EMA/555779/2014

European Medicines Agency decision

P/0238/2014

of 19 September 2014

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-000495-PIP01-08-M08) 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/104/2009 issued on 5 June 2009, the decision P/180/2009 issued on 7 September 2009, the decision P/143/2010 issued on 30 July 2010, the decision P/185/2011 issued on 4 August 2011, the decision P/0220/2012 issued on 28 September 2012, the decision P/0051/2013 issued on 1 March 2013, and the decision P/0284/2013 issued on 8 November 2013,

Having regard to the application submitted by Grünenthal GmbH on 24 April 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 10 September 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, following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) Regulation (EC) No 1901/2006, 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 tapentadol (hydrochloride) (Palexia and associated names, Yantil and associated names, Tapentadol and associated names), film-coated tablet, solution for injection/infusion, oral solution, oral use, intravenous 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 Grünenthal GmbH, Zieglerstrasse 6, 52078 - Aachen, Germany.

Done at London, 19 September 2014

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

EMA/PDCO/554932/2014

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan (after re-examination)

EMEA-000495-PIP01-08-M08

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

Solution for injection/infusion

Oral solution

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

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Grünenthal GmbH submitted to the European Medicines Agency on 24 April 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/104/2009 issued on 5 June 2009, the decision P/180/2009 issued on 7 September 2009, the decision P/143/2010 issued on 30 July 2010, the decision P/185/2011 issued on 4 August 2011, the decision P/0220/2012 issued on 28 September 2012, the decision P/0051/2013 issued on 1 March 2013, and the decision P/0284/2013 issued on 8 November 2013.

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

An Opinion was adopted by the Paediatric Committee on 18 July 2014 for the above mentioned product. Grünenthal GmbH received the Paediatric Committee Opinion on 28 July 2014.

On 11 August 2014 Grünenthal GmbH submitted to the European Medicines Agency a written request including detailed grounds for a re-examination of the Opinion.

The re-examination procedure started on 12 August 2014.

A meeting with the Paediatric Committee took place on 10 September 2014.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

Final Opinion

1. The Paediatric Committee, having assessed the detailed grounds for re-examination, in accordance with Article 25(3) of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

1.1. to revise its opinion and

- to agree to the changes regarding the measures in the scope set out in the Annex I of this opinion.

The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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, 10 September 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 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:** Pharmacokinetic trial in children aged from 6 to less than 18 years. **Study 5** 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 of age. **Study 7:** Pharmacokinetic and safety trial in children aged from 0 to 23 months including exploratory efficacy. **Study 8:** Pharmacokinetic and safety trial in 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:	No
Date of completion of the paediatric investigation plan:	By April 2017
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