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 (MHRA-100447-PIP01-22-M01)

MHRA-100447-PIP01-22-M02

Scope of the Application

Active Substance(s)

Tirzepatide

Condition(s)

Treatment of type 2 diabetes mellitus

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Eli Lilly Nederland B.V

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Eli Lilly Nederland B.V submitted to the licensing authority on 31/10/2022 14:59 GMT an application for a Modification

The procedure started on 20/03/2023 16:58 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 accept change(s) to the agreed paediatric investigation plan

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-100447-PIP01-22-M02

Of 31/03/2023 11:30 BST

On the adopted decision for Tirzepatide (MHRA-100447-PIP01-22-M02) 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 Tirzepatide, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Eli Lilly Nederland B.V, Papendorpseweg 83, Utrecht, NETHERLANDS, 3528 BJ

ANNEX I

1. Waiver

1.1 Condition:

Treatment of type 2 diabetes mellitus The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 10 years of age Pharmaceutical form(s): Solution for injection Route(s) of administration: SUBCUTANEOUS USE Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of type 2 diabetes mellitus

2.2 Indication(s) targeted by the PIP:

Treatment of type 2 diabetes mellitus in paediatric patients 10 years of age and above.

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

The paediatric population from 10 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	1	Study 1 Definitive juvenile toxicity study to assess the potential toxicity of tirzepatide to juvenile rats.
Clinical Studies	1	Study 2 (GPGV) Randomised, double-blind, parallel arm, placebo-controlled study to assess the safety, efficacy and PK/PD of tirzepatide as compared to placebo as add-on to metformin and/or basal insulin in paediatric patients from 10 years to less than 18 years of age with an open-label safety extension.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
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:	30/06/2030
Deferral of one or more studies contained in the paediatric investigation plan:	Yes