European Medicines Agency

Doc. Ref.: EMEA/575788/2007
P/4/2007

EUROPEAN MEDICINES AGENCY DECISION

of 11 December 2007

on the application for a product specific waiver for Blopress Comp and associated names, Candesartan/Hydrochlorothiazide (EMEA-000040-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)

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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 Ltd on 2 July 2007 under Article 13 of Regulation (EC) No 1901/2006 as amended,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, formulated on 26 October 2007 in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended,

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

WHEREAS:

(1) The Paediatric Committee has given a positive opinion,

(2) It is therefore appropriate to adopt a Decision granting a waiver.

HAS ADOPTED THIS DECISION:

[1] OJ L 378, 27.12.2006, p. 1
[2] OJ L 136, 30.4.2004, p. 1

Article 1

A waiver for Blopress Comp and associated names, Candesartan/Hydrochlorothiazide, tablet, oral use, in essential hypertension, details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 2

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

Done at London, 11 December 2007

For the European Medicines Agency
Thomas Lönngren
Executive Director

Signature: (On file)

European Medicines Agency

EMEA/575788/2007
EMEA-000040-PIP01-07

POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON A PRODUCT-SPECIFIC WAIVER

Scope of the application

Active substance:
Candesartan/Hydrochlorothiazide

Invented name:
Blopress Comp and associated names

Condition(s):
Essential hypertension

Pharmaceutical form(s):
Tablet

Route(s) of administration:
Oral use

Name/corporate name of the waiver applicant:
Takeda Global Research & Development Centre Ltd

Information about the authorised medicinal product: see Annex I

Basis for opinion

Pursuant to Article 13(1) of Regulation (EC) No 1901/2006 of 12 December 2006, as amended, Takeda Global Research & Development Centre Ltd submitted for agreement to the EMEA on 02/07/2007 an application for a waiver pursuant to Article 11(1) of Regulation (EC) No 1901/2006, as amended for the above mentioned medicinal product.

The procedure started on 30 August 2007.

Opinion

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 waiver for all subsets of the paediatric population for the above mentioned condition in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006, as amended, 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.

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

London, 26 October 2007

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

Signature: (On file)

ANNEX I

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

Invented name	Strength	Pharmaceutical Form	Route of administration
Blopress Comp and associated name (including Blopress Comp Forte, Blopresid, Blopress Plus, Parapres Comp Forte, CoKenzen)	8/12.5 mg 16/12.5 mg	Tablet	oral use