



European Medicines Agency

Doc. Ref. EMEA/516800/2009
P/177/2009

EUROPEAN MEDICINES AGENCY DECISION

of 7 September 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver for 6,7-dihydro-5H-pyrrolo[1,2-c] imidazol-5-yl) - (benzo derivative) (EMEA-000315-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)

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 726/2004¹,

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 26 June 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 24 July 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation, and 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 agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver.
- (2) It is therefore appropriate to adopt a Decision agreeing a Paediatric Investigation Plan.
- (3) It is therefore appropriate to adopt a Decision granting a deferral.
- (4) 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 6,7-dihydro-5H-pyrrolo[1,2-c] imidazol-5-yl) - (benzo derivative), film-coated tablet, 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 deferral for 6,7-dihydro-5H-pyrrolo[1,2-c] imidazol-5-yl) - (benzo derivative), film-coated tablet, 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 granted.

Article 3

A waiver for 6,7-dihydro-5H-pyrrolo[1,2-c] imidazol-5-yl) - (benzo derivative), film-coated tablet, 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 granted.

Article 4

This decision is addressed to Novartis Europharm Ltd., Wimblehurst Road, Horsham, RH12 5AB, United Kingdom.

Done at London 7 September 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/388089/2009
EMEA-000315-PIP01-08

**OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF
A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL AND A WAIVER**

Scope of the application

Active substance(s):

6,7-dihydro-5H-pyrrolo[1,2-c] imidazol-5-yl) - (benzo derivative)

Condition(s):

Hypertension

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Novartis Europharm Ltd.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Ltd. submitted for agreement to the EMA on 26 June 2008 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 31 July 2008.

Supplementary information was provided by the applicant on 14 May 2009.

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 said Regulation,
- to grant a deferral in accordance with Article 21 of said Regulation,
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation, and concluded in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

The Norwegian Paediatric Committee member agrees 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.

London, 24 July 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

B. WAIVER

- **Condition**

Hypertension

The waiver applies to:

- Preterm newborn infants, Term newborn infants (from birth to less than 28 days, Infants and toddlers (from 28 days to less than 24 months), Children (from 2 to less than 6 years), for film-coated tablet, oral use, on the grounds that the specific medicinal product is likely to be unsafe.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Hypertension

- **Proposed PIP indication**

Treatment of Hypertension not at blood pressure goal with other antihypertensive medication

- **Subset(s) of the paediatric population concerned by the paediatric development**

From 6 to less than 18 years.

- **Formulation(s)**

Film-coated tablet, oral use

- **Studies**

Area	Number of studies	Description
Quality		Not applicable
Non-clinical	2	1) Dose-range finding study in juvenile rats. 2) Toxicity study in juvenile rats.
Clinical	3	3) A PK/PD and safety study in children with hypertension aged 6 to less than 18 years. 4) A double-blind, randomized, dose-response study with a 4 week placebo withdrawal period. 5) A 52 week, double-blind, randomized, active-controlled study with a one year follow-up.

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2017
Deferral for some or all studies contained in the paediatric investigation plan:	Yes