EMA/775944/2013

European Medicines Agency decision

P/0321/2013

of 19 December 2013

on the acceptance of a modification of an agreed paediatric investigation plan for lisdexamfetamine (dimesylate) (EMEA-000553-PIP01-09-M04) 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/52/2010 issued on 9 April 2010, the decision P/122/2010 issued on 26 July 2010, the decision P/104/2011 issued on 3 May 2011, and the decision P/0053/2012 issued on 23 March 2012,

Having regard to the application submitted by Shire Pharmaceutical Contracts Ltd on 21 November 2013 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 6 December 2013, 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.

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

[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, 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, 19 December 2013

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

EMA/PDCO/725731/2013

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

EMEA-000553-PIP01-09-M04

Scope of the application

Active substance(s):

Lisdexamfetamine (dimesylate)

Condition(s):

Treatment of 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 21 November 2013 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 decision P/122/2010 issued on 26 July 2010, the decision P/104/2011 issued on 3 May 2011, and the decision P/0053/2012 issued on 23 March 2012.

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

The procedure started on 4 December 2013.

Scope of the modification

Some key elements of the Paediatric Investigation Plan 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 in the scope set out in the Annex I of this opinion.

   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 and appendix.

London, 6 December 2013

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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 (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.

2. Paediatric Investigation Plan

2.1. Condition: treatment of attention deficit hyperactivity disorder (ADHD)

2.1.1. Indication(s) targeted by the PIP

Treatment of attention deficit hyperactivity disorder (ADHD).

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)

Capsules, hard.

2.1.4. Measures

Area	Number of measures	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

Area	Number of measures	Description
		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).

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