EMA/642354/2011

European Medicines Agency decision

P/198/2011

of 30 August 2011

on the acceptance of a modification of an agreed paediatric investigation plan for ulipristal acetate (EllaOne), (EMEA-000305-PIP01-08-M02) 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.

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

European Medicines Agency decision

P/198/2011

of 30 August 2011

on the acceptance of a modification of an agreed paediatric investigation plan for ulipristal acetate (EllaOne), (EMEA-000305-PIP01-08-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/71/2009 issued on 20 April 2009, the decision P/1/2010 issued on 25 January 2010,

Having regard to the application submitted by Laboratoire HRA Pharma on 2 May 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 15 July 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 ulipristal acetate (EllaOne), 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 Laboratoire HRA Pharma, 15 rue Béranger, 75003 – Paris, France.

Done at London, 30 August 2011

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

EMA/PDCO/473214/2011

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

EMEA-000305-PIP01-08-M02

Scope of the application

Active substance(s):

Ulipristal acetate

Invented name:

EllaOne

Condition(s):

Contraception

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Laboratoire HRA Pharma

Information about the authorised medicinal product:

See Annex II

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Laboratoire HRA Pharma submitted to the European Medicines Agency on 2 May 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/71/2009 issued on 20 April 2009, the decision P/1/2010 issued on 25 January 2010.

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

The procedure started on 18 May 2011.

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 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(es) and appendix.

London, 15 July 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: Contraception

The waiver applies to:

- Boys from birth to less than 18 years;
- for ulipristal tablet, oral use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

The waiver applies to:

- Girls from birth to age of menarche;
- for ulipristal tablet, oral use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

2. Paediatric Investigation Plan

2.1. Condition: Contraception

2.1.1. Indication(s) targeted by the PIP

Emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure.

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

Girls from age at menarche to less than 18 years.

2.1.3. Pharmaceutical form(s)

Ulipristal tablet, oral use, 30 mg

2.1.4. Studies

Area	**Number of studies**	**Description**
Quality		Not applicable.
Non-clinical	1	1. Peri/post-natal study in rats from day 6 of gestation to day 21 of lactation
Clinical	2	1. Single-blind, multicentre, randomized, parallel group safety and efficacy study of ulipristal acetate 30 mg versus levonorgestrel 1.5 mg for emergency contraception within 120 hours of unprotected

		intercourse, in adolescents (and in adults). 2. Open-label, observational safety study of ulipristal acetate for emergency contraception within 120 hours of unprotected intercourse, in adolescents (and in adults).

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 October 2013
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. Contraception:

Authorised indication: Emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure.

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/09/522/001	ellaOne	30 mg	Tablet	Oral use	blister (PVC/PE/PVDC//alu)	1 tablet	30 mg