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-102134-PIP01-25

Scope of the Application

Active Substance(s)

Synthetic peptide biased dual GLP-1/GIP receptor agonist (RO7795068 (CT-388))

Condition(s)

Treatment of obesity

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Roche Products Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Roche Products Limited submitted to the licensing authority on 19/12/2025 10:11 GMT an application for a Paediatric Investigation Plan

The procedure started on 09/01/2026 12:34 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.

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Final Decision Letter

MHRA-102134-PIP01-25

Of 19/05/2026 08:16 BST

On the adopted decision for Enicepatide (MHRA-102134-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 Enicepatide, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Roche Products Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, UNITED KINGDOM, AL7 1TW

ANNEX I

1. Waiver

1.1 Condition:

Treatment of obesity The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age Pharmaceutical form(s): Solution for injection Route(s) of administration: Subcutaneous use Reason for granting waiver: 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):

Treatment of obesity

2.2 Indication(s) targeted by the PIP:

Chronic weight management

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

The paediatric population from 6 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 Multicentre, double-blind, randomised, placebo-controlled trial to evaluate pharmacokinetics, safety, efficacy, and immunogenicity of enicepatide as add-on to lifestyle intervention in adolescents aged 12 years to less than 18 years of age with obesity or overweight with at least one weight related comorbidity. Study 2 Multicentre, double-blind, randomised, placebo-controlled trial to evaluate pharmacokinetics, safety, efficacy, and immunogenicity of enicepatide as add-on to lifestyle intervention in children from age 6 years to less than 12 years of age with obesity.
Extrapolation, Modeling & Simulation Studies	2	Study 3 Use of population PK/PD modelling (PopPK/PD) to predict adolescent doses of enicepatide. Study 4 Use of model simulations based on the population PK/PD (PopPK/PD) model incorporating adolescent data to support dose selection of enicepatide for paediatric patients aged 6 years to less than 12 years of age.
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:	31/01/2036
Deferral of one or more studies contained in the paediatric investigation plan:	Yes