

UPDATE OF THE HEALTH TECHNOLOGY ASSESSMENT PROGRESS IN UKRAINE: IMPLEMENTATION AND IMPACT IN 2021

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OBJECTIVES

A significant stage in the development of HTA in Ukraine was the approval of the first Decree №1300 "On the approval of the procedure for the state HTA" by the Cabinet of Ministers of Ukraine on 23 December, 2020 and the approval of the first HTA Guideline "The state health technology assessment for medicines" by the Order of the MoH of Ukraine №593 on 29 March, 2021. The study aims to provide a review of HTA progress in 2021 in Ukraine.

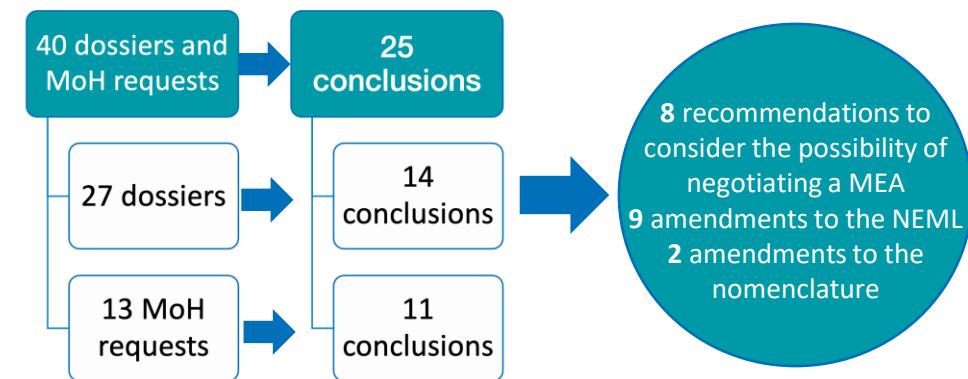
METHODS

Precise data analysis was conducted to obtain analytics on HTA conclusions published in open access in Ukraine in 2021.

RESULTS

Decree №1300 outlines the process of the state HTA conducting, while the first HTA Guideline provides stakeholders with updated methodological recommendations for planning and conducting HTA. Moreover, in 2021 leading HTA experts of the HTA Department developed a training program for industry representatives. All these efforts by the HTA Department lead to the following main results in 2021: 40 dossiers and MoH requests were submitted, of which for 25 assessments of medicines with conclusions were prepared. The total number includes 27 dossiers for the state HTA for expertise and 13 MoH requests. 25 conclusions which include 14 conclusions with recommendations for MoH based on company submissions and 11 conclusions under the abbreviated procedure at the request of the MoH were developed. As a result of the work done in the context of state HTA by full and abridged procedure, 9 amendments to the NEML and 2 amendments to the nomenclature were done. Among 14 HTA conclusions based on dossiers 8 contain a recommendation to consider the possibility of negotiating a managed entry agreement (MEA). MoH has already addressed applicants with a proposal to negotiate a MEA for 5 INNs (brentuximab vedotin, pembrolizumab, venetoclax, cabozantinib, risdiplam).

Figure 1: HTA results in Ukraine in 2021



CONCLUSIONS

The approval of the first Decree №1300 and the first HTA Guideline, together with training sessions for stakeholders, lead to successful practical implementation of the state HTA in Ukraine in 2021 and use HTA recommendations in the decision making process to improve patient access to medicines.

REFERENCES

1. Decree №1300: <https://zakon.rada.gov.ua/laws/show/1300-2020-n#Text>
2. HTA Guideline for medicines in Ukraine: https://moz.gov.ua/uploads/5/29631-dn_593_29_03_2021_dod.pdf
3. HTA Department page at the website of the SEC of MOH of Ukraine: <https://www.dec.gov.ua/ua/department-omt/>