European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 14 October 2008

on the application for agreement of a Paediatric Investigation Plan for valsartan (Diovan) (EMEA-000005-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 Novartis Europharm Limited on 1 August 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 29 August 2008, 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, has given a positive opinion,

(2) It is therefore appropriate to adopt a Decision following the Paediatric Committee's opinion on the Paediatric Investigation Plan.

(3) 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 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, is hereby agreed.

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 is addressed to Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom.

Done at London, 14 October 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

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

EMEA/PDCO/445606/2008
EMEA-000005-PIP01-07

POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON A REQUEST FOR AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN FOR

Scope of the application

Active substance:
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 16.1of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted for agreement to the EMEA on 26 June 2007 a paediatric investigation plan and request for a waiver for the above mentioned medicinal product.

The procedure started on 1 August 2007.

Supplementary information was provided by the applicant on 16 June 2008
A meeting with the Paediatric Committee took place on 27 August 2008

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report :

- to agree the paediatric investigation plan in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended,
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended and concluded in accordance with:
  Article 11(1)(a) of Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population
  Article 11(1)(b) of Regulation (EC) No 1901/2006 as amended, on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations
  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.

2. 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 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(ces).

London, 29 August 2008

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) / DISEASE(S)

Hypertension
Heart failure
Heart failure after recent myocardial infarction

B. WAIVER

- **Condition**

Hypertension

  - **Subset(s) of the paediatric population, pharmaceutical form(s) and route(s) of administration covered**

The waiver applies to:

- Preterm newborn infants, term newborn infants (0-27 d), infants and toddlers aged less than 6 months for film-coated tablet, and hard gelatin capsule for oral use

- **Condition**

Heart failure

  - **Subset(s) of the paediatric population, pharmaceutical form(s) and route(s) of administration covered**

The waiver applies to

- All paediatric age groups (0 to less than 18 years) for film-coated tablet, hard gelatin capsule for oral use

- **Condition**

Heart failure after recent myocardial infarction

  - **Subset(s) of the paediatric population, pharmaceutical form(s) and route(s) of administration covered**

The waiver applies to:

- All paediatric age groups (0 to less than 18 years) for film-coated tablet, hard gelatin capsule for oral use

C. PAEDIATRIC INVESTIGATION PLAN

C.1. Condition to be investigated

Hypertension

- **Subset(s) covered**

Infants and toddlers aged more than 6 months, Children (2-11 y), Adolescents (12 years to less than 18 years)

- **Formulation(s)**

Age appropriate liquid formulation and strength for oral use

- **Proposed PIP indication**

Treatment of Hypertension

- **Studies / Measures**

Hypertension

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 6 months 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

- **Need for specific measures for long term follow up in relation to potential use in paediatric population:** Yes
- **Date of completion of the paediatric investigation plan:** by September 2009
- **A deferral has been granted:** 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