INTRODUCTION

The WHO defines infertility as a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse.\(^{11}\) In Portugal a study involving 2,632 individuals pointed out to an infertility rate of around 8.9% in the whole population.\(^{12}\) Gonal-f® (r-hFSH) was the first ever product approved by the centralized procedure within the European Union (process EU/2005/001), having been on the market for 20 years. It is currently approved in the European Union for the stimulation of multifollicular development in women undergoing superovulation for assisted reproductive technologies (ART) such as in vitro fertilization (IVF), gamete intra-fallopian transfer and zygote intra-fallopian transfer.\(^{13}\)

Over these last 20 years Gonal-f® has established itself as a gold-standard for the worldwide treatment of this women population, with more than 10,000,000 cycles of treatment performed and more than 2,000,000 new born babies obtained as a result of it. In the last years two new r-hFSH biosimilar drugs (Bemfola® and Ovaleap®) have been approved by the European Commission based on non-inferiority clinical trial data, using as clinical endpoint the number of oocytes retrieved, which in the authors’ opinion is a poor endpoint for the true objective of treatment, obtaining new-born babies.\(^{14,15}\) Previous work by some of the authors has shown evidence that when using new-born babies as the measure of success, the r-hFSH biosimilar drug Bemfola® may be actually less cost-effective than the original Gonal-f®.\(^{16}\)

Considering the importance given by the current Portuguese authorities to the preferential use of biosimilars\(^{17}\) and the previous evidence regarding Bemfola®, it seems appropriate to also evaluate the cost-effectiveness of Ovaleap®, using as clinical endpoint the proportion of parents obtaining a new-born baby.

OBJECTIVES

To estimate the cost-effectiveness of the original r-hFSH (Gonal-f®) when compared with one biosimilar (Ovaleap®) using the evidence from a head-to-head registration trial.

METHODS

A TreeAge Pro decision-tree model was developed depicting the different relevant outcomes that result from fertility treatment with r-hFSH (Figure 1). Probabilities within the model were populated using the data from a head-to-head trial used by the biosimilar for its registration in the European Union, using as relevant outcome the take-away baby rates found in the trial.\(^{18,19}\) Total probabilities used in the model can be found in Table 1, alongside its respective sources.

Costs were populated from Portuguese official sources and include the cost of the two drugs (Gonal-f® and Ovaleap®), as well as the costs related with treatment, such as costs for in vitro fertilization, intra-cytoplasmic sperm injection (ICSI), child delivery and abortion/complications. The analysis was performed from a societal perspective including only direct medical costs with no discounting since all costs occur in a period inferior to 12 months (less than 1 year).\(^{20}\)

RESULTS

According to the specified model, treatment of 1,000 women with Gonal-f® will result in a total number of 351 pregnancies, with 322 women achieving a new-born child. Total cost per woman treated will be €3,023.51, for a cost per woman achieving a new-born child of €9,380,95.

Respective values for Ovaleap® were 291 pregnancies and 268 women with new-born children. Total cost for this alternative is €2,941.68, resulting in a cost per new-born child of €10,976.04.

Incremental cost-effectiveness ratio obtained for Gonal-f® vs Ovaleap® is 1,516.68 €/woman with a new-born child. Sensitivity analysis did not change the hierarchy in the results except on extreme values. Summary of results from the model can be found in Table 3.

One-way sensitivity analysis are shown in Tables 4 and 5. As can be observed, under most circumstances the ICER results for Gonal-f® vs Ovaleap® never surpass the CER value for Ovaleap® in the base case.

CONCLUSIONS

As previously seen for the biosimilar Bemfola®, Ovaleap® is also extensively dominated by Gonal-f®, with its cost-effectiveness ratio being higher than the one found for Gonal-f®.

Under the current scenario the use of this biosimilar is not a cost-effective alternative to the use of Gonal-f® and thus should also be avoided.

REFERENCES


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DISCLOSURES

All authors are employees of Merck SA, Portugal.