

EMA/2926/2017

European Medicines Agency decision

P/0028/2017

of 10 February 2017

on the acceptance of a modification of an agreed paediatric investigation plan for rilpivirine /
dolutegravir (EMEA-001750-PIP01-15-M01) 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 726/2004¹,

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 European Medicines Agency's decision P/0030/2016 issued on 29 January 2016,

Having regard to the application submitted by ViiV Healthcare Limited on 22 September 2016 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 16 December 2016, 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 and to the waiver.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the 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

Changes to the agreed paediatric investigation plan for rilpivirine / dolutegravir, film-coated tablet, age appropriate pharmaceutical form, oral use, including changes to the waiver, 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 ViiV Healthcare UK Limited, 980 Great West Road, TW8 9GS - Brentford, United Kingdom.

EMA/PDCO/652155/2016
London, 16 December 2016

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-001750-PIP01-15-M01

Scope of the application

Active substance(s):

Rilpivirine / Dolutegravir

Condition(s):

Treatment of human immunodeficiency virus (HIV-1) infection

Pharmaceutical form(s):

Film-coated tablet

Age appropriate pharmaceutical form

Route(s) of administration:

Oral use

Name / corporate name of the PIP applicant:

ViiV Healthcare Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, ViiV Healthcare Limited submitted to the European Medicines Agency on 22 September 2016 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/0030/2016 issued on 29 January 2016.

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

The procedure started on 18 October 2016.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified. A waiver for a new paediatric subset has been added.

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 and to the waiver 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 annex 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 therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition:

Treatment of human immunodeficiency virus 1 (HIV-1) infection

2.1.1. Indication(s) targeted by the PIP

Treatment of human immunodeficiency virus 1 (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

Age appropriate pharmaceutical form

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1 Development of age-appropriate dosage form(s) to cover ages from 6 to less than 18 years.
Non-clinical studies	0	Not applicable.
Clinical studies	2	Study 2 Single dose, crossover pivotal bioequivalence evaluation of up to 2 fixed dose combination tablets of dolutegravir/rilpivirine compared to the co-administered reference formulations TIVICAY (dolutegravir) 50mg and EDURANT (rilpivirine) 25mg in healthy male and female

		adult volunteers. Study 3 Open-label, randomized, active controlled non-inferiority study to evaluate the maintenance of Efficacy and Safety of dual therapy, Dolutegravir (DTG) plus Rilpivirine (RPV), in anti-retroviral therapy (ART)-experienced HIV-1-Infected Children, from 6 to less than 18 years of age who are virologically suppressed on their current anti-retroviral (ARV) regimen.
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes