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# Health Technology Assessment in Sweden, France, Bulgaria, and Greece. the Seniors, the Junior, and the Newborn Htas

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## Abstract

**Purpose:** We compared the Greek Health Technology Assessment- HTA with the European organizations, in Sweden, France, and Bulgaria.

**Design/Methodology/Approach:** The HTAs in Greece, Sweden, France, and Bulgaria were described and compared according to the definitions of Health Technologies, Health Technologies Evaluation (HTA), and their specific characteristics in Europe. The data was mainly extracted from ISPOR, INAHTA, and EUnetHTA and were presented in detail and in tables.

**Findings:** To achieve HTA's objectives in Greece, the principles of recent legislation should be applied and the best elements of existing European HTAs should be selected to "reclaim" the delay in the creation of the Greek HTA.

**Keywords:** Health Technology Assessment; HTA; Health Expenditures; Access in new technologies

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## Introduction

Modern societies have limited financial resources to cover the increased health needs of their members. The technological progress made today has a decisive role in the reduction of morbidity and mortality and leads to an increase in an average life and quality-adjusted life expectancy.

To achieve "Pareto efficient" allocations of health, modern societies must sacrifice as little as possible the well-being of some citizens to increase the well-being of some others with health problems. This need has led policy decision-makers to seek robust evidence on the effects of health technologies, in terms of both resource use impacts and public health consequences and has ultimately led them to develop independent technology assessment (HTA) organizations [1].

HTA aims to evaluate new medicines and some new medical devices, providing common clinical and economic assessments in these areas. Countries with HTA can use common HTA tools, methods, and procedures and cooperate, while countries without HTA are responsible for assessing non-clinical (e.g. economic, social, ethical) aspects of health technology and for making decisions on pricing and compensation [2]. Greece only 3 years ago (2018) established the HTA committee [3].

The purpose of this work is to describe and compare the Greek HTA with the respective HTAs of Sweden, France, and Bulgaria. The choice of countries was made because both Sweden and France are pioneers in the HTA organization and also are 2 of the nine countries that are considered as reference countries for drug compensation in 4512/2018 Greek low and Bulgaria has a recent HTA [3,4]. Sweden is the first country to acquire HTA in Europe in 1987 and France followed in 2005 [5,6].

## Methodology

This study reviewed the literature and the local legislation in the scope counties. The review was conducted in late 2021 and thus, reflects the effective legislations for the corresponding period. This review is structured as follows, firstly the definitions of health technologies and health technology assessment are given and the procedures that define the context of HTA organization are defined. Subsequently, the Greek, Swedish, French, and Bulgarian HTA are described. For Sweden the information was given from the Swedish Council On Technology Assessment In Health Care (Statens Beredning for Utvardering Av Medicinsk Teknologi- SBU),[5] for France from the National Authority for Health (Haute Autorité De Santé - HAS)[6] and for Bulgaria from National Council at Prices and Reimbursement of Medicinal Products (NPRC)[7,8]. In the third chapter, Greek HTA, and the other three HTAs are compared, and finally, conclusions are drawn regarding the newly established Greek organization and the "experienced" European ones.

### Definition of Health Technologies and Health Technology Assessment

Health technology is defined as an intervention that can be used to promote health, prevention, diagnosis, or treatment of acute or chronic diseases or for rehabilitation. Health technologies include pharmaceuticals, devices, procedures, and organizational systems used in healthcare [1]. Health technology assessment is the systematic evaluation of the properties, effects, and/or effects of health technologies and medical interventions. It covers both the immediate, intended effects of technologies and interventions and their indirect, unintended consequences. HTA can be used to inform political leadership and to make decisions in the field of healthcare, regarding the best way to allocate limited resources for interventions and health technologies. Interdisciplinary groups using explicit and analytical frameworks, utilizing clinical, epidemiological, and economic and other health information and methodologies carry out the evaluation. The results can be applied to interventions such as the introduction of a new drug into a compensation program, the development of broad public health programs (such as immunization or cancer screening), and the setting of priorities in healthcare [9-11].

### Health Technology Assessment Procedure

When conducting an HTA, the corresponding health technology is objectively evaluated by a transparent and systematic process, based on the best available data. A key aspect of HTA is considered the interdisciplinary approach.

Countries with HTA can use common HTA tools, methods, and processes and collaborate in four key areas:

(1) Joint clinical evaluations focusing on the most innovative health technologies with more likely effects on patients.

(2) Joint scientific consultations, by which developers may request advice from HTA authorities.

(3) On the identification of emerging health technologies for the timely identification of promising technologies and

(4) To continue voluntary cooperation in other areas.

