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Policy Briefs on Pharmaceutical Policy Interventions in Greece and their Impact

Health Technology Assessment (HTA) and Negotiation: Do they achieve efficiency in resource allocation?

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Abbreviations

ASMR	Amélioration du Service Médical Rendu (France)
CEESP	Commission d'Évaluation Économique et de Santé Publique (France)
CEPS	Comité Economique des Produits de Santé (France)
EOPYY	National Organization for the Provision of Health Services (Greece)
EU	European Union
FEK	Issue of the Official Gazette of the Hellenic Republic (Greece)
HAS	Haute Autorité de Santé (France)
HTA	Health Technology Assessment
NICE	National Institute for Health and Care Excellence (England)
PBAC	Pharmaceutical Benefits Advisory Committee (Australia)
PBS	Pharmaceutical Benefits Scheme (Australia)
SMR	Service Medical Rendu (France)
UNCAM	Union Nationale des Caisses d'Assurance Maladie (France)

Introduction

In health systems that use value assessment to inform coverage decisions, HTA and reimbursement negotiation operate as closely connected and mutually reinforcing processes that jointly shape patient access to new medicines. HTA provides a structured evaluation of the clinical benefit and/or cost-effectiveness of new treatments against appropriate comparators based on critical review of the available evidence. Appraisal outputs subsequently feed into the negotiation between the payer(s) and pharmaceutical manufacturers, with explicit and direct implications on pricing outcomes and reimbursement conditions.

In France, for example, overall clinical benefit (SMR) and added clinical benefit (ASMR) ratings issued by the French National Authority for Health (HAS), along with economic opinions from the Economic and Public Health Evaluation Committee (CEESP), guide the price negotiations conducted by the Economic Committee for Health Products (CEPS) and the setting of reimbursement rates by French National Union of Health Insurance Funds (UNCAM) (HAS, 2024). In England, technology appraisals by the National Institute for Health and Care Excellence (NICE) evaluate the clinical and cost-effectiveness of new treatments (NICE, 2018) and serve as the formal basis for NHS England's commercial negotiations with manufacturers, including managed access and risk-sharing agreements designed to manage uncertainty and align price with demonstrated value (NHS England, 2025). Similar approaches are followed across many other European countries. Beyond Europe, Australia, among other countries, is also a clear example of an integrated pathway, where a positive recommendation by the Pharmaceutical Benefits Advisory Committee (PBAC) is required for listing on the Pharmaceutical Benefits Scheme (PBS) (Storen et al., 2022). Subsequently, the Department of Health, Disability and Ageing negotiates price premiums and access conditions relying on PBAC's assessment of the treatment's superiority or equivalence to standard of care (Department of Health, Disability and Ageing, 2017).

Collectively, these systems illustrate how HTA and negotiation function as complementary components of a coherent value-based pricing and reimbursement framework. This synergy remains underdeveloped in Greece.

Background

Rational pharmaceutical policy thinking emphasises the integration of value, evidence, and sustainability in decision-making. Health Technology Assessment (HTA) and reimbursement negotiation mechanisms are central to maintaining this balance, enabling systematic evaluation of therapeutic benefit relative to cost. In Greece, the 2018 establishment of the HTA and Negotiation Committees (Greek Government Gazette, 2018a) aimed to operationalise these principles. However, weak coordination and maintaining fiscal balance by relying on the rebate system, have prevented these mechanisms from fulfilling their intended objective and potential. The fragmentation between evidence assessment and price negotiation illustrates a critical institutional gap within the Greek pharmaceutical system's transition toward value-based governance.

Objective and Approach

In this brief, we examine the structure, operation, and interrelation of the HTA and Negotiation Committees in Greece, assessing their role in enabling or constraining value-based pricing and reimbursement.

The analysis is based on detailed review of legislation, ministerial decisions, and operational guidelines governing the HTA and Negotiation Committees in Greece, published in the Official Gazette of the Hellenic Republic during the period from 2018 to 2024.

Legislative Review

Table 1 summarizes and presents the series of legislation acts that introduced the HTA and Negotiation Committees in Greece, specified their remit and operation framework and subsequently enacted key changes in their evolution from 2018 to 2024.

