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EDITORIAL
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Implementing health technology assessment (HTA) in Greece
Myths, reality and cautionary tales

BACKGROUND

The burden posed by the economic crisis on the Greek healthcare system has been significant –almost unprecedented– over the past decade. Despite the fiscal challenges facing the Greek health care system, partly as a result of a 10 year-long economic depression, great effort has been made to improve its performance on a variety of fronts, including prescription medicines. Currently, prescription medicines account for approximately 25% of the total healthcare spending and about 70% of that is spending on new, in-patent medicines. Considering that many new and expensive medicines come to market, having a robust assessment method is critical to ensure that scarce resources are allocated efficiently and that affordability is safeguarded.

Implementing health technology assessment (HTA) in the Greek context is a critical and much needed reform in terms of rationalising expenditure in general and pharmaceutical expenditure in particular. HTA can promote resource allocation decisions as well as address the issue of affordability with regards to new and expensive therapies coming to market. A new law on HTA was introduced in January 2018,[1] with another two supplementary pieces of legislation following in July and August 2018.[2,3] While this is a good first attempt in a country that has painstakingly avoided to introduce any meaningful new process in its national pharmaceutical policy over the past 15 years, it is not without imperfections. In this paper we offer a critique of the new HTA legislative framework and outline areas where we feel additional intervention is needed. We do so for a number of reasons: First, in order to help improve the functionality of the new system as well as make it leaner; second, to help make the current framework fit for purpose, because we feel that there are still several points that require improvement; and, third, because the legislative framework does not amount simply to an incremental evolution to the existing positive list committee, but to a more fundamental shift towards a meaningful and robust value assessment model that has broader macroeconomic implications.

OBJECTIVES OF HELATH TECHNOLOGY ASSESSMENT AND ANALYTICAL FRAMEWORK

The way HTA is implemented in different settings subscribes to a set of principles. Whether integrated into existing institutional structures (as it seems to be the case in Greece at the moment), or being a process conducted by an independent, arms' length body (such as National Institute for Health and Care Excellence [NICE] in England or the Haute Autorité de Santé [HAS] in France),[4,5] the assessment of health care technologies entails multiple phases, which include horizon scanning, scientific advice/early engagement, evidence, assessment and appraisal. Broadly speaking, during the assessment phase, the evidence submitted on a specific technology –whether this is clinical, economic or both– is reviewed from a comparative perspective with regards to its robustness; during the appraisal phase, the evidence is interpreted and a judgement is made based on scientific evidence and a number of additional (but relevant to the health care context concerned) value dimensions about the extent to which the new technology is relevant for the health care system assessing it.[6] Implementation of HTA recommendations follows the appraisal phase, assuming these recommendations are adopted by health care decision-makers. Figure 1 captures the salient features of this process.

THE GREEK NEW HEALTH TECHNOLOGY ASSESSMENT LEGISLATION IN A NUTSHELL

The new legislation established the Committee on Health Technology Assessment and Reimbursement of Medicinal Products for Human Use *("HTA Committee")* with the main task to assess medicines with marketing authorization (MA) and to issue recommendations to the

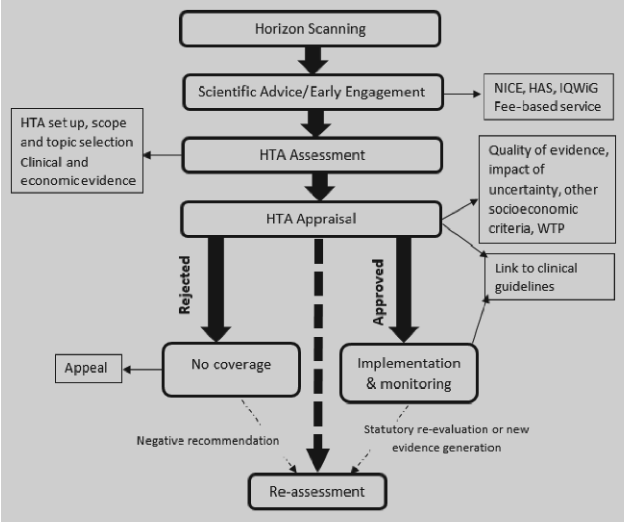

Figure 1. Assessment and appraisal process *(source: The authors)*.

