



European Medicines Agency

Doc. Ref. EMEA/351862/2009  
P/115/2009

**EUROPEAN MEDICINES AGENCY DECISION**

**of 15 June 2009**

**on the granting of a product specific waiver for Pravastatin sodium / Fenofibrate  
(EMEA-000501-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European  
Parliament and of the Council as amended**

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

*DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of  
Regulation (EC) No 1901/2006, as amended.*

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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 Laboratoires SMB s.a. on 30 January 2009 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 30 April 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 granting of a product specific waiver,
- (2) It is therefore appropriate to adopt a Decision granting 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

<sup>3</sup> OJ L 378, 27.12.2006, p.1

<sup>4</sup> OJ L 136, 30.4.2004, p. 1

HAS ADOPTED THIS DECISION:

*Article 1*

A waiver for pravastatin sodium / fenofibrate, hard capsule, 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 Laboratoires SMB s.a., 26 - 28 rue de la Pastorale, 1080, Brussels, Belgium..

Done at London, 15 June 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/253590/2009  
EMEA-000501-PIP01-08

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

### **Scope of the application**

Active substance(s):

Pravastatin sodium / Fenofibrate

Condition(s):

Disorders of lipoprotein metabolism and other hyperlipidaemias

Pharmaceutical form(s):

Hard capsule

Route(s) of administration:

Oral use

Name/corporate name of the waiver applicant:

Laboratoires SMB s.a.

### **Basis for opinion**

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Laboratoires SMB s.a. submitted to the EMA on 30 January 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 5 March 2009.

## 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 all the above mentioned condition(s) 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 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 Agency, together with its Annex.

London, 30 April 2009

On behalf of the Paediatric Committee  
Dr Daniel Brasseur, Chairman

(Signature on file)

**ANNEX I**

**GROUND S FOR THE GRANTING OF THE WAIVER**

## GROUNDINGS FOR THE GRANTING OF THE WAIVER

The waiver applies to :

- **Condition**

Disorders of lipoprotein metabolism and other lipidemia

Paediatric subsets:

- All subsets of the paediatric population, for Pravastatin sodium / Fenofibrate, hard capsule, oral use, on the grounds that clinical studies cannot fulfil a therapeutic need of the paediatric population.