Countries without HTA have "primitive" tools for the evaluation of non-clinical (e.g. economic, social, ethical) aspects of health technology and for making decisions on pricing and compensation [2,12].

Depending on the theme and scope of the HTA report, data on **effectiveness, security,** and economic **efficiency**, as well as ethical**, social, legal, and organizational impacts**, shall be assessed. We could say without exaggeration that HTA is bridging the gap between scientific research and market or more simply between the research lab and the pharmacy counter.

The HTA studies are based on the collection of a wealth of data and the construction of economic tools such as Budget Impact Models (BIM), Cost-Effectiveness (CE) models, or Cost-Utility (CU) models that consider the impact on patients' quality of life. Budget impact models show the extent to which new technology is expected to increase or reduce the total annual expenditure of the National Health Organization for the treatment of this disease. Cost-effectiveness and cost-utility studies measure how many years of life, on average, the patient earns because of an intervention (e.g., a drug) with the financial burden per patient resulting from this intervention for the state. Typically, years of life are adapted based on Quality Adjusted Life Years (QALY) or Disability Adjusted Life Years (DALY). When an HTA system is active in a country, the competent bodies may decide what the "acceptable limit" will be for a "product" and this decision varies considerably from country to country [13,14].

## History of Health Technologies' Evaluation

Over the past 30 years, several European countries have created specific bodies and developed various HTA implementation programs. However, there are significant differences between the national HTA services between the Member States of the European Union (EU). The different philosophy of these organizations is the result of political, social, and economic factors that European health systems have developed [15]. The Article 168 of the Treaty of the Functioning of the European Union (TFEU) (2008) defines the functioning of HTA in the EU and in April 2019 was supplemented by legislation aimed at facilitating common evaluations, saving costs and time, and enhancing cooperation between countries in the field of health technology evaluation. Sweden (the first HTA organization in Europe), France, the United Kingdom, and Germany are considered leaders in the introduction of HTA in Europe and also have a very strong influence on the methods and tools applied to HTA and its use in policymaking [16,17].

## The Evaluation of Health Technologies in Greece

In Greece until January 2018, there was no HTA institutionalized body. According to N4512/2018 low, this year an Evaluation and Compensation Committee and a Negotiating Committee were established [3].

The Evaluation and Compensation Committee has 11 members and has 2 tasks:

• The evaluation of medicinal products authorized and circulated in Greece and thereafter.

• The review of an opinion for the medicinal products to the Minister of Health, in order to decide on (a) the inclusion or release of medicinal products from the Positive List in Article 12 of Law 3816/2010 (A'6) (List of Reimbursed Medicines) and (b) the revision of the List of Reimbursed Medicines.

The Minister of Health may decide differently from the opinion of the Evaluation Committee for specific reasons [3]. The main criteria used by the Commission for the evaluation of medicinal products are:

(a) Clinical benefit such as this is assessed considering the severity and the burden of the disease, the effect on mortality and morbidity indicators, as well as safety and tolerability data.

(b) A comparison with medicines already available.

(c) The degree of reliability of clinical studies data.

(d) The cost/effectiveness ratio.

(e) The impact on the budget.

The opinion of the Evaluation Committee to the Minister of Health for the inclusion of a medicinal product in the List of Reimbursed Medicines shall include the specific therapeutic indication for which will be compensated, and informations

about pharmaceutical forms, dosages, and contents. Together with each therapeutic indication, the review should include the clinical patient's characteristics for whom the drug is proposed to be compensated, the stage of the therapeutic line (the therapeutic algorithm) for which the drug is proposed to be compensated, as well as the size of the population, to which the treatment can be applied to assess the impact on the budget.

Pharmaceutical products in a period of protection of their data, already authorized are subject to an assessment and are included in the List of Reimbursed Pharmaceutical Products only if:

- Shall be compensated in at least two-thirds (2/3) of the EU Member States markets.

- Shall be marketed in at least nine (9) countries and at least half of them are in the following list: Austria, Belgium, Great Britain, France, Spain, the Netherlands, Portugal, Sweden, and Finland.

The following products that shall be excluded from the application are: (a) medicinal products authorized as orphan medicinal products only if they are covered by international protocols (b) the medicinal products of Thalassemia, (c) the vaccines referred to in paragraph 5, Article 2 of Regulation 3a/G.P.32221/2013 (B΄1049), etc., (d) medicinal products based on human blood or blood plasma as defined in paragraph; 11 of Article 2 of No 11 of the Year 2004, in the D.Y.Y.3a/G.P.32221/2013

The Nine-Member Negotiating Committee shall have the responsibility of:

- Negotiate the prices or discounts of medicines, which are compensated by the E.O.P.Y.Y. or procured by public hospitals.