Minister of Health on the inclusion or removal from the List of Reimbursable Medicinal Products *("Positive List")*.[1,2] Supervised by the Ministry of Health (MoH), the HTA Committee is based at the National Organization for Medicines (EOF). If a drug receives a positive recommendation by the HTA Committee, the case is referred to the newly established Drug Pricing Negotiation Committee *("Negotiation Committee")*.[3] Also supervised by the MoH, the Negotiation Committee is established in the Greek National Organization for the Healthcare Provision (EOPYY), which has ultimate responsibility as a national payer, and its main tasks are (a) to negotiate prices or discount rates of medicines that are reimbursed directly from EOPYY or supplied to public hospitals and (b) to inform the HTA Committee about the budget impact of a medicine and enter into agreements with manufacturers.[3] The HTA Committee subsequently evaluates the Negotiation Committee's recommendation and makes a final recommendation to the Minister of Health who is the ultimate decision-maker.

The clinical assessment focuses on three key aspects: Data quality, added therapeutic value and innovation level. Data quality will be informed by the GRADE criteria, a method for assessing the quality of evidence in clinical trials. To determine the added therapeutic value, the Greek system is strikingly similar to the German IQWiG (Institut für Qualität and Wirtschaftlichkeit im Gesundheitswesen) approach to determine the extent of an effect. The level of evidence for an additional benefit is assessed based on four levels, and the extent of added therapeutic value is assessed as major, significant, marginal or non-quantifiable. Finally, the Greek legislation also adopts the Ahlqvist-Rastad system, a five-category system to define "the level of innovation" of medicines. In table 1 we briefly present the main points raised in legislation and the challenges arising.

Table 1. Key challenges in the Greek health technology assessment (HTA) legislation.

Legislation stipulation(s) ***place in the FEK, where stipulation is raised***	**Challenges arising**
All new prescription drugs are subject to HTA *Annex II, Ch 1, p. 35558, MD no 52029/2018* *Art 249, §2, L. 4512/2018*	No horizon scanning or early warning mechanism to identify new and emerging technologies that might require prioritisation or early/urgent assessment No prioritisation mechanism or topic selection process Inclusion of generics with no economic or clinical rationale for HTA No differentiation based on drug type and the challenges these may face in terms of evidentiary requirements (orphans or ultra-orphans, vaccines, cell-based technologies, gene therapies) No provision for early access schemes for innovative medicines that have not received MA yet
HTA Committee as an integrated body to EOF, composed by 11 members and assisted by external experts/assessors *Arts 247 and 248, section Θ΄, L. 4512/2018*	Inadequate staffing levels for the assessment of new drugs in any given year, let alone all drugs (i.e. those introduced in previous years and still under patent); Unclear legislation about (a) level and employment status of human resources; (b) the number of technologies to be assessed in a year; (c) resources and infrastructure (including capacity-building) needed; Not an independent body – implications for transparency, objectivity and responsibility; No clinical medicine experts are included among the HTA Committee members.
Timelines: (a) Recommendation should be made within 180 days from manufacturer submission, and (b) minimum wait of 6 months before re-submission *Art 251, §2, section Θ΄, L. 4512/2018* *Art 6, §1–8, p. 35536–35537, and art 11, §6, p. 35539, MD 52029/2018*	Unrealistic timelines due to the small number of reviewers, the volume of technologies to be assessed and the multiplicity of institutional stakeholders No mention of what happens if a competitor comes in the same indication and ambiguity on whether there should be a "class" assessment Minimum wait of 6 months before re-submission undermines the transparency of the process and constitutes a barrier

Table 1. (continued) Key challenges in the Greek health technology assessment (HTA) legislation.

