European Medicines Agency

Doc. Ref. EMEA/386713/2009
P/125/2009

EUROPEAN MEDICINES AGENCY DECISION

of 26 June 2009

on the acceptance of a modification of an agreed Paediatric Investigation Plan for valsartan (Diovan), (EMEA-000005-PIP01-07-M01) 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.

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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 decision P/84/2008 of the European Medicines Agency on 14 October 2008,

Having regard to the application submitted by Novartis Europharm Limited on 20 March 2009 under Article 22 of Regulation (EC) No 1901/2006 as amended proposing changes and a waiver to the agreed Paediatric Investigation Plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 29 May 2009, in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, and in accordance with Article 21 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 has given an opinion on the acceptance of changes to an agreed Paediatric Investigation Plan and on the granting of a waiver.

(2) It is therefore appropriate to adopt a Decision on the acceptance of changes to an agreed Paediatric Investigation Plan.

(3) It is therefore appropriate to adopt a Decision on the granting of 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

Changes to the agreed Paediatric Investigation Plan for valsartan (Diovan), film-coated tablet, hard gelatin capsule, age appropriate formulation: liquid formulation, 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, are hereby accepted.

Article 2

A waiver for valsartan (Diovan), film-coated tablet, hard gelatin capsule, age appropriate formulation: liquid formulation, 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 3

This decision, that supersedes previous decision of the European Medicines Agency P/84/2008, is addressed to Novartis Europharm Limited, Wimblehurst Road, Horsham, RH12 5AB, United Kingdom.

Done at London, 26 June 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

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

Doc. Ref. EMEA/PDCO/296110/2009
EMEA-000005-PIP01-07-M01

OPINION OF THE PAEDIATRIC COMMITTEE ON THE ACCEPTANCE OF A MODIFICATION OF AN AGREED PAEDIATRIC INVESTIGATION PLAN

Scope of the application

Active substance(s):
Valsartan

Invented name and associated names
Diovan

Condition(s):
Hypertension
Heart failure
Heart failure following recent myocardial infarction

Pharmaceutical form(s):
Film-coated tablet, hard gelatin capsule
Age appropriate formulation: liquid formulation

Route(s) of administration:
Oral use

Name/corporate name of the PIP applicant:
Novartis Europharm Limited

Information about the authorised medicinal product:
See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted to the EMEA on 20 March 2009 an application for modification of the agreed paediatric investigation plan and a waiver as set out in the EMEA decision P/84/2008 of 14 October 2008 proposed changes and a waiver.

The procedure started on 02 April 2009.

Scope of the modification

The modifications concern:
- The extension of the current waiver in hypertension to also cover children less than 1 year of age;
- Reduction of extension studies;
- Pharmacovigilance.

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Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

    - to agree to the changes proposed by the applicant regarding the measures and the timelines of the paediatric investigation plan and to amend the scope of the waiver,

The Icelandic and the Norwegian Paediatric Committee members do agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

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

London, 29 May 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

THE MEASURES AND TIMELINES OF THE AGREED PAEDIATRIC INVESTIGATION PLAN AND THE SUBSET(S) OF THE PAEDIATRIC POPULATION AND CONDITION(S) COVERED BY THE WAIVER

A. CONDITION(S)

Hypertension
Heart failure
Heart failure after recent myocardial infarction

B. WAIVER

- **Condition**

  Hypertension

  The waiver applies to:

  Preterm newborn infants, term newborn infants (0-27 d), infants and toddlers aged less than 1 year for film-coated tablet, and hard gelatin capsule for oral use and age appropriate formulation: liquid formulation on the grounds that the specific medicinal product is likely to be unsafe.

- **Condition**

  Heart failure

  The waiver applies to:

  All paediatric age groups (0 to less than 18 years) for film-coated tablet, hard gelatin capsule for oral use and age appropriate formulation: liquid formulation on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

- **Condition**

  Heart failure after recent myocardial infarction

  The waiver applies to:

  All paediatric age groups (0 to less than 18 years) for film-coated tablet, hard gelatin capsule for oral use and age appropriate formulation: liquid formulation on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

  Hypertension

- **Proposed PIP indication**

  Treatment of Hypertension

- **Subset(s) covered**

  Infants and toddlers aged over 1 year, Children (2-11 y), Adolescents (12 years to less than 18 years).

- **Formulation(s)**

  Age appropriate liquid formulation for oral use.

- **Studies**

Area	Subarea	Number	Description
Quality	Formulation		Age-appropriate strength and industrially-prepared liquid formulation
Clinical	Efficacy Safety	1	Randomized, multicentre, double-blind, parallel-group active-controlled study to evaluate the safety and efficacy of valsartan compared with enalapril in 6 to less than 18 years old
Clinical	Efficacy, Safety	1	Randomized, multicentre, double-blind dose-ranging study in 1 year to less than 6 years old children with hypertension.
Clinical	Pharmacokinetics	1	Bioequivalence of extemporaneous suspension used in clinical trials versus new age-appropriate liquid formulation
Clinical		1	Survey of uses of medicinal products in children with heart failure

Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	**by September 2009**
Deferral for some or all studies contained in the paediatric investigation plan:	**No**

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented name Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Content (concentration)	Package size
N/A	Diovan and associated names	40 mg; 80 mg; 160 mg; 320 mg	film-coated tablet; hard gelatine capsule	oral	N/A	N/A	N/A