



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/655072/2010

## European Medicines Agency decision

P/214/2010

of 29 October 2010

on the granting of a product specific waiver for dronabinol (EMEA-000643-PIP01-09) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

**Only the English text is authentic.**



# European Medicines Agency decision

P/214/2010

of 29 October 2010

on the granting of a product specific waiver for dronabinol (EMA-000643-PIP01-09) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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<sup>1</sup>,

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<sup>2</sup>,

Having regard to the application submitted by Bionorica AG on 17 July 2009 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 10 September 2010 in accordance with Article 13 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.

---

<sup>1</sup> OJ L 378, 27.12.2006, p.1.

<sup>2</sup> OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

**Article 1**

A waiver for dronabinol, oral solution, 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 Bionorica AG, Kerschensteinerstraße 11-15, 92318 Neumarkt, Germany.

Done at London, 29 October 2010

For the European Medicines Agency  
Thomas Lönngrén  
Executive Director

(Signature on file)



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/PDCO/553804/2010

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

EMA-000643-PIP01-09

### Scope of the application

#### Active substance(s):

Dronabinol

#### Condition(s):

Treatment of central and peripheral neuropathic pain

#### Pharmaceutical form(s):

Oral solution

#### Route(s) of administration:

Oral use

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

Bionorica AG

### Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Bionorica AG submitted to the European Medicines Agency on 17 July 2009 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 20 August 2009.

Supplementary information was provided by the applicant on 5 August 2010.



## Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 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 in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

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 central and peripheral neuropathic pain.

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age,
- for oral solution, oral use,
- on the grounds that the specific medicinal product is likely to be unsafe.