European Medicines Agency

Doc. Ref. EMEA/387209/2009
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EUROPEAN MEDICINES AGENCY DECISION

of 15 July 2009

on the refusal of a Paediatric Investigation Plan and on the refusal of a deferral and on the granting of a waiver for estradiol valerate / dienogest (Qlaira) (EMEA-000526-PIP01-08) 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 726/2004[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 application submitted by Bayer Schering Pharma AG on 25 February 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 29 May 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 estradiol valerate / dienogest (Qlaira), film-coated 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 estradiol valerate / dienogest (Qlaira), film-coated 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 estradiol valerate / dienogest (Qlaira), film-coated 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 Bayer Schering Pharma AG, Muellerstrasse 178, 13353 Berlin, Germany.

Done at London, 15 July 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/284420/2009
EMEA-000526-PIP01-08

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

Scope of the application

Active substance(s):
Estradiol valerate / Dienogest

Invented name:
Qlaira

Condition(s):
Contraception
Excessive, frequent and irregular menstruation

Pharmaceutical form(s):
Film-coated tablet

Route(s) of administration:
Oral use

Name/corporate name of the PIP applicant:
Bayer Schering Pharma AG

Information about the authorised medicinal product: see Annex II

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Bayer Schering Pharma AG submitted for agreement to the EMEA on 25 February 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 2 April 2009.

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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 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 subsets of the paediatric population, and 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;

- to grant a product-specific waiver for some subsets 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, 29 May 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

GROUNDS FOR THE GRANTING OF THE WAIVER

GROUNDS FOR THE GRANTING OF THE WAIVER

- **Condition**

  Contraception

  The waiver applies to:

  – Boys from birth to less than 18 years of age,

    for estradiol valerate / dienogest, film-coated tablet, oral use,

    on the grounds that the specific medicinal product is likely to be unsafe;

  – Girls from birth to menarche,

    for estradiol valerate / dienogest, film-coated 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 subset.

  – Girls from menarche to less than 18 years,

    for estradiol valerate / dienogest, film-coated tablet, oral use,

    on the grounds that the specific medicinal product does not represent a significant therapeutic benefit.

- **Condition**

  Excessive, frequent and irregular menstruation

  The waiver applies to:

  – Boys from birth to less than 18 years of age and girls from birth to menarche,

    for estradiol valerate / dienogest, film-coated 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;

  – Girls from menarche to less than 18 years,

    for estradiol valerate / dienogest, film-coated tablet, oral use,

    on the grounds that clinical studies cannot fulfil a therapeutic need of the paediatric population.

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented name Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Content (concentration)	Package size
	Qlaira		Film-coated tablets	Oral use			