

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 (MHRA-100068-PIP01-21)

MHRA-100068-PIP01-21-M01

Scope of the Application

Active Substance(s)

VEDOLIZUMAB

Condition(s)

Treatment of pouchitis

Pharmaceutical Form(s)

Powder for concentrate for solution for infusion Solution for injection

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 08/09/2022 15:20 BST an application for a Modification

The procedure started on 14/02/2023 14:50 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

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-M01

Of 06/03/2023 11:04 GMT

On the adopted decision for VEDOLIZUMAB (MHRA-100068-PIP01-21-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 VEDOLIZUMAB, Powder for concentrate for solution for infusion Solution for injection , 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 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 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

