Strengthening of the National Health Technology Assessment (HTA) Framework in Greece

Greece's health technology assessment (HTA) system plays a critical role in health-care decision-making, including the evaluation, selection, pricing, reimbursement and procurement of medicines and medical devices. Greece established a national HTA process in 2018, expanding it legally in 2022 to also cover medical devices. The European Union (EU) developed a new HTA Regulation (EU) 2021/2282 (HTAR), to apply to all member states from Q1 2025. The project "Strengthening of the National Health Technology Assessment (HTA) Framework in Greece" was implemented to support Greece preparedness for the implementation of this Regulation.

This initiative is part of Greece's national efforts to streamline HTA assessments, reduce delays and improve patient access to cost-effective treatments and medical devices, ultimately improving population health and strengthening the sustainability of the health-care system. This 20-month project was led by WHO Region Office for Europe and the WHO Office on Quality of Care and Patient Safety in Athens, in collaboration with the European Commission's Reform and Investment Task Force (SG REFORM) and the Greek Ministry of Health. It was funded by EU via the Technical Support Instrument (TSI) and ran from the first of July 2024 until the 28th of February 2026.

1. Assessment of alignment between the Greek HTA system and EU regulations through a situation analysis, needs assessment and stakeholder interviews
Q4 2024

2. Development of methods, guidance and a national framework for HTA
Q1 - Q2 2025

3. Capacity-building to empower Greek HTA and Reimbursement Committee and Negotiation Committee to pilot guidance documents
Q3 2025

4. Testing and refining guidance using a pilot case study medical product
Q4 2025 - Q1 2026

5. Ongoing dissemination to ensure transparent HTA implementation to foster support for evidence-informed healthcare decisions in Greece
Q4 2024 - Q1 2026

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Assessing alignment with the EU HTAR: Situation Analysis

The first major deliverable of the project was a comprehensive situation analysis and needs assessment of the HTA system in Greece. Its purpose was to establish a clear baseline of existing structures, processes and capacities, and to identify priority areas for reform in view of the, then forthcoming EU HTAR. The situation analysis was based on a review of the regulation, relevant literature, in-depth interviews with key national stakeholders, and validation through technical meetings and a national stakeholder workshop. It examined governance arrangements, legal and methodological frameworks, technical capacity, data availability, transparency and stakeholder engagement.

The analysis found that, while Greece has made important progress in establishing HTA, significant challenges remain. These include limited human and technical capacity, fragmented data systems, weak decision-support tools, low transparency, and a strong dependence of HTA outcomes on price negotiations, meaning that even when clinical value is assessed positively, reimbursement is primarily determined by the outcome of financial negotiations. Capacity in health economics and indirect clinical comparisons was identified as particularly underdeveloped, and stakeholder involvement was found to be minimal, with patient engagement in particular lacking from the HTA process. It also identified that though there was the legal basis for HTA to also occur for medical devices, currently it was only restricted in practice to medicinal products.

Overall, the situation analysis provided a shared evidence base to guide subsequent project activities and informed a set of strategic recommendations to strengthen HTA governance, build sustainable capacity, and support effective alignment with the EU HTAR.

Capacity building and peer learning

A core component of the project focused on strengthening Greek HTA capacity through structured peer learning and international cooperation. With support from the European Commission (TAIEX) and WHO/Europe, Greek HTA stakeholders participated in a series of virtual and in-person study visits with established HTA agencies in Portugal (INFARMED), France (HAS), Italy (AIFA and AGENAS), and the United Kingdom (NICE), as well as the WHO Collaborating Centre at the University of Utrecht.

These exchanges provided practical insights into governance models, stakeholder engagement, conflict of interest management, clinical and economic assessment methods, real-world evidence use, managed entry agreements, and HTA for medical devices. Key lessons included the importance of having a dedicated technical agency or unit with sufficient staff, clear separation of assessment and appraisal functions, systematic stakeholder involvement (including patients and clinicians), transparent links between clinical added value and reimbursement, and strong data infrastructure.

Examples from Portugal and France highlighted good practices in Population, Intervention, Comparators, Outcomes (PICO) development, economic evaluation, and patient engagement. Italy provided leading models for medical device HTA (AGENAS) and innovative medicines and registries (AIFA). The UK contributed practical frameworks for managed access agreements and innovation funds.