Legislation stipulation(s) ***place in the FEK, where stipulation is raised***	**Challenges arising**
Appeals process *Art 251, §5, section Θ΄, L. 4512/2018*	No specific timeline set for appeals; clarity is needed on the length of appeals process No detail on appeals process, i.e. (a) who examines the appeal, (b) what are the criteria, and (c) whether there is arbitration The appeals process should be a completely independent process
Stakeholder engagement *Art 250, §7, section Θ΄, L. 4512/2018*	No provisions for early engagement or any kind of interaction between the HTA committee and the manufacturer No adequate involvement of all relevant stakeholders (patients, MAHs, or clinicians)
Clinical assessment *Annex I, Ch 2, pp. 35542–35546, MD 52029/2018;* *Annex II, Ch 4.4, p. 35560, MD 52029/2018*	GRADE is a time-consuming method that requires some training and detailed guidance on how it will be adapted to modern-day clinical data constraints No guidance on how to address data constraints from an HTA perspective (e.g., data cross-overs, single-arm trials, surrogate endpoints, clinical trial size, suitable comparators, among others) The Ahlqvist-Rastad's rating system poses risk of duplication of effort when combined with GRADE Ranking of products should be clearer and more explicit Need to link between assessment/appraisal and implementation and monitoring
Economic assessment *Annex II, Ch 6, pp. 35560–35561, MD 52029/2018*	The role of economic evaluations in the assessment process is totally unclear (just a very brief mention in the instructions for submission) Lack of formal guidelines for economic evaluation Unclear how economic evaluations will be used in the decision-making process Unclear how economic evaluations conducted in other settings can inform local decision-making process Lack of robust local epidemiological data, costing data and registries in Greece to inform economic models and apply economic evaluation
Appraisal *Annex I, Ch 3, p. 35546, MD 52029/2018*	It is not clear what role, if any, other criteria or considerations may have in the HTA process; important considerations regarding appraisal are missing Lack of clarity on how new technologies fit along disease therapeutic pathways beyond issuing prescribing protocols for specific drugs based on recommendations made on the latter Might be desirable to calibrate drugs based on whether they cure, prevent or offer symptomatic relief to a disease Might be desirable to have stricter criteria for awarding "top rank", e.g., demonstrably impacting a clinical endpoint in a severe disease only
Implementation and monitoring *Art 251, §6, section Θ΄, L. 4512/2018*	Greater clarity is needed on how HTA recommendations are incorporated into clinical or prescribing guidance and how their mandatory uptake by clinicians will be monitored There is no monitoring process to determine how HTA recommendations are implemented and no impact assessment
Negotiation Committee *Art 255, section Θ΄, L. 4512/2018;* *Art 6, §12, p. 35537; and art 11, §3, p. 35539, MD 52029/2018;* *Art 2, p. 45119, MD 63025/2018*	No clarity on the rules and the criteria applied by the Negotiation Committee Possible types of agreements between the committee and the manufacturer are not described
Coordination and inter-operability	Unclear what the backward and forward links are with other institutions Need clarity and commitment on the timelines between HTA and Negotiation Committees in order to avoid unnecessary delays in process
Transparency *Art 247, section Θ΄; art 250, §6, section Θ΄, and art 251, §2, section Θ΄, L. 4512/2018;* *Art 2, p. 45119, MD 63025/2018;* *Art 13, p. 35539, MD 52029/2018*	Rejections by HTA Committee are not communicated to manufacturers but are only inferred after a certain period of time elapses No provision of transparent processes and tools to be used for negotiations The fact that the HTA and the Negotiation Committees are not independent bodies, and their assessments rely on a pool of experts, while EOF and EOPYY are the overall responsible organisations, can undermine their transparency and credibility There is no publication of the HTA outcome (positive or negative), nor an HTA report published, but only a summary of the key findings of the HTA Committee and only for the positive recommendations

