EMA/244179/2017

European Medicines Agency decision

P/0120/2017

of 5 May 2017

on the acceptance of a modification of an agreed paediatric investigation plan for tapentadol (hydrochloride) (Palexia and associated names, Yantil and associated names, Tapentadol and associated names), (EMEA-000018-PIP01-07-M13) 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/48/2008 issued on 11 August 2008, the decision P/174/2009 issued on 7 September 2009, the decision P/137/2010 issued on 30 July 2010, the decision P/183/2011 issued on 4 August 2011, the decision P/0218/2012 issued on 28 September 2012, the decision P/0049/2013 issued on 1 March 2013, the decision P/0279/2013 issued on 8 November 2013, the decision P/0236/2014 issued on 19 September 2014, the decision P/0056/2015 issued on 1 April 2015, the decision P/0090/2016 issued on 18 March 2016 and the decision P/0315/2016 issued on 2 December 2016,

Having regard to the application submitted by Grünenthal GmbH on 22 December 2016 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 24 March 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 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 tapentadol (hydrochloride) (Palexia and associated names, Yantil and associated names, Tapentadol and associated names), film-coated tablet, oral solution, solution for injection/infusion, oral use, intravenous 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 Grünenthal GmbH, Zieglerstrasse 6, 52078 – Aachen, Germany.

EMA/PDCO/26586/2017
London, 24 March 2017

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

EMEA-000018-PIP01-07-M13

Scope of the application

Active substance(s):

Tapentadol (hydrochloride)

Invented name:

Palexia and associated names

Yantil and associated names

Tapentadol and associated names

Condition(s):

Treatment of acute pain

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Oral solution

Solution for injection/infusion

Route(s) of administration:

Oral use

Intravenous use

Name/corporate name of the PIP applicant:

Grünenthal GmbH

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Grünenthal GmbH submitted to the European Medicines Agency on 22 December 2016 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/48/2008 issued on 11 August 2008, the decision P/174/2009 issued on 7 September 2009, the decision P/137/2010 issued on 30 July 2010, the decision P/183/2011 issued on 4 August 2011, the decision P/0218/2012 issued on 28 September 2012, the decision P/0049/2013 issued on 1 March 2013, the decision P/0279/2013 issued on 8 November 2013, the decision P/0236/2014 issued on 19 September 2014, the decision P/0056/2015 issued on 1 April 2015, the decision P/0090/2016 issued on 18 March 2016 and the decision P/0315/2016 issued on 2 December 2016.

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

The procedure started on 24 January 2017.

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 acute pain

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- film-coated tablets, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition

Treatment of acute pain

2.1.1. Indication(s) targeted by the PIP

Treatment of acute pain

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

From birth to less than 18 years

2.1.3. Pharmaceutical form(s)

Oral solution

Solution for injection/infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	2	**Study 1** Development of liquid formulation, with two strengths appropriate for all paediatric population. **Study 2** Development of intravenous formulation.
Non-clinical studies	1	**Study 3** Juvenile rat toxicity study.
Clinical studies	5	**Study 4** Single-dose pharmacokinetic trial in children aged from 6 to less than 18 years.

		Study 5 Single-dose pharmacokinetic trial in children aged from 2 to less than 18 years. **Study 6** Efficacy, safety and tolerability trial in children and adolescents aged from 2 years to less than 18 years. **Study 7** Single-dose pharmacokinetic and safety trial in children aged from 1 to 23 months including exploratory efficacy. **Study 8** Single-dose pharmacokinetic and safety trial in children from birth to less than 24 months of age, including preterm neonates
Extrapolation, modelling and simulation studies	1	**Study 9** Modelling and simulation study.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By March 2020
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of acute pain

Authorised indication(s):

- relief of moderate to severe acute pain in adults, which can be adequately managed only with opioid analgesics.

2. Treatment of chronic pain

Authorised indication(s):

- management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics.

Authorised pharmaceutical form(s):

Film-coated tablet

Prolonged-release tablet

Oral solution

Authorised route(s) of administration:

Oral use