RISKS OF THE DRUGS ASSESSMENT PROCESS IN THE SLOVAK REPUBLIC

Analytical commentary, July 2021

Summary

The analysis confirmed that there were significant risks in the process of drug assessment in the period 2017 to 2020 in Slovakia and this process was not optimally set.

- In the period 2017 to 2020 cost-effectiveness was assessed on the basis of pharmaco-economic models in electronic form for only 35 (7%) of the total number of assessed drugs. The Ministry of Health of the Slovak Republic was in this period not obliged to require pharmaco-economic models for evaluating the cost-effectiveness of categorized drugs, even though the law authorized the Ministry of Health of the Slovak Republic to issue an edict to determine details of models for evaluating the cost-effectiveness of categorized drugs.
- International guidelines consider pharmacoeconomic models to be an essential part of the drug assessment process. Their non-use increases the degree of subjective and incorrect evaluation, reduces the transparency of the process of categorization of drugs, which potentially contributes to the inefficient spending of funds on drugs from General Health Insurance Company. In 2017 and 2018 some of the published opinions of the expert working group for pharmacoeconomics, clinical outcomes and evaluation of health technologies did not mention names of the assessors. This shortcoming was eliminated after the Supreme Audit Office of the Slovak Republic audit at the Ministry of Health of the Slovak Republic in 2019.
- Examples of good practice for the Slovak Republic can also be the procedures used in other EU countries (Austria, Czech Republic, France). In an international comparison, the biggest difference was identified when there was a professional team that assessed either the clinical benefits or the economic aspects or both in case of the new drug compared to the standard used drug. In all participating countries a professional team is working on this assessment, however in Slovakia it was not the case during the analyzed period.

Following the analysis of the currently set process of drug assessment in Slovakia and the information obtained on the procedures used in other countries, the SAO SR recommends to implement the following steps:

- to ensure the professionalization of the process of assessment of categorized drugs (in accordance with internationally valid methodological recommendations), including the use of pharmaco-economic models for the evaluation of cost-effectiveness in the conditions of the Slovak Republic;

- to carry out a revision of the legislation regarding the state drug policy (adjustment of the valid legislation taking into account efficiency, transparency with an emphasis on the publication of all available process information, predictability and financial sustainability of the overall process).