

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

[gov.uk/mhra](http://gov.uk/mhra)

## **Decision Cover Letter**

### **Decision of the licensing authority to:**

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-100469-PIP01-22

### **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

#### **Basis for the Decision**

Pursuant to the Human Medicines Regulations 2012, LEO Pharma submitted to the licensing authority on 30/03/2022 15:27 BST an application for a Paediatric Investigation Plan

The procedure started on 03/10/2022 07:55 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.

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

[gov.uk/mhra](http://gov.uk/mhra)

## Final Decision Letter

MHRA-100469-PIP01-22

Of 09/11/2022 15:38 GMT

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

This decision is addressed to LEO Pharma, Horizon, Honey Lane, Hurley, UNITED KINGDOM, SL6 6RJ

## 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:	30/06/2023

<b>Deferral of one or more studies contained in the paediatric investigation plan:</b>	Yes
--	-----