EMA/469385/2010

European Medicines Agency decision

P/137/2010

of 30 July 2010

on the refusal of a modification of an agreed paediatric investigation plan for tapentadol hydrochloride (EMEA-000018-PIP01-07-M02) 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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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,

Having regard to the application submitted by Grünenthal GmbH on 29 March 2010 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 11 June 2010, 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 refusal of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the refusal 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, immediate release tablets, oral formulation, oral use, intravenous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, are hereby refused.

Article 2

This decision is addressed to Grünenthal GmbH, Zieglerstrasse 6, 52078 Aachen, Germany.

Done at London, 30 July 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/360033/2010

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

EMEA-000018-PIP01-07-M02

Scope of the application

Active substance(s):

Tapentadol hydrochloride

Condition(s):

Acute pain

Pharmaceutical form(s):

Immediate release tablets

Oral formulation

Route(s) of administration:

Oral use

Intravenous use

Name/corporate name of the PIP applicant:

Grünenthal GmbH

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Grünenthal GmbH submitted to the European Medicines Agency on 29 March 2010 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 application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 15 April 2010.

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Scope of the modification

Changes in the timelines of the paediatric investigation plan.

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 refuse the changes proposed by the applicant regarding the paediatric investigation plan.

   The Norwegian Paediatric Committee member(s) agree(s) 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 remain unchanged and are set out in the Annex I.

3. The scientific conclusions and the grounds for refusal are set out in the summary report appended to this opinion.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex(es) and appendix.

London, 11 June 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

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

1. Condition(s)

Acute pain

2. Waiver

2.1. Condition

Acute pain

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age
- for immediate release tablets
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Acute pain

3.1.1. Indication targeted by the PIP

Treatment of acute pain

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

From birth to less than 18 years.

3.1.3. Pharmaceutical form(s)

Oral liquid for oral use

Intravenous formulation for intravenous use

3.1.4. Studies

Area	Study #	Study Type
Formulation		Development of liquid formulation, with two strengths appropriate for all paediatric population. Development for 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

Area	Study #	Study Type
		age including exploratory efficacy. Pharmacokinetic and safety trial in preterm neonates.
	1	Efficacy, safety and tolerability trial in children and adolescents aged from 2 years to 17 years of age.

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues efficacy in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By September 2014
Deferral for some or all studies contained in the paediatric investigation plan:	Yes