13 October 2016
EMA/CHMP/635107/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rekovelle

follitropin delta

On 13 October 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Rekovelle, intended for controlled ovarian stimulation in women undergoing assisted reproductive technologies (ART). The applicant for this medicinal product is Ferring Pharmaceuticals A/S.

Rekovelle will be available as a solution for injection (12 µg/0.36 ml, 36 µg/1.08 ml and 72 µg/2.16 ml). The active substance of Rekovelle is follitropin delta, a recombinant human follicle-stimulating hormone (FSH) belonging to the pharmacotherapeutic class of gonadotropins (ATC code: G03GA10). The amino acid sequences of the two FSH subunits in follitropin delta are identical to the endogenous human FSH sequences.

The benefits with Rekovelle are its ability to stimulate the development of multiple mature follicles in the ovaries. The most common side effects are headache, pelvic discomfort, ovarian hyperstimulation syndrome (OHSS), pelvic or adnexal pain, nausea and fatigue.

The full indication is:

“Controlled ovarian stimulation for the development of multiple follicles in women undergoing assisted reproductive technologies (ART) such as an in vitro fertilisation (IVF) or intracytoplasmic sperm injection (ICSI) cycle. There is no clinical trial experience with Rekovelle in the long GnRH agonist protocol”.

It is proposed that Rekovelle be prescribed by physicians experienced in the treatment of fertility problems.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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