



European Medicines Agency

Doc. Ref. EMEA/155675/2009  
P/44/2009

**EUROPEAN MEDICINES AGENCY DECISION**

**of 23 March 2009**

**on the refusal of a product specific waiver for dexamethasone (EMEA-000198-PIP02-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended**

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

## EUROPEAN MEDICINES AGENCY DECISION

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**on the refusal of a product specific waiver for dexamethasone (EMEA-000198-PIP02-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended**

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<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 Allergan Pharmaceuticals Ireland on 7 November 2008 under Article 13 of Regulation (EC) No 1901/2006 as amended,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 February 2009 in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended,

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

WHEREAS:

- (1) The Paediatric Committee has given an opinion on the refusal of a product specific waiver,
- (2) It is therefore appropriate to adopt a Decision refusing a waiver.

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<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 dexamethasone, intravitreal implant in applicator, intravitreal 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 refused.

*Article 2*

This decision is addressed to Allergan Pharmaceuticals Ireland, Castlebar Road, County May, 00000 Westport, Ireland.

Done at London, 23 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/62336/2009  
EMEA- 000198-PIP02-08

## **OPINION OF THE PAEDIATRIC COMMITTEE ON THE REFUSAL OF A PRODUCT-SPECIFIC WAIVER**

### **Scope of the application**

Active substance:

Dexamethasone

Condition(s):

Chronic non-infectious intermediate or posterior uveitis

Pharmaceutical form(s):

Intravitreal implant in applicator

Route(s) of administration:

Intravitreal use

Name/corporate name of the waiver applicant:

Allergan Pharmaceuticals Ireland

### **Basis for opinion**

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Allergan Pharmaceuticals Ireland submitted to the EMEA on 7 November 2008 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 11 December 2008.

## **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 refuse the granting of a product-specific waiver for all subsets of the paediatric population and the above mentioned condition as it does not meet the grounds detailed in Article 11(1) of said Regulation.

The Icelandic Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. 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 Agency.

London, 6 February 2009

On behalf of the Paediatric Committee  
Dr Daniel Brasseur, Chairman

(Signature on file)