

**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 and to the deferral.

MHRA-100089-PIP01-21-M02

### **Scope of the Application**

#### **Active Substance(s)**

DUPILUMAB

#### **Condition(s)**

Treatment of eosinophilic oesophagitis

#### **Pharmaceutical Form(s)**

Solution for injection

#### **Route(s) of Administration**

SUBCUTANEOUS USE

#### **Name / Corporate name of the PIP applicant**

Regeneron Ireland DAC

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

Pursuant to the Human Medicines Regulations 2012, Regeneron Ireland DAC submitted to the licensing authority on 27/10/2023 10:49 BST an application for a Modification

The procedure started on 06/02/2024 13:40 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 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-100089-PIP01-21-M02

Of 27/02/2024 08:27 GMT

On the adopted decision for DUPILUMAB (MHRA-100089-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 , SUBCUTANEOUS USE .

This decision is addressed to Regeneron Ireland DAC, One Warrington Place, Dublin, IRELAND, D02 HH27

## ANNEX I

### 1. Waiver

#### 1.1 Condition:

Treatment of eosinophilic oesophagitis 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 clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfill a therapeutic need of the specified paediatric subset(s).

### 2. Paediatric Investigation Plan:

#### 2.1 Condition(s):

Treatment of eosinophilic oesophagitis

## 2.2 Indication(s) targeted by the PIP:

Treatment of eosinophilic oesophagitis

## 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	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 1 (R668-EE-1774) Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of dupilumab as add-on to best standard of care compared to placebo in children from 12 to less than 18 years of age (and adults) with eosinophilic oesophagitis Study 2 (R668-EE-1877) Double-blind, randomised, placebo-controlled trial to evaluate PK, safety and efficacy of dupilumab as add-on to best standard of care compared to placebo in children from 2 years to less than 12 years of age with eosinophilic oesophagitis
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:	30/09/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes

