



## Final Appraisal Recommendation

Advice No: 4114 – December 2014

**Follitropin alfa (Bemfola<sup>®</sup>▼) 75 IU/0.125 ml, 150 IU/0.25 ml, 225 IU/0.375 ml, 300 IU/0.5 ml and 450 IU/0.75 ml solution for injection in a pre-filled pen**

**Submission by Gedeon Richter (UK) Ltd**

### Recommendation of AWMSG

**Follitropin alfa (Bemfola<sup>®</sup>▼) is recommended as an option for use within NHS Wales for the following licensed indications:**

- **Anovulation (including polycystic ovarian syndrome, PCOS) in women who have been unresponsive to treatment with clomiphene citrate;**
- **Stimulation of multifollicular development in women undergoing superovulation for assisted reproductive technologies (ART) such as in vitro fertilisation (IVF), gamete intra-fallopian transfer (GIFT) and zygote intra-fallopian transfer (ZIFT);**
- **In association with a luteinising hormone (LH) preparation for the stimulation of follicular development in women with severe LH and FSH deficiency. In clinical trials these patients were defined by an endogenous serum LH level < 1.2 IU/l;**
- **Stimulation of spermatogenesis in men who have congenital or acquired hypogonadotropic hypogonadism with concomitant human Chorionic Gonadotropin (hCG) therapy.**

**Follitropin alfa (Bemfola<sup>®</sup>▼) should be prescribed by brand name to avoid automatic substitution and therefore help with pharmacovigilance.**

#### Additional note(s):

- In accordance with EMA guidance, the licence for the use of follitropin alfa (Bemfola<sup>®</sup>▼) was granted on the basis of assumed bioequivalence.
- Due to the potential for small differences between biosimilars from different manufacturers and/or the reference product (Gonal-f<sup>®</sup>), post-marketing pharmacovigilance is essential and will be facilitated by the Risk Management Plan.



NICE has accredited the process used by the All Wales Medicines Strategy Group (AWMSG) to produce its final appraisal recommendation. Accreditation is valid for 5 years from October 2011. More information on accreditation can be viewed at [www.evidence.nhs.uk](http://www.evidence.nhs.uk).

For full details on our accreditation visit: [www.nice.org.uk/accreditation](http://www.nice.org.uk/accreditation).

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 2088), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation has been ratified by Welsh Government and will be considered for review every three years.

Marketing authorisation holder on first issue	FINOX Biotech
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