EMA/200228/2010

European Medicines Agency decision

P/43/2010

of 31 March 2010

on the acceptance of a modification of an agreed paediatric investigation plan for rilpivirine (hydrochloride) (EMEA-000317-PIP01-08-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 726/2004[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 decision P/144/2009 of the European Medicines Agency issued on 17 July 2009,

Having regard to the application submitted by Janssen-Cilag International NV on 7 December 2009 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 19 February 2010, 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), tablets and age-appropriate formulation, 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, 31 March 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

19 February 2010
EMA/PDCO/71902/2010

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

EMEA-000317-PIP01-08-M01

Scope of the application

Active substance(s):

Rilpivirine (hydrochloride)

Condition(s):

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

Pharmaceutical form(s):

Tablets
Age-appropriate formulation

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 7 December 2009 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 of 17 July 2009. The application for modification proposed changes to the agreed paediatric investigation.

The procedure started on 23 December 2009.

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Scope of the modification

The modifications relates to some changes concerning the design of the proposed clinical study as well as the timelines 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 the changes proposed by the applicant regarding the measures and the timelines of the paediatric investigation plan

   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 annex and appendix.

London, 19 February 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

1. Condition(s)

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

2. Waiver

Not applicable.

3. Paediatric Investigation Plan

3.1 Condition to be investigated

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

3.2 Proposed PIP indication

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.

3.3 Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years.

3.4 Formulation(s)

- Tablets for oral use
- Age-appropriate formulation under development (granules or oral solution or oral suspension) for oral use

3.5 Studies

Area	Number of studies	Description
Quality	**1**	Age-appropriate formulation for oral use
Clinical	**1**	Open-label, randomized, crossover trial to compare the oral bioavailability of the age-appropriate pediatric formulation(s) of Rilpivirine hydrochloride.
Clinical	**1**	Multi-center, open-label, noncomparative study in HIV-1 infected treatment-naïve adolescents from 12 years to less than 18 years.
Clinical	**1**	Multi-center, open-label, noncomparative study in HIV-1 infected treatment-naïve children from birth to less than 12 years of age

4. 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 December 2016
Deferral for some or all studies contained in the paediatric investigation plan:	Yes