European Medicines Agency

Doc. Ref. EMEA/615793/2009
P/200/2009

EUROPEAN MEDICINES AGENCY DECISION

of 1 October 2009

on the acceptance of a modification of an agreed Paediatric Investigation Plan for montelukast sodium (Singulair), (EMEA-000012-PIP01-07-M01) 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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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 decision P/12/2008 of the European Medicines Agency on 29 February 2008,

Having regard to the application submitted by Merck Sharp & Dohme Ltd. on 14 May 2009 under Article 22 of Regulation (EC) No 1901/2006 as amended proposing changes to the agreed Paediatric Investigation Plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 24 July 2009, in accordance with Article 22 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 of the European Medicines Agency has given an opinion on the acceptance of changes to an agreed Paediatric Investigation Plan,

(2) It is therefore appropriate to adopt a Decision on the acceptance of changes to an agreed Paediatric Investigation Plan.

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

HAS ADOPTED THIS DECISION:

Article 1

Changes to the agreed Paediatric Investigation Plan for montelukast sodium (Singulair), chewable tablets, oral granules, 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, are hereby accepted.

Article 2

This decision, that supersedes previous decisions of the European Medicines Agency P/12/2008 and P/173/2009, is addressed to Merck Sharp & Dohme Ltd., Clos du Lynx 5, Woluwe, 1200, Belgium.

Done at London, 1 October 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/388228/2009
EMEA-000012-PIP01-07-M01

OPINION OF THE PAEDIATRIC COMMITTEE ON THE ACCEPTANCE OF A MODIFICATION OF AN AGREED PAEDIATRIC INVESTIGATION PLAN

Scope of the application

Active substance(s):
Montelukast sodium

(Invented) name:
Singulair

Condition(s):
Asthma

Pharmaceutical form(s):
Chewable tablets
Oral granules

Route(s) of administration:
Oral use

Name/corporate name of the PIP applicant:
Merck Sharp & Dohme Ltd.

Information about the authorised medicinal product:
See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Merck Sharp & Dohme Ltd. submitted to the EMEA on 14 May 2009 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the EMEA decision P/12/2008 of 29 February 2008. The application for modification proposed changes.

The procedure started on 28 May 2009.

Scope of the modification

The modifications concern clarification on some of the agreed measures.

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Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree to the changes proposed by the applicant regarding the measures of the paediatric investigation plan.

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

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) 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 annex(es) and appendix.

London, 24 July 2009

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 SUBSET(S) OF THE PAEDIATRIC POPULATION AND CONDITION(S) COVERED BY THE WAIVER

A. CONDITION(S) / DISEASE(S)

Asthma
Seasonal 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 (from birth to less than 28 days), 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 (from birth to less than 28 days), Infants and toddlers (from 28 days to less than 24 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 (from birth to less than 28 days), Infants below 6 month, Children and Adolescents 6 years to less than 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 (from birth to less than 28 days), Infants and toddlers (from 28 days to less than 24 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 less than 6 years of age.

- **Formulation(s)**

  Oral granules and chewable tablet.

- **Studies / Measures**

Area	Number of studies	Description
Clinical	1	Randomized, placebo-controlled, parallel-group, multi-centre efficacy and safety study

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	**By September 2009**
Deferral for some or all studies contained in the paediatric investigation plan:	**No**

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented name	Strength	Pharmaceutical Form	Route of administration	Packaging	Content (concentration)	Package size
N/A	Singulair	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