EMA/828307/2011

European Medicines Agency decision

P/273/2011

of 28 October 2011

on the acceptance of a modification of an agreed paediatric investigation plan for etravirine (Intelence), (EMEA-000222-PIP01-08-M05) 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/10/2009 issued on 27 January 2009, the decision P/257/2009 issued on 23 December 2009, the decision P/110/2010 issued on 6 July 2010, the decision P/43/2011 issued on 11 February 2011 and the decision P/129/2011 issued on 8 June 2011,

Having regard to the application submitted by Janssen-Cilag International NV on 26 September 2011 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 14 October 2011, 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 etravirine (Intelence), tablet, 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, 28 October 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/796724/2011

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

EMEA-000222-PIP01-08-M05

Scope of the application

Active substance(s):

Etravirine

Invented name:

Intelence

Condition(s):

Treatment of Human Immunodeficiency Virus Infection

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Janssen-Cilag International N.V.

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 N.V. submitted to the European Medicines Agency on 26 September 2011 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/10/2009 issued on 27 January 2009, the decision P/257/2009 issued on 23 December 2009, the decision P/110/2010 issued on 6 July 2010, the decision P/43/2011 issued on 11 February 2011 and the decision P/129/2011 issued on 8 June 2011.

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

The procedure started on 12 October 2011.

Scope of the modification

The applicant is changing 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 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 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, 14 October 2011

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

1.1. Condition: Treatment of Human immunodeficiency virus infection

The waiver applies to:

- Preterm newborn infants, term newborn infants (from birth to less than 28 days), infants and toddlers (from 28 days to less than 2 months);
- for tablets for 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 infection

2.1.1. Indication(s) targeted by the PIP

Treatment of HIV-1 infection in antiretroviral treatment-experienced adolescents and children from 2 months to less than 18 years of age.

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

From 2 months to less than 18 years.

2.1.3. Pharmaceutical form(s)

Tablet.

2.1.4. Studies

Area	**Number of studies**	**Description**
Quality	1	Study 1: Development of a 25 mg scored tablet
Non-clinical	0	Not applicable.
Clinical	2	Study 2: Open-label trial to evaluate the safety, tolerability and antiviral activity of etravirine in antiretroviral experienced HIV-1 infected children and adolescents from 6 years to less than 18 years of age. Study 3: Open-label trial to evaluate the safety, tolerability, pharmacokinetics and antiretroviral activity of etravirine in antiretroviral experienced HIV-1 infected children aged from 2 months to less than 6 years.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By March 2015
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment Human Immunodeficiency Virus infection

   Authorised indications:

Intelence, in combination with a boosted protease inhibitor and other antiretroviral medicinal products, is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-experienced adult patients (see sections 4.4, 4.5 and 5.1).

This indication is based on week 48 analyses from 2 randomised, double-blind, placebo-controlled Phase III trials in highly pre-treated patients with viral strains harbouring mutations of resistance to non-nucleoside reverse transcriptase inhibitors and protease inhibitors, where INTELENCE was investigated in combination with an optimised background regimen (OBR) which included darunavir/ritonavir (see section 5.1).

EU Number	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of Administration**	**Packaging**	**Package size**
EU/1/08/468/001	INTELENCE	100 mg	Tablet	Oral use	bottle (HDPE)	120 tablets

EMA Number	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of Administration**	**Packaging**	**Package size**
EMEA/H/C/000900/X/0012/002	INTELENCE	200 mg	Tablet	Oral use	bottle (HDPE)	60 tablets