EMA/544597/2011

European Medicines Agency decision

P/182/2011

of 3 August 2011

on the acceptance of a modification of an agreed paediatric investigation plan for corifollitropin alfa (Elonva) (EMEA-000306-PIP01-08-M01) 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 European Medicines Agency's decision P/131/2008 issued on 19 December 2008,

Having regard to the application submitted by N.V. Organon on 31 March 2011 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 17 June 2011, 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 corifollitropin alfa (Elonva), solution for injection, subcutaneous 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, Molenstraat 110, 5342 CC Oss, The Netherlands.

Done at London, 3 August 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/391849/2011

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

EMEA-000306-PIP01-08-M01

Scope of the application

Active substance(s):

Corifollitropin alfa

Invented name:

Elonva

Condition(s):

Hypogonadotrophic hypogonadism

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

N.V. Organon

Information about the authorised medicinal product:

See Annex I

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 31 March 2011 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/131/2008 issued on 19 December 2008.

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The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 20 April 2011.

Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified.

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 changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees 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 annexes and appendix.

London, 17 June 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed Paediatric Investigation Plan

1. Waiver

1.1. Condition: Hypogonadotrophic hypogonadism

1.1.1. Indication: Controlled Ovarian Stimulation (COS) for the development of multiple follicles and pregnancy in women participating in an Assisted Reproductive Technology (ART) program.

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for solution for injection, subcutaneous use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

1.1.2. Indication: Treatment of hypogonadotrophic hypogonadism.

The waiver applies to:

- girls from birth to less than 18 years of age and boys from birth to less than 14 years of age;
- for solution for injection, subcutaneous use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

2. Paediatric Investigation Plan

2.1. Condition: Hypogonadotrophic hypogonadism

2.1.1. Indication(s) targeted by the PIP

Treatment of hypogonadotrophic hypogonadism

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

Boys from 14 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection, subcutaneous use, 100 and 150 micrograms/0.5 mL

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1: Solution for injection, subcutaneous use, 100 and 150 micrograms/0.5 mL
Non-clinical		Not applicable.
Clinical	1	Study 2: Open-label, non-comparative, multi-centre safety and efficacy study of corifollitropin in association with hCG in male adults and male adolescents with hypogonadotrophic hypogonadism.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2014
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of hypogonadotrophic hypogonadism:

   Authorised indication: Controlled Ovarian Stimulation (COS) in combination with a GnRH antagonist for the development of multiple follicles in women participating in an Assisted Reproductive Technology (ART) program

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
EMEA/H/C/1106/001	Elonva	100 micrograms	Solution for injection	Subcutaneous use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe + 1 needle
EMEA/H/C/1106/002	Elonva	150 micrograms	Solution for injection	Subcutaneous use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe + 1 needle