EMA/136005/2012

European Medicines Agency decision

P/0050/2012

of 2 March 2012

on the acceptance of a modification of an agreed paediatric investigation plan for guanfacine (hydrochloride) (EMEA-000745-PIP01-09-M01) 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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on the acceptance of a modification of an agreed paediatric investigation plan for guanfacine (hydrochloride) (EMEA-000745-PIP01-09-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/186/2010 issued on 24 September 2010,

Having regard to the application submitted by Shire Pharmaceuticals Contracts Ltd. on 21 October 2011 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 January 2012, in accordance with Article 22 of Regulation (EC) No 1901/2006, and of its own motion in accordance with Article 12 of said Regulation,

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 guanfacine (hydrochloride), prolonged-release tablet, 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 Shire Pharmaceuticals Contracts Ltd., Hampshire International Business Park, RG24 8EP – Basingstoke, United Kingdom.

Done at London, 2 March 2012

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/136005/2012

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

EMEA-000745-PIP01-09-M01

Scope of the application

Active substance(s):

Guanfacine (hydrochloride)

Condition(s):

Treatment of Attention Deficit Hyperactivity Disorder (ADHD)

Pharmaceutical form(s):

Prolonged-release tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Shire Pharmaceuticals Contracts Ltd.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Shire Pharmaceuticals Contracts Ltd. submitted to the European Medicines Agency on 21 October 2011 an application for modification of the agreed paediatric investigation plan and a waiver as set out in the European Medicines Agency's decision P/186/2010 issued on 24 September 2010.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 16 November 2011.

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Scope of the modification

Some measures and timelines of the paediatric investigation plan and the scope of the waiver have been modified.

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 in the scope set out in the Annex I of this opinion.
   - to change the scope of the waiver on its own motion in accordance with Article 12 of said Regulation in the scope set out in the Annex I and concluded 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 members 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 European Medicines Agency, together with its annex(es) and appendix.

London, 13 January 2012

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: Treatment of Attention Deficit Hyperactivity Disorder

The waiver applies to:

- The paediatric population from birth to less than 6 years of age;
- for Prolonged-Release Tablet, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of Attention Deficit Hyperactivity Disorder

2.1.1. Indication(s) targeted by the PIP

Treatment of Attention Deficit Hyperactivity Disorder

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

From 6 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Prolonged-Release Tablet

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	1	Study 1 3 months juvenile toxicity study in rats.
Clinical	3	Study 2 Double blind, randomised, multicentre, placebo controlled, dose optimisation trial to evaluate safety, efficacy and tolerability of guanfacine hydrochloride in adolescents from 13 to less than 18 years of age with Attention Deficit Hyperactivity Disorder. Study 3 Double-blind, randomised, placebo-controlled, withdrawal study to evaluate the long-term maintenance of efficacy and safety of guanfacine hydrochloride in children from 6 years to less than 18 years of age with Attention Deficit Hyperactivity Disorder.

		Study 4 Double-blind, randomised, multicentre, parallel-group, placebo-controlled, dose-optimisation study, with an active reference arm (atomoxetine) to evaluate efficacy and safety of guanfacine hydrochloride in children from 6 to less than 18 years with Attention Deficit Hyperactivity Disorder.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By August 2013
Deferral for one or more studies contained in the paediatric investigation plan:	No