EMA/54350/2012

European Medicines Agency decision

P/0030/2012

of 2 February 2012

on the acceptance of a modification of an agreed paediatric investigation plan for rilpivirine (hydrochloride) (000317-PIP01-08-M03) 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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An agency of the European Union

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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 and the decision P/242/2011 issued on 30 September 2011,

Having regard to the application submitted by Janssen-Cilag International NV on 24 October 2011 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 13 January 2012, 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), 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, Turnhoutseweg 30, 2340 - Beerse, Belgium.

Done at London, 2 February 2012

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

EMA/PDCO/910461/2011

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

000317-PIP01-08-M03

Scope of the application

Active substance(s):

Rilpivirine (hydrochloride)

Condition(s):

Treatment of Human Immunodeficiency Virus (HIV-1) infection in ARV-naïve patients

Pharmaceutical form(s):

Film coated tablet

Granules

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Janssen-Cilag International NV

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 24 October 2011 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 and the decision P/242/2011 issued on 30 September 2011.

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

The procedure started on 16 November 2011.

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Scope of the modification

The modification relates to some changes concerning the design and timelines of the proposed clinical studies of the agreed measures.

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.

   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 annex(es) and appendix.

London, 13 January 2012

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 in ARV- naïve patients

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)

Tablets for oral use.

Granules for oral use.

2.1.4. Studies

Area	**Number of studies**	**Description**
Quality	Total number of quality studies 1	Study 1: Age-appropriate formulation for oral use
Non-clinical	Total number of studies	Not applicable.
Clinical	Total number of studies 3	Study 2: Open-label, randomized, crossover trial to compare the oral bioavailability of the age-appropriate pediatric formulation(s) of Rilpivirine hydrochloride. Study 3: Multi-center, open-label, noncomparative study in HIV-1 infected treatment-naïve adolescents from 12 years to less than 18 years. Study 4: Multi-center, open-label, noncomparative study in HIV-1 infected treatment-naïve children from birth to less than 12 years of age

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By November 2018
Deferral for one or more studies contained in the paediatric investigation plan:	Yes