- Conclude agreements with the Marketing Authorization Holders (MAH) involved in the relevant negotiation procedure as to the above subject of the negotiation.

- Recommend to the Evaluation Committee on the impact on the budget of the compensation of medicinal products.

Agreements concluded between the Compensation Committee and the Marketing Authorization Holder shall become binding on the E.O.P.Y.Y., the MAH, and public hospitals after the entry into force of the decision of the Minister of Health on the inclusion or exclusion or revision of the List of Reimbursed Medicines, provided that in the relevant decision the Minister of Health accepts the opinion of the Evaluation Committee incorporating the above recommendation of the Negotiating Committee.

In July 2018, the two committees (evaluation and negotiation) provided by low N4512/2018 were set up [18,19]

## The Evaluation of Health Technologies in Sweden [5].

In 1987, the Swedish Minister for Health created and financed the Swedish Council for Health Care Evaluation (Statens Beredning for Utvardering av Medicinsk Teknologi, SBU). SBU which became a governmental agency in 1992, is headed by a Board of Directors, (15 persons) representing key organizations, both in the Swedish healthcare system and in social services. Scientific Advisory Committees (10 persons in each one) provides specialist expertise.

The Government's main incentives for establishing the SBU included

(i) concern about the increasing cost of healthcare

(ii) The need to speed up the dissemination and use of new, efficient, and cost-effective technologies to increase access and quality of care

(iii) To obtain reliable scientific information on the value of the established and new technology in medicine as a basis for defining priorities in healthcare.

The government's instructions to the SBU in 1987 were as follows:

❖ The Agency should provide evidence of information on health technology issues contributing to health policy and practice and inform the public.

❖ The Agency did not have any regulatory purpose.

❖ The Agency must compose the research data and understandably present this information even to the public.

❖ The Agency must focus not only on medical issues, but also on the economic, ethical, and social impact of the various technologies, procedures, and programs for the prevention, diagnosis, and treatment of diseases and disabilities.

❖ Its functions should include measures to disseminate the findings of the research.

Today the government's instructions to the SBU are not very different: The SBU is instructed to make scientific assessments of new and established health technologies from a medical, economic, social, and moral perspective. The organization must present and disseminate these assessments so that both health care providers and others can use their findings and assessments. The organization evaluates how the findings have been used and what results have been achieved.

The government appoints the Chairman of the Board of Directors (CBD), and a 10-member board representing the clinical, scientific, management, and policymaking in health. The CBD shall appoint a scientific advisory committee of fifteen members representing various fields, for example, basic and applied medical research, clinical medicine, nursing, epidemiology, economy, management, administration, and public health.

The SBU receives proposals from a variety of sources for evaluation plans, for example, individuals, organizations, government agencies, and other decision-making bodies. The SBU's scientific advisory committee also recommends issues for a new evaluation. The Department of Health may requires the SBU to conduct specific evaluations. Among the topics are:

(i) there must be a scientific basis for evaluation

(ii) The subject must be of great importance for people's health and quality of life

(iii) must concern many people, and/or be a common health problem and/or have significant economic, ethical, organizational, or human consequences;

(iv) Indications of amendments in practice

The Board often prioritizes important health sectors including all technologies used, for example, in the prevention, diagnosis, and treatment of alcohol and drug abuse, back pain, depression, obesity, hypertension, asthma, dementia, and chronic pain.

The SBU's evaluations include, in short, the following:

(i) a systematic review, based on clearly defined protocols on inclusion and exclusion criteria and for the classification of evidence presented in all relevant studies in international literature, i.e. clinical studies, financial evaluations and studies dealing with other issues related to the subject, such as nursing, ethics, and social aspects;

(ii) A synthesis of the findings, including recommendations on health policy and practice.

The SBU regularly reports the results of all its assessments to the Ministry of Health and occasionally refers to the Social Affairs Committee in the Swedish Parliament. An annual report, including the final plans and their impact on health policy and practice, is sent to the Ministry of Health. In reviewing the annual report, the Ministry may or may not propose changes to the SBU's plans regarding government priorities in the field of health care.

SBU studies are usually cost-benefit studies. These are studies of excellent accuracy and validity, but the evaluation system is very time-consuming and can take up to 3 years to evaluate Health Technology.

