EMA/441032/2019

# European Medicines Agency decision

P/0283/2019

of 16 August 2019

on the granting of a product specific waiver for human chorionic gonadotrophin, (EMEA-002547-PIP01-19) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

**Only the English text is authentic.**

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# European Medicines Agency decision

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on the granting of a product specific waiver for human chorionic gonadotrophin, (EMEA-002547-PIP01-19) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council,

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[1],

Having regard to the application submitted by Regulis Consulting Europe Ltd on 28 February 2019 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 28 June 2019 in accordance with Article 13 of Regulation (EC) No 1901/2006,

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

Whereas:

(1) The Paediatric Committee has given an opinion on the granting of a product specific waiver.

(2) It is therefore appropriate to adopt a decision granting a waiver.

Has adopted this decision:

***Article 1***

A waiver for human chorionic gonadotrophin, powder and solvent for solution for injection , intramuscular use, 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 granted.

***Article 2***

This decision is addressed to Regulis Consulting Europe Ltd, The Black Church, St Marys Place, DO7 P4AX – Dublin, Ireland.

[1] OJ L 136, 30.4.2004, p. 1.

EMA/PDCO/228625/2019
Amsterdam, 28 June 2019

# Opinion of the Paediatric Committee on the granting of a product-specific waiver

EMEA-002547-PIP01-19

## Scope of the application

**Active substance(s):**

Human chorionic gonadotrophin

**Condition(s):**

Treatment of female infertility

**Pharmaceutical form(s):**

Powder and solvent for solution for injection

**Route(s) of administration:**

Intramuscular use

Subcutaneous use

**Name/corporate name of the PIP applicant:**

Regulis Consulting Europe Ltd

## Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Regulis Consulting Europe Ltd submitted to the European Medicines Agency on 28 February 2019 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 30 April 2019.

## Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to grant a product-specific waiver for all subsets of the paediatric population and the above mentioned condition in accordance with Article 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; and 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 Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The grounds for the granting of the waiver are set out in Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex and appendix.

# Annex I

# Grounds for the granting of the waiver

# 1. Waiver

## *1.1. Condition:*

Treatment of female infertility

The waiver applies to:

- all boys from birth to less than 18 years of age and girls from birth to menarche;
- powder and solvent for solution for injection, intramuscular use and subcutaneous 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.

and

- girls from menarche to less than 18 years of age;
- powder and solvent for solution for injection, intramuscular use and subcutaneous use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset.