European Medicines Agency

Doc. Ref. EMEA/525373/2009
P/188/2009

EUROPEAN MEDICINES AGENCY DECISION

of 11 September 2009

on the acceptance of a modification of an agreed Paediatric Investigation Plan for vicriviroc maleate(EMEA-000122-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/104/2008 of the European Medicines Agency on 1 December 2008,

Having regard to the application submitted by Schering-Plough Europe on 20 April 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 and on the granting of a deferral,

(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 vicriviroc maleate, film-coated tablets / 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, are hereby accepted.

Article 2

A deferral for vicriviroc maleate, film-coated tablets / oral solution, oral use, 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, that supersedes previous decision of the European Medicines Agency P/104/2008, is addressed to Schering-Plough Europe, Rue de Stalle 73, 1180 – Brussels, Belgium.

Done at London, 11 September 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/437190/2009
EMEA-000122-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):
Vicriviroc maleate

Condition(s):
Human immunodeficiency virus infection

Pharmaceutical form(s):
Film-coated tablets
Oral solution

Route(s) of administration:
Oral use

Name/corporate name of the PIP applicant:
Schering-Plough Europe

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Schering-Plough Europe submitted to the EMEA on 20 April 2009 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the EMEA decision P/104/2008 of 1 December 2008. The application for modification proposed changes.

The procedure started on 28 May 2009.

Scope of the modification

The applicant proposed modifications to the agreed PIP to clarify and revise some of the agreed measures and timelines.

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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 and the timelines of the paediatric investigation plan,

The Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan 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 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

A. CONDITION(S)

Human immunodeficiency virus infection

B. WAIVER

Not applicable.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Human immunodeficiency virus infection

- **Proposed PIP indication**

Treatment of human immunodeficiency virus (HIV-1) infection in antiretroviral treatment experienced children patients, when co-administered with ritonavir containing protease inhibitor antiretroviral regimens.

- **Subset(s) of the paediatric population concerned by the paediatric development**

All subsets of the paediatric population.

- **Formulation(s)**

Film-coated tablet
Oral solution

- **Studies**

Area	Subarea	Number	Description
Quality	Formulation		Development of the film-coated tablet Development of an age appropriate oral formulation
	Bioequivalence		Measure to conclude on the bioequivalence of the oral solution and the tablets.
Non-clinical	Toxicity	1	Oral juvenile toxicity and toxicokinetic study in rats
Clinical	Pharmacokinetic, efficacy and safety	1	Open-Label Pharmacokinetic, Safety, Tolerability and Antiviral Activity of Vicriviroc in Combination Regimens in Antiretroviral Therapy Experienced Children and Adolescents The need for including children less than 2 years of age would have to be agreed with the PDCO

Measures to address long term follow-up of potential safety issues efficacy in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	**by September 2014**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**