European Medicines Agency

Doc. Ref. EMEA/95882/2009
P/24/2009

EUROPEAN MEDICINES AGENCY DECISION

of 23 February 2009

on the refusal of a Paediatric Investigation Plan and on the granting of a waiver for drospirenone / ethinylestradiol bethadex clathrate, Yaz and associated names (EMEA-000148-PIP01-07) 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 11 February 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 9 January 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Articles 12 and 13 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 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 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 drospirenone / ethinylestradiol bethadex clathrate, Yaz and associated names , 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 waiver for drospirenone / ethinylestradiol bethadex clathrate, Yaz and associated names, 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 3

This decision is addressed to Bayer Schering Pharma AG, Muellerstrasse 178, 13342 Berlin, Germany.

Done at London, 23 February 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/639178/2008
EMEA-000148-PIP01-07

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:
Drospirenone / ethinylestradiol bethadex clathrate

Invented name:
Yaz and associated names

Condition(s):
Acne
Contraception

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 I.

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 11 February 2008 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 13 March 2008.

Supplementary information was provided by the applicant on 30 October 2008.

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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.

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

London, 9 January 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented name Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Content (concentration)	Package size
	Yaz and associated names	Drospirenone 3 mg Ethinylestradiol 0.02 mg	Film-coated tablet	Oral use			