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BEMFOLA (Follitropin alpha for injection) is indicated for the same indications as Gonal-f

## Publication Alert

Abstract | Case report/series | Retrospective study | Controlled study | Randomized, placebo-controlled study | Review article| **Commentary**

**Title: Biosimilars to recombinant human FSH medicines: comparable efficacy and safety to the original biologics**

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### SUMMARY

Recently, two recombinant follicle-stimulating hormone (rFSH) medicines (Bemfola and Ovaleap; both designated follitropin alfa) have been authorized by the European Medicine Agency. These are 'biosimilars' to the first available rFSH, Gonal-f registered in 1996. The term biosimilar is a regulatory concept alluding to the evidence-based high-standard comparability studies needed to demonstrate its equivalence to a reference original biologic. Contrary to chemically-synthesized medicines (replicates are termed generics), biologics, which are complex glycoproteins, are subject to an inherent molecular variability (molecular isoforms).

From the experience with original biologics, regulatory authorities have accumulated a wealth of knowledge as to what minor batch-to-batch physicochemical variations may be therapeutically acceptable in each product.

Furthermore, despite analytically detectable differences, the two initially registered rFSH medicines (Gonal-f and Puregon, follitropin beta) share fundamentally the same therapeutic profile. Unlike those original medicines, a FSH biosimilar such as Bemfola and its corresponding reference biologic (Gonal-f) share essentially the same active pharmaceutical ingredient. This article reviews the background evidence over which the biosimilarity principle has been built, and highlights the therapeutic potential for follitropin biosimilars to reassure physicians on their benefit.


**Key Communication Support**

- A biosimilar is not a generic.
- A biosimilar such as Bemfola is administered via the same route, at the same dose, and for the same indications as the originator, Gonal-f
- Equivalent in all efficacy endpoints to reference products
- No detrimental effects, notably immunogenicity
- No increased incidence of adverse events
- No unexpected reactions
- Biosimilar medicines increase patient access to treatment with modern biologic therapies while at the same time supporting the sustainability of healthcare budgets