## The Evaluation of Health Technologies in France [6].

In 2005, the French National Authority for Health (Haute Autorité De Santé -HAS) was founded in France. HAS is a public body that operates independently from the government, responsible for the evaluation of medicines, appliances and medical equipment, surgical interventions, and biological examinations. It was formed by the merger of ANAES (French National Agency for Accreditation and Evaluation in Health), the Transparency Committee, and the Committee for the assessment of devices and health technologies (CEPP) – two committees previously run by AFSSAPS (Agency for the Safety of Healthcare Products) – and FOPIM (Fund for the Promotion of Medical and Health Economics Information). The objective was to bring together into a single body all the expertise needed for patient-centred continuous quality improvement. HAS is governed by a board of eight members responsible for setting our strategic priorities and policies. The Board Chair is appointed by the Head of State. There are eight specialist committees, each chaired by a Board member. Each Board member is responsible for the policy, strategy and executive powers of their committee,

and sets up working groups. Each Chair is supported by an operational manager who reports to the Director of HAS.

HAS manages an accreditation program with 775 inspectors performing accreditation visits. HAS certifies that doctors are specialized in practice and provides information to national health and insurance related to service coverage and compensation. However, the Ministry of Health makes decisions on pricing and coverage. According to HAS, three principles are of paramount importance in its work: scientific rigor, anticipation, and discretion. The main criterion for a positive recommendation is the therapeutic benefit of the drug and the results of the evaluation are used to negotiate "fair" prices for social security. An interesting new approach by HTA in France is to certify sources of information, such as specific websites on the internet.

**The Evaluation of Health Technologies in Bulgaria [7].**

In Bulgaria, the respective agencies were set up in 2013 and consist of a subordinate unit or department within the Ministry of Health. The Health Technologies Assessment in Bulgaria is carried out by the National Council on Prices and Reimbursement of Medicinal Products (NPRC) in December 2015 and entered into force in April 2019 (committee on HTA). NPRC is responsible for the inclusion and exclusion of pharmaceutical products on the Positive Drugs List (PDL), as well as its amendments. The purpose of the HTA is mainly to optimize resources for technologies such as medicines that the Marketing Authorization Holder (MAH) applies for a refund [20].

In Bulgaria, the HTA Committee critically evaluates the application and provides a recommendation to advise the final decision-making body. A common key feature is the evaluation of the added therapeutic value compared to existing alternatives. Bulgarian HTA is consulted on the decisions of other European HTA bodies but especially the final decisions of the HTA bodies in the United Kingdom, France, and Germany are considered important for the final affirmative or negative decision. The main tool used for the final decision is a scorecard [21].

The results of the budget impact analysis are also important for the final decision. The budget impact of introducing a new drug into the health system is valuable for assessing the economic impact and, consequently, of whether the product will be included in the health basket. Even though specific appraisal criteria representative of their health system is set, their ultimate objectives often remain unclear, which could lead to a lack of transparency [22].

NPRC decisions are based on legislative requirements of the Law for Medicine, the Health Insurance Act, and related regulations. Overall inclusion PDL takes at least 60 days. Adapted or locally prepared pharmacoeconomic analysis, as well as budget impact analysis, must be part of the company submission. No HTA guidelines have been published yet. Company submissions received by NPRC are assessed by external experts in pharmacoeconomics, appointed by the minister of health. Current requirements for gaining reimbursement are:

(a) a registered price in Bulgaria

(b) a positive reimbursement decision in at least 5 EU countries

(c) favorable results from pharmacoeconomic analysis submitted with the application.

Only medicinal products included in the PDL can be reimbursed by public funds. Once a product has a marketing authorization it must have its price registered, for over-the-counter (OTC) products, or regulated, for prescription medicines. Pharmaceutical products for retail sales are subject to maximum price registration. The maximum price of a prescription product (referred to as ''approved ceiling price") is subject to regulation and approval by the NPRC. To obtain approval, the manufacturer or holder of the marketing authorization must submit to the NPRC an application detailing the elements included in the ceiling price. The decision is based on experts' opinions. Since its establishment, the NPRC has assessed 271 medicines included in the PDL; detailed reports are not publicly available. The level of payment for medicinal products with the same international nonproprietary names and the same formulation reimbursed by the National Health Insurance Fund is determined by the abovementioned HTA criteria. Clinical efficacy, safety data, and results from health economics analysis are considered. The Pricing and Reimbursement Committee evaluate submissions [23].

## Comparison of Health Technology Evaluation Bodies in Greece, Sweden, France, and Bulgaria Policy Implementation Level

The main characteristics of the level of execution policy for the countries concerned are shown in Table 1. It should be stressed that the Greek HTA has been defined in its legal framework two years ago but only recently implemented in practice [18]

France HTA institutions are public bodies operating independently of the government, while the respective organization in Sweden (SBU), Bulgaria (the NPRC), and Greece, are government agencies [18,24]. All HTA agencies were set up by government bodies as part of broader reforms under evidence-based medicine principles, improving the safety and quality of care, as well as and promoting equality and efficiency in the use of health care budgets.

