EMA/655503/2010

# European Medicines Agency decision

P/213/2010

of 29 October 2010

on the granting of a product specific waiver for fampridine (EMEA-000614-PIP01-10-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

**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/247/2009 issued on 4 December 2009,

Having regard to the application submitted by Acorda Therapeutics, Inc. on 28 June 2010 under Article 22 of Regulation (EC) No 1901/2006 proposing a modification of the agreed paediatric investigation plan with a deferral and a waiver by means of granting a product-specific waiver pertaining to all conditions covered by that paediatric investigation plan on the grounds set out in Article 11 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 10 September 2010 in accordance with Article 13 and 22 of Regulation (EC) No 1901/2006,

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

Whereas:

(1) The Paediatric Committee has given an opinion on the granting of a product specific waiver.

(2) 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 waiver for fampridine, prolonged release tablets, 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 2***

This decision is addressed to Acorda Therapeutics, Inc., 15 Skyline Dr, 10532 Hawthorne, New York, The United States.

Done at London, 29 October 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/551621/2010

# Opinion of the Paediatric Committee on the granting of a product-specific waiver

EMEA-000614-PIP01-10-M01

## Scope of the application

**Active substance(s):**

Fampridine

**Condition(s):**

Treatment of multiple sclerosis with walking disability

**Pharmaceutical form(s):**

Prolonged release tablets

**Route(s) of administration:**

Oral use

**Name/corporate name of the PIP applicant:**

Acorda Therapeutics, Inc.

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Acorda Therapeutics, Inc. submitted to the European Medicines Agency on 28 June 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/247/2009 issued on 4 December 2009 by means of granting a product-specific waiver, on the grounds set out in Article 11 of said Regulation. The applicant did not request a modification of any measures or timelines of the above mentioned paediatric investigation plan, but instead requested a waiver pertaining to all conditions covered by that paediatric investigation plan.

The procedure started on 15 July 2010.

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## Opinion

1. The Paediatric Committee, having assessed the submitted application in accordance with Articles 13 and 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to grant a product-specific waiver for all subsets of the paediatric population and the above mentioned condition(s) in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population, and 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 grounds for the granting of the waiver are set out in 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, 10 September 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

# Annex I

# Grounds for the granting of the waiver

# 1. Grounds for the granting of the waiver

## *1.1. Condition*

Treatment of multiple sclerosis with walking disability

The waiver applies to:

- The paediatric population from birth to less than 12 years of age,
- for prolonged release tablet, oral use,
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

The waiver applies to:

- The paediatric population from 12 to less than 18 years of age,
- for prolonged release tablet, oral use,
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.