FEK: Government gazette of the Hellenic Republic, Art: Article, MD: Ministerial decision, MA: Marketing authorization, MAH: Marketing authorization holder, EOF: National Organisation for Medicines, EOPYY: Greek National Organization for the Healthcare Provision, §: Section

Source: The authors

IMPLEMENTING HEALTH TECHNOLOGY ASSESSMENT IN GREECE: MYTHS, REALITY AND CAUTIONARY TALES

Scope of health technology assessment

The new legislation suggests that in scope are new active substances, new indications of already reimbursed drugs, new drug combinations, new generics, drugs appearing in the positive list during the last 3 years, and all therapeutic analogues for which an application for inclusion has been filed. Assessing all new medicines is in principle acceptable, as the assessment is linked to a coverage recommendation and inclusion into the list of reimbursable products, but, overall, some prioritisation needs to take place. A number of issues arise in this context. The first is the inclusion of generics. The introduction of generic medicines serves the objective of disinvestment from expensive to cheaper –but equally effective– alternatives. Because generics do not represent therapeutic advances or innovations they should really be excluded from this HTA process. Overall, therefore, scarce resources cannot be wasted in order to assess generics.

Second, the assessment of therapeutic analogues implies class assessment, pretty much along the lines of a "multiple HTA", but legislation is unclear, particularly since there does not seem to exist a prioritisation rule. The fact that there is no scope or provision for a topic selection process and that there is no exclusion or flexibility for specific categories of products to be prioritised based on criteria such as severity or unmet medical need (e.g., orphan or ultra-orphan drugs, cell-based technologies, gene therapies, vaccines, etc.) can create distortions and lead to potential misuse of effort and resources. In the case of orphan drugs, for example, variable thresholds apply in different settings (e.g., as far as £ 100,000/QALY in England), while in other settings if their total cost to the health care system does not exceed a certain limit (€ 30m in France and € 50m in Germany), they are not included in assessments, but are subject to a different process.[7]

Finally, there are no provisions for medicines without an MA or medicines approved via an accelerated access pathway. This can be troublesome and a barrier to timely access to new technologies. For instance, ATU (autorisation temporaire d' utilisation) in France grants temporary reimbursement status for medicines, which show significant therapeutic promise prior to obtaining their MA.[5-]

Overall, clear rules of prioritisation must be established, as is the case elsewhere, where priorities are based on specific criteria, such as burden of disease, resource impact, clinical and policy importance, presence of inappropriate variation in practice, the potential factors affecting the timeliness of guidance and the likelihood of the guidance having an impact. In order to make HTA guidance useful what is needed is an understanding of how the outcome will be used and, specifically, whether it will feed into a prescribing guidance for wider use in the Greek NHS.[4]

Staff levels

There are 11 members in the HTA Committee plus external assessors. Assuming these are full-time employees, this level would be inadequate to complete the workload envisaged in a timely fashion. The legislation is also totally unclear about a number of other issues: First, the number of human resources engaged in the assessment process and their level of expertise; second, who the external assessors are and their terms of engagement; third, the expected number of technologies to be assessed in a given year to be matched against staff levels; and fourth the financial resources needed for this purpose. As a rule of thumb, for a comprehensive review of up to 40 new health technologies in any given year, the minimum staff levels approach 25 experts on a full-time basis, without taking into consideration appeals, re-assessments, multiple HTAs "triggered if two or more compounds are on the market for a specific indication", contact with the verification of the arrangements made by the Negotiation Committee, and correspondence with market authorisation holders (MAH), among others. This also assumes a mix of skills ranging from pharmacy, pharmacology, clinical medicine, statistics and economics. For the HTA recommendations to be appropriately implemented, disseminated and monitored and for clinical guidance to be produced and/or updated, there are additional requirements in staff as well as direct collaboration with academic centres of excellence.

