Health Technology Assessment in Greece: evaluation of current status and prospects

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Introduction and Objectives

Health Technology Assessment (HTA) was formally introduced in the decision-making process on the pricing and reimbursement of medicines in Greece in 2018, with the establishment of a Committee on the Assessment and Reimbursement of Medicinal Products for Human Use (so called *"HTA Committee"*) responsible for the clinical and economic assessment of new prescription medicines; and a Price Negotiation Committee. The Price Negotiation Committee negotiates prices of medicines with a positive assessment by the HTA Committee and provides a recommendation to the HTA Committee regarding the medicines' budget impact. The HTA Committee issues its final opinion to the Minister of Health, who makes the final decision. The aforementioned process was introduced as an intermediate step towards the establishment of an HTA organization. In order to inform the public discussion for the further development of HTA in Greece, the objective of the present study was to investigate strengths, weaknesses and opportunities for development of the recently established HTA framework in Greece.

Methods

The study was conducted through qualitative interviews with former and current members of the medicines assessment and reimbursement Committee. To this end, a semi-structured questionnaire was constructed. Eligible participants were sent an invitation letter through e-mail. Virtual interviews were conducted in June-August 2021 and recorded upon informed consent. The recorded interviews were then transcribed and fully anonymized. Thematic analysis was the method of choice for the analysis of the transcripts, in order to identify the main themes of the study.

Results

Overall, 5 former and current members of the Committees participated in the study. The main findings of the analysis can be summarized under the following themes: (1) institutional framework, (2) organizational issues, (3) prospects for an independent national HTA organization.

Institutional framework

The framework on which the HTA process is based is assessed positively, however a few concerns arise with relevance to its structure in order for it to be implemented correctly.

Regarding the assessment criteria, based on the analysis, the institutional framework is considered by participants to be adequate in its clinical parameters, but requires some improvements in the pharmacoeconomic ones. Also, participants suggested that the assessment criteria could be updated and that consideration should be given to prioritization of medicines, based on specific parameters, such as degree of innovation. However, concern was expressed regarding what makes a medicine really innovative and the definition of innovation -which they believe must be specified for the HTA process with clearly defined criteria. In addition, they considered that there is ambiguity on the relative weighting that should be applied to the assessment criteria.

Participants strongly agreed with the inclusion in the law of specific requirements regarding the synthesis of the HTA committee, in order to have representation of all the necessary specialties. Finally, participants were supportive of the prospect of an HTA report being published, in order to enhance transparency.

Organizational issues

Regarding organizational issues, participants identified issues in the operation of the Committee due to inadequate support on both administrative and scientific levels, which hinder the ability of the Committee to meet deadlines. In particular, it was highlighted that the Committee' Secretariat has been understaffed, not following the requirements stated in the institutional framework, whereas in parallel, there were personnel changes, thus, the Secretariat employees could not become really familiar with the process and the needs of the Committee. Consequently, it is suggested that the Committees should be supported by permanent, as well as qualified administrative and scientific personnel.

Deadlines foreseen for the completion of each file assessment were characterized by participants as practically infeasible, mainly due to the inadequate administrative support of the Committee and the difficulty to find available external evaluators. Another issue raised was the significant delays in paying the reimbursement fee to the Committee members and the external evaluators, which constitutes a major disincentive to participate in the HTA process. Weaknesses were reported also regarding the coordination between the assessment and the negotiation Committees, with participants highlighting the lack of communication and feedback between the two. An "open communication channel" was considered necessary to improve the Committees' operation.

Regarding the participation of relevant stakeholders in the HTA process, patients was the group most emphasized by participants. In particular, patient experience and concerns were considered important inputs in the assessment process, however, participants were not supportive of patients' involvement in the process with a right to vote. Availability of data requested from other public organizations related to the HTA process was reported as adequate.

Participants considered that the awaited common EU HTA framework is expected to contribute significantly to time and resource savings, by centralizing many procedures that are now done separately by the member-states, although its feasibility remains a matter of concern. Greece's participation in the joint HTA assessments was viewed positively, although it was also noted that the country still has limited experience in the field.

Prospects for an independent national HTA organization

The establishment of an independent HTA organization is supported by the participants, provided it can be really independent from the Ministry of Health and staffed with the appropriate administrative and scientific staff. It was also highlighted by some participants that the HTA organization should have been established by now, since the current system was supposed to be only a transitional stage.

There was consensus that the future national HTA organization should be independent from the Ministry of Health, both administratively and financially, in order to achieve higher credibility. Also, it is strongly suggested that the role of the HTA organization should be decisive and not advisory, and completely disconnected from the Minister of Health. It was also suggested that the scope of HTA in the case of the HTA organization should include all health technologies (not only medicines but also medical devices and products) and that the organization should undertake both the assessment and negotiation procedures.

With regard to the staffing of the future national HTA organization, participants suggested that its human resources should consist of permanent scientific and administrative personnel, so as to achieve financial stability and effective operation. This, however, does not preclude the use of external assessors. Lastly, participants held the view that the establishment of a national HTA organization with the aforementioned characteristics can improve adherence to schedules and deadlines.

Conclusions

First introduced in 2018, HTA in Greece is a big step forward towards evidence-based resource allocation decisions. The present study identified various positive elements, but also some serious shortcomings in the concept and the operation of the current HTA process. Further measures to strengthen its core procedure, in terms of methodology and structure, and its organisational scheme, through the establishment of an independent HTA organization could be beneficial. Regarding the latter, our study brings forward the need for future planning to pay special attention to the HTA organization's infrastructure, appropriate staffing levels and employment status, and the development of a coherent set of assessment guidelines.

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