Abstract

Objectives: As of 1st January 2011 the German drug market is regulated by the act of the reorganization of the pharmaceutical market (AMNOG). Since then the normal procedure for reimbursement of a new pharmaceutical is an evaluation by the joint federal committee (G-BA) which determines one of six additional benefit levels. According to AMNOG any specification of the reimbursement price shall be based on the outcomes of the early benefit assessment. Hence this assessment is a key role for marking access of a new drug in Germany, which poses the question whether it is possible to predict the level of additional benefit that will be established by the G-BA.

Methods: In order to evaluate a possible predictor of G-BA decisions, the ‘evaluation of pharmaceutical innovations (EVITA)’ score was calculated and retrospectively compared with 40 published G-BA decisions. The EVITA algorithm evaluates a new compound for a given indication and in relation to a relevant comparator on the basis of randomized controlled trial (RCT) evidence. EVITA translates the RCT outcomes on the therapeutic benefit and risk profile into rating points, which are expressed as a total EVITA score.

Results: Univariate ordinary least squares and ordered logit regression analyses show statistically significant correlations between EVITA scores and the G-BA additional benefit level. Moreover, for the prediction of an additional benefit level of at least ‘minor’, an EVITA score cutoff of 3 is associated with a sensitivity of 100% and a specificity of 80%. For the prediction of an additional benefit level of at least ‘considerable’, an EVITA score cutoff of 2.7 is associated with a sensitivity of 100% and a specificity of 91.1%.

Conclusions: The present investigation indicates that the EVITA score may have the potential for the prediction of G-BA decisions related to AMNOG early benefit assessments.

Introduction

Due to this act the means of obtaining cost reimbursement for pharmaceuticals from the German statutory health insurance (DSG) is regulated by the G-BA. The G-BA determines one of six additional benefit levels which the Stiftung Warentest (SW) will now be negotiated during the first year after their market release.

In order to answer this question, which is of particular importance for the pharmaceutical industry, the aim of our study was to evaluate a possible predictor for the G-BA additional benefit level on the basis of the compound benefit profile of a new compound.

Material and Methods

Using the EVITA approach, two regression models (2) were used to investigate the potential of EVITA score to predict the level of additional benefit.”

Results

As shown in figure 1, the two regression models indicate a correlation between the EVITA score and the G-BA additional benefit level. The regression analysis approach provided a statistically significant correlation between the EVITA score and the G-BA additional benefit level has been obtained.

Discussion

As shown in figure 2, the predicted cumulative probabilities according to the ordered logit regression model as presented in table 1 (model 2).

Conclusions

Although there are some limitations to be considered, especially the limited scale of our sample of forty G-BA decisions and the retrospective character of the analysis, the assessment of the potential therapeutic advantage of a new drug by applying the EVITA algorithms may have the potential to act as a predictor of G-BA decisions related to AMNOG early benefit assessments.

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References