Timelines

HTA should be a dynamic and continuous process. The Greek HTA process does not seem to be so for three important reasons: assessment timelines, re-submission timelines, transparency of process. First, the target of completing an assessment in 180 days seems very optimistic, considering (a) the small number of reviewers, (b) the multiplicity of institutional stakeholders, who are not always cooperating well, and (c) the verification process by the HTA Committee on what the Negotiation Committee has approved. The time allocated and required to complete an assessment varies between HTA agencies in different countries. Timelines for a standard appraisal by

NICE in the UK, for example, range between 290–350 days;[4] it is also important to underscore that NICE assesses fewer products than the Greek HTA Committee aspires to, has a significant number of staff, a reasonable operating budget, and operates a thorough and deliberative process. The Greek timelines, given the scope of the technologies to be assessed, are slightly unrealistic: If an assessment takes an average of 30 days from start to finish (15–45 days in legislation) and if 40 technologies are assessed in a given year, it will probably take a minimum of 2 years to address these sequentially assuming a team of four reviewers per case and no appeals submitted by the MAH.

Second, in terms of the re-submission timelines, in case of a negative recommendation, the manufacturer has the right to submit a new dossier only after 6 months following a negative recommendation. However, the 6-month limitation has no apparent justification and is assumed to be a minimum time requirement for evidence –whether new or existing– to be (re-)packaged; as such, it could be perceived as an unnecessary barrier to entry.

Third, as negative recommendations are not published but are only implied, the time when a manufacturer can re-submit is somewhat vague and unclear. Importantly, this provision breaches the transparency of process principle in that no feedback is given to applicants on the reasons for the negative recommendation and what improvements would need to be made upon re-submission.

Appeals

The law rightly makes provision for an appeals process but fails to provide timelines for their conduct and completion. Because of that, appeals threaten to be a never-ending process with no commitments made from the side of the legislator. Additionally, guidance is missing on who examines the appeal, what the criteria are or if there is arbitration as part of the process. To ensure transparency and fairness, the appeals process should be completely independent, and the timelines should also be clear. From an international perspective, an appeal is handled over a period of 30–45 days.

Stakeholder engagement

The law seems to disallow different stakeholders from engaging with the process. Stakeholder engagement involves two separate components that fulfil different objectives: early engagement –in the context of offering scientific advice– and engagement with the assessment process.

Contrary to what other HTA bodies do, such as NICE, HAS or IQWiG, no early engagement and communication between the HTA Committee and the stakeholder community (particularly MAHs) is provisioned in the Greek legislation. This is usually an important provision, particularly for MAHs when they are finalising their evidence generation and preparing for submission. One might argue that this provision may be beyond the current HTA Committee's remit, but to the extent that explicit value assessment rules are made, it would also be important for this flexibility to be part of the new process.

With regards to opportunities to engage with the assessment process itself, the law does not make any provision for engagement by the MAH; there is no hearing process before the HTA outcome, neither is there an opportunity for MAHs to present their case. MAHs are informed only in the case of a positive assessment in order to proceed to the negotiation process, and if this does not happen after 180 days, then a rejection is implied. The role of physicians and patient representatives is also missing from the Greek HTA process, despite being vaguely mentioned in the law.

Beyond submissions made by MAHs, stakeholders such as patient groups should be able to actively submit evidence, comment on draft reports and the rationale for the final decision and remain involved during the review process. The same holds for re-assessments. At a more advanced level, the HTA Committee should accommodate requests for meetings by specific stakeholders.

Methods of clinical assessment

The clinical assessment is rightfully focuses on three key aspects: data quality, added therapeutic value and innovation level. However, there is always a danger that the methods and tools that have been included as part of the assessment may duplicate effort. One wonders what purpose the adoption of these different methods and tools serves, and what their respective weight is.

Data quality will be informed by the GRADE criteria, a method for assessing the quality of evidence in clinical trials. Although GRADE is widely used, it does require some training and experience, and the credibility of the new system will be dependent on the ability of its assessors to implement it.

