



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/195529/2016

## European Medicines Agency decision

P/0114/2016

of 15 April 2016

on the granting of a product specific waiver for montelukast (sodium) / levocetirizine (dihydrochloride) (EMA-001908-PIP01-15) 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 Invest Bielany Sp. z o.o. on 20 November 2015 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 26 February 2016 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.

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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 montelukast (sodium) / levocetirizine (dihydrochloride), film-coated tablet, 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 Invest Bielany Sp. z o.o., Al. Stanów Zjednoczonych 51, 04-028 – Warsaw, Poland.

Done at London, 15 April 2016

For the European Medicines Agency  
Zaide Frias  
Head of Division  
Human Medicines Research and Development Support  
(Signature on file)



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/PDCO/845623/2015  
London, 26 February 2016

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

EMA-001908-PIP01-15

### Scope of the application

**Active substance(s):**

Montelukast (sodium) / levocetirizine (dihydrochloride)

**Condition(s):**

Treatment of asthma

**Pharmaceutical form(s):**

Film-coated tablet

**Route(s) of administration:**

Oral use

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

Invest Bielany Sp. z o.o.

### Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Invest Bielany Sp. z o.o. submitted to the European Medicines Agency on 20 November 2015 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 4 January 2016.



## 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(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 Norwegian Paediatric Committee member agrees 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.

## **Annex I**

### **Grounds for the granting of the waiver**

# 1. Waiver

## 1.1. Condition:

Treatment of asthma

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for film-coated tablet, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.