



European Medicines Agency

Doc. Ref. EMEA/572815/2008
P/98/2008

EUROPEAN MEDICINES AGENCY DECISION

of 3 November 2008

**on the application for agreement of a Paediatric Investigation Plan for dienogest
(EMEA-000147-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)

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**on the application for agreement of a Paediatric Investigation Plan for dienogest
(EMA-000147-PIP01-07) in accordance with Regulation (EC) No 1901/2006 of the European
Parliament and of the Council as amended**

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 Bayer Schering Pharma AG on 7 February 2008 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 19 September 2008, 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 a positive opinion,
- (2) It is therefore appropriate to adopt a Decision following the Paediatric Committee's opinion on the Paediatric Investigation Plan,
- (3) It is therefore appropriate to adopt a Decision granting a waiver,
- (4) It is therefore appropriate to adopt a Decision granting a deferral.

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 dienogest, 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 agreed.

Article 2

A waiver for dienogest, tablet, oral use, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A deferral for dienogest, tablet, oral use, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

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

Done at London, 3 November 2008

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/470465/2008
EMEA-000147-PIP01-07

**POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON
A REQUEST FOR AGREEMENT OF
A PAEDIATRIC INVESTIGATION PLAN FOR**

Scope of the application

Active substance:

Dienogest

Condition(s):

Endometriosis

Pharmaceutical form(s):

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Bayer Schering Pharma AG

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 EMA on 7 February 2008 a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 13 March 2008.

A meeting with the Paediatric Committee took place on 17 September 2008.

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 agree the paediatric investigation plan in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended,
- to grant a deferral in accordance with Article 21 of Regulation (EC) No 1901/2006 as amended,
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended and concluded in accordance with Article 11(1)(b) of Regulation (EC) No 1901/2006 as amended, 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.

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

2. 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 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 and appendix.

London, 19 September 2008

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) / DISEASE(S)

Endometriosis

B. WAIVER

- **Condition**

Endometriosis

The waiver applies to:

- Boys from birth to less than 18 years;
- Pre-menarcheal girls

for dienogest, 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.

C. PAEDIATRIC INVESTIGATION PLAN

C.1. Condition to be investigated

Endometriosis

○ **Proposed PIP indication**

Treatment of endometriosis

○ **Subset of the paediatric population concerned by the paediatric development**

Girls from menarche to less than 18 years

○ **Formulation(s)**

Tablet, oral use

○ **Studies**

Area	Number of studies	Description
Clinical	2	• Physiologically-based pharmacokinetic model. • Single-arm, open label safety study of dienogest in postmenarcheal patients with suspected or ascertained endometriosis.

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:

June 2013

A deferral has been granted for initiation of some or all studies contained in the paediatric investigation plan:

Yes

A deferral has been granted for completion of some or all studies contained in the paediatric investigation plan:

Yes