Table 1: Legislation on the HTA and Negotiation Committees in Greece

Legislation Act	Date of Introduction	Description of Intervention
Law 4512	January 2018	Established the HTA and Negotiation Committees, under the supervision of the MoH, specifying the structure, remit and mission of each one.
FEK B2768	July 2018	Full methodology of HTA (clinical and economic assessment) as implemented by the Greek HTA Committee outlined.
Law 4633	October 2019	Generic medicines with the same active ingredient and indication as already reimbursed originator products excluded from HTA assessment. Biosimilars subject to abbreviated assessment process (1-month). Establishment of the '5 out of 11' condition for new on-patent medicines to be eligible for HTA in Greece, requiring prior award of reimbursement in a select set of EU member-states with HTA mechanisms.
Law 4865	December 2021	Negotiation criteria for the Negotiation Committee outlined for the first time: a) magnitude of the clawback and rebate of the drug in question; b) volume of sales of the drug in other EU member-states; c) price in other EU countries, especially in case that is lower than the domestic price for an on-patent product; d) timing of patent expiry, if the drug is under patent protection.
FEK B1300	March 2022	4 additional negotiation criteria incorporated; e) the agreement between the MAH and the Negotiation Committee; f) the manner in which the reimbursement price of the drug in question would be determined; g) the therapeutic (clinical) value of the treatment and treatment need; h) the impact of reimbursement of the drug on the pharmaceutical budget.
Law 5161	November 2024	Clinical value criterion withdrawn from list of negotiation criteria.
FEK B7630	December 2024	Clinical value criterion reinstated in the list of negotiation criteria.

Source: The authors from review of the Official Gazette of the Hellenic Republic, 2018-2024.

Results

The HTA Committee in Greece assesses clinical and economic evidence on new treatment technologies, but its procedures and outputs remain largely opaque and non-transparent; there is no publication of full appraisal documents, no public visibility of the evidence reviewed and few explicit statements in legislation of the decision rules or thresholds employed in the assessment. At the same time, the requirement for new on-patent medicines to have been previously awarded reimbursement in 5 out of a list of 11 EU Member-States with established HTA mechanisms[1] in order to be eligible for *prima facie* appraisal in Greece (Greek Government Gazette, 2019), establishes an HTA referencing practice which can lead to delays in access.

[1] The 11 EU member-states on the list: Austria, Belgium, France, Spain, the Netherlands, Portugal, Sweden, Finland, Germany, Denmark and Italy (Greek Government Gazette, 2019).

For the clinical assessment, a comparative evaluation of the benefit and risk of the intervention against the standard of care is applied (Greek Government Gazette, 2018b). However, a clear explanation of how judgements of "greater", "comparable" or "smaller" benefit are made based on the available clinical evidence on different measures of treatment effectiveness (such as mortality, survival and HRQoL) is lacking in legislation. Similarly, while the concept of Added Therapeutic Value (ATV) is referenced in law, the criteria used to assess its extent are incomplete – defined only for circumstances where therapeutic effectiveness has been captured via binary and time-to-event endpoints (Greek Government Gazette, 2018b). Importantly, the published HTA methodology provides no, or, at best very little information on how indirect treatment comparisons, single-arm trial designs and clinical evidence uncertainties are considered or addressed in the appraisal process (Greek Government Gazette, 2018b).

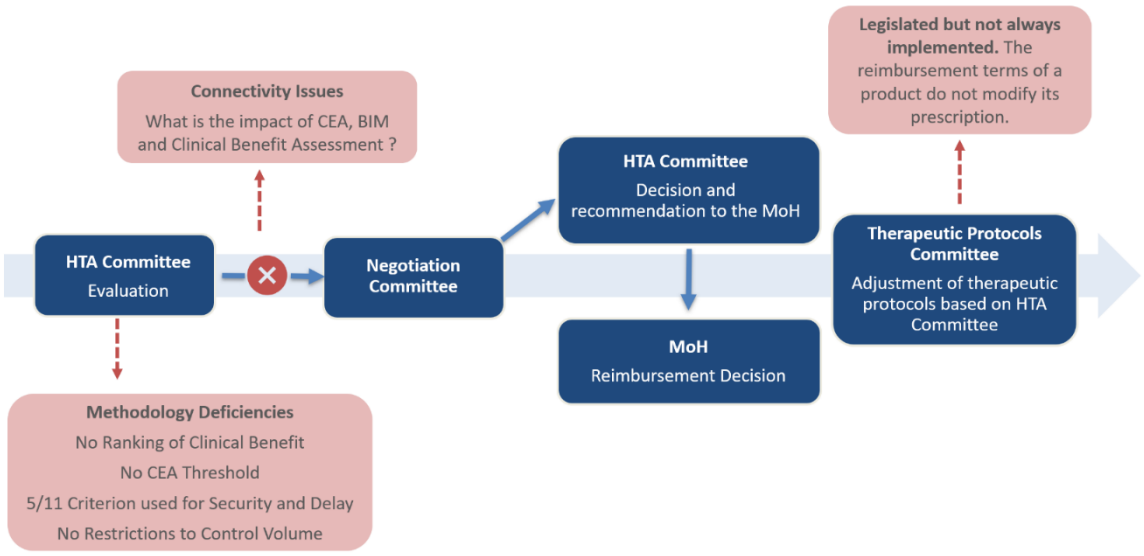
Economic assessment is even less developed in legislation. Law 4512/2018 positions cost-effectiveness and budget impact as fundamental value assessment criteria. In practice, however, only the latter appears to have been implemented meaningfully (Greek Government Gazette, 2018a), although the emphasis is on price and very little, if at all, relates to volume. No cost-effectiveness threshold has been defined or adopted in Greece, and there is no evidence that incremental cost-effectiveness ratios (ICERs) or health gain metrics (e.g., QALYs, although this is by no means the only acceptable metric) are used to guide decisions. Indeed, following Law 4512, cost-effectiveness analysis is not referred to in any subsequent legislation concerning the HTA or the Negotiation Committee's processes, methods or duties. On the other hand, a treatment's expected budget impact is specified in law as a negotiation criterion (Greek Government Gazette, 2022) and estimated by the Negotiation Committee after a reimbursement agreement has been reached with Marketing Authorisation Holders (Greek Government Gazette, 2018a).

