



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/352334/2010

European Medicines Agency decision

P/100/2010

of 11 June 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for dapagliflozin (EMA-000694-PIP01-09) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Bristol Myers Squibb/AstraZeneca EEIG on 8 September 2009 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 21 May 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting a deferral.
- (4) It is therefore appropriate to adopt a decision granting a waiver.

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for dapagliflozin, tablet, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for dapagliflozin, tablet, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for dapagliflozin, tablet, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Bristol Myers Squibb/AstraZeneca EEIG, Bristol Myers Squibb House, Uxbridge Business Park, Sanderson Road, UB8 1DH Uxbridge, United Kingdom.

Done at London, 11 June 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/220422/2010

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMA-000694-PIP01-09

Scope of the application

Active substance(s):

Dapagliflozin

Condition(s):

Type 2 Diabetes

Pharmaceutical form(s):

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Bristol Myers Squibb/AstraZeneca EEIG

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Bristol Myers Squibb/AstraZeneca EEIG submitted for agreement to the European Medicines Agency on 8 September 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 15 October 2009.

Supplementary information was provided by the applicant on 25 February 2010.



Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
 - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
 - to grant a deferral in accordance with Article 21 of said Regulation ,
 - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

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

2. The measures and timelines of the agreed 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.

London, 21 May 2010

On behalf of the Paediatric Committee

Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

The measures and timelines of the agreed Paediatric Investigation Plan and the subset(s) of the paediatric population and condition(s) covered by the waiver

1. Condition(s)

Type 2 Diabetes

2. Waiver

2.1. Condition

Type 2 Diabetes

The waiver applies to:

- the paediatric population from birth to less than 10 years of age.
- for 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 subset(s).

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Type 2 Diabetes

3.1.1. Indication targeted by the PIP

Treatment of Type 2 Diabetes

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

From 10 to less than 18 years of age.

3.1.3. Pharmaceutical form(s)

Tablet

3.1.4. Studies

Area	Number of studies	Description
Quality	1	1. Assessment of acceptability of tablets in children (ability to swallow 2.5, 5 or 10 mg tablets) in the paediatric PK/PD study.
Non-clinical	2	2. Oral carcinogenicity study in mice. 3. Oral carcinogenicity study in rats.
Clinical	2	4. Randomised, multi-centre, parallel, single-dose study to explore the pharmacokinetics and pharmacodynamics of dapagliflozin in children, 10 to less than 18years of age with Type 2 Diabetes receiving one of

Area	Number of studies	Description
		three dose levels of dapagliflozin: 2.5, 5, or 10 mg. 5.a) Main study: Randomised, double-blind, multicentre, international, placebo-controlled, 12 week add-on to metformin study with a 40-week extension period to evaluate dapagliflozin versus placebo in paediatric patients with Type 2 Diabetes who are inadequately controlled on metformin monotherapy. 5.b) Monotherapy Substudy: Non-randomised, open-label dapagliflozin monotherapy substudy in drug-naïve patients with inadequately controlled Type 2 Diabetes.

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By September 2017
Deferral for one or more studies contained in the paediatric investigation plan:	Yes