OBJECTIVES: In the The Netherlands, a new drug is priced to the level of an existing drug cluster, if these are considered similar. However, when a drug is not considered similar to a cluster, a separate price can be requested. Before this separate price is approved, sufficient cost-effectiveness and budget impact (BI) data have to be provided to the Dutch Health Care Insurance Board (CVZ). The present analysis investigated how close the submitted BI-forecasts were to the actual BIs for cancer treatments in the The Netherlands. METHODS: The publicly available evaluations by the CVZ were assessed for cancer agents. From these, forecasted number of users, drug costs, treatment lengths, and the BIs were derived. The predicted BIs were compared with actual BIs from the GIP database (Dutch Drug Information System). The predicted BI was standardized with respect to time to ensure that actual and forecasted BIs shared the same starting point. Broadening of the indication was taken into account and substitution was considered. To further explain any difference in forecasted and actual BI, various factors such as drug cost, number of users, market share (when applicable), and treatment lengths were investigated. RESULTS: The search provided five relevant cases. The forecasted budgets were lower than the actual ones in four out of the five cases. The forecasted and actual BI differed up to 250%. Data on drug substitution was insufficient and therefore not considered. The differences between predicted and observed BIs were explained primarily by an underestimation of the number of patients eventually receiving the evaluated treatments. The published BI forecasts contained no very limited sensitivity analyses. CONCLUSIONS: Most BI forecasts underestimated the actual BI for new cancer drugs. One explanation was that the growth of the patient population was often underestimated. Improvements in predicting total market size and penetration should be considered, as well as more elaborate sensitivity analysis.

IMPACT BUDGETING IN CROATIA: FULVESTRANT EXAMPLE

Chemotherapy is standard choice as third-line treatment in patients with hormone-dependent metastatic breast cancer. The field research has shown that there is a need for additional hormonal drug in order to delay expensive and harmful chemotherapy. The aim to assess the impact on the budget Croatian Health Insurance Administration (CHII) budget including the drug fulvestrant 250 mg on the basic drug list as a third-line treatment in patients with hormone-dependent metastatic breast cancer. METHODS: Markov model was used to develop a new treatment scenario. Projected total cost of antiemetic prophylaxis impact on the budget was developed in Microsoft Excel. RESULTS: The scenario with fulvestrant given as a third line of treatment in a period of 4 months, followed by 4 months of palonosetron, 3 months capecitabine, and, finally, 4 months with only supportive care was designed. This would delay the application of chemotherapy for an average of 4 months. Therefore, significantly fewer patients will be treated with chemotherapy. Additionally to that, a small part of patients would receive chemotherapy over a shorter period. The quality of life of metastatic breast cancer patients during their life expectancy would be significantly better, expected survival rate and potentially lower cost of treatment. The impact budget analysis has reduced (4,202,922 Croatian Kuna or €579,713). CONCLUSIONS: A need for additional line of hormonal drug as a third-line treatment that can delay the implementation of poorly tolerated and expensive chemotherapy was established. The effectiveness of fulvestrant qualified it as a good candidate after the failure of the current endocrine therapy. The economic evaluation using Markov models and analysis of the budget impact in Croatia has been proven that adding fulvestrant in sequential treatment of metastatic breast cancer HR+ patients is cost-effective as third-line hormonal therapy in advanced breast cancer.

BUDGET IMPACT ANALYSIS OF CAPECITABINE IN ADJUVANT TREATMENT OF PATIENTS WITH RESECTED DUKES' C COLON CANCER (CC) FROM POLISH PUBLIC PAYERS AND PATIENT'S PERSPECTIVES

OBJECTIVES: The aim of the analysis is to determine budget impact of reimbursement of capecitabine monotherapy used in the adjuvant therapy of patients after resection of stage III CC (Dukes’ C). METHODS: Cost data were collected from Polish public payer’s (National Health Fund) and patient’s perspectives and calculated for a 3-year time horizon. The population was estimated based on the Polish National Cancer Register. The following direct medical costs were included: cost of drugs used in adjuvant and I and II line chemotherapy, drug administration costs, adverse events, and monitoring costs. In “scenario A,” capecitabine was not reimbursed by the public payer, while the “scenario B” was developed under assumption of 100% capecitabine reimbursement. The proportion of patients treated with capecitabine and other drugs used in CC treatment was assessed based on the results of a questionnaire study conducted among Polish clinical experts. A cohort Markov model was used for simulation of long-term health outcomes and costs, a range of variables was tested in one- and multi-way sensitivity analyses. RESULTS: “Scenario B” introduction led to savings equal to 24,730,000 PLN in the first year, 25,379,000 PLN in the second year, and 26,712,000 PLN in the third year from public payer’s perspective (1 EURO = 4.1 PLN). Similarly, savings were observed when patient’s perspective was assumed. Results of sensitivity analysis confirmed conclusions from base-case analysis. CONCLUSIONS: One hundred percent reimbursement of capecitabine used in adjuvant therapy of patients after the resection for Dukes’ C CC leads to savings from both public payer’s and patient’s perspectives in Poland.