EMA/589982/2011

European Medicines Agency decision

P/183/2011

of 4 August 2011

on the acceptance of a modification of an agreed paediatric investigation plan for tapentadol (hydrochloride) (Palexia) (EMEA-000018-PIP01-07-M03) 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, and the decision P/137/2010 issued on 30 July 2010,

Having regard to the application submitted by Grünenthal GmbH on 27 May 2011 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 July 2011, 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

(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), film-coated tablets, oral solution, solution for injection/infusion, 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, 4 August 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/504076/2011

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

EMEA-000018-PIP01-07-M03

Scope of the application

Active substance(s):

Tapentadol (hydrochloride)

Invented name:

Palexia

Condition(s):

Treatment of acute pain

Pharmaceutical form(s):

Film-coated tablets

Oral solution

Solution for injection/infusion

Route(s) of administration:

Oral use

Intravenous use

Name/corporate name of the PIP applicant:

Grünenthal GmbH

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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 27 May 2011 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, and the decision P/137/2010 issued on 30 July 2010.

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

The procedure started on 15 June 2011.

Scope of the modification

Some 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 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 annex and appendix.

London, 15 July 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, 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

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;
- for film-coated tablets;
- 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 to be investigated

Treatment of acute pain

2.1.1. Indication 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. Studies

Area	Study Number	Study Type
Formulation		Development of liquid formulation, with two strengths appropriate for all paediatric population. Development of intravenous formulation.
Non clinical	1	Juvenile rat study
Clinical	4	Pharmacokinetic trial in children from 6 years to 17 years of age. Pharmacokinetic trial in children from 2 years to 5 years of age. Pharmacokinetic and safety trial in children aged from 0 to 23 months of age including exploratory efficacy. Pharmacokinetic and safety trial in preterm neonates.

Area	Study Number	Study Type
	1	Efficacy, safety and tolerability trial in children and adolescents aged from 2 years to 17 years of age.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By September 2016
Deferral for some or all studies contained in the paediatric investigation plan:	Yes