**Table 1:** HTA System Components: Policy Implementation

| Item | Greece | France | Sweden | Bulgaria |
|---|---|---|---|---|
| **Establishment: Relationship with the MoH and other organizations** | Committee for the Evaluation and Compensation of Medicinal Products for Human Use and Committee for the Trading of Prices of Medicinal Products (2018)<br>Government service | HAS (2004) Autonomous public scientific authority Established by the Ministry of Health | SBU (2002)<br>Government Service | NPRC (2015)<br>Under the supervision of the MoH |
| **Objective: Broader political objectives** | The opinion is issued to the Minister of Health, following an evaluation of the medicinal products authorized and circulated in Greece | Provide health authorities with the information required to make decisions on compensation for health technologies, to improve the quality of care, to provide information to the public on the quality of care, to provide health economy assessments and opinions on the most effective strategies for healthcare, prescribing or management | Acting on the pricing and compensation of medicinal products,<br>review of medicinal products already returned,<br>improvement of the quality of the pharmaceutical care provided supervision of certain areas of the pharmaceutical market | Sets price limits for prescription drugs, records the maximum retail prices, and<br>decides on the inclusion, amendments, or exclusion of pharmaceuticals from the positive list of medicinal products |

| | | | | |
|---|---|---|---|---|
| **Application: Scope** | All licensed medications, 726/2004/EC (OJ L 136), are subject to an assessment and are included in the List of Repensating Medicinal Products only if they are compensated at least two thirds (2/3) of the European Member States and should not be less than nine (9) and at least half of them should be: Austria, Belgium, Great Britain, France, Spain, the Netherlands, Portugal, Sweden, and Finland. | All new medicines marketed (clinical evaluation).<br>From October 2013: financial evaluation for all new innovative medicines with a possible significant impact on health spending or on the organization/provision of health care | New medicines marketed applying for compensation<br>All medicines included in the benefits system before 2002 | For newly marketed innovative medicines, products not included in the positive drug list |
| **Implementation: Role in the final decision-making** | Published in the Gazette as state law | Recommendation Final return decision: UNCAM and MoH | Final decision with legal force | Recommendation Final decision: MoH |
| **Transparency** | It is posted on the E.O.F. website. | The final evaluation report and the decision are published on the HAS website | Decisions and evaluation reports are available to the public | The decision and assessments are not available to the public |

SBU: Statens Beredning for Utvardering av Medicinsk Teknologi -Swedish Council on Technology Assessment in Healthcare, HAS: Haute Autorité de Santé -National Authority for Health, UNCAM: Union National des Caisses d' Assurance Maladie (French National Union of Health Insurance Funds). MoH: Ministry of Health, EOF: National Medicines Agency, NPRC: National Pricing and Reimbursement Council

Sources: 1.AlexandraBeletsi (2018) Comparing Use of Health Technology Assessment in Pharmaceutical Policy among Earlier and More Recent Adopters in the European Union, 2. Law 4512/2018 - Government Gazed 5/A/17-1-2018 ( Articles 239 - 406)

## Technology decision level

The main findings on the level of technology application for the countries concerned are presented in Tables 2 and 3.

**Table 2**: HTA system data: technological decisions of Greece, France Sweden, and Bulgaria: evaluation and evaluation

| Item | Greece | France | Sweden | Bulgaria |
|---|---|---|---|---|
| **Competent body (preparation, processing, and reporting)** | MoH, Greek HTA | HAS | SBU/ and/or Swedish health assessment and evaluation service | NPRC |
| **Competent body** | Committee for the Evaluation and Compensation of Medicinal Products for Human Use | Department of Drug Evaluation (clinical evaluation) Department of Economic and Public Health (economic health assessment) | SBU Workgroups | Expert opinion: HTA Committee |
| **Competent body / committee** | Greek HTA | Committee on Transparency (compensation) Economic and Public Health Assessment Committee CEPS (pricing) | SBU Council on Pharmaceutical Benefits | Expert opinion |
| **Clinical data/safety** | Yes | Yes | Yes | Yes |
| **Relative efficacy** | Yes | Yes | Yes | Yes |
| **Economic analysis** | CBA/CEA/CUA | CEA / CUA (tidy) | CEA/CUA, cost comparison, cost, depending on the treatment | CEA/CUA |
| **Evaluation criteria** | Clinical benefit,<br>Comparison with the medicines already available.<br>Degree of reliability of clinical studies data.<br>Cost/efficiency ratio.<br>Impact on the budget. | Clinical benefit, disease severity availability of other treatments. Purpose of use (preventive, symptomatic, or therapeutic)<br>Effects on public health.<br>Cost/efficacy ratio<br>Prices in European countries | Principle of human value<br>Principle of need and solidarity<br>Principle of cost-effectiveness<br>Negative disease<br>Managed entry agreement between country councils and pharmaceutical company | Scorecard with specific criteria:<br>•Clinical effectiveness and safety<br>•Economic evidence<br>•Budget impact analysis<br>Opinion in France, the United Kingdom, and Germany<br>HTA assessments of other EU countries |
| **Minimum cost / QALY** | Not | Not | Not | No |
| **The evaluation report is available to the public** | Yes | Yes | Yes | No |

