European Medicines Agency

Doc. Ref. EMEA/161790/2009
P/55/2009

EUROPEAN MEDICINES AGENCY DECISION

of 24 March 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral for tapentadol hydrochloride (EMEA-000485-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 application submitted by Grünenthal GmbH on 7 November 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a deferral under Article 20 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 February 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 21 of said Regulation**,**

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a Paediatric Investigation Plan and on the granting of a deferral,

(2) It is therefore appropriate to adopt a Decision granting a Paediatric Investigation Plan,

(3) It is therefore appropriate to adopt a Decision granting a 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

A Paediatric Investigation Plan for tapentadol hydrochloride, oral liquid, prolonged-release tablet, prolonged-release granules, oral 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, is hereby agreed.

Article 2

A deferral for tapentadol hydrochloride, oral liquid, prolonged-release tablet, prolonged-release granules, oral 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, is hereby granted.

Article 3

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

Done at London, 24 March 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref.EMEA/PDCO/79439/2009
EMEA-000485-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL

Scope of the application

Active substance:
Tapentadol hydrochloride

Condition(s):
Chronic pain

Pharmaceutical form(s):
Oral liquid
Prolonged-release tablet
Prolonged-release granules

Route(s) of administration:
Oral use

Name/corporate name of the PIP applicant:
Grünenthal GmbH

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Grünenthal GmbH submitted for agreement to the EMEA on 7 November 2008 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 11 December 2008.

A meeting with the Paediatric Committee took place on 4 February 2009.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,

- to grant a deferral in accordance with Article 21 of said Regulation.

The Norwegian Paediatric Committee member agrees 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 Agency, together with its annex(es) and appendix.

London, 6 February 2009

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

A. CONDITION(S)
Chronic pain

B. WAIVER
Not applicable.

- **Condition**

No waiver was granted

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Chronic pain

- **Proposed PIP indication**

- **Subset(s) of the paediatric population concerned by the paediatric development**

From birth to less than 18 years.

- **Formulation(s)**

Development of prolonged-release granules (multiparticulate)

- **Studies**

Area	Number of studies	Description
Quality	1	A Randomized, Open-Label, Relative Bioavailability Trial to compare a tapentadol multiparticulate (or alternative) formulation and the Prolonged Release Tablets in Healthy Subjects
Non-clinical	1	Juvenile animal toxicity study
Clinical	3	A randomized, open-label, active-controlled, multi-centre study to evaluate the safety and the efficacy of tapentadol PR in patients between 6 and 17 years old suffering from chronic malignant or non-malignant pain requiring opioid treatment. A randomized open-label, active-controlled, multi-centre study to evaluate the safety and the efficacy of tapentadol PR in patients between 2 and 5 years old suffering from chronic malignant or non-malignant pain requiring opioid treatment. Modeling and simulation of PK in children less than 2years. Proposal to be submitted to the PDCO for review at a later date when necessary data is available.

Measures to address long term follow-up of potential safety or efficacy issues in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	**By October 2016**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**