EMA/207913/2022

European Medicines Agency decision

P/0174/2022

of 13 May 2022

on the acceptance of a modification of an agreed paediatric investigation plan for tirzepatide (EMEA-002360-PIP01-18-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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on the acceptance of a modification of an agreed paediatric investigation plan for tirzepatide (EMEA-002360-PIP01-18-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0311/2019 issued on 10 September 2019 and the decision P/0540/2021 issued on 31 December 2021,

Having regard to the application submitted by Ely Lilly and Company Ltd on 14 December 2021 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 25 March 2022, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for tirzepatide, solution for injection, subcutaneous use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Eli Lilly and Company Ltd, 8 Arlington Square West, Downshire Way, RG12 1PU – Bracknell, United Kingdom.

EMA/PDCO/7636/2022
Amsterdam, 25 March 2022

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-002360-PIP01-18-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:

Ely Lilly and Company Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Ely Lilly and Company Ltd submitted to the European Medicines Agency on 14 December 2021 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0311/2019 issued on 10 September 2019 and the decision P/0540/2021 issued on 31 December 2021.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 31 January 2022.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Treatment of Type 2 diabetes mellitus

The waiver applies to:

- the paediatric population from birth to less than 10 years of age;
- solution for injection, subcutaneous use;
- 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

Treatment of type 2 diabetes mellitus

2.1.1. Indication(s) targeted by the PIP

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

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 10 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Subcutaneous use

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable.
Non-clinical studies	**Study 1** Definitive juvenile toxicity study to assess the potential toxicity of tirzepatide to juvenile rats.
Clinical studies	**Study 2** 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 (GPGV).
Extrapolation, modelling and simulation studies	Not applicable.

Other studies	Not applicable.
Other measures	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2030
Deferral for one or more measures contained in the paediatric investigation plan:	Yes