EMA/67881/2011

European Medicines Agency decision

P/39/2011

of 4 February 2011

on the acceptance of a modification of an agreed paediatric investigation plan for azilsartan medoxomil (EMEA-000237-PIP01-08-M03) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This Decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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An agency of the European Union

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

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 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 European Medicines Agency's decision P/105/2009 issued on 15 June 2009, the decision P/234/2009 issued on 27 November 2009, and the decision P/106/2010 issued on 25 June 2010,

Having regard to the application submitted by Takeda Global Research and Development Centre (Europe) Ltd on 3 November 2010 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 14 January 2011, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the waiver.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the 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 azilsartan medoxomil, tablets, granules for oral suspension, oral use, including changes to the waiver, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Takeda Global Research and Development Centre (Europe) Ltd, 61 Aldwych, London, WC2B 4AE, United Kingdom.

Done at London, 4 February 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/693908/2010

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000237-PIP01-08-M03

Scope of the application

Active substance(s):

Azilsartan medoxomil

Condition(s):

Hypertension

Pharmaceutical form(s):

Tablets
Granules for oral suspension

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Takeda Global Research and Development Centre (Europe) Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Takeda Global Research and Development Centre (Europe) Ltd submitted to the European Medicines Agency on 3 November 2010 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/105/2009 issued on 15 June 2009, the decision P/234/2009 issued on 27 November 2009, and the decision P/106/2010 issued on 25 June 2010.

The applicant proposed modifications to the paediatric investigation plan and the waiver.

The procedure started on 18 November 2010.

Scope of the modification

Some of the agreed measures and timelines of the original Opinion have been modified.

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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 changes to the paediatric investigation plan and to the waiver in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees 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 European Medicines Agency, together with its annex and appendix.

London, 14 January 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed Paediatric Investigation Plan

1. Waiver

1.1. Condition:

Hypertension

The waiver applies to:

- preterm newborn infants, term newborn infants (from birth to less than 28 days), infants less than 1 year of age,
- for tablets and granules for oral suspension, oral use,
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan

2.1. Condition to be investigated

Hypertension

2.1.1. Indication targeted by the PIP

Treatment of essential and secondary hypertension.

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 1 year to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

- Tablets
- Granules for oral suspension

2.1.4. Studies

Area	**Number of studies**	**Description**
Quality		Development of age appropriate formulation (granules for oral suspension).
Non-clinical	2	1) Repeat-dose range-finding toxicity study in neonatal rats. 2) Repeat-dose toxicity study with recovery in neonatal rats.

Clinical	4	1) Relative bioavailability, safety, and tolerability study in adults. 2) Single-dose PK, safety, and tolerability of TAK 491 in children and adolescents. 3) Double-blind, active-controlled, efficacy and safety study with 8-week treatment period and 44-week open-label extension in children aged 6 years to less than 18 years with essential and secondary hypertension. 4) Double-blind, placebo-controlled efficacy and safety study with 8-week randomized treatment period and 2-year open-label extension in young children 1 year and older and with a weight of less than 25 kg with mild to moderate secondary hypertension.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By April 2021
Deferral for one or more studies contained in the paediatric investigation plan:	Yes