

Scope of vignette:

- authorised products (with marketing authorisation)
- decision process about routine use (and not individual requests for reimbursement)
- submissions for P&R made by manufacturers

Green= related to/any special considerations for OMPs/UOMPs

Greece	Standard HTA process
<p>Overview of health system and P&R/HTA process</p>	<p>Combined tax and social insurance based health system [1]</p> <p>Within the National Organization for Medicines (EOF), the Committee on Health Technology Assessment and Reimbursement of Medicinal Products for Human Use (HTA Committee) assesses medicines and give recommendations to the MoH. If a drug receives a positive recommendation, the case is referred to a newly established Drug Pricing Negotiation Committee (Negotiation Committee) established within the Greek National Organization for Healthcare Provision (EOPYY) [2]</p> <p>The Negotiation Committee negotiates prices/discounts of medicines reimbursed directly from EOPYY or supplied to public hospitals, and informs the HTA Committee about the budget impact of a medicine. The HTA Committee issues the final recommendation to the MoH. Positive list used. The MoH makes the final decision. [2]</p> <p>This process is based on the new HTA legislation introduced in January 2018 [2].</p> <p>The state institute for pharmaceutical research and technology (IFET) is the state wholesaler, responsible for direct importation of drugs that are not licensed in Greece or drugs that are not in circulation because of small market size or limited commercial interest to manufacturers.</p>
<p>Differentiation of rare disease treatments in the P&R system</p>	<p>None</p>
<p>Eligible medicines</p>	<p>All new medicines with marketing authorisation [2]</p>
<p>Process</p>	<p>Regular pricing and reimbursement processes as for all other medicines</p> <p>All new prescription drugs are subject to HTA, which lasts up to 180 days. [2]</p> <p>There are two alternative channels through which patients can have access to an OMP, depending on whether it is licensed in Greece or not. In the first case, the patient can take the drug through the hospital pharmacy or the pharmacy of EOPYY if it is not available at the hospital pharmacy. In the second case, a patient can get the drug through a public sector organization (the state wholesaler, IFET), which imports the drug directly from the country of origin and pays the market price [3]. This last case is a named patient programme, where a</p>

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	doctor would certify a request for a patient that qualifies for a specific treatment.
Disease specific expert input (e.g. clinicians or patients in any stage of the process)	None
Key domains in assessment	<p>Clinical-effectiveness Cost-effectiveness Other</p> <p>Clinical assessment focuses on data quality, added therapeutic value and innovation level [2].</p> <p>Therapeutic added value is ranked across four levels: major, significant, marginal and non-quantifiable [2].</p> <p>Innovation level is assessed based on the Ahlqvist-Rastad system across a five-category system [2].</p>
Evidentiary requirements	GRADE criteria followed, no leniency for RDTs. [2]
PROMs	Quality of life can be accounted for but there are no specific requirements on this.
Appraisal framework	No additional criteria to the key domains in assessment are being considered. If other dimensions or criteria are to be considered, these are raised as part of the negotiation process.
Reimbursement decision	Positive (include on positive list) or negative recommendation (do not include on positive list). In the case of a negative recommendation, the MAH can submit a new dossier after 6 months. MAH's are only informed in the case of a positive recommendation. If this does not happen within 180 days, a negative recommendation is implied. [2] The drug goes into the negotiation process once it is referred to by the HTA Committee (after a positive recommendation). In legislative amendments that were undertaken (and approved by Parliament) in September 2019, the minister of health can refer a case directly to the negotiation committee, without having to go through the HTA committee first.
Pricing process	The Negotiation Committee negotiates prices/discounts of medicines reimbursed directly from EOPYY or supplied to public hospitals, and informs the HTA Committee about the budget impact of a medicine. [2] Its role is currently very limited and only few negotiations have taken place.

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Managed entry agreements	Yes, until now only discounts have been agreed [2]
Main challenges in appraising medicines for rare diseases	<input type="checkbox"/> Lack of good quality clinical data <input checked="" type="checkbox"/> Lack of real world data <input checked="" type="checkbox"/> Introducing value for money <input type="checkbox"/> Monitoring treatment efficacy <input type="checkbox"/> Managing budget impact <input checked="" type="checkbox"/> Lack of criteria of OMP P&R processes <input type="checkbox"/> Making arrangements to work for all stakeholders <input checked="" type="checkbox"/> Lack of long-term meaningful outcomes <input type="checkbox"/> Other
Impact of special processes	Currently N/A
Proposed policy change	It is likely that when the government revisits the overall plan for the establishment of an independent HTA agency, there may be changes in the status of OMPs, but this is not envisaged before 2021.
Joint initiatives	
SOURCES	
1	http://www.euro.who.int/__data/assets/pdf_file/0006/373695/hit-greece-eng.pdf
2	Kanavos, P., Tzouma, V., Frontrier, A.M., & Souliotis, K. (2019). Implementing health technology assessment (HTA) in Greece Myths, reality and cautionary tales. <i>Archives of Hellenic Medicine</i> , 36(4).
3	Tsiantou, V., Mylona, K., Karampli, E., Boubouchairopoulou, N., Kyriopoulos, I.I., Athanasakis, K., Gabriel, E., Makridaki, D., & Kyriopoulos, J. (2014). Access to orphan drugs in Greece during economic crisis. <i>Value in Health</i> , A323-A686.

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This vignette was compiled based on information provided by country experts and desk research. The information provided may be incomplete or contain inaccuracies. If you have any comments or updates, please email us at the following email addresses:

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