

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

[gov.uk/mhra](https://www.gov.uk/mhra)

## **Decision Cover Letter**

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

accept change(s) to the agreed paediatric investigation plan (MHRA-100068-PIP01-21-M01)  
MHRA-100068-PIP01-21-M02

### **Scope of the Application**

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

VEDOLIZUMAB

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

Treatment of pouchitis

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

Solution for injection, Powder for concentrate for solution for infusion

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

INTRAVENOUS USE SUBCUTANEOUS USE

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

Takeda UK Limited

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

Pursuant to the Human Medicines Regulations 2012, Takeda UK Limited submitted to the licensing authority on 30/05/2023 15:54 BST an application for a Modification

The procedure started on 18/10/2023 09:52 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

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-100068-PIP01-21-M02

Of 11/12/2023 16:18 GMT

On the adopted decision for VEDOLIZUMAB (MHRA-100068-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 VEDOLIZUMAB, Solution for injection, Powder for concentrate for solution for infusion , INTRAVENOUS USE SUBCUTANEOUS USE .

This decision is addressed to Takeda UK Limited, 1 Kingdom Street, London, UNITED KINGDOM, W2 6BD

## ANNEX I

### 1. Waiver

#### 1.1 Condition:

Treatment of pouchitis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Powder for concentrate for solution for infusion Solution for injection Route(s) of administration: INTRAVENOUS USE SUBCUTANEOUS USE Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

### 2. Paediatric Investigation Plan:

#### 2.1 Condition(s):

Treatment of pouchitis

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

Treatment of active chronic pouchitis

## 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):

Powder for concentrate for solution for infusion 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	1	Study 1 (Vedolizumab-3041) Open label, single-arm trial to evaluate the efficacy, safety, tolerability, pharmacokinetics and immunogenicity of intravenous vedolizumab in children from 2 years to less than 18 years of age with active chronic pouchitis.
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:	No
Date of completion of the paediatric investigation plan:	31/07/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes

