

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

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## **Decision Cover Letter**

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

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

MHRA-101356-PIP01-24

### **Scope of the Application**

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

Inebilizumab

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

Treatment of myasthenia gravis

#### **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 17:39 GMT an application for a Paediatric Investigation Plan

The procedure started on 06/08/2024 15:18 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.

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## Final Decision Letter

MHRA-101356-PIP01-24

Of 09/09/2024 07:45 BST

On the adopted decision for Inebilizumab (MHRA-101356-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

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

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 myasthenia gravis 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).

### 2. Paediatric Investigation Plan:

#### 2.1 Condition(s):

Treatment of myasthenia gravis

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

Treatment of myasthenia gravis
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**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
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**2.4 Pharmaceutical Form(s):**

Concentrate for solution for infusion
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**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 from 2 years to less than 18 years of age with juvenile myasthenia gravis.
Extrapolation, Modeling & Simulation Studies	2	Study 2 Modelling and simulation study to support dose finding of inebilizumab in children from 2 years to less than 18 years of age with juvenile myasthenia gravis. Extrapolation plan Studies 1 and 2 are part of an extrapolation plan covering the paediatric population from 2 years to less than 18 years of age with myasthenia gravis.
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:	31/12/2029
Deferral of one or more studies contained in the paediatric investigation plan:	Yes