HTA: Health Technology Assessment, SBU: Swedish Council on Technology Assessment in Healthcare, HAS: Haute Autorité de Santé -National Authority for Health, MoH: Ministry of Health, NPRC: National Pricing and Reimbursement Council, CBA: cost-benefit analysis, CEA: cost-effectiveness analysis, CUA: cost-utility analysis Sources: 1. Alexandra Beletsi (2018) Comparing Use of Health Technology Assessment in Pharmaceutical Policy among Earlier and More Recent Adopters in the European Union, 2. Law 4512/2018 - Government Gazed 5/A/17-1-2018 ( Articles 239 - 406)

**Table 3:** Elements of an HTA system: decision, appeal, and implementation

| Item | Greece | France | Sweden | Bulgaria |
|---|---|---|---|---|
| **Decision-making body** | MoH<br>E.O.P.Y.Y. | UNCAM<br><br>MoH, CEPS | SBU | MoH according to the recommendation of NPRC |
| **Type of decision** | MoH<br>E.O.P.Y.Y. | UNCAM /MoH compensation level/inclusion in the CEPS positive list / pricing | SBU / Joint Decision on refund and pricing | NPRC/ reimbursement and pricing |
| **Stakeholder participation** | Yes | Yes | Yes | No |
| **Possibility of limited compensation (i.e., Defined indications, patient groups, and arrangements) or managed entry agreements** | Yes | Yes | Yes | Yes/No |
| **Application / disagreement** | Yes | Yes | Yes | Yes |
| **Revisions / reassessment** | Yes | Yes | Yes (drugs before 2002) | No information found |

E.O.P.P.Y.: National Health Service Organization, SBU: Statens Beredning for Utvardering av Medicinsk Teknologi -Swedish Council on Technology Assessment in Health Care, HAS: Haute Autorité de Santé -National Authority for Health, UNCAM: Union ***National des Caisses d' Assurance Maladie*** (French National Union of Health Insurance Funds), NPRC: National Pricing and Reimbursement Council, MoH: Ministry of Health, CEPS: ***Comité 'Economique des Produits de Santé*** -Financial Committee on Health Products

Sources: 1.AlexandraBeletsi (2018) Comparing Use of Health Technology Assessment in Pharmaceutical Policy among Earlier and More Recent Adopters in the European Union, 2. Law 4512/2018 - Government Gazed 5/A/17-1-2018 ( Articles 239 - 406)

## Evaluation and implementation

The type of evidence required is similar in all principles. The data on clinical efficacy, relative clinical efficacy, safety, target population, characteristics of the disease and the availability of other treatments for the same indication and so on are part of the evidentiary approach. Both Sweden and France have published guidelines describing documentation and methodological requirements for technology implementation but neither Bulgaria nor Greece have clinical guidelines published. However, there are differences in critical points, such as the selection of prioritization criteria for technologies, the quality of the required documents, and the methodological approaches used [25,26].

The health economic analysis has recently been included as a requirement in the HTA process of medicinal products marketed in France. These products are classified as innovative and are expected to have a significant impact on costs and healthcare provision. The results of the health economic analysis, apart from the decision on added therapeutic benefit, form the basis of the price negotiations with the MAH. In France and Sweden, internal staff based on the dossier submitted by the MAH prepare the evaluation report. However, additional evidence may be gathered through a systematic literature review and/or consultation of interested parties. The evaluation is carried out by committees or councils incorporated into HTA. In France, the main criterion for a positive recommendation is the therapeutic benefit of the drug. In Sweden, cost-effectiveness is an important criterion that is explicitly considered during the evaluation phase. In Bulgaria and Greece, both the therapeutic benefit and the cost-effectiveness are described as very important criteria [27,28].

