



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/75594/2018

European Medicines Agency decision

P/0059/2018

of 16 March 2018

on the granting of a product specific waiver for dapagliflozin / metformin (hydrochloride)
(EMA-001151-PIP02-17) in accordance with Regulation (EC) No 1901/2006 of the European
Parliament and of the Council

Only the English text is authentic.



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on the granting of a product specific waiver for dapagliflozin / metformin (hydrochloride) (EMA-001151-PIP02-17) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 AstraZeneca AB on 18 October 2017 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 26 January 2018 in accordance with Article 13 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

- (1) The Paediatric Committee has given an opinion on the granting of a product specific waiver.
- (2) It is therefore appropriate to adopt a decision granting a waiver.

Has adopted this decision:

Article 1

A waiver for dapagliflozin / metformin (hydrochloride), modified-release 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 2

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

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

EMA/PDCO/758796/2017

London, 26 January 2018

Opinion of the Paediatric Committee on the granting of a product-specific waiver

EMA-001151-PIP02-17

Scope of the application

Active substance(s):

Dapagliflozin / metformin (hydrochloride)

Condition(s):

Treatment of type 2 diabetes mellitus

Pharmaceutical form(s):

Modified-release tablet

Route(s) of administration:

Oral use

Name / corporate name of the PIP applicant:

AstraZeneca AB

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted to the European Medicines Agency on 18 October 2017 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 28 November 2017.

Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to grant a product-specific waiver for all subsets of the paediatric population and the above mentioned condition(s) 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 and Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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

2. The grounds for the granting of the waiver are set out in Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex and appendix.

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition

Treatment of type 2 diabetes mellitus

The waiver applies to:

- all subsets of the paediatric population from birth to less than 10 years of age;
- modified-release 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).

And to:

- all subsets of the paediatric population from 10 to less than 18 years of age;
- modified-release tablets, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.