Linking oncologic drug price to its value: the Italian proposal for a solution

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Pharmaceutical expenditure is rapidly increasing in many European Countries and in the United States (Adamski J et al. 2010), due to introduction of novel high-cost therapies in particular in oncology field (McCabe C, et al. 2009). National Health Systems have adopted several cost-containment strategies in order to overcome this problem, like the so called performance-based risk-sharing arrangements (PBRSAs) that generally link reimbursement of a new medication to health outcomes in real world (Carlson JJ, et al. 2010). However, defining a drug price adequate to its value during negotiation is the ultimate goal of Regulatory Agencies, even if it is difficult for the lack of reliable data about the risk/benefit ratio when pharmaceutical company requires drug approval. Different authors highlighted the need for a value-based system in determining cancer drug prices and proposed various solutions.We used a modified method developed by Guirgis (2012) in order to assess the adequacy of cancer drugs price approved in Italy in recent years.

Methods

Ratios of cost per survival per day (cost/survival/d) were obtained dividing total costs of evaluated drugs for median survival gain in days in terms of overall survival (OS) or progression free survival (PFS), reported in pivotal trials. This survival gain must be clinically significant, according to ASCO criteria (survival gain of at least 20%) (Lee M. Ellis, et al. 2014). Each cost/survival/d corresponds to a score within 0 and 100, fixed taking into account thresholds for acceptability of treatment costs set by English NHS (£20,000-£30,000 per year) and willingness to pay for Italian NHS, which in turn derives from the GDP Per capita. As our GDP Per Capita is equal to 84.6% of the English one (as estimated by the International Monetary Fund in 2012), we define that cancer drugs should be paid up to a maximum of approximately €32,000 per year of life gained in good health, corresponding to €2,650 per month (Table 1). Starting from these limits, €94 per day gained (€2,650/28 days) was considered the maximum adequate price corresponding to a 75 crude score, 0 was assigned to a cost/survival/d of more than €565 and 100 to a cost/survival/d of less than €20 (Table 2). Crude scores have to be adjusted using correction factors for efficacy, safety, quality of life (QoL), prevalence of disease (Figure 1).

Results

We used this method for the assessment of various drugs approved in Italy in recent years, or drugs that are still in negotiation (data not shown for confidentiality). We report the evaluations for abiraterone, afatinib, aflibercept, bevacizumab, dabrafenib and ipilimumab, performed using ex-factory prices reported in Italian Official Gazette (therefore not considering possible discounts) and efficacy-safety data from clinical trials submitted to Regulatory Agency for approval procedures. As shown in Table 3, none of the evaluated drugs achieved a final score of 75, corresponding to an adequate price which does not require a conditioned-payment agreement. Afatinib final score resulted the highest with 55 points, that corresponds to an adequate price but requires a conditioned-payment agreement (a payment-by results was actually negotiated). Prices of all other drugs were not adequate, with final scores negative for bevacizumab, dabrafenib and ipilimumab, and all these costs should be reduced in order to obtain a score of at least 50.

Conclusions

We propose a simple method useful to evaluate adequacy of oncologic drugs prices. As shown from the examples reported in this study, most of drugs' costs are not adequate according to their value in terms of efficacy, safety, QoL and prevalence of disease.

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