European Medicines Agency

Doc. Ref. EMEA/96351/2009
P/22/2009

EUROPEAN MEDICINES AGENCY DECISION

of 20 February 2009

on the refusal of a Paediatric Investigation Plan and on the refusal of a waiver for candesartan cilexetil (Blopress and associated names), (EMEA-000023-PIP01-07) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 70
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

EUROPEAN MEDICINES AGENCY DECISION

of 20 February 2009

on the refusal of a Paediatric Investigation Plan and on the refusal of a waiver for candesartan cilexetil (Blopress and associated names), (EMEA-000023-PIP01-07) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 application submitted by Takeda Global Research & Development Centre (Europe) Ltd on 12 July 2007 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 February 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation**,**

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

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency, following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) of Regulation (EC) No 1901/2006 as amended, has given an opinion on the refusal of a Paediatric Investigation Plan and on the refusal of a waiver,

(2) It is therefore appropriate to adopt a Decision refusing a Paediatric Investigation Plan.

(3) It is therefore appropriate to adopt a Decision refusing 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 candesartan cilexetil, (Blopress and associated names), tablets, suspension for oral use, 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 refused.

Article 2

A waiver for candesartan cilexetil, (Blopress and associated names), tablets, suspension for oral use, 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 refused.

Article 3

This decision is addressed to Takeda Global Research & Development Centre (Europe) Ltd, Arundel Great Court, 2 Arundel Street, London, WC2R 3DA, United Kingdom.

Done at London, 20 February 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDCO/73749/2009
EMEA-000023-PIP01-07

OPINION OF THE PAEDIATRIC COMMITTEE ON THE REFUSAL OF A PAEDIATRIC INVESTIGATION PLAN AND A WAIVER (AFTER RE-EXAMINATION)

Scope of the application

Active substance:
Candesartan cilexetil

Invented name:
Blopress and associated names

Condition(s):
Essential hypertension
Heart failure
Diabetic retinopathy

Pharmaceutical form(s):
Tablets
Suspension for oral use

Route(s) of administration:
Oral use

Name/corporate name of the PIP applicant:
Takeda Global Research & Development Centre (Europe) Ltd

Information about the authorised medicinal product:
See Annex I

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Takeda Global Research & Development Centre (Europe) Ltd submitted for agreement to the EMEA on 12 July 2007 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

An Opinion was adopted by the Paediatric Committee on 12 December 2008 for the above mentioned product. Takeda Global Research & Development Centre (Europe) Ltd received the Paediatric Committee Opinion on 18 December 2008.

On 14 January 2009 Takeda Global Research & Development Centre (Europe) Ltd submitted to the EMEA a written request including detailed grounds for a re-examination of the Opinion.

The re-examination procedure started on 15 January 2009.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 40
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Final Opinion

1. The Paediatric Committee, having assessed the detailed grounds for re-examination, in accordance with Article 25(3) of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to maintain its opinion and:

  - to refuse the paediatric investigation plan in accordance with Article 18 of said Regulation, as the measures and the timelines are not appropriate to ensure the generation of the necessary data determining the conditions in which the medicinal product may be used to treat the paediatric population or some subsets, nor to adapt a paediatric formulation, or do not bring expected significant therapeutic benefit,

  - to refuse the granting of a waiver in accordance with Article 13 of said Regulation, for some of the above mentioned conditions as it does not meet the grounds detailed in Article 11(1) of Regulation (EC) No 1901/2006 as amended.

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

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

London, 6 February 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

ANNEX I

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented name	Strength	Pharmaceutical Form	Route of administration
N/A	Blopress and associated names	2, 4, 8, 16, 32 mg	Tablet	Oral use