EMA/333490/2023

European Medicines Agency decision

P/0285/2023

of 24 July 2023

on the acceptance of a modification of an agreed paediatric investigation plan for tirzepatide (Mounjaro), (EMEA-002360-PIP02-22-M01) 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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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/0033/2023 issued on 13 January 2023,

Having regard to the application submitted by Eli Lilly and Company on 17 March 2023 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 23 June 2023, 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 (Mounjaro), 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 covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0311/2019 issued on 10 September 2019, including subsequent modifications thereof.

Article 3

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

EMA/PDCO/139818/2023
Amsterdam, 23 June 2023

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

EMEA-002360-PIP02-22-M01

Scope of the application

Active substance(s):

Tirzepatide

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of obesity

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Eli Lilly and Company

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Eli Lilly and Company submitted to the European Medicines Agency on 17 March 2023 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/0033/2023 issued on 13 January 2023.

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

The procedure started on 24 April 2023.

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 annexes 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 obesity

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- solution for injection, subcutaneous use;
- 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:

Treatment of obesity

2.1.1. Indication(s) targeted by the PIP

Chronic weight management

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

From 6 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1 (I8F-MC-GPHV)** Double-blind, randomised, placebo-controlled study to assess safety, tolerability, and pharmacokinetics (PK) after 8 weeks of treatment with tirzepatide administered via the subcutaneous route in children aged from 6 years to less than 12 years with obesity. **Study 2 (I8F-MC-GPHP)** Randomised, double-blind, parallel-arm, multicentre, placebo controlled trial to assess the efficacy, safety, and pharmacokinetics (PK) of tirzepatide as an adjunct to lifestyle intervention in children

	and adolescents aged from 12 years to less than 18 years with overweight and obesity. **Study 3 (I8F-MC-GPHQ)** Randomised, double-blind, parallel-arm, multicentre, placebo controlled trial to assess the efficacy, safety, and pharmacokinetics (PK) of tirzepatide as an adjunct to lifestyle intervention in children aged from 6 years to less than 12 years with obesity.
Modelling and simulation studies	**Study 4** Population pharmacokinetic (PK) model to assist with dose finding in children from 6 years to less than 12 years with obesity.
Other studies	Not applicable
Extrapolation plan	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By August 2031
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Treatment of type 2 diabetes mellitus

Authorised indication(s):

Treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise:

- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications
- in addition to other medicinal products for the treatment of diabetes.
  - Invented name(s): Mounjaro
  - Authorised pharmaceutical form(s): Solution for injection
  - Authorised route(s) of administration: Subcutaneous use
  - Authorised via centralised procedure