The lack of formal connectivity between the two committees further amplifies this imbalance (**Figure 1**). While the HTA Committee's (positive) recommendations are forwarded to the Negotiation Committee (Greek Government Gazette, 2018a), there are no legal provisions explicitly and consistently linking the outcome of clinical appraisal to the negotiation process and the resultant reimbursement conditions. Instead, the Negotiation Committee places predominant emphasis on budget impact, clawback liabilities, and short-term affordability. This misalignment undermines the principle of value-based reimbursement by focusing exclusively on cost containment rather than efficiency. Additionally, the lack of streamlined guidance from the HTA Committee on possible subgroups that are likely to benefit more within the treatment indication, leaves no option for the Negotiation Committee other than focusing almost exclusively on price and using the average rebate or payback as a means of arriving at a price for the health care system.

The law's ambivalence on the role of the "clinical benefit" criterion in negotiation — introduced only in 2022 (Greek Government Gazette, 2022), withdrawn in 2024 (Greek Government

Gazette, 2024a), and ultimately reinstated a month later (Greek Government Gazette, 2024b) — illustrates the instability and conflicted design of the framework.

Figure 1: Pitfalls and fragmentation between HTA and Negotiation Committees in the current approach to reimbursement in Greece



Source: The authors based on legislation review from the Official Gazette of the Hellenic Republic, 2018-2024.

Empirically, the consequences of this fragmentation are visible in the pattern of reimbursement outcomes. Eighty three percent of new originator medicines introduced between 2019 and 2023 in Greece are approved without indication restrictions in Greece, compared with less than 54% in France and 34% in England, while virtually none are rejected (compared with 12% in France and 18% in England) (Therianos et al., 2025).

Discussion and Implications

Incomplete methodological guidance, insufficient transparency, and weak inter-committee coordination have constrained the capacity of HTA and negotiation to promote value-based reimbursement in Greece. The absence of a clear clinical and cost-effectiveness framework and threshold undermines consistency and accountability in treatment appraisal, while overreliance on budget impact as the dominant negotiation criterion prioritizes cost-containment over efficient and sustainable resource allocation.

To realise its intended purpose, HTA in Greece must be embedded within a fully integrated evidence-driven reimbursement process. This entails establishing explicit clinical and economic assessment rules, adopting measurable thresholds for cost-effectiveness, ensuring publication of HTA appraisals and negotiation outcomes for all new technologies, and linking evidence assessment/appraisal with the production of mandatory prescribing guidelines. In order for negotiation to be productive and conducive to optimal use of the public healthcare system's resources, it must be underpinned and directed by the conclusions of HTA on a new treatment's clinical effectiveness, evidence uncertainties, comparative benefit and value-for-money.

Procedural connectivity between the committees should be formalized through shared methodologies and decision protocols that guarantee the translation of HTA recommendations into pricing and access agreements with manufacturers which will reflect value assessment and mitigate risk for the national payer (EOPYY).

Moreover, HTA should play a proactive role in promoting rational medicine use. By incorporating evidence-based prescribing restrictions and guidance for specific sub-populations into its recommendations, the Committee could directly influence clinical practice and reduce wasteful expenditure.

Aligning national procedures with the new EU HTA Regulation (EU 2021/2282) offers a timely opportunity to achieve these reforms in order to move Greece closer to a sustainable value-based pharmaceutical policy framework. While the Greek government is very actively pursuing this reform, what should be borne in mind is that the strategic re-positioning of HTA and Negotiation cannot occur in silo. Reforms need to be triggered in other areas of pharmaceutical policy, in particular, the payback system, the procurement and implementation of mandatory prescribing guidance based on clinical and cost-effectiveness criteria, and the continuous monitoring of prescribing, all of which are inter-connected.

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