



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/360007/2011

European Medicines Agency decision P/124/2011

of 7 June 2011

on the agreement of a paediatric investigation plan and on the granting of a deferral for cobicistat (EMA-000969-PIP01-10) 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.



European Medicines Agency decision

P/124/2011

of 7 June 2011

on the agreement of a paediatric investigation plan and on the granting of a deferral for cobicistat (EMA-000969-PIP01-10) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Gilead Sciences International Limited on 4 June 2010 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 20 April 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 cobicistat, film-coated tablet, age appropriate oral solid dosage form, age appropriate oral liquid formulation, 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 cobicistat, film-coated tablet, age appropriate oral solid dosage form, age appropriate oral liquid formulation, 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, 7 June 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/110725/2011

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

EMA-000969-PIP01-10

Scope of the application

Active substance(s):

Cobicistat

Condition(s):

Treatment of human immunodeficiency virus disease HIV-1 infection

Pharmaceutical form(s):

Film-coated tablet

Age appropriate oral solid dosage form

Age appropriate oral liquid formulation

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 4 June 2010 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 July 2010.

Supplementary information was provided by the applicant on 7 February 2011. The applicant proposed modifications to the paediatric investigation plan.



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 and the subset(s) of the paediatric population and condition(s) 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, 20 April 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 disease (HIV-1) infection

2.1.1. Indication(s) targeted by the PIP

Treatment of human immunodeficiency virus disease (HIV-1) infection - pharmacoenhancer for use in combination with antiretroviral agents.

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

From birth to less than 18 years of age.

2.1.2. Pharmaceutical form(s)

Film-coated tablet

Age appropriate oral solid dosage form

Age appropriate oral liquid formulation

2.1.3. Studies

Area	Number of studies	Description
Quality	2	Study 1: Development of an appropriate oral solid dosage form. Study 2: Development of an age-appropriate oral liquid formulation.
Non-clinical	0	Not applicable.
Clinical	2	Study 3: Randomised, open-label, crossover study in healthy adult subjects to determine the relative bioavailability of adult cobicistat film-tablets to an age appropriate tablet (cohort 1) and to an age appropriate liquid formulation (Cohort 2). Study 4: Open-label, multicenter, multi-cohort, 2-part study evaluating pharmacokinetics, safety, and efficacy of once-daily cobicistat-boosted atazanavir administered with a background regimen in HIV-1 infected, treatment-experienced children aged from 3 months to less than 18 years of age or twice-daily cobicistat-boosted darunavir administered with an optimised background regimen in HIV-1 infected, treatment-experienced children aged from 3 years to less than 18 years of age.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By August 2017
Deferral for one or more studies contained in the paediatric investigation plan:	Yes