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 and to the deferral

MHRA-100444-PIP01-22-M01

Scope of the Application

Active Substance(s)

ETELCALCETIDE

Condition(s)

Treatment of hyperparathyroidism

Pharmaceutical Form(s)

Solution for injection

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 10/03/2022 16:29 GMT an application for a Modification

The procedure started on 07/09/2022 16:03 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 and to the deferral

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-100444-PIP01-22-M01

Of 11/10/2022 16:53 BST

On the adopted decision for ETELCALCETIDE (MHRA-100444-PIP01-22-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 ETELCALCETIDE, Solution for injection , Intravenous use .

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

ANNEX I

1. Waiver

1.1 Condition:

Treatment of hyperparathyroidism The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Solution for injection Route(s) of administration: Intravenous use Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of hyperparathyroidism

2.2 Indication(s) targeted by the PIP:

Treatment of secondary hyperparathyroidism in paediatric patients with chronic kidney disease receiving maintenance haemodialysis

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):

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	2	Study 1 Single arm, open-label, single-dose PK, PD and safety study in children and adolescents from 2 years to less than 18 years with secondary hyperparathyroidism receiving maintenance haemodialysis. Study 2 Single arm, open-label, multi-dose, titration, PK, PD and safety study in children and adolescents 2 years to less than 18 years with secondary hyperparathyroidism receiving maintenance haemodialysis.
Extrapolation, Modeling & Simulation Studies	1	Study 3 Comparative pharmacokinetic/ pharmacodynamic modelling study between adult and paediatric patients with secondary hyperparathyroidism on maintenance haemodialysis.
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:	Yes
Date of completion of the paediatric investigation plan:	31/01/2026
Deferral of one or more studies contained in the paediatric investigation plan:	Yes