



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/483218/2013

European Medicines Agency decision

P/0219/2013

of 6 September 2013

on the acceptance of a modification of an agreed paediatric investigation plan for loxapine, (EMA-001115-PIP01-10-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 loxapine, (EMA-001115-PIP01-10-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 726/2004¹,

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 European Medicines Agency's decision P/220/2011 issued on 30 September 2011,

Having regard to the application submitted by Alexza UK, Limited on 23 April 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 19 July 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 loxapine, inhalation powder, pre-dispensed, inhalation 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 Alexza UK, Limited, 10 Station Road, RG9 1AY - Henley-on-Thames, Oxfordshire, United Kingdom.

Done at London, 6 September 2013

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

EMA/PDCO/260299/2013

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-001115-PIP01-10-M01

Scope of the application

Active substance(s):

Loxapine

Condition(s):

Treatment of schizophrenia

Treatment of bipolar disorder

Pharmaceutical form(s):

Inhalation powder, pre-dispensed

Route(s) of administration:

Inhalation use

Name / corporate name of the PIP applicant:

Alexza UK, Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Alexza UK, Limited submitted to the European Medicines Agency on 23 April 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/220/2011 issued on 30 September 2011.

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

The procedure started on 22 May 2013.

Scope of the modification

Some timelines of the Paediatric Investigation Plan 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.

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, 19 July 2013

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 schizophrenia

The waiver applies to:

- All subsets of the paediatric population from birth to less than 12 years of age;
- for inhalation powder, pre-dispensed for inhalation use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

1.2. Condition: Treatment of bipolar disorder

The waiver applies to:

- All subsets of the paediatric population from birth to less than 10 years of age;
- for inhalation powder, pre-dispensed for inhalation use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan

2.1. Condition: Treatment of schizophrenia

2.1.1. Indication(s) targeted by the PIP

Rapid control of agitation in patients with schizophrenia.

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

From 12 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Inhalation powder, pre-dispensed for inhalation use

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	1	Study 1: Single-dose inhalation developmental tolerability and toxicokinetic study in rats
Clinical	2	Study 2: Safety, tolerability, and pharmacokinetics of loxapine inhalation powder in children and adolescents with schizophrenia or bipolar I disorder Study 3: A multicenter, randomised, double-blind, placebo- and active-controlled efficacy and safety study of loxapine inhalation powder for the treatment of agitation in children and adolescents with schizophrenia or bipolar I disorder

2.2. Condition: Treatment of bipolar disorder

2.2.1. Indication(s) targeted by the PIP

Rapid control of agitation in patients with bipolar disorder.

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

From 10 to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Inhalation powder, pre-dispensed for inhalation use.

2.2.4. Studies

Same as the studies specified for the condition Treatment of schizophrenia.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No.
Date of completion of the paediatric investigation plan:	By October 2014.
Deferral for one or more studies contained in the paediatric investigation plan:	Yes.