European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 22 January 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
FERTAVID

International Non proprietary Name (INN): ***follitropin beta***

On 22 January 2009, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Fertavid intended for treatment of female infertility and deficient spermatogenesis in male. The applicant for this medicinal product is Schering-Plough Europe.

The active substance of Fertavid is follitropin beta, a recombinant follicle-stimulating hormone (FSH) (G03GA06). FSH is indispensable in normal follicular growth and maturation, and gonadal steroid production. In the female, the level of FSH is critical for the onset and duration of follicular development, and consequently for the timing and number of follicles reaching maturity.

The benefits with Fertavid are the stimulation of follicular development and steroid production in selected cases of disturbed gonadal function. Furthermore, Fertavid can be used to promote multiple follicular development in medically assisted reproduction programs. Treatment with Fertavid is generally followed by administration of human chorionic gonadotrophin (hCG) to induce the final phase of follicle maturation, resumption of meiosis and rupture of the follicle.

In men deficient in FSH, Fertavid should be used concomitantly with hCG for at least four months to promote spermatogenesis.

The most common side effects when taking Fertavid are local reactions at the site of injection (bruising, pain, redness, swelling and itching). In women, symptoms related to ovarian hyperstimulation syndrome (OHSS) have been reported.

Fertavid is the same medicinal product as Puregon, which is already authorised in the European Union.

A pharmacovigilance plan for Fertavid, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is:

In the female:
Fertavid is indicated for the treatment of female infertility in the following clinical situations:
- Anovulation (including polycystic ovarian disease, PCOD) in women who have been unresponsive to treatment with clomifene citrate.
- Controlled ovarian hyperstimulation to induce the development of multiple follicles in medically assisted reproduction programs (e.g. in vitro fertilisation/embryo transfer (IVF/ET), gamete intra-fallopian transfer (GIFT) and intracytoplasmic sperm injection (ICSI)).

In the male:
Deficient spermatogenesis due to hypogonadotrophic hypogonadism.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data of the reference product Puregon, considers that there is a favourable benefit-risk balance for Fertavid and therefore recommends the granting of the marketing authorisation.