

Drugs assessment goes back to the old way

The Supreme Audit Office of the Slovak Republic (SAO SR) released an analytical commentary in July 2021, focusing on the risks associated with the drug assessment process in Slovakia¹. In the analytical commentary, we stated that there were significant risks in the process of assessment of medicinal products in the period 2017 – 2020 in Slovakia and that the process was not optimally set up. Based on this finding, the SAO SR formulated the following recommendation in the commentary:

- *undertake a review of the legislation of the state medicines policy - modification of the current legislation taking into account efficiency, transparency (publish assessments with names of assessors), predictability and financial sustainability of the overall process.*

In the interest of transparency, all statements of the expert working group on pharmaco-economics, clinical outcomes and health technology assessment should have been published on the website of the Ministry of Health of the Slovak Republic,² including the names of the assessors. One of the serious risks of the process pointed out by the SAO SR in its commentary was the failure to mention the names of the assessors in some of the published reports. In 2017, two expert reports were published in this way and in 2018, 28 reports were published without the names of the assessors.

The SAO SR also dealt with this area during the audits at the Ministry of Health of the Slovak Republic, carried out in the framework of the preparation of a report on the draft state final accounts for the years 2019 and 2020. Based on the findings of these audits, it can be stated that the deficiency identified in the non-disclosure of names in the opinions of the working group has been eliminated in the following years. For the years 2019 to 2021, the names of the assessors have already been included in all the published expert statements of this working group.

However, from April 2022, after a change in the staff at the Ministry of Health of the Slovak Republic, expert statements without the names of the assessors started to be published again. It is in the contrary to the recommendation of the SAO SR. Table 1 shows that in 2022, 40 expert statements without the names of the assessors were registered by 15th July, which represented 59% of the total number of expert statements issued.

Table 1: Number of statements issued by the expert working group on pharmaco-economics, clinical outcomes and health technology assessment

Rok	2017	2018	2019	2020	2021	2022*
Total number of expert statements issued	98	128	144	112	54	68
Statements without names of assessors (number/%)	2/2%	28/22%	0	0	0	40/59%

Source: Protocol on the result of the audit Statement on the draft state final accounts for 2019 (KA-021/2020/1026); (<https://kategorizacia.mzsr.sk/Lieky/Common/Summaries>)

* until 15th July 2022

The Supreme Audit Office of the Slovak Republic hereby points out the recurring lack of adherence to a transparent process in the assessment of drugs. **A potential solution to the current situation would be to amend the Decree of the Ministry of Health of the Slovak Republic No. 422/2011 Coll. on the details of the pharmaco-economic analysis of drugs, by including the disclosure of the names of assessors and mandatory standardized requirements for the preparation of expert opinions by professional working groups.** The proposed solution is feasible, as demonstrated by the years 2019 – 2021, and is independent of structural changes within the ministry, ensuring sustainable transparency of the processes.

¹ SAO SR, 2021. Risks of the drug assessment process in the Slovak Republic. [online]

² [online]