IMPaCT Of INTROdUcING COSTs/QaLY THRESHold
ON ACCESS TO ONCOLOGY MEDICINES IN SLOVAKIA

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The access to innovative treatments has dramatically changed after the change in legislation. As a result of very low threshold, there is an increase of non-reimbursed treatments and therefore the manufacturer don’t apply for inclusion in the List of reimbursed drugs (Table 1). There is a gradual acceptance of new, non-reimbursed medicines. If mutual agreement is achieved between the manufacturer and health insurance fund, these drugs can be covered on exemptions! Such agreements usually change the reimbursement scheme or price discounts.

In the first year after introduction of the legislative change, the biggest General Health Insurance Fund (GHIF) received 4,688 submissions for inclusion to the reimbursement list (by 120% compared to 2013), while these costs accounted for 2% of the total costs of drugs. Annual growth in 2013 is at 63% of 4.4% (Figure 3).

If a reimbursement application is submitted by a manufacturer, the financial indicators still remain the most important parameters in decision-making on drug reimbursement. From the analysis of all manufacturers’ submissions from January 2012 – 2014 it was discovered that the biggest impact of new drug applications on a reimbursement list was statistically significant on the success rate of inclusion to the List of reimbursed drugs (Figure 4).

Another important factor in the success of reimbursement application concern assessment of the pharmaco-economic analysis by the MoH expert working group on pharma-economics, clinical outcomes and medical technology assessment. A negative assessment of the pharmaco-economic analysis was the most common reason for a rejection to include a new drug in the reimbursement list in 68% of the cases. The most frequent reason was the wrong selection of comparator drugs and miscalculation of the QALY. 13% of rejected submissions were justified by a lack of data on drug safety, from which the greatest barrier was a conditional marketing authorization (Table 2).

The results of the analysis are summarized in Table 3. H1 hypothesis were confirmed.

The analysis of consumption and reimbursement submissions was supplemented by a qualitative survey among physicians on the list of reimbursed drugs. The results (Table 4) were analyzed and calculated with the help of SAS software, and then compared to the IMS data.

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CONCLUSION

In Slovakia, the willingness to pay for an additional unit of health defined as a cost/QALY was anchored in the legislation. The regulatory barrier limited the availability of innovative oncological treatments. The health system in Slovakia needs to introduce efficient and transparent mechanisms that enable the treatment of chronic patients with the least possible waiting times, while keeping abreast for new efficacious drugs within economic possibilities.

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