EMA/319518/2014

European Medicines Agency decision

P/0146/2014

of 13 June 2014

on the acceptance of a modification of an agreed paediatric investigation plan for agomelatine (Valdoxan, Thymanax), (EMEA-001181-PIP01-11-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 agomelatine (Valdoxan, Thymanax), (EMEA-001181-PIP01-11-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/0102/2012 issued on 30 May 2012,

Having regard to the application submitted by Les Laboratoires Servier on 31 January 2014 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 25 April 2014, 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 agomelatine (Valdoxan, Thymanax), film-coated tablet, oral use, including changes to the 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 Les Laboratoires Servier, 50, Rue Carnot, 92284 - Suresnes cedex, France.

Done at London, 13 June 2014

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

EMA/PDCO/68632/2014

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

EMEA-001181-PIP01-11-M01

Scope of the application

Active substance(s):

Agomelatine

Invented name:

Valdoxan

Thymanax

Condition(s):

Treatment of major depressive episodes

Treatment of generalised anxiety disorder

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:

Les Laboratoires Servier

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, Les Laboratoires Servier submitted to the European Medicines Agency on 31 January 2014 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/0102/2012 issued on 30 May 2012.

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

The procedure started on 26 February 2014.

Scope of the modification

Some measures and 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 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 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 annexes and appendix.

London, 25 April 2014

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 (PIP)

1. Waiver

1.1. Condition: treatment of major depressive episodes

The waiver applies to:

- all subsets of the paediatric population from birth to less than seven years of age;
- for film-coated tablet, oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in children from birth to less than 24 months of age;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible in children from 2 years to less than 7 years of age.

1.2. Condition: treatment of generalised anxiety disorder

The waiver applies to:

- all subsets of the paediatric population from birth to less than seven years of age;
- for film-coated tablets 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.

2. Paediatric Investigation Plan

2.1. Condition: treatment of major depressive episodes

2.1.1. Indication(s) targeted by the PIP

Treatment of major depressive episodes.

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

From 7 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	1	**Study 1** 10 weeks toxicity study of Agomelatine in juvenile rats

Clinical	3	**Study 2** Open-label, multicentre, three dose levels, trial to evaluate pharmacokinetics of Agomelatine in children from 7 to less than 18 years of age with depressive or anxiety disorder **Study 3** Double blind, randomised, multicentre, two dose levels, active and placebo controlled, trial to evaluate efficacy and safety of Agomelatine to treat children from 7 to less than 18 years of age with major depressive disorder **Study 4** Double blind, randomised, multicentre, one dose level, placebo controlled, trial to prevent depressive relapse of Agomelatine in children from 7 to less than 18 years of age with major depressive disorder

2.2. Condition: treatment of generalised anxiety disorder

2.2.1. Indication(s) targeted by the PIP

Treatment of generalised anxiety disorder.

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

From 7 to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Film-coated tablet.

2.2.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	1	**Study 1** Same study as for condition “treatment of major depressive episodes”
Clinical	2	**Study 5** Double blind, randomised, multicentre, two dose levels, placebo controlled, trial to evaluate efficacy and safety of Agomelatine in children from 7 to less than 18 years of age with generalised anxiety disorder **Study 6** Double blind, randomised, multicentre, one dose level, placebo controlled, trial to evaluate prevention of anxious relapse of Agomelatine in children from 7 to

		less than 18 years of age with generalised anxiety disorder

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2022
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 major depressive episodes

Authorised indication(s): treatment of major depressive episodes in adults

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use