EMA/251732/2024

European Medicines Agency decision

P/0189/2024

of 14 June 2024

on the acceptance of a modification of an agreed paediatric investigation plan for ertugliflozin (Steglatro), (EMEA-001533-PIP01-13-M03) 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/0214/2014 issued on 1 September 2014, the decision P/0324/2018 issued on 12 September 2018 and the decision P/0141/2019 issued on 17 April 2019,

Having regard to the application submitted by MSD Europe Belgium SRL on 19 January 2024 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 26 April 2024, 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 ertugliflozin (Steglatro), film-coated tablet, oral 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 MSD Europe Belgium SRL, Boulevard du Souverain 25 / Vorstlaan 25, 1170 - Bruxelles / Brussel, Belgium.

EMA/PDCO/47453/2024
Amsterdam, 26 April 2024

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

EMEA-001533-PIP01-13-M03

Scope of the application

Active substance(s):

Ertugliflozin

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of type II diabetes mellitus

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

MSD Europe Belgium SRL

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, MSD Europe Belgium SRL submitted to the European Medicines Agency on 19 January 2024 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/0214/2014 issued on 1 September 2014, the decision P/0324/2018 issued on 12 September 2018 and the decision P/0141/2019 issued on 17 April 2019.

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

The procedure started on 26 February 2024.

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 type 2 diabetes mellitus

The waiver applies to:

- the paediatric population from birth to less than 10 years;
- film-coated tablets, oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subsets.

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

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

From 10 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable.
Non-clinical studies	**Study 1** Juvenile toxicity study in the rat to further evaluate the safety profile of ertugliflozin on the developing organism.
Clinical studies	**Study 2** Randomized, double-blind, placebo-controlled trial to evaluate the safety and efficacy of two doses of ertugliflozin in paediatric patients from 10 to less than 18 years of age with type 2 diabetes mellitus and inadequate glycaemic control on metformin therapy, ± insulin.
Extrapolation, modelling and simulation studies	**Study 3** Population PK modelling study to evaluate the appropriate dose of ertugliflozin in the treatment of type 2 diabetes mellitus in children from 10 to less than 18 years of age.

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 March 2026.
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

  For study results with respect to combinations of therapies, effects on glycaemic control, cardiovascular events, and the populations studied, see sections 4.4, 4.5, and 5.1.
- Invented name(s): Steglatro
- Authorised pharmaceutical form(s): Film-coated tablet
- Authorised route(s) of administration: Oral use
- Authorised via centralised procedure