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

MHRA-101893-PIP01-25

Scope of the Application

Active Substance(s)

eneboparatide

Condition(s)

Treatment of hypoparathyroidism

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Alexion Europe SAS

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Alexion Europe SAS submitted to the licensing authority on 18/06/2025 17:30 BST an application for a Paediatric Investigation Plan

The procedure started on 20/08/2025 12:32 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

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-101893-PIP01-25

Of 15/10/2025 07:11 BST

On the adopted decision for eneboparatide (MHRA-101893-PIP01-25) 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 eneboparatide, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Alexion Europe SAS, 103-105 rue Anatole France, Levallois-Perret, FRANCE, 92300

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of hypoparathyroidism

2.2 Indication(s) targeted by the PIP:

Treatment of chronic hypoparathyroidism

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

All subsets of the paediatric population from birth 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	1	Study 1 Development of a lower strength and an administration device suitable for the use of the adult formulation of eneboparatide in the paediatric population.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 Open-label, single-arm PK, safety and activity study of eneboparatide in paediatric participants from birth to less than 18 years of age with chronic hypoparathyroidism.
Extrapolation, Modeling & Simulation Studies	2	Study 3 Development of a population pharmacokinetic (PopPK) model to predict paediatric doses for use in Study 2, confirm or modify the posology, and support extrapolation of efficacy from adults to all subsets of the paediatric population with chronic hypoparathyroidism. Extrapolation plan Studies 2 and 3 are part of an extrapolation plan of efficacy data from adult patients to the paediatric population from birth to less than 18 years of age with chronic hypoparathyroidism.
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:	31/07/2029

Deferral of one or more studies contained in the paediatric investigation plan:	Yes