EMA/652550/2017

European Medicines Agency decision

P/0302/2017

of 12 October 2017

on the acceptance of a modification of an agreed paediatric investigation plan for dapagliflozin (Forxiga), (EMEA-000694-PIP02-14-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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An agency of the European Union

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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/0064/2015 issued on 1 April 2015 and the decision P/0063/2016 issued on 18 March 2016,

Having regard to the application submitted by AstraZeneca AB on 22 June 2017 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 15 September 2017, 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 dapagliflozin (Forxiga), film-coated tablet, age-appropriate oral dosage form, 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 covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/100/2010 issued on 11 June 2010, including subsequent modifications thereof.

Article 3

This decision is addressed to AstraZeneca AB, SE-151 85 - Södertälje, Sweden.

EMA/PDCO/431284/2017
London, 15 September 2017

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

EMEA-000694-PIP02-14-M02

Scope of the application

Active substance(s):

Dapagliflozin

Invented name:

Forxiga

Condition(s):

Treatment of type 1 Diabetes Mellitus

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Age-appropriate oral dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

AstraZeneca AB

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted to the European Medicines Agency on 22 June 2017 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/0064/2015 issued on 1 April 2015 and the decision P/0063/2016 issued on 18 March 2016.

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

The procedure started on 18 July 2017.

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 1 Diabetes Mellitus

The waiver applies to:

- the paediatric population from birth to less than 2 years;
- film-coated tablet, age-appropriate oral dosage form, oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Treatment of type 1 Diabetes Mellitus

2.1.1. Indication(s) targeted by the PIP

As an adjunct to insulin treatment to improve glycaemic control in patients with type 1 diabetes mellitus when insulin alone does not provide adequate control

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

From 2 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

Age-appropriate oral dosage form

2.1.4. Measures

Area	**Number of measures**	**Description**
Quality-related studies	1	**Study 1** Development of an age appropriate oral dosage form
Non-clinical studies		Not applicable

Clinical studies	2	**Study 2** Multi-centre, randomized, double-blind, placebo-controlled, 3-arm study to evaluate the safety and efficacy of 2 dose levels of dapagliflozin plus insulin in children from 10 years to less than 18 years with type 1 diabetes mellitus (D1695C00003) **Study 3** Multi-centre, randomized, double-blind, placebo-controlled, 3-arm, study to evaluate the safety and efficacy of dapagliflozin plus insulin in children from 2 years to less than 18 years with type 1 diabetes mellitus (D1695C00004)
Extrapolation, modelling and simulation studies	1	**Study 4** Modelling and simulation study for dose selection in children from 2 years to less than 18 years of age with type 1 diabetes mellitus
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 December 2023
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):

1. Treatment of type 2 diabetes mellitus

Authorised indications:

Forxiga is indicated in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as:

- Monotherapy:

When diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance.

- Add-on combination therapy:

In combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.

Authorised pharmaceutical formulation(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use