European Medicines Agency

Doc. Ref. EMEA/96354/2008
P/12/2008

EUROPEAN MEDICINES AGENCY DECISION

of 29 February 2008

on the application for agreement of a Paediatric Investigation Plan for Singulair and associated names, montelukast sodium (EMEA-000012-PIP01-07) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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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[1],

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[2],

Having regard to the application submitted by Merck Sharp & Dohme (Europe) Inc. on 28 June 2007 under Article 16.1 of Regulation (EC) No 1901/2006 as amended also including a request for a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, formulated on 18 January 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation,

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

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given a positive opinion,

(2) It is therefore appropriate to adopt a Decision following the Paediatric Committee's opinion on the Paediatric Investigation Plan.

(3) It is therefore appropriate to adopt a Decision granting a waiver.

[1] OJ L 378, 27.12.2006, p.1
[2] OJ L 136, 30.4.2004, p. 1

HAS ADOPTED THIS DECISION:

Article 1

A Paediatric Investigation Plan for Singulair and associated names, montelukast sodium, chewable tablets, oral granules, oral, 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 agreed.

Article 2

A waiver for Singulair and associated names, montelukast sodium, chewable tablets, oral granules, oral, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Merck Sharp & Dohme (Europe) Inc., 5 Clos du Lynx, B-1200 Brussels, Belgium.

Done at London, 29 February 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

EMEA/96354/2008
EMEA-000012-PIP01-07

POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON A REQUEST FOR AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN FOR

Scope of the application

Active substance:
Montelukast sodium

Invented name:
Singulair and associated names

Condition:
Asthma

Pharmaceutical form(s):
Chewable tablets
Oral granules

Route of administration:
Oral

Name/corporate name of the PIP applicant:
Merck Sharp & Dohme (Europe) Inc.

Information about the authorised medicinal product:
See Annex II

Basis for opinion

Pursuant to Article 16.1 of Regulation (EC) No 1901/2006 as amended, Merck Sharp & Dohme (Europe) Inc. submitted for agreement to the EMEA on 29 June 2007 a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 2 August 2007.

Supplementary information was provided by the applicant on 16 November 2007.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended,
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended and concluded in accordance with
  Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, 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 measures and timelines of the agreed paediatric investigation plan and the subsets of the paediatric population and conditions covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annexes and appendix.

London, 18 January 2008

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

THE MEASURES AND TIMELINES OF THE AGREED PAEDIATRIC INVESTIGATION PLAN AND THE SUBSETS OF THE PAEDIATRIC POPULATION AND CONDITIONS COVERED BY THE WAIVER

A. CONDITION(S) / DISEASE(S)

Asthma
Allergic Rhinitis

B. WAIVER

- **Condition**

Persistent Asthma, (Add-on Indication)

- **Subset(s) of the paediatric population, pharmaceutical form(s) and route(s) of administration covered**

The waiver applies to:
Preterm newborn infants, Term newborn infants (0-27 d), Infants below 6 months for 4 mg chewable tablets and 4 mg oral granules for oral use.

- **Condition**

Chronic Asthma, (Monotherapy Indication)

- **Subset(s) of the paediatric population, pharmaceutical form(s) and route(s) of administration covered**

The waiver applies to:
Preterm newborn infants, Term newborn infants (0-27 d), Infants & toddlers (28 d-23 months) for 4 mg chewable tablets and 4 mg oral granules for oral use.

- **Condition**

Episodic (Intermittent) Asthma

- **Subset(s) of the paediatric population, pharmaceutical form(s) and route(s) of administration covered**

The waiver applies to:
Preterm newborn infants, Term newborn infants (0-27 d), Infants below 6 month, Children and Adolescents >5 to <18 years for 4 mg chewable tablets, 4 mg oral granules, 5mg chewable tablets, and 10 mg film-coated tablets for oral use.

- **Condition**

Seasonal Allergic Rhinitis

- **Subset(s) of the paediatric population, pharmaceutical form(s) and route(s) of administration covered**

The waiver applies to:
Preterm newborn infants, Term newborn infants (0-27 d), Infants & toddlers (28 d-23 months) for 4 mg chewable tablets and 4 mg oral granules for oral use.

C. PAEDIATRIC INVESTIGATION PLAN

C.1. Condition to be investigated

Episodic (Intermittent) Asthma

- **Subset(s) covered**

Infants and children 6 months to 5 years of age

- **Formulation(s)**

No further development to existing formulation: oral granules and chewable tablet

- **Studies / Measures**

Area	Subarea	Number	Description
Clinical	Efficacy and safety	1	Randomized, placebo-controlled, parallel-group multi-centre phase 3 study

Need for paediatric measures in a EU-Risk Management Plan: No
Date of completion of the paediatric investigation plan: September 2009
A deferral has been granted: No

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented name[3]	Strength	Pharmaceutical Form	Route of administration	Packaging	Content (concentration)	Package size
N/A	Singulair and associated names	10 mg 5 mg 4 mg 4 mg	film-coated tablet chewable tablet chewable tablet oral granules	Oral use	N/A	N/A	N/A