



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/779486/2012

European Medicines Agency decision

P/0010/2013

of 22 January 2013

on the granting of a product specific waiver for amlodipine (besylate) / atorvastatin (calcium), (EMA-001353-PIP01-12) 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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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 Billev Pharma ApS on 29 August 2012 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 7 December 2012 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.

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 waiver for amlodipine (besylate) / atorvastatin (calcium), film-coated 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 Billev Pharma ApS, Elmegaardsvej 1A, Toerslev, 3630 – Jaegerspirs, Denmark.

Done at London, 22 January 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/616496/2012

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

EMA-001353-PIP01-12

Scope of the application

Active substance(s):

Amlodipine (besylate) / atorvastatin (calcium)

Condition(s):

Treatment of concomitant hypertension and dyslipidaemia

Treatment of concomitant angina and dyslipidaemia

Prevention of cardiovascular events in hypertensive patients and in diabetes mellitus type 2 patients with multiple risk factors for cardiovascular disease

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name / corporate name of the PIP applicant:

Billev Pharma ApS

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Billev Pharma ApS submitted to the European Medicines Agency on 29 August 2012 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 10 October 2012.

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 all 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 occurs only in adult populations, 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 Icelandic and the Norwegian Paediatric Committee members agree 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.

London, 7 December 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition: Treatment of concomitant hypertension and dyslipidaemia

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- for film-coated tablets for oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.2. Condition: Treatment of concomitant angina and dyslipidaemia

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- for film-coated tablets for oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended only occurs in adults.

1.3. Condition: Prevention of cardiovascular events in hypertensive patients and in diabetes mellitus type 2 patients with multiple risk factors for cardiovascular disease

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- for film-coated tablets for oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.