### Decision

Sweden is the only country where there is a joint decision on Pricing and Reimbursement (P&R). In France, another body takes the final decision considering the outcome of the evaluation phase. In France, the assessment of the clinical benefit by the French National Health Authority is used by the ***Union National des Caisses d'Assurance Maladie*** (French National Association of Health Insurance Funds), which is responsible for return decisions. In Sweden, the decisions of the HTA organizations carrying out the evaluation are final and mandatory for regional or local authorities. In all countries, the decision may be positive or negative or the refund may be granted with restrictions (e.g., for specific indications or specific patient groups). A decision on the provisional refund may also be made due to uncertainty about the evidence provided if additional evidence is gathered. Generally, in Greece and Bulgaria, the Ministry of Health is taking the final decision [29,30].

## Results

In all countries, the application of the decision relates mainly to the rate of reimbursement or the price of the medicinal product. In France, the drug is included in a positive list of refunds, and price negotiations begin. In Sweden, regional councils have some discretion in implementing the decisions taken by the Dental and Pharmaceutical Product Agency and can take a more restrictive compensation decision, mainly due to budgetary parameters. In both Bulgaria and Greece, medicines are included in a positive reimbursement list [24,31].

## Discussion

Sweden and France have a long experience of over two decades in implementing HTA and have made a significant investment in the development of the HTA process. The results of the HTA process are used in P&R decisions and as a contribution to the development of clinical guidelines. The main objective of the introduction of HTA in these countries was to improve the quality of care, ensure equal access to care, and assess the cost/benefit of returning medicines. Although estimation of healthcare costs has led to a systematic assessment of innovative medicines recently in France, the evaluation results are used to negotiate 'fair' prices for social security. The HTA process in these countries has reached a high level. At the same time, these countries are trying to impart their experiences and knowledge at the European and international HTAs.

In Bulgaria, it is officially accepted to use the appraisal decision of other European countries (the United Kingdom, France, and Germany), and this plays an important role in the final decision. The key question, in this case, is whether this information can be used as such, and to what extent it can reflect the conditions of a specific country that uses them.

In Greece, the existence of the legislative framework providing for the procedures for the creation of the HTA does not automatically imply the existence of an HTA. The new legislation certainly seeks to remove past distortions by setting scientific criteria related to unmet medical needs, added therapeutic value, clinical data, and impact on the budget. It remains to be applied in practice to see if all that is legally described as complete and ideally also has practical application.

The procedure for the operation of the Health Technology Assessment Committee requires the selection of regular members with proven scientific expertise and experience in areas such as pharmacology, clinical pharmacology, pharmacoepidemiology, evaluation of clinical studies, or cost/efficacy analyses in Health Technology. HTA can lead to the creation of a market for healthy competition focusing on innovation.

The main principles for Health Technology Assessment, according to EUnetHTA, are transparency, independence, and the free expression of scientists that participate. This principle guarantees the credibility and prestige of the HTA, which will play a catalytic role in the process of negotiating and pricing medicines and evaluating health technology.

In Greece, instead of providing guaranteed operational independence of the committee, which would give prestige and credibility, the Commission is appointed and dismissed by the political leadership of the ministry, which degrades the credibility of the committee from the outset.

HTA organizations should be small and flexible schemes aimed at using the country's scientific staff. The evaluation process should be developed and updated, in line with good practices and international developments, with joint clinical assessments. The time horizon for assessing efficacy should be extended beyond two years to take into account the savings in the pharmaceutical expenditure budget from the long-term benefits of such treatments. The Health Technology Assessment Committee should facilitate patients' access to new technologies by defining the added value of each treatment, in the context, of course, of the sustainability of the health system.

We should be led to performance-based agreements, in order to compensate for new treatments based on their value. There are two main categories of performance-based deals: either on the basis of utilization in real life or on the basis of the uncertainty that exists and whether this is guaranteed by real data. The reasons for financial agreements relating to the time it takes for patients to have access to treatment, the cost of treatment, the complexity of performance-based agreements, as well as the greater predictability of financial agreements. This situation could be improved by horizon scanning procedures, early dialogue at the European and national levels, as well as by the existence of patient registries.

It is also necessary to amend the legislative framework and simplify the regulations and procedures regarding generic medicines, the participation of patients in the event of successful negotiations, the inclusion in the List of Reimbursed Medicines, and the re-evaluation of all the distortions that burden the cost. It should be noted that Greece does not take into account the way a treatment is administered, which is an important issue for both the patient and the payer, nor the severity of the disease and the facilitation that the drug offers to the patient.

For medical devices, no evaluation procedure is provided in Greece, unlike in other countries. In Europe, only 4 countries (England, France, The Netherlands, and Sweden) have established an independent procedure for medical devices.

Following the approval of medicine by the European Medicines Agency (EMA), it takes about 2.5 years to complete the evaluation and pricing process for it to be placed on the market. By speeding up procedures, 2.5 years could be reduced to 1, in order to provide patients with timely access to more innovative therapies.

