EMA/488816/2010

European Medicines Agency decision

P/150/2010

of 6 August 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for tenofovir disoproxil fumarate/emtricitabine/rilpivirine hydrochloride, (EMEA-000774-PIP01-09) 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8670
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

European Medicines Agency decision

P/150/2010

of 6 August 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for tenofovir disoproxil fumarate/emtricitabine/rilpivirine hydrochloride, (EMEA-000774-PIP01-09) 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 11 December 2009 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 July 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 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 and on the granting of a waiver.

(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.

(4) It is therefore appropriate to adopt a decision granting a waiver.

[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 tenofovir disoproxil fumarate/emtricitabine/rilpivirine hydrochloride, film-coated tablet and age-appropriate formulation for oral use, 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 tenofovir disoproxil fumarate/emtricitabine/rilpivirine hydrochloride, film-coated tablet and age-appropriate formulation for oral use, 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

A waiver for tenofovir disoproxil fumarate/emtricitabine/rilpivirine hydrochloride, film-coated tablet and age-appropriate formulation for oral use, 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 4

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

Done at London, 6 August 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/309227/2010

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

EMEA-000774-PIP01-09

Scope of the application

Active substance(s):

Tenofovir disoproxil fumarate/emtricitabine/rilpivirine hydrochloride

Condition(s):

Treatment of human immunodeficiency virus (HIV-1) infection

Pharmaceutical form(s):

Film-coated tablet

Age-appropriate formulation for oral use

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 11 December 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 21 January 2010.

Supplementary information was provided by the applicant on 26 April 2010.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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,
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with

     Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   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) 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.

London, 16 July 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

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

1. Condition(s)

Treatment of human immunodeficiency virus (HIV-1) infection

2. Waiver

2.1. Condition

Treatment of human immunodeficiency virus (HIV-1) disease

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 formulation, oral use,
- on the grounds that the specific medicinal product does not represent a significant benefit over existing treatment.

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Treatment of human immunodeficiency virus (HIV-1) infection

3.1.1. Indication targeted by the PIP

Treatment of human immunodeficiency virus (HIV-1) infection

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

From 6 to less than 18 years of age.

3.1.3. Pharmaceutical form(s)

Film-coated tablet for oral use

Age-appropriate formulation for oral use

3.1.4. Studies

Area	Number of studies	Description
Quality	2	Study 1: Development of an age-appropriate formulation for oral use 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

Area	Number of studies	Description
		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

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	By September 2017
Deferral for one or more studies contained in the paediatric investigation plan:	Yes