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European Medicines Agency decision

P/0232/2015

of 27 October 2015

on the acceptance of a modification of an agreed paediatric investigation plan for emtricitabine / rilpivirine (hydrochloride) / tenofovir (disoproxil fumarate), (Eviplera), (EMEA-000774-PIP01-09-M02) 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 6 August 2010, and the decision P/0176/2012 issued on 3 August 2012,

Having regard to the application submitted by Gilead Sciences International Ltd on 22 June 2015 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 11 September 2015, 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.

(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), (Eviplera), film-coated tablet, 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 Ltd, Granta Park, CB216GT – Cambridge, United Kingdom.

Done at London, 27 October 2015

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

EMA/PDCO/432131/2015
London, 11 September 2015

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

EMEA-000774-PIP01-09-M02

Scope of the application

Active substance(s):

Emtricitabine / rilpivirine (hydrochloride) / tenofovir (disoproxil fumarate)

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

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Gilead Sciences International Ltd

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 Ltd submitted to the European Medicines Agency on 22 June 2015 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, and the decision P/0176/2012 issued on 3 August 2012.

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

The procedure started on 14 July 2015.

Scope of the modification

Some measures 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 annexes and appendix.

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 (PIP)

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;
- film-coated tablet, 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

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	1	**Study 1:** Development of an age-appropriate film coated tablet [**Study 2:** deleted in EMEA-000774-PIP01-09-M02]
Non-clinical studies	0	Not applicable.
Clinical studies	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 film-coated tablet. **Study 5**: Open-label, non-randomised, multicentre, single-arm study to describe the safety, activity, and pharmacokinetics of the age-appropriate film-coated tablet 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/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(s):

- Eviplera is indicated for the treatment of adults infected with human immunodeficiency virus type 1 (HIV-1) without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine, and with a viral load ≤ 100,000 HIV-1 RNA copies/mL.

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use