



European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 20 July 2008

on the application for product specific waiver for amlodipine besylate, valsartan, hydrochlorothiazide (fixed combination), EMEA-000225-PIP01-08, 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 726/2004¹,

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 Novartis Europharm Ltd. on 6 March 2008 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, issued [s1]on 4 June 2008 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.

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, valsartan, hydrochlorothiazide (fixed combination), film-coated tablet, oral use, the 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 Novartis Europharm Ltd., Wimblehurst Road, RH12 5AB Horsham, United Kingdom.

Done at London, 20 July 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)



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

EMA/PDCO/284750/2008

EMA-000225-PIP01-08

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

Scope of the application

Active substance:

Amlodipine besylate, valsartan, hydrochlorothiazide (fixed combination)

Condition(s):

Essential Hypertension

Pharmaceutical form(s):

Film-coated Tablet

Route(s) of administration:

Oral use

Name/corporate name of the waiver applicant:

Novartis Europharm Ltd.

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Ltd. submitted for agreement to the EMA on 06 March 2008 an application for a waiver on the grounds set out in Article 11 of Regulation (EC) No 1901/2006 as amended for the above mentioned medicinal product.

The procedure started on 10 April 2008.

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 and all above mentioned conditions 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 member(s) agree 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 appendix.

London, 04 June 2008

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)