



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/343627/2010

## European Medicines Agency decision

P/116/2010

of 7 July 2010

on the refusal of a product specific waiver for sodium sulfate/potassium sulfate/magnesium sulfate heptahydrate (EMA-000816-PIP01-09) 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<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 Ipsen Pharma on 14 December 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 21 May 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 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 sodium sulfate/potassium sulfate/magnesium sulfate heptahydrate, 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 refused.

**Article 2**

This decision is addressed to Ipsen Pharma, 65 quai Georges Gorse, 92100 Boulogne Billancourt, France.

Done at London, 7 July 2010

For the European Medicines Agency  
Thomas Lönngrén  
Executive Director

(Signature on file)



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EMA/PDCO/327100/2010

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

EMA-000816-PIP01-09

### Scope of the application

**Active substance(s):**

Sodium sulfate/potassium sulfate/magnesium sulfate heptahydrate

**Condition(s):**

Diseases of the intestines

**Pharmaceutical form(s):**

Oral solution

**Route(s) of administration:**

Oral use

**Name/corporate name of the PIP applicant(s):**

Ipsen Pharma

### Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Ipsen Pharma submitted to the European Medicines Agency on 14 December 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 21 January 2010.

Supplementary information was provided by the applicant on 5 April 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 refuse the granting of a product-specific waiver for all subsets of the paediatric population and the above mentioned condition(s) as it does not meet the grounds detailed in Article 11(1) of said Regulation.

The Norwegian Paediatric Committee member(s) agree(s) 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.

3. The grounds for refusal are summarised in Annex I.

This opinion is forwarded to the applicant(s) and the Executive Director of the European Medicines Agency, together with its appendix(ces).

London, 21 May 2010

On behalf of the Paediatric Committee

Dr Daniel Brasseur, Chairman

(Signature on file)

## **Annex I**

### **Grounds for the refusal of the waiver**

# 1. GROUNDS FOR THE REFUSAL OF THE WAIVER

## 1.1. *The waiver is refused for the following:*

### ***Condition***

Diseases of the intestines

Indication

Diagnosis of diseases of the intestines

The request for the waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age.
- for oral solution, oral use

as the waiver request does not provide evidence to support any of the following grounds set out in Article 11(1) of Regulation (EC) No 1901/2006 that:

(a) the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population, or

(b) the disease or condition for which the specific medicinal product is intended occurs only in adult populations, or

(c) the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients

because:

Measures would be justified by the expected therapeutic benefit and clinical trials may be feasible and clinical studies may fulfil a therapeutic need of the paediatric population.