In Greece, it is necessary to reduce the median time from the moment a file becomes complete, until its recommendation, so that it does not exceed 1.5 months, but also to reduce the time of evaluation of medicines to 3-6 months, as provided by the Law

I believe that by correcting some distortions we may have an effective HTA organization

• We should try to transform the existing evaluation structure into a fully staffed HTA Organization according to the standards of developed European countries. Until this is achieved, we should take care to better staff and support the present structure. At the same time, it is also necessary to utilize more evaluators by ensuring the appropriate incentives to attract and stay.

• The normalization of the operation of the HTA Committee enables us to immediately abolish the external criterion of 5/11 (medicines are subject to evaluation only if they are compensated in at least 5 of 11 pre-selected member states that have a health technology assessment mechanism). The external criteria artificially limit the speed of evaluation that in a fully staffed and smoothly flowing committee have no reason to exist.

• To review the insurance prices every three months and the Positive List every two months. This will ensure faster implementation of decisions taken and justified by the committees and more direct access for patients to new treatments or indications.

• To make the planning of both committees public for better business predictability, as is the case in other states. To have greater access to data for pharmaceutical operators and pharmaceutical companies, acheiving transparency among the participants in the process, but also increased ability to submit proposals.

• Negotiations should take place on the basis of the existing evaluation of pharmaceutical therapeutic solutions and the documentation provided or are available and should not be determined by previous reimbursement limits. Negotiations on the basis of existing returns (which by all market participants are considered to be particularly high and unsustainable) lead to horizontal pressure on the medicinal products under negotiation without the ability to highlight the real need and therapeutic value of each treatment.

• To establish a framework for the participation of patient representatives in the evaluation process of specific medicines that cover important unmet therapeutic needs. Their presence can help in a more complete assessment of needs.

• To create soon - within 12 months - a Register of Medicines. In the coming years, all Health Technology Assessment systems must be prepared for the reception of many new products necessary for patients that may put to the test the readiness, effectiveness, and collaborations in the drug reimbursement system. What we should keep in mind, however, is that we all share a common purpose, for patients to have access, without delay, to innovative therapies necessary for their lives

As a clinical cardiologist, I must admit that the development of HTA in the field of cardiology is vital, especially in the field of invasive cardiology. Industry, medicines, patients, decision‐makers, policymakers, politicians, ministries of health, and governments must have a clear perception of the cost and the benefit of therapies, new therapies, or alternative therapies.

There is a clear need for more HTA in the main topics of cardiology. HTA can assist decision‐makers in utilizing the information related to the effectiveness and efficacy of an intervention. We hope that this review could be used as a consistent HTA summary for clinicians.

The "evidence-based decision-making" process is a dynamic springboard, which will allows the right movements to be carried out. The field of medical technology is a dynamic space, and any approach should be clear and attentive for the reliability of the system to patients. We are no longer just talking about price, but about the value of a product. There should be close cooperation between all involved, drawing on European experience, to the extent that it is consistent with the particularities of the Greek health system.

## Abbreviations

**HTA:** Health Technology Assessment

**ISPOR:** International Society for Pharmacoeconomics and Outcomes Research

**INAHTA:** ***International Network of Agencies for Health Technology Assessment***

**EUnetHTA:** European Network for Health Technology ***Assessment***

**WHO:** World Health Organization

**SBU:** Statens Beredning for Utvardering av Medicinsk Teknologi -Swedish Council on Technology Assessment in Health Care

**HAS:** Haute Autorité de Santé -National Authority for Health

**QALY:** Quality Adjusted Life Years

**DALY:** Disability Adjusted Life Years

**EU:** European Union

**EOPPY:** National Health Organization (Εθνικός Οργανισμός Παροχής Υπηρεσιών Υγείας)

**MAH:** Marketing Authorization Holder

**WHO:** World Health Organization

**GDP:** Gross National Product per capita

**PDL:** Positive Drugs List

**OTC:** over-the-counter products

**P&R:** Pricing and Reimbursement

**CBA:** cost-benefit analysis

**CEA:** cost-effectiveness analysis

**CUA:** cost-utility analysis

**EOF:** Greek Medicines Agency (ΕΟΦ- Ελληνικός Οργανισμός Φαρμάκων)

**UNCAM:** Union ***Nationale des Caisses d'Assurance Maladie*** - French National Union of Health Insurance Funds

**MoH:** Ministry of Health

**CEPS:** ***Comité 'Economique des Produits de Santé*** -Economic Heath Product Committee

**NPRC:** National Pricing and Reimbursement Council

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