European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 19 December 2008

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver for corifollitropin alfa (EMEA-000306-PIP01-08) 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 N.V. Organon on 28 May 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 12 December 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 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 granting 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 corifollitropin alfa, solution for injection, subcutaneous 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 corifollitropin alfa, solution for injection, subcutaneous 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 waiver for corifollitropin alfa, solution for injection, subcutaneous 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.

This decision is addressed to N.V. Organon, KR4419, Kloosterstraat 6, NL 5349 AB Oss, The Netherlands.

Done at London, 19 December 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/639100/2008
EMEA-000306-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL AND A WAIVER

Scope of the application

Active substance:
Corifollitropin alfa

Condition(s):
Hypogonadotrophic hypogonadism

Pharmaceutical form(s):
Solution for injection

Route(s) of administration:
Subcutaneous use

Name/corporate name of the PIP applicant:
N.V. Organon

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, N.V. Organon submitted to the EMEA on 28 May 2008 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 31 July 2008.

Supplementary information was provided by the applicant on 2 October 2008, and pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, N.V. Organon submitted for agreement to the EMEA a proposal 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.

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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 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 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.

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(es) and appendix.

London, 12 December 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

Hypogonadotrophic hypogonadism

B. WAIVER

- **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, 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.

- **Indication**

Treatment of hypogonadotrophic hypogonadism.

The waiver applies to:

- Girls from birth to less than 18 years of age, 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;
- Boys from birth to less than 14 years of age, 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.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

  Hypogonadotrophic hypogonadism

- **Proposed PIP indication**

  Treatment of hypogonadotrophic hypogonadism

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

  Boys from 14 to less than 18 years

- **Formulation(s)**

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

- **Studies**

Area	Number of studies	Description
Quality	1	Solution for injection, subcutaneous use, 100 and 150 micrograms/0.5 mL.
Non-clinical		Not applicable.
Clinical	1	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.

Measures to address long term follow-up of potential safety or efficacy issues in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	**By December 2012**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**