Overall, the peer learning activities demonstrated that Greece can draw on multiple European models to design a fit-for-purpose HTA system aligned with EU HTAR.

Virtual peer learning:

In-person learning:

Guidance development for HTA

Building on the situation analysis and the peer learning activities, a comprehensive national HTA methods and process guide for Greece were developed. These documents form the core technical output of the project and provide a standardized framework for conducting HTA in line with the requirements of the EU HTAR.

The guides were developed by WHO/Europe through an iterative and highly consultative process led by the Greek Ministry of Health, including input from the Scientific Advisory Group, the Greek HTA Committee and Greek patient and industry organizations. They draw directly on international best practices observed during site visits to INFARMED (Portugal), HAS (France), AIFA and AGENAS (Italy), and NICE (UK), and were adapted to the specific legal, institutional and data context of Greece as well as the legal requirements of the EU HTAR.

The methods guide provides detailed guidance on defining assessment scope using PICO criteria, conducting clinical assessments (including real-world evidence and indirect comparisons), assessing quality of evidence using GRADE, and performing economic evaluations through a national reference case. The accompanying process guide sets out operational workflows, roles and responsibilities, stakeholder engagement mechanisms, and links between assessment, appraisal and decision-making.

Together, these documents establish a coherent national HTA framework that supports national implementation of full HTA, as well as Greece's ability to effectively participate in and benefit from the collaborative EU Joint Clinical Assessments and Joint Scientific Consultations processes.

Trainings and pilot to test and refine the HTA guidance

Trainings on HTA have been delivered to a wide range of Greek stakeholders to support use and implementation of the new guidance documents. Trainings began with a one-day, in-person methods workshop held in Athens, Greece on the 22nd of September 2025. Subsequently, three training topics were delivered through four virtual training sessions between November 2024 and January 2025, covering PICO development, clinical assessment, economic evaluation and other considerations.

To test the feasibility and practical application of the new HTA methods and process guides, these trainings were delivered alongside a structured pilot exercise using a real medicinal product dossier. The pilot focused on capivasertib (Truqap) in combination with fulvestrant for the treatment of breast cancer and was designed to simulate a workflow in the style of an EU Joint Clinical Assessment.

The Greek HTA Committee applied the corresponding part of the guidance after each virtual training session to assess the company's submission, progressively building a full HTA assessment in line with the new national framework.

Clinical and patient experts contributed to defining PICO and interpreting the evidence during the pilot. The HTA Committee highlighted the value of their contribution in clarifying clinical relevance, patient needs and prioritizing outcomes, demonstrating the practical benefits of structured stakeholder engagement.

The pilot confirmed that the Greek HTA Committee is well equipped to apply the new HTA methods and to engage effectively with EU HTA processes. The Greek team demonstrated strong technical capacity in clinical and economic assessment, good adherence to the guidance, and readiness to participate in EU Joint Clinical Assessment processes. The exercise also validated the operational feasibility of the new framework and reinforced the importance of expert and patient involvement in strengthening the quality and legitimacy of HTA decision-making.

In addition, WHO/Europe is supporting Greece in developing initial guidance for HTA of medical devices, providing a methodological starting point that Greece will further refine and develop as part of its ongoing HTA reform.

Strengthening the HTA Framework in Greece

Communications and stakeholder engagement

Strong communication and broad stakeholder engagement have been central to the project's approach. From the outset, the initiative was designed as a collaborative process, bringing together national authorities, the HTA Committee, clinical experts, patient organizations, academia, industry representatives, and international partners. The project technical launch took place at the Athens patient summit on 20th September 2024. Three national stakeholder workshops have also been held in Athens, enabling dialogue and validation of the strengthened HTA framework.

The first workshop, held on the 13th of December 2024, presented the findings of the situation analysis and helped shape priorities for reform. The second workshop, held on the 23rd of September 2025, focused on discussing and refining the draft HTA methods and process guides, and providing preliminary training to a wide group of stakeholders.

The focus for the third and final workshop, held on the 9th of February 2026, was to present the results of the project, including the piloting of the methods and process guides, and to build consensus around the future direction of the Greek HTA system. In addition to in-person events, regular technical meetings, virtual consultations and bilateral discussions supported continuous engagement throughout the project lifecycle. These activities enabled real-time feedback, strengthened trust between institutions, and ensured that diverse perspectives, including those of patients and clinicians, informed the development of the national framework.

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