



European Medicines Agency

Doc. Ref. EMEA/687582/2009
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EUROPEAN MEDICINES AGENCY DECISION

of 30 October 2009

on the refusal of a Paediatric Investigation Plan and on the refusal of a deferral and on the granting of a waiver for ulipristal acetate (EMA-000629-PIP01-09) 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.

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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 726/2004¹,

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 Agency²,

Having regard to the application submitted by PregLem S.A. on 18 June 2009 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 September 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation and Article 21 of said Regulation,

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 refusal of a Paediatric Investigation Plan and on the refusal of a deferral and on the granting of a waiver,
- (2) It is therefore appropriate to adopt a Decision refusing a Paediatric Investigation Plan.
- (3) It is therefore appropriate to adopt a Decision refusing a deferral.
- (4) It is therefore appropriate to adopt a Decision granting a waiver.

¹ OJ L 378, 27.12.2006, p.1

² OJ L 136, 30.4.2004, p. 1

HAS ADOPTED THIS DECISION:

Article 1

A 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, is hereby refused.

Article 2

A deferral 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, is hereby refused.

Article 3

A waiver 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, is hereby granted.

Article 4

This decision is addressed to PregLem SA, Domaine de Quincy, 32 route de l'église, 74140 – Massongy, France.

Done at London, 30 October 2009

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/565856/2009
EMEA-000629-PIP01-09

**OPINION OF THE PAEDIATRIC COMMITTEE ON THE REFUSAL OF
A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL AND ON THE GRANTING
OF A PRODUCT-SPECIFIC WAIVER**

Scope of the application

Active substance(s):

Ulipristal acetate

Condition(s):

Leiomyoma of uterus

Pharmaceutical form(s):

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

PregLem S.A.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, PregLem S.A. submitted for agreement to the EMEA on 18 June 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 23 July 2009.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to refuse the paediatric investigation plan in accordance with Article 18 of said Regulation as the measures and the timelines are not appropriate to ensure the generation of the necessary data determining the conditions in which the medicinal product may be used to treat the paediatric population or some subsets, nor to adapt a paediatric formulation, or do not bring expected significant therapeutic benefit;
- to refuse a deferral in accordance with Article 21 of said Regulation;
- to grant a product-specific waiver for some subsets of the paediatric population, in accordance with Article 13 of said Regulation, and concluded in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subsets;
- to grant a product-specific waiver for a subset of the paediatric population on its own motion, in accordance with Article 12 of said Regulation, and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The grounds for the granting of the waiver are set out in Annex I.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annex and appendix.

London, 18 September 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

GROUND S FOR THE GRANTING OF THE WAIVER

GROUNDS FOR THE GRANTING OF THE WAIVER

- **Condition**

Leiomyoma of uterus

The waiver applies to:

- Boys from birth to less than 18 years of age, and girls from birth to age at menarche;
- for ulipristal acetate, tablet, oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subsets.

and to:

- girls from age at menarche to less than 18 years of age;
- for ulipristal acetate, tablet, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.