European Medicines Agency

Doc. Ref. EMA/28385/2010
P/1/2010

EUROPEAN MEDICINES AGENCY DECISION

of 25 January 2010

on the acceptance of a modification of an agreed Paediatric Investigation Plan for Ulipristal acetate (EMEA-000305-PIP01-08-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 70
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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/71/2009 of the European Medicines Agency on 20 April 2009,

Having regard to the application submitted by Laboratoire HRA Pharma on 6 November 2009 under Article 22 of Regulation (EC) No 1901/2006 as amended proposing changes to the agreed Paediatric Investigation Plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 December 2009, in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended,

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to an agreed Paediatric Investigation Plan,

(2) It is therefore appropriate to adopt a Decision on the acceptance of changes to an 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, tablet, oral use, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, are hereby accepted.

Article 2

This decision, that supersedes previous decision of the European Medicines Agency P/71/2009, as far as the agreed changes to the PIP for Ulipristal acetate are concerned, is addressed to Laboratoire HRA Pharma, 15 rue Béranger, 75003 Paris, France.

Done at London, 25 January 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDCO/775442/2009
EMEA-000305-PIP01-08-M01

OPINION OF THE PAEDIATRIC COMMITTEE ON THE ACCEPTANCE OF A MODIFICATION OF AN AGREED PAEDIATRIC INVESTIGATION PLAN

Scope of the application

Active substance(s):
Ulipristal acetate

Condition(s):
Contraception

Pharmaceutical form(s):
Tablet

Route(s) of administration:
Oral use

Name/corporate name of the PIP applicant:
Laboratoire HRA Pharma

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Laboratoire HRA Pharma submitted to the EMEA on 6 November 2009 an application for modification of the agreed paediatric investigation plan as set out in the EMEA decision P/71/2009 of 20 April 2009. The application for modification proposed changes.

The procedure started on 19 November 2009.

Scope of the modification

Postponement of the date of completion of the PIP by 5 months, to May 2012.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 70
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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 timelines of the paediatric investigation plan.

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 Agency, together with its annex(es) and appendix.

London, 11 December 2009

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 AND THE SUBSET(S) OF THE PAEDIATRIC POPULATION AND CONDITION(S) COVERED BY THE WAIVER

A. CONDITION(S)

Contraception

B. WAIVER

- **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;

  – Girls from birth to age at 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.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

  Contraception

- **Proposed PIP indication**

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

- **Subset(s) of the paediatric population concerned by the paediatric development**

  Girls from age at menarche to less than 18 years.

- **Formulation(s)**

  Ulipristal tablet, oral use, 30 mg

- **Studies**

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical	1	Peri/post-natal study in rats from day 6 of gestation to day 21 of lactation
Clinical	2	– 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). – Open-label, observational safety study of ulipristal acetate for emergency contraception within 120 hours of unprotected intercourse, in adolescents (and in adults).

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 May 2012**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**