EMA/693832/2013

European Medicines Agency decision

P/0310/2013

of 19 December 2013

on the acceptance of a modification of an agreed paediatric investigation plan for elvitegravir (EMEA-000968-PIP02-11-M03) 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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on the acceptance of a modification of an agreed paediatric investigation plan for elvitegravir (EMEA-000968-PIP02-11-M03) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/0010/2012 issued on 24 January 2012, the decision P/0066/2013 issued on 26 March 2013, and the decision P/0186/2013 issued on 2 August 2013,

Having regard to the application submitted by Gilead Sciences International Limited on 16 August 2013 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 8 November 2013, 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 elvitegravir, film coated tablet, age appropriate tablet, age appropriate powder for oral suspension, 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, Flowers Building, Granta Park, Abington, CB21 6GT – Cambridge, United Kingdom.

Done at London, 19 December 2013

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

EMA/PDCO/516504/2013 Corr

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

EMEA-000968-PIP02-11-M03

Scope of the application

Active substance(s):

Elvitegravir

Condition(s):

Treatment of human immunodeficiency virus (HIV-1) infection

Pharmaceutical form(s):

Film coated tablet

Age appropriate tablet

Age appropriate powder for oral suspension

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Gilead Sciences International Limited

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 16 August 2013 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0010/2012 issued on 24 January 2012, the decision P/0066/2013 issued on 26 March 2013, and the decision P/0186/2013 issued on 2 August 2013.

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

The procedure started on 12 September 2013.

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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 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 and appendix.

London, 8 November 2013

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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

Not applicable.

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 birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

- Film coated tablet;
- Age appropriate tablet;
- Age appropriate powder for oral suspension.

2.1.4. Measures

Area	Number of measures	Description
Quality	2	**Measure 1:** Development of age-appropriate tablet for oral use. **Measure 2:** Development of an age appropriate powder for oral suspension.
Non-clinical	0	Not applicable.
Clinical	4	**Measure 3:** Randomised, open-label, crossover study in healthy adult subjects to determine the relative bioavailability of adult elvitegravir film-coated tablet to an age appropriate tablet (Cohort 1) and to an age appropriate powder for oral suspension formulation (Cohort 2). **Measure 4:** An open-label, multi-cohort, 2-part study evaluating pharmacokinetics, safety, and anti-viral activity of elvitegravir administered with an optimised background regimen containing a ritonavir-boosted protease inhibitor (PI/r) in HIV-1 infected paediatric patients.

Area	Number of measures	Description
		Measure 5: Open-label, randomised, non-inferiority trial in HIV-1 infected patients from 6 to less than 18 years responsive to stable antiretroviral therapy (ART) containing any boosted PI or NNRTI and 2 nucleoside reverse transcriptase inhibitors (NRTIs) with no history of darunavir (DRV) or integrase inhibitor mutations. **Measure 6:** A multicentre, open –label, non-randomised, multicohort study to evaluate the pharmacokinetics, safety and anti-viral activity of cobicistat boosted elvitegravir in HIV-1 infected, anti-retroviral treatment naive paediatric patients.

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 April 2021
Deferral for one or more studies contained in the paediatric investigation plan:	Yes