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

London, 19 November 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
ELONVA

International Nonproprietary Name (INN): ***corifollitropin alfa***

On 19 November 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Elonva 100 micrograms/0.5 ml, 150 micrograms/0.5 ml, solution for injection intended for the 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. The applicant for this medicinal product is N.V. Organon.

The active substance of Elonva is corifollitropin alfa, a gonadotrophin (G03GA09), a follicle stimulant with prolonged duration of FSH (follicle stimulating hormone) activity. Its prolonged activity was achieved by adding the carboxy-terminal peptide of the β-subunit of human chorionic gonadotropin (hCG) to the β-chain of human FSH. Elonva is produced by recombinant DNA technology

The benefits with Elonva are its ability to initiate and sustain multiple follicular growth for an entire week. A single subcutaneous injection of the recommended dose of Elonva may replace the first seven injections of any daily (recombinant) FSH preparation in a COS treatment cycle. The most common side effects are OHSS, pelvic pain and discomfort, headache, nausea, fatigue and breast complaints (including tenderness).

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

The approved indication is: "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." Treatment with Elonva should be initiated under the supervision of a physician experienced in the treatment of fertility problems.

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 submitted, considers that there is a favourable benefit to risk balance for Elonva and therefore recommends the granting of the marketing authorisation.

* 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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