EMA/93279/2021

European Medicines Agency decision

P/0115/2021

of 17 March 2021

on the acceptance of a modification of an agreed paediatric investigation plan for agomelatine (Valdoxan and associated names), (EMEA-001181-PIP01-11-M06) 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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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, the decision P/0146/2014 issued on 13 June 2014, the decision P/0068/2015 issued on 1 April 2015, the decision P/0191/2016 issued on 15 July 2016 and the decision P/0432/2019 issued on 6 December 2019,

Having regard to the application submitted by Les Laboratoires Servier on 23 October 2020 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 29 January 2021, 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 and associated names), 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.

EMA/PDCO/610279/2020
Amsterdam, 29 January 2021

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

EMEA-001181-PIP01-11-M06

Scope of the application

Active substance(s):

Agomelatine

Invented name:

Valdoxan and associated names

Condition(s):

Treatment of major depressive episodes

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

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 23 October 2020 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 decision P/0146/2014 issued on 13 June

2014, the decision P/0068/2015 issued on 1 April 2015, the decision P/0191/2016 issued on 15 July 2016 and the decision P/0432/2019 issued on 6 December 2019.

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

The procedure started on 1 December 2020.

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.

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;
- 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 the paediatric population 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 the paediatric population from 2 years to less than 7 years of age.

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	2	**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. (CL2-20098-075)

		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. (CL3-20098-076) **Study 4 deleted during procedure EMEA-001181-PIP01-11-M06**

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 January 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