

## IMPLEMENTATION OF EARLY SCIENTIFIC ADVICE AND PUBLIC ENGAGEMENT FOR THE HTA DEVELOPMENT IN UKRAINE

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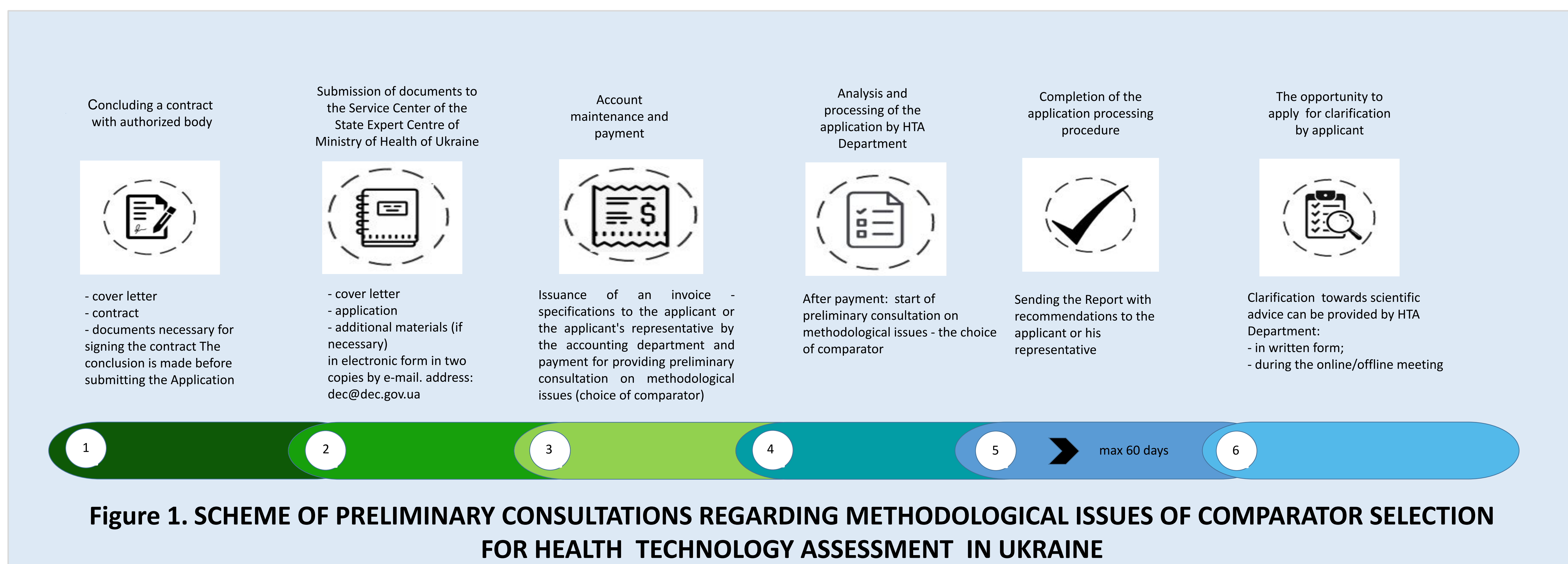
**OBJECTIVES:** The study aims to analyze approaches for improving the HTA in Ukraine, in particular, the implementation of early scientific advice for applicants and public engagement in the review of the project of HTA conclusions.

**METHODS:** A comprehensive review of the current HTA legislation in terms of cooperation with stakeholders for providing early scientific advice and access to the project of HTA conclusions was conducted.

**RESULTS:** In 2023, the Decree of the Cabinet of Ministers of Ukraine No. 1365 "On Amendments to the Decree No. 1300 "On Approval of the Procedure of the State Health Technology Assessment" dated 22 December 2023 was adopted. Among these legislative changes were implemented new procedures: early scientific advice and public engagement in the state HTA procedure.

Early scientific advice for applicants involves providing recommendations in selection of a comparator by the HTA Department of the State Expert Center of the Ministry of Health of Ukraine (SEC of MOH). Applicants are enabled to use these recommendations for dossier submissions for the HTA. Early scientific advice contributes to improving the methodological quality of dossier submissions. Due to the legislative changes, projects of HTA conclusions are now available for public review. According to amendments to the Decree, a project of HTA conclusion is sent to applicants and published on the website of the SEC of MOH. Applicants and other stakeholders are allowed to submit their comments on the project of HTA conclusions within 14 calendar days.

Noteworthy, in October 2023, the HTA Guideline "The State Health Technology Assessment for Medicines" was amended and approved by the Order of MoH No.1741 dated 06 October 2023. The Guideline was elaborated also on stakeholder determination and their engagement.



**CONCLUSIONS:** The state HTA, as a part of a comprehensive ecosystem of access to medicines, implies transparency and openness of the procedure. The legislative changes have enabled early scientific advice for applicants and public engagement in the HTA procedure in Ukraine.