



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/249209/2010

European Medicines Agency decision

P/75/2010

of 5 May 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for levonorgestrel (EMEA-000606-PIP01-09) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This Decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.



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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

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 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 22 May 2009 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 March 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 of said Regulation,

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

Whereas:

- (1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting 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 levonorgestrel, intrauterine delivery system, intrauterine 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 deferral for levonorgestrel, intrauterine delivery system, intrauterine 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

A waiver for levonorgestrel, intrauterine delivery system, intrauterine 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, 5 May 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/57068/2010

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation plan and a deferral and a waiver

EMA-000606-PIP01-09

Scope of the application

Active substance(s):

Levonorgestrel

Condition(s):

Contraception

Pharmaceutical form(s):

Intrauterine delivery system

Route(s) of administration:

Intrauterine use

Name/corporate name of the PIP applicant:

Bayer Schering Pharma AG

Basis for opinion

Pursuant to Article 15 of Regulation (EC) No 1901/2006 as amended, Bayer Schering Pharma AG submitted for agreement to the European Medicines Agency on 22 May 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.

Supplementary information was provided by the applicant on 14 December 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 agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
- to grant a deferral in accordance with Article 21 of said Regulation,
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Articles 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 subset(s) of the paediatric population.

The Norwegian Paediatric Committee member agrees 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 European Medicines Agency, together with its annex and appendix.

London, 19 March 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

1. Condition(s)

Contraception

2. Waiver

2.1. Condition

Contraception

The waiver applies to:

- Boys from birth to less than 18 years of age.
- Girls from birth to age of menarche

for intrauterine delivery system, intrauterine 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(s).

3. Paediatric Investigation plan

3.1. Condition to be investigated

Contraception

3.2. Indication targeted by the PIP

Contraception

3.3. Subset(s) of the paediatric population concerned by the paediatric development

Girls from age of menarche to less than 18 years of age.

3.4. Formulation(s)

Intrauterine delivery system

3.5. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	1	Multi-center, single arm study to assess the safety, bleeding pattern, discontinuation rates (compliance), pharmacokinetics, and efficacy of the ultra low dose LNG intrauterine contraceptive system (LCS) in adolescents between menarche and 18 years of age over 1 year

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues, efficacy in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By Sept 2013
Deferral for one or more studies contained in the paediatric investigation plan:	Yes