EMA/387190/2011

European Medicines Agency decision

P/150/2011

of 10 June 2011

on the granting of a product specific waiver for progesterone (EMEA-001137-PIP01-11) 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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An agency of the European Union

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on the granting of a product specific waiver for progesterone (EMEA-001137-PIP01-11) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 application submitted by IBSA Farmaceutici Italia Srl on 14 February 2011 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 20 May 2011 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.

[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 waiver for progesterone, solution for injection, powder for solution for injection, subcutaneous use, intramuscular 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 IBSA Farmaceutici Italia Srl, Via Martiri di Cefalonia 2, 26900 Lodi, Italy.

Done at London, 10 June 2011

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

EMA/PDCO/350379/2011

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

EMEA-001137-PIP01-11

Scope of the application

Active substance(s):

Progesterone

Condition(s):

Prevention of recurrent spontaneous abortion

Treatment of female infertility

Pharmaceutical form(s):

Solution for injection

Powder for solution for injection

Route(s) of administration:

Subcutaneous use

Intramuscular use

Name/corporate name of the PIP applicant:

IBSA Farmaceutici Italia Srl

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, IBSA Farmaceutici Italia Srl submitted to the European Medicines Agency on 14 February 2011 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 23 March 2011.

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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 all the above mentioned condition(s) 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 subsets of the paediatric population and 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 the specified paediatric subsets.

   The Icelandic and the Norwegian Paediatric Committee members agree 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.

London, 20 May 2011

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

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 all premenarchial girls
- For powder for solution for injection and solution for injection, intramuscular route and subcutaneous use
- On the grounds that the disease or condition for which the specific medicinal product does not exist in this paediatric subset.

And to:

- All postmenarchal girls.
- For powder for solution for injection and solution for injection, intramuscular route and 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.

1.2. Condition: Prevention of recurrent pregnancy loss

The waiver applies to:

- All boys from birth to less than 18 years of age
- And all premenarchial girls
- For powder for solution for injection and solution for injection, intramuscular route and subcutaneous use
- On the grounds that the disease or condition for which the specific medicinal product does not exist in this paediatric subset.

And to:

- All postmenarchal girls
- For powder for solution for injection and solution for injection, intramuscular route and 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.