To determine the added therapeutic value, the Greek HTA legislation seems to be adopting IQWiG's system to determine the extent of an effect. The level of evidence for an additional benefit is assessed based on four levels, and the extent of added therapeutic value is assessed as

major, significant, marginal or non-quantifiable. While the German system continues a step further to the appraisal of the technology concerned, the Greek HTA Committee is only focusing on assessment. In Germany, the extent of the therapeutic value defines if the medicine will undergo a negotiation or it will be automatically included in a reference basket. Such an appraisal is not explicitly included in the Greek case, and all products with a positive recommendation from the HTA Committee are automatically subject to a negotiation procedure. However, there are inconsistencies in the law, as in the same FEK[2] one article (article 6, §12) suggests that the Negotiation Committee process is mandatory, while another (article 11, §3) implies that there may be an involvement of the Negotiation Committee, but this would be at the discretion of the HTA Committee,[2] and, therefore the negotiations process is not mandatory for all products with a positive recommendation.

The new Greek system also adopts the Ahlqvist-Rastad system, a five-category system to define "the level of innovation" of medicines. This rating system coincides with the rating system of the added therapeutic value, and there is a risk of duplication of effort by the HTA Committee. Again, there is no explanation for this choice or the way this methodology should be approached and applied. The Ahlqvist-Rastad system is not described in the methodology section of the legislation, but it is only requested from the MAH in the "Instructions to manufacturers", where a table of the rating system is provided for MAHs to complete and include in their dossiers. It is unclear how Ahlqvist-Rastad counts towards any recommendation or indeed the purpose for including it. The range of criteria used to inform the ranking of products need to be clearer and more explicit and the current legislative framework avoids providing an obvious explanation. As a thought, the Ahlqvist-Rastad method could be used to prioritise products in an A- and a B-list, the former constituting top priority for assessment, the latter to be placed in a waitlist.

Appraisal

Appraisal, as a concept, is very nebulous in the current legislation; it is not clear what role, if any, other criteria or considerations may have in the HTA process, beyond additional benefit. Yet, there are a number of tradeoffs, which are both relevant and important in this context. First, beyond value assessment based on GRADE, the HTA Committee needs to decide where a new technology fits within a disease or therapeutic pathway and, in so doing, what actual need will it fulfil. For example, and based on GRADE criteria, it could be the case that the award of a low rank may need to be weighed against unmet need. Second, the law implicitly assumes that all drugs should be treated equally; while the basic premise behind this argument is valid, the HTA Committee may come to realise that, *sensu stricto*, some drugs may be more valuable to the health care system than others; for example, should one prioritise or assess drugs offering symptomatic relief in the same way as drugs that have a demonstrable effect on reversing or curing disease? And how drugs that prevent disease should be treated? Third, in an environment where a large number of potentially valuable and life-saving new therapies may come to market in the near future, it may be necessary to introduce stricter criteria to determine whether a drug receives the top rank on the evaluation scale. For example, only drugs that demonstrate significant impact on a clinical endpoint (e.g., reduction in mortality) and in the context of a severe disease could be awarded the top rank. Fourth, apart from the clinical and economic value assessment criteria, other non-elicited considerations, the so-called social value judgments that many HTA agencies in Europe are using, and which are often instrumental in achieving coverage in other settings, are missing.[8] There are some elicited special considerations taken into account (e.g., burden of disease), but other social, ethical and legal parameters are, broadly speaking, absent. Fifth, an important function of HTA Committees or Agencies is to make decisions that reduce uncertainty; this frequently implies restricting the use of new medicines to appropriate subgroups. It is not clear how this will be achieved in the context of the current regulation.

Unless the HTA Committee takes the above considerations seriously into account, the danger is that drugs will be assessed for the sake of being assessed; that there will be inadequate understanding of where new drugs fit into the therapeutic continuum, and, as a result, there is a risk that the benefits from HTA will not be diffused into health care delivery and resources will still continue to be used inefficiently.

