EMA/785324/2014

European Medicines Agency decision

P/0344/2014

of 22 December 2014

on the acceptance of a modification of an agreed paediatric investigation plan for rilpivirine (hydrochloride) (EDURANT) (EMEA-000317-PIP01-08-M07) 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 726/2004[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/144/2009 issued on 17 July 2009, the decision P/43/2010 issued on 31 March 2010, the decision P/242/2011 issued on 30 September 2011, the decision P/0030/2012 issued on 2 February 2012, the decision P/0192/2013 issued on 15 August 2013, the decision P/0323/2013 issued on 19 December 2013 and the decision P/0194/2014 issued on 8 August 2014.

Having regard to the application submitted by Janssen-Cilag International NV on 18 September 2014 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 12 December 2014, 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 rilpivirine (hydrochloride) (EDURANT), film-coated tablet, granules, 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 Janssen-Cilag International NV, Tuenhoutseweg 30, 2340 – Beerse, Belgium.

Done at London, 22 December 2014

For the European Medicines Agency
Zaide Frias
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/586653/2014

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

EMEA-000317-PIP01-08-M07

Scope of the application

Active substance(s):

Rilpivirine (hydrochloride)

Invented name:

EDURANT

Condition(s):

Treatment of human immunodeficiency virus (HIV-1) infection

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Granules

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Janssen-Cilag International NV

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Janssen-Cilag International NV submitted to the European Medicines Agency on 18 September 2014 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/144/2009 issued on 17 July 2009, the decision P/43/2010 issued on 31 March 2010, the decision P/242/2011 issued on 30 September 2011, the decision P/0030/2012 issued on 2 February 2012, the decision P/0192/2013 issued on 15 August 2013, the decision P/0323/2013 issued on 19 December 2013 and the decision P/0194/2014 issued on 8 August 2014.

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

The procedure started on 14 October 2014.

Scope of the modification

Some timelines 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 Icelandic and the Norwegian Paediatric Committee members agree 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 annexes and appendix.

London, 12 December 2014

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 (PIP)

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

Rilpivirine is indicated in combination with other antiretroviral (ARV) medicinal products, for the treatment of human immunodeficiency virus (HIV-1) infection in ARV-naïve paediatric patients of all ages with a baseline viral load ≤100,000 HIV-1 RNA copies/ml.

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

From birth to less than 18 years years of age.

2.1.3. Pharmaceutical form(s)

Film-coated tablet

Granules

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of age-appropriate formulation for oral use.
Non-clinical studies	0	Not applicable.
Clinical studies	3	**Study 2** Open-label, randomised, crossover trial to compare the oral bioavailability of the age-appropriate paediatric formulation(s) of rilpivirine hydrochloride. **Study 3** Open-label, noncomparative trial to evaluate pharmacokinetics, safety, tolerability and antiviral activity of rilpivirine (as hydrochloride) in HIV-1 infected treatment-naïve adolescents from 12 years to less than 18 years of age. **Study 4** Open-label, noncomparative trial to evaluate

		pharmacokinetics, safety, tolerability and antiviral activity of rilpivirine (as hydrochloride) in HIV-1 infected treatment-naïve children from birth to less than 12 years of age.
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 safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2019
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of Human Immunodeficiency Virus (HIV-1) infection

Authorised indication(s):

- EDURANT, in combination with other antiretroviral medicinal products, is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with a viral load ≤ 100,000 HIV-1 RNA copies/ml.

  As with other antiretroviral medicinal products, genotypic resistance testing should guide the use of EDURANT.

Authorised pharmaceutical form(s):

Film-coated tablet.

Authorised route(s) of administration:

Oral use.