The relation between real costs of drugs temporarily reimbursed in mode of coverage with evidence development and budget impact analysis submitted as a mandatory requirement of the application

Zizalova J, Rrahmaniova D, Svorcikova J, Vrubel F
Ambruz & Dark Deloitte Legal, Prague 8, Czech Republic

OBJECTIVES

The Coverage with evidence development (CED) is a mode of reimbursement intended for highly innovative drugs (HID) in the P&R system in the Czech Republic. There is possibility for HID to obtain CED even if the data of their cost effectiveness or outcomes in real clinical practice remain uncertain when P&R application submitted. However to prove high innovativeness of the new drug in pre-specified effectiveness and safety criteria is the base of the assessment, a cost-effectiveness analysis and budget impact analysis (BIA) are mandatory requirements for setting the reimbursement. BIA estimation is crucial for the budget planning of the health insurance companies and also for the specialized hospitals providing the healthcare. The objective of the present study was to assess whether the drug costs stated in BIA matches to real costs.

METHODS

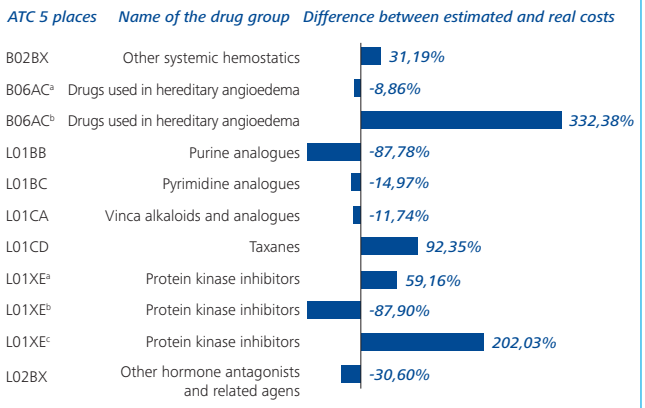
Twelve HID obtained CED in 2013. The drug costs predicted by MAH were identified in BIA of eleven HID. Their therapeutic use based on ATC (5 places) and criteria met to prove their high innovativeness are shown in the table below. Real costs of General Health Insurance Company (VZP) were found out for each HID in the first year of their use in therapeutic practice in the Czech Republic. As VZP holds 60% of the health insurance market, the data were extrapolated to the whole population. The differences between estimated and real drug costs were analyzed and a correlation between this differences and drug characteristics justifying their HID status or other factors were investigated.

ATC 5 places	Name of the drug group	Reason of HID	Difference between estimated and real costs
B02BX	Other systemic hemostatics	absence of an alternative	31,19%
B06AC[a]	Drugs used in hereditary angioedema	absence of an alternative	-8,86%
B06AC[b]	Drugs used in hereditary angioedema	absence of an alternative	332,38%
L01BB	Purine analogues	higher effectiveness compared with current treatment	-87,78%
L01BC	Pyrimidine analogues	mortality reduction	-14,97%
L01CA	Vinca alkaloids and analogues	absence of an alternative	-11,74%
L01CD	Taxanes	absence of an alternative	92,35%
L01XE[a]	Protein kinase inhibitors	adverse effects reduction compared with current treatment	59,16%
L01XE[b]	Protein kinase inhibitors	adverse effects reduction compared with current treatment	-87,90%
L01XE[c]	Protein kinase inhibitors	absence of an alternative	202,03%
L02BX	Other hormone antagonists and related agens	absence of an alternative	-30,60%

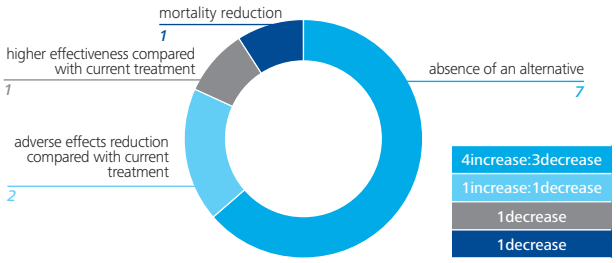
RESULTS

The estimated costs were exceeded in five cases (overrun between 31-332%). In six cases real costs did not achieve the estimation (12-91% of estimated costs) as shown in the graph 1. Concerning effectiveness and safety characteristics of investigated drugs, within seven drugs granted as HID because of absence of an alternative drug, four exceeded the estimation. One of two drugs granted as HID because of adverse effects reduction compared with current treatment exceeded the estimation. Remaining two drugs did not achieve the estimation, one was granted as HID because of mortality reduction, another because of higher effectiveness compared with current treatment as shown in the graph 2. There was no correlation identified based on covered therapeutic indications.

Graph 1: Comparison between estimated and real costs for each individual HID



Graph 2: The reason for granting as HID



CONCLUSIONS

However HID costs estimated in BIA are submitted in order to predict costs of public health insurance, the analysis did not prove their validity and contribution to a reasonable decision making. Despite the fact that BIA is a mandatory requirement and it is cost and time consuming, its role is formal only and its premises have no significant practical impact. As long as MAHs are obliged to submit a P&R application of HID two years after its approval including the submission of current data, the further step of this survey will be to analyze whether the real world data and costs are considered in new BIA and whether they impact the recent assessment of coverage.

ISPOR 18th Annual European Congress, 7-11 November 2015, MiCo - Milano Congressi, Milan, Italy