Economic evaluation

The role of economic evaluations in the new HTA process is unclear; although not outlined in the methodology, cost-effectiveness analysis (CEA) is requested in the "Instructions to manufacturers". Nevertheless, it is unclear how CEA would be conducted in Greece, as the epidemiological and costing data are inadequately captured and registries are not available with very few exceptions. A number of short-term actions must be made in order for this to happen in the future. For instance, at least in the short-term, cost data

will need to be based on national data/evidence, where available. A health system –rather than societal– perspective is recommended, unless a broader perspective can be justified; admissible costs will include direct medical costs and may include direct non-medical costs only if they are relevant to the intervention. Indirect costs can only be included if their relevance to the intervention is proven. In order to enable a more systematic use of clinical and cost-effectiveness analysis, a database of unit costs needs to be put in place, which will be updated regularly in order to enable decision-makers and suppliers to have access to local cost data.

Monitoring and implementation

The Greek HTA law outlines a process of implementing recommendations automatically, including newly approved medicines into the reimbursement list and incorporating these into prescribing protocols with mandatory uptake by prescribing physicians. What is unclear and most likely missing, however, is an understanding of how specialty drugs, an ever-increasing proportion of newly approved technologies, fit along clinical/therapeutic pathways, which are often "congested" from the availability of therapeutic alternatives. Most medicines that receive positive recommendations do so on the basis on numerous restrictions in their use; one of them relates to availability to specific patient subgroups only, which practically, implies a restriction in the indication; another relates to restrictions regarding the positioning of the new medicine along the therapeutic pathway and stages of the disease they are meant to treat. A further omission relates to the monitoring of the implemented guidelines and assessment of their impact.

Consequently, issuing clinical guidance based on the outcome of the HTA process –once this is completed– and the mandatory uptake of such guidance by prescribers are necessary essential steps towards optimal resource allocation, but not sufficient ones. Addressing the positioning of new medicines along treatment pathways, monitoring their use and assessing the impact they have, are critical next steps towards linking the supply –with the demand– side and ensuring appropriate use of medicines.

Link to the Negotiation Committee

The current legislation does not make any reference to the tools that may be used in the negotiation process and neither are the negotiation principles mentioned in any meaningful detail. The responsibility of the Negotiation Committee is to negotiate prices and discounts, but it is not clear what types of agreements are considered (financial, outcomes-based, or a combination of the two). Importantly, as the HTA Committee relies on the ability of the Negotiation Committee to deliver its verdict in a timely fashion for it to be validated and for a final recommendation to be made to the Minister of Health, the law should make provisions for the timelines between the two committees.

Coordination and inter-operability across institutional stakeholders

A final aspect –strictly speaking not related to the HTA legislation– is to ensure the inter-operability of all those institutions that are connected with this "new" infrastructure, notably, EOF, the HTA Committee, the Negotiation Committee, EOPYY and other organisations which may be related to this process, such as HDIKA, the state-owned body that stores prescribing data. Previous experience suggests that there is lack of collaboration, coordination failures, and significant bureaucracy, all of which need to be addressed urgently. Failure to do so would mean that the credibility of the HTA Committee will be called into question and potentially fall into disrepute: In that context, Greece would certainly want to avoid a situation similar to the tobacco ban, where a very good piece of legislation is all but defunct due to poor implementation.[9]

CONCLUSIONS

There is a vision attached to every reform. In the context of HTA, the vision is to improve efficiency in the use of scarce resources as well as access to treatment and, through that, contribute to the goal of universal health coverage. In the context of the HTA reform, legislators should pay attention to the issues identified in this paper as well as try to link the HTA outcome with clinical and prescribing guidance. They should try to leverage evidence that comes from local registries and set these up; and they should safeguard and enhance the status and credibility of the new institution. This requires bold initiatives; only if the above become possible, will the Greek HTA deliver what is purported to as well as stand a chance of becoming a centre of reference and excellence in the broader geographical region.

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