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-100259-PIP01-21-M01

Scope of the Application

Active Substance(s)

DULAGLUTIDE

Condition(s)

Treatment of type 2 diabetes mellitus

Pharmaceutical Form(s)

Solution for injection in pre-filled pen

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 15/10/2021 14:46 BST an application for a Modification

The procedure started on 13/04/2022 15:30 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-100259-PIP01-21-M01

Of 28/04/2022 07:37 BST

On the adopted decision for DULAGLUTIDE (MHRA-100259-PIP01-21-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 DULAGLUTIDE, Solution for injection in pre-filled pen , Subcutaneous use .

This decision is addressed to Eli Lilly Nederland B.V, Papendorpseweg 83, Utrecht, Netherlands, 352

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 in pre-filled pen 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

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 in pre-filled pen

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of a pre-filled pen for subcutaneous use.
Non-Clinical Studies	2	Study 2 Juvenile toxicity study to evaluate potential effects on sexual maturation, reproductive function, and neurobehavioural development and function in immature rats exposed to dulaglutide. Study 3 Comparative analysis of the tumourigenic potential of dulaglutide versus liraglutide. Comparative analysis of affinity (IC50) and potency (EC50) for the GLP-1 receptor binding of dulaglutide versus liraglutide.
Clinical Studies	1	Study 4 (H9X-MC-GBGC) Double blind, randomised, multi-centre, placebo-controlled superiority trial to evaluate pharmacokinetics, pharmacodynamics, safety and efficacy of dulaglutide in children from 10 to less than 18 years of age with open-label extension to evaluate safety.
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:	30/06/2022

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