EMA/568637/2021

European Medicines Agency decision

P/0283/2021

of 29 October 2021

on the acceptance of a modification of an agreed paediatric investigation plan for empagliflozin (Jardiance), (EMEA-000828-PIP01-09-M09) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/33/2011 issued on 28 January 2011, the decision P/0309/2012 issued on 21 December 2012, the decision P/0016/2014 issued on 22 January 2014, the decision P/0016/2015 issued on 30 January 2015, the decision P/0211/2015 issued on 2 October 2015, the decision P/0326/2016 issued on 2 December 2016, the decision P/0028/2018 issued on 30 January 2018 and the decision P/0201/2018 issued on 19 July 2018 and the decision P/0089/2021 issued on 19 March 2021,

Having regard to the application submitted by Boehringer Ingelheim International GmbH on 11 May 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 10 September 2021, 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 and to the deferral.

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

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for empagliflozin (Jardiance), film-coated tablet, oral use, including changes to the deferral, 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 Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 - Ingelheim am Rhein, Germany.

EMA/PDCO/325751/2021
Amsterdam, 10 September 2021

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

EMEA-000828-PIP01-09-M09

Scope of the application

Active substance(s):

Empagliflozin

Invented name:

Jardiance

Condition(s):

Treatment of type 2 diabetes mellitus

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Boehringer Ingelheim International GmbH

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Boehringer Ingelheim International GmbH submitted to the European Medicines Agency on 11 May 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/33/2011 issued on 28 January 2011, the decision P/0309/2012 issued on 21 December 2012, the decision P/0016/2014 issued on 22 January 2014, the

decision P/0016/2015 issued on 30 January 2015, the decision P/0211/2015 issued on 2 October 2015, the decision P/0326/2016 issued on 2 December 2016, the decision P/0028/2018 issued on 30 January 2018 and the decision P/0201/2018 issued on 19 July 2018 and the decision P/0089/2021 issued on 19 March 2021.

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

The procedure started on 12 July 2021.

Scope of the modification

Some measures and timelines 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 and to the deferral in the scope set out in the Annex I of this opinion.

The Norwegian Paediatric Committee member 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 of age;
- film-coated tablet, 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 subset.

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	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	2	**Study 1** Randomised, single-dose, parallel group, study to investigate the pharmacokinetics and pharmacodynamics of empagliflozin in children and adolescents aged 10 to less than 18 years (and adults below 25 years) with type 2 diabetes mellitus (1245.87)

		Study 2 *This study is the same as Study 2 of the linagliptin PIP EMEA-000498-PIP01-08-M04 and subsequent modifications thereof.* Double-blind, randomised, placebo controlled, add-on to diet and exercise alone in patients not tolerating metformin, and add-on to metformin and/or insulin therapy trial to evaluate efficacy and safety, with a double- blind safety extension period to 52 weeks, comparing linagliptin and empagliflozin versus placebo in children and adolescents from 10 to less than 18 years of age with type 2 diabetes mellitus (1218-0091).
Extrapolation, modelling and simulation studies	0	Not applicable
Other studies	0	Not applicable
Other measures	0	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 July 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

Treatment of type 2 diabetes mellitus

Authorised indication(s):

Jardiance is indicated for the 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,
- in addition to other medicinal products for the treatment of diabetes.

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use