EMA/501660/2017

European Medicines Agency decision

P/0257/2017

of 4 September 2017

on the refusal of a modification of an agreed paediatric investigation plan for lurasidone (hydrochloride) (Latuda), (EMEA-001230-PIP01-11-M03) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Only the English text is authentic.

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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/0145/2012 issued on 23 July 2012, the decision P/0269/2013 issued on 30 October 2013, and the decision P/0214/2016 issued on 12 August 2016,

Having regard to the application submitted by Sunovion Pharmaceuticals Ltd. on 2 May 2017 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 21 July 2017, 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 refusal of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the refusal 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 lurasidone (hydrochloride) (Latuda), film-coated tablet, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, are hereby refused.

Article 2

This decision is addressed to Sunovion Pharmaceuticals Ltd., First Floor, Southside, 97-105 Victoria Street, SW1E 6QT - London, United Kingdom.

EMA/PDCO/289713/2017 Corr
London, 21 July 2017

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

EMEA-001230-PIP01-11-M03

Scope of the application

Active substance(s):

Lurasidone (hydrochloride)

Invented name:

Latuda

Condition(s):

Treatment of schizophrenia

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Sunovion Pharmaceuticals Ltd.

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sunovion Pharmaceuticals Ltd. submitted to the European Medicines Agency on 2 May 2017 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/0145/2012 issued on 23 July 2012, the decision P/0269/2013 issued on 30 October 2013, and the decision P/0214/2016 issued on 12 August 2016.

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

The procedure started on 24 May 2017.

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 refuse the changes proposed by the applicant regarding the paediatric investigation plan.

   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 remain unchanged and are set out in the Annex I.

3. The scientific conclusions and the grounds for refusal are set out in the summary report appended to this opinion.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

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 13 years of age;
- for film-coated tablet for oral 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

Treatment of schizophrenia

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

From 13 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	4	**Study 1** Open-label, multicentre, single and multiple fixed ascending dose study to evaluate pharmacokinetics, safety, and tolerability of lurasidone in the paediatric population (D1050300). **Study 2** Randomised, parallel, double-blind, placebo-controlled, fixed-dose regimen, multicentre, study to evaluate the efficacy and safety of lurasidone in adolescent patients with schizophrenia (D1050301).

		Study 3 A 104-week, flexible-dose, open-label multicentre extension study to evaluate the long-term safety and effectiveness of lurasidone in adolescent patients with schizophrenia (D1050302). **Study 4** Randomised, double-blind, active-controlled, non-inferiority, flexible dose study to evaluate the maintenance of the efficacy of lurasidone compared to aripiprazole in the treatment of adolescent patients with schizophrenia (5474).

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety or efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By April 2018
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s)

1. Treatment of schizophrenia

Authorised indication(s):

- treatment of schizophrenia in adults aged 18 years and over

Authorised pharmaceutical form(s)

Film-coated tablet

Authorised route(s) of administration

Oral use