EMA/505530/2012

European Medicines Agency decision

P/0176/2012

of 3 August 2012

on the acceptance of a modification of an agreed paediatric investigation plan for emtricitabine / rilpivirine (hydrochloride) / tenofovir (disoproxil fumarate) [FTC/RPV/TDF] (Eviplera), (EMEA-000774-PIP01-09-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This Decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

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[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 European Medicines Agency's decision P/150/2010 issued on 06 August 2010,

Having regard to the application submitted by Gilead Sciences International Limited on 19 April 2012 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 July 2012, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the 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 emtricitabine / rilpivirine (hydrochloride) / tenofovir (disoproxil fumarate) [FTC/RPV/TDF] (Eviplera), film-coated tablet, age-appropriate oral solid dosage form, oral use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Gilead Sciences International Limited, Granta Park, Abington, CB21 6GT – Cambridge, United Kingdom.

Done at London, 3 August 2012

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/299578/2012

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000774-PIP01-09-M01

Scope of the application

Active substance(s):

Emtricitabine / rilpivirine (hydrochloride) / tenofovir (disoproxil fumarate) [FTC/RPV/TDF]

Invented name:

Eviplera

Condition(s):

Treatment of human immunodeficiency virus (HIV-1) infection

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Age-appropriate oral solid dosage form

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Gilead Sciences International Limited

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Gilead Sciences International Limited submitted to the European Medicines Agency on 19 April 2012 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/150/2010 issued on 6 August 2010.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 15 May 2012.

Scope of the modification

Some measures and/or timelines of the Paediatric Investigation Plan have been modified.

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 changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   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 European Medicines Agency, together with its annex(es) and appendix.

Langen, Germany, 6 July 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed Paediatric Investigation Plan

1. Waiver

1.1. Condition: Treatment of human immunodeficiency virus (HIV-1) infection

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- for the film-coated tablet and the age appropriate oral solid dosage form, oral use;
- on the grounds that the specific medicinal product does not represent a significant benefit over existing treatment.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of human immunodeficiency virus (HIV-1) infection

2.1.1. Indication(s) targeted by the PIP

Treatment of human immunodeficiency virus (HIV-1) infection

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 6 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Film-coated tablet for oral use

Age-appropriate oral solid dosage form

2.1.4. Studies

Area	Number of studies	Description
Quality	2	Study 1: Development of an age-appropriate oral solid dosage form Study 2: Development of a film-coated tablet.
Non-clinical	0	Not applicable.
Clinical	3	Study 3: Open-label, non-randomised, multicentre, single-arm study to describe the safety, activity, and pharmacokinetics of the fixed dose combination tablet of emtricitabine/rilpivirine/tenofovir disoproxil fumarate in HIV-1 infected adolescents aged from 12 to less than 18 years. Study 4: Randomised, open-label, single-dose study to compare the oral bioavailability of emtricitabine/rilpivirine/tenofovir disoproxil fumarate fixed-dose combination film coated tablets to the. age-appropriate pediatric formulation. Study 5: Open-label, non-randomised, multicentre, single-arm study to describe the safety, activity, and pharmacokinetics of the age-appropriate formulation of the fixed dose combination of emtricitabine/rilpivirine/tenofovir disoproxil fumarate in HIV-1 infected children aged from 6 to less than 12 years.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No.
Date of completion of the paediatric investigation plan:	By September 2019.
Deferral for one or more studies contained in the paediatric investigation plan:	Yes.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of human immunodeficiency virus (HIV-1) infection

Authorised indication

Treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with a viral load ≤ 100,000 HIV-1 RNA copies/ml.

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Package size
EU/1/11/737/001	Eviplera	--[1]	Film-coated tablet	Oral use	bottle (HDPE)	30 tablets
EU/1/11/737/002	Eviplera	--[1]	Film-coated tablet	Oral use	bottle (HDPE)	3 x 30 tablets

[1] 25 mg rilpivirine (as hydrochloride) / 200 mg emtricitabine / 245 mg tenofovir disoproxil (as fumarate)