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

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-101357-PIP01-24

Scope of the Application

Active Substance(s)

inebilizumab

Condition(s)

Treatment of immunoglobulin G4-related disease (IgG4-RD)

Pharmaceutical Form(s)

Concentrate for solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Amgen Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Amgen Limited submitted to the licensing authority on 26/02/2024 17:52 GMT an application for a Paediatric Investigation Plan

The procedure started on 15/02/2025 10:57 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 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

Final Decision Letter

MHRA-101357-PIP01-24

Of 16/05/2025 11:11 BST

On the adopted decision for inebilizumab (MHRA-101357-PIP01-24) 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; Refusal to agree a paediatric investigation plan; Granting a waiver in all age groups for the listed condition(s); Refusal to grant a waiver in all age groups for the listed condition(s); Revoking a waiver agreed as part of a paediatric investigation plan; Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan); Refusal to agree a modification of a paediatric investigation plan (including a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Paediatric Investigation Plan for inebilizumab, Concentrate for solution for infusion , INTRAVENOUS .

This decision is addressed to Amgen Limited, 216 Cambridge Science Park, Milton Road, Cambridge, UNITED KINGDOM, CB4 0WA

ANNEX I

1. Waiver

1.1 Condition:

Treatment of immunoglobulin G4-related disease (IgG4-RD) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Concentrate for solution for infusion Route(s) of administration: INTRAVENOUS 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). Reason for Refusing Waiver: Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of immunoglobulin G4-related disease (IgG4-RD)

2.2 Indication(s) targeted by the PIP:

Treatment of immunoglobulin G4-related disease (IgG4-RD)

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

From 2 years to under 18 years of age

2.4 Pharmaceutical Form(s):

Concentrate for solution for infusion

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 Open-label, uncontrolled trial to evaluate pharmacokinetics, pharmacodynamics and safety of inebilizumab in children form 2 years to less than 18 years with immunoglobulin G4-related disease (IgG4 RD).
Extrapolation, Modeling & Simulation Studies	1	Study 2 Modelling and Simulation study to support dose finding of inebilizimab in children 2 years to less than 18 years of age with immunoglobulin G4-related disease (IgG4-RD).
Other Studies	0	Not applicable
Other Measures	1	Studies 1 and 2 are part of an extrapolation plan covering the paediatric population from 2 years to less than 18 years of age, as agreed by the Regulatory Agency

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:	31/03/2031
Deferral of one or more studies contained in the paediatric investigation plan:	Yes