EMA/306400/2013

European Medicines Agency decision

P/0145/2013

of 3 July 2013

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for cebranopadol (EMEA-001305-PIP01-12) 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 7523 7040
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 application submitted by Grünenthal GmbH on 31 May 2012 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 17 May 2013, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

(4) It is therefore appropriate to adopt a decision granting a waiver.

[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 cebranopadol, film-coated tablet, 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 cebranopadol, film-coated tablet, 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

A waiver for cebranopadol, film-coated tablet, 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 4

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

Done at London, 3 July 2013

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

EMA/PDCO/122557/2013

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-001305-PIP01-12

Scope of the application

Active substance(s):

Cebranopadol

Condition(s):

Treatment of chronic pain

Pharmaceutical form(s):

Film-coated tablet

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 European Medicines Agency on 31 May 2012 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 11 July 2012.

Supplementary information was provided by the applicant on 22 February 2013. The applicant proposed modifications to the paediatric investigation plan.

A meeting with the Paediatric Committee took place on 16 May 2013.

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E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   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 annex and appendix.

London, 17 May 2013

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 chronic pain

The waiver applies to:

- The paediatric population from birth to less than 2 years of age;
- for film-coated tablet and for granules for 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 chronic pain

2.1.1. Indication(s) targeted by the PIP

Treatment of severe chronic nociceptive pain

Treatment of peripheral neuropathic pain

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

From 2 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet and granules for oral use

2.1.4. Measures

Area	Number of measures	Description
Quality	1	**Measure 1:** Development of appropriate strengths of film-coated tablet for oral use for paediatric patients from 6 to less than 18 years of age (1361259441774). **Measure 2:** Development of granules for oral use as an age-appropriate pharmaceutical form for paediatric patients from 2 to less than 6 years of age (1361259596054).
Non-clinical	1	**Measure 3:** Juvenile toxicity study to evaluate the potential effects of cebranopadol on development of juvenile rats through sexual maturity (1361260316840).

Area	Number of measures	Description
Clinical	3	**Measure 4:** An open label, multi-centre, single arm, multi-part pharmacokinetics and tolerability/safety trial of a single oral dose and multiple oral doses of cebranopadol in male and female children and adolescents from 2 to less than 18 years of age experiencing chronic pain (1361260893642). **Measure 5:** An open label, multi-center, single arm trial to evaluate activity, safety, and tolerability of multiple oral doses of cebranopadol in male and female children and adolescents from 2 to less than 18 years of age experiencing chronic pain (1361263010528). **Measure 6:** Double-blind, randomised, placebo-controlled tolerability, safety and efficacy study in male and female children and adolescents from 2 to less than 18 years of age experiencing peripheral neuropathic pain (1366975695401).

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By June 2024
Deferral for one or more measures contained in the paediatric investigation plan:	Yes