EMA/7469/2012

European Medicines Agency decision

P/0010/2012

of 24 January 2012

on the agreement of a paediatric investigation plan and on the granting of a deferral for elvitegravir (EMEA-000968-PIP02-11) 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 agreement of a paediatric investigation plan and on the granting of a deferral for elvitegravir (EMEA-000968-PIP02-11) 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 application submitted by Gilead Sciences International Limited on 10 May 2011 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 9 December 2011, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

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

Has adopted this decision:

Article 1

A paediatric investigation plan for elvitegravir, film coated tablet, age appropriate tablet, age appropriate powder for oral suspension, 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, is hereby agreed.

Article 2

A deferral for elvitegravir, film coated tablet, age appropriate tablet, age appropriate powder for oral suspension, 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, is hereby granted.

Article 3

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

Done at London, 24 January 2012

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

EMA/PDCO/439892/2011

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMEA-000968-PIP02-11

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 16(1) of Regulation (EC) No 1901/2006 as amended, Gilead Sciences International Limited submitted for agreement to the European Medicines Agency on 10 May 2011 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 15 June 2011.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
   - to grant a deferral in accordance with Article 21 of said Regulation.

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

2. The measures and timelines of the agreed 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, 9 December 2011

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

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. Studies

Area	Number of studies	Description
Quality	2	**Study 1:** Development of age-appropriate tablet for oral use. **Study 2:** Development of an age appropriate powder for oral suspension.
Non-clinical	0	Not applicable.
Clinical	4	**Study 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). **Study 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 treatment-experienced HIV-1 infected paediatric patients failing their current regimen. **Study 5:** A multicenter, open –label, randomised, multicohort study to evaluate the safety and anti-viral activity of elvitegravir administered with an optimised background regimen containing a ritonavir boosted protease inhibitor in HIV-1 infected paediatric patients experiencing stable virological

Area	Number of studies	Description
		control. **Study 6:** A multicenter, 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.