerup, DENMARK, 2750

ANNEX I

1. Waiver

1.1 Condition:

Treatment of chronic hand eczema The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 12 years of age Pharmaceutical form(s): Cream Route(s) of administration: CUTANEOUS 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 hand eczema

2.2 Indication(s) targeted by the PIP:

Treatment of chronic hand eczema

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

The paediatric population from 12 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Cream

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	3	Study 1 (77052) Dose range-finding juvenile toxicity study in minipigs to evaluate the pharmacokinetic profile of delgocitinib. Study 2 (SB95TY) Definitive juvenile toxicity study in rats to evaluate the toxicity of delgocitinib. Study 3 (R-1208) Reprotox: (enhanced) pre- and postnatal development in rats to evaluate the adverse effects on pregnant/ lactating females and on development of the conceptus and the offspring.
Clinical Studies	1	Study 4 (LP0133-1426) Double-blind, randomised, 2-arm, vehicle-controlled, parallel-group trial to evaluate safety and efficacy of delgocitinib cream in adolescents from 12 years to less than 18 years of age with moderate to severe chronic hand eczema.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
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:	30/06/2024

Deferral of one or more studies contained in the paediatric investigation plan:	Yes