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

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Decision Cover Letter

Decision of the licensing authority to:

grant a product specific waiver

MHRA-101230-PIP01-23

Scope of the Application

Active Substance(s)

teprotumumab

Condition(s)

Treatment of thyroid eye disease

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

Amgen Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Amgen Limited submitted to the licensing authority on 13/11/2023 08:23 GMT an application for a Waiver

The procedure started on 12/02/2024 07:06 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 grant a product specific 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-101230-PIP01-23

Of 28/02/2024 18:02 GMT

On the adopted decision for teprotumumab (MHRA-101230-PIP01-23) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Granting a waiver in all age groups for the listed condition(s)

This decision applies to a Waiver for teprotumumab , Powder for concentrate for solution for infusion, Solution for injection , INTRAVENOUS USE; SUBCUTANEOUS 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 thyroid eye disease The waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 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: For the paediatric population from birth to adolescence before growth is complete: - on the grounds that the specific medicinal product is likely to be unsafe. For the paediatric population from adolescents whose growth is complete to less than 18 years: - on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Not Applicable

2.2 Indication(s) targeted by the PIP:

Not Applicable

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

Not Applicable

2.4 Pharmaceutical Form(s):

Not Applicable

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures		
Non-Clinical Studies		
Clinical Studies		
Extrapolation, Modeling & Simulation Studies		
Other Studies		
Other Measures		

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	