EMA/216040/2010

European Medicines Agency decision

P/61/2010

of 9 April 2010

on the acceptance of a modification of an agreed paediatric investigation plan for nomegestrol acetate / 17 beta - estradiol (EMEA-000250-PIP01-08-M02) 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 726/2004[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 decision P/100/2008 of the European Medicines Agency issued on 3 November 2008, and the decision P/46/2009 of the European Medicines Agency issued on 24 March 2009,

Having regard to the application submitted by N.V. Organon on 22 December 2009 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 March 2010, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for nomegestrol acetate / 17 beta - estradiol, film-coated tablets, oral use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to N.V. Organon, Kloosterstraat 6, 5349 AB Oss, The Netherlands.

Done at London, 9 April 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/150556/2010

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000250-PIP01-08-M02

Scope of the application

Active substance(s):

Nomegestrol acetate / 17 beta - estradiol

Condition(s):

Contraception

Pharmaceutical form(s):

Film-coated tablets

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

N.V. Organon

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, N.V. Organon submitted to the European Medicines Agency on 22 December 2009 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/46/2009 of 24 March 2009. The application for modification proposed changes and a deferral and a waiver.

The procedure started on 21 January 2010.

Scope of the modification

Some inclusion criteria of the clinical study of the original Opinion have been modified.

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Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to the changes proposed by the applicant regarding the measures of the paediatric investigation plan.

   The Norwegian Paediatric Committee member(s) agree(s) with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the 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(es) and appendix.

London, 19 March 2010

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:

- Males: All subsets of the paediatric population from birth to less than 18 years of age,
- Females: Preterm newborn infants, Term newborn infants (from birth to less than 28 days), Infants and toddlers (from 28 days to less than 24 months), Children (from 2 to less than 12 years), Adolescents before menarche,
- for film-coated tablet for 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(s).

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Contraception

3.1.1. Indication targeted by the PIP

Contraception

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

Female adolescents after menarche

3.1.3. Pharmaceutical form(s)

Film-coated tablet containing 2.5 mg nomegestrol acetate /1.5 mg 17 beta-estradiol

3.1.4. Studies

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	1	Single center, open-label parallel group trial to compare the pharmacokinetics of nomegestrol acetate after single-dose administration of nomegestrol acetate / 17β-estradiol tablets between

Area	Number of studies	Description
		healthy female adolescents (aged 12-17 years) and healthy female adults (aged 18-50 years).

4. Follow-up, completion and deferral of PIP

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:	By December 2010
Deferral for one or more studies contained in the paediatric investigation plan:	Yes