EMA/470611/2010

European Medicines Agency decision

P/122/2010

of 26 July 2010

on the acceptance of a modification of an agreed paediatric investigation plan for lisdexamfetamine dimesylate, (EMA-000553-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 lisdexamfetamine dimesylate, (EMA-000553-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/52/2010 issued on 9 April 2010,

Having regard to the application submitted by Shire Pharmaceutical Contracts Ltd on 1 April 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 11 June 2010, 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 deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

[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 lisdexamfetamine dimesylate, capsules, hard, oral use, including changes to a deferral 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 Pharmaceutical Contracts Ltd, Hampshire International Business Park, RG24 8EP – Basingstoke, United Kingdom.

Done at London, 26 July 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director
(Signature on file)

EMA/470611/2010

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

EMA-000553-PIP01-09 – M01

Scope of the application

Active substance(s):

Lisdexamfetamine dimesylate

Condition(s):

Attention Deficit Hyperactivity Disorder (ADHD)

Pharmaceutical form(s):

Capsules, hard

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Shire Pharmaceutical Contracts Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Shire Pharmaceutical Contracts Ltd submitted to the European Medicines Agency on 1 April 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/52/2010 issued on 9 April 2010.

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

The procedure started on 15 April 2010.

Scope of the modification

Some measures and timelines of the original Opinion have been modified and a deferral of a study was granted.

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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 deferral 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 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, 11 June 2010

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

1. Condition(s)

Attention Deficit Hyperactivity Disorder (ADHD)

2. Waiver

2.1. Condition

Attention Deficit Hyperactivity Disorder (ADHD)

The waiver applies to:

- The paediatric population from birth to less than 6 years of age;
- for capsules, hard; for oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Attention Deficit Hyperactivity Disorder (ADHD).

3.2. Indication targeted by the PIP

Treatment of Attention Deficit Hyperactivity Disorder (ADHD).

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

From 6 years to less than 18 years of age.

3.4. Pharmaceutical form(s)

Capsules, hard

3.5. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	2	Study 1 8-Week Subchronic Oral Neonatal Toxicity Study in the Sprague-Dawley Rat. Study 2 2-Week Dose Range-Finding and 26-Week Oral Toxicity Study in the Juvenile Beagle Dog.
Clinical	6	Study 3 Randomized, double-blind, multicentre, parallel-group, placebo-controlled study to evaluate safety and efficacy of lisdexamfetamine dimesylate (LDX) in adolescents from 13 to less than 18 years with Attention-Deficit/Hyperactivity Disorder (ADHD). Study 4 Open-label, 12 months extension, multicentre study to evaluate long-term safety of lisdexamfetamine dimesylate (LDX) in adolescents aged from 13 years to less than 18 years with Attention-Deficit/Hyperactivity Disorder (ADHD). Study 5 Randomised, double-blind, multicentre, parallel-group, placebo- and active-controlled (modified-release methylphenidate) dose-optimisation study to evaluate safety and efficacy of lisdexamfetamine dimesylate (LDX) in children aged 6 years to less than 18 years with Attention-Deficit/Hyperactivity Disorder (ADHD). Study 6 Double-blind, placebo-controlled, randomised withdrawal, multicentre, extension, safety and efficacy study of Lisdexamfetamine Dimesylate (LDX) in children aged 6 years to less than 18 years with Attention-Deficit/Hyperactivity Disorder (ADHD). Study 7 Double-blind, randomised, active-controlled, parallel-group study to evaluate safety and efficacy of lisdexamfetamine dimesylate compared to atomoxetine hydrochloride in children aged 6 years to less than 18 years with Attention Deficit/Hyperactivity Disorder (ADHD). Study 8 Long-term (24 months), open-label, multicentre study to evaluate safety of lisdexamfetamine dimesylate (LDX) in children aged 6 years to less than 18 years with Attention-Deficit/Hyperactivity Disorder (ADHD).

4. 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 October 2014.
Deferral for one or more studies contained in the paediatric investigation plan:	Yes.