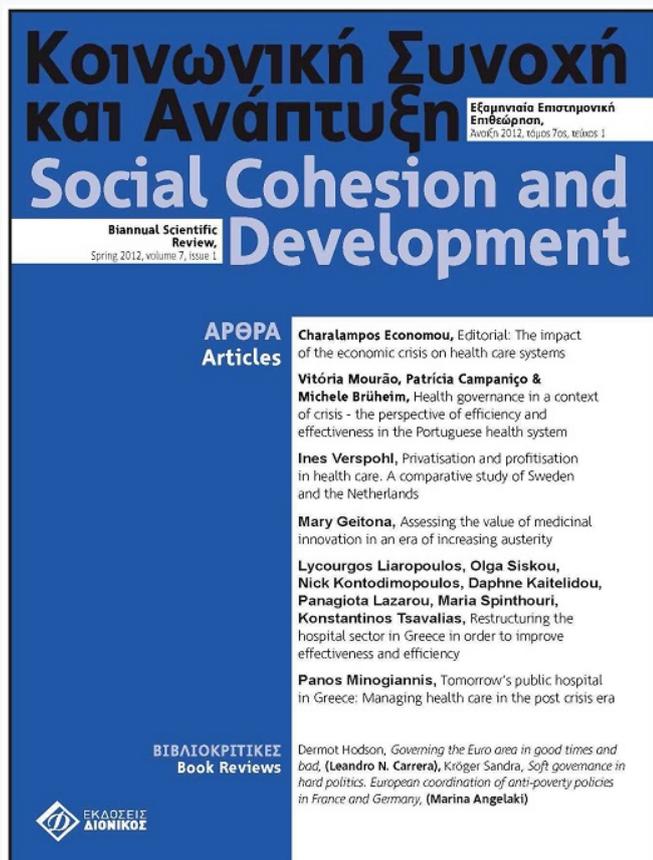


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Assessing the value of medicinal innovation in an era of increasing austerity

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Assessing the value of medicinal innovation in an era of increasing austerity

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Η αποτίμηση της αξίας της φαρμακευτικής καινοτομίας σε μια εποχή αυξανόμενης λιτότητας

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ABSTRACT

In this paper an overview of the rewarding innovation pharmaceutical regulatory systems has been presented, focusing on the emerging role of innovation and health technology assessment (HTA). In a time of political and financial turmoil, benefits could be obtained through the pooling of resources and experiences among various countries. For this purpose, recent major pharmaceutical reforms in Greece have been critically discussed taking into consideration the dynamic and complex environment among cost containment measures and the recent implementation of HTA in combination with some of the critical factors that influence today's key decision makers, such as the economic crisis, increasing austerity as well as political and international pressures.

KEY WORDS: HTA, innovation, pharmaceutical pricing and reimbursement, Greece.

ΠΕΡΙΛΗΨΗ

Το άρθρο παρουσιάζει τα επικρατέστερα συστήματα ρύθμισης της αγοράς φαρμάκου διεθνώς, δίνοντας έμφαση σε αυτά που επιβραβεύουν την καινοτομία και αναδεικνύουν το σημαντικό ρόλο της Αξιολόγησης της Τεχνολογίας Υγείας (ΑΤΥ). Η ανασκόπηση των διεθνών προτύπων κρίνεται ιδιαίτερα σημαντική για την παρούσα πολιτική και οικονομική συγκυρία που αντιμετωπίζει η χώρα. Γι αυτό το σκοπό, στο άρθρο επιχειρείται κριτική προσέγγιση των πρόσφατων μεταρρυθμίσεων στην Ελλάδα, πρώτον ως προς την επίτευξη ή μη των στόχων των πολιτικών συγκράτησης και ελέγχου των δαπανών υγείας, και δεύτερον ως προς τα δυνητικά οφέλη που θα προκύψουν από την εφαρμογή της ΑΤΥ στη χώρα.

ΛΕΞΕΙΣ-ΚΛΕΙΔΙΑ: Αξιολόγηση Τεχνολογίας Υγείας (ΑΤΥ), καινοτομία, τιμολόγηση και αποζημίωση φαρμάκων, Ελλάδα.

1. Introduction

The varying nature and emerging complexity of health technologies, in combination with limited healthcare resources, have resulted in efforts to deliver cost-effective healthcare, improve Research and Development (R&D) and sustain the entrepreneurship and manufacturing by maintaining the societal benefit of the healthcare sector. Growth in demand for healthcare is strong and expenditure is increasing due to the continuing increasing demand for health technologies and especially for pharmaceuticals.

In Europe, the research-based pharmaceutical industry is one of the leading high technology industries, amounting to about 19% of global business R&D investments and about 3.5% of the total EU manufacturing added value (EFPIA, 2011). The European pharmaceutical market is highly fragmented and strictly driven by cost containment and regulatory policies that many times prevent rewarding innovation. This refers as the reason behind the US pharmaceutical market dominates over the European, given that 65% of sales of new medicines marketed since 2002 are generated on the US market, compared to 24% on the European market (IMS, 2011).

In an era of increasing austerity, the fact that pharmaceutical industry is one of Europe's best performing high-technology sectors should always be taken into consideration. It is increasingly important to achieve a balance between affordable healthcare and the use of innovative health technologies, at national, European and international level. In this context, the aim of paper is to make an overview of the value-based regulatory systems rewarding innovation, widely used in the EU. The increase in the use of health technology assessment (HTA) and its impact on today's key decision makers are also discussed. Finally, a critical review is made regarding the major pharmaceutical reforms taken place in Greece, giving emphasis in the reasoning behind the failure or the success of the policies implemented.

2. The value of pharmaceutical innovation

Innovation in pharmaceuticals plays a critical role in both the industrial and health fields. A drug can be considered a pharmaceutical innovation only if it meets otherwise unmet or inadequately met health care needs. Pharmaceutical innovations create value to society by generating improvements in patient health (net of treatment risks) that were previously unattainable (Morgan et al., 2008). There is growing evidence at macro and micro-economic level regarding the added value of medicines in the healthcare sector, not only in terms of global cost savings but also in terms of increasing the quality of care. Medicines not only improve health status, but also generate savings by substantially reducing costs through the substitution of hospital care etc. Therefore, decision makers should take into consideration the overall therapeutic and economic value of medicines

Medicines remain the prime target of cost containment policies, despite the fact that on average pharmaceutical spending accounts for only 16.6% of total health expenditure in Europe (EFPIA, 2011). Although rises in pharmaceutical spending are observed, recent increases in health spending are not primarily caused by increases in spending on pharmaceuticals. Since 2005 the contribution towards total increases in health spending attributed to pharmaceuticals is 17.3% in Canada, 13.8% in France, 15.1% in Germany, 5.6% in Italy, 14.0% in Spain, 5.4% in the United Kingdom and 10.9% in the United States (US Department of Trade, 2004; OECD Health Data, 2010). Hence, reforms or cost containment policies focusing on pharmaceutical expenditure alone are unlikely to achieve significant cost savings and achieve their targets.

Innovation remains a predictor for increasing healthcare expenditures. Rational criteria in terms of safety, efficiency, effectiveness and equity, used in the pricing and reimbursement mechanisms should provide incentives and reward innovation. Certainly, it is very difficult to measure spill over effects of medical technology in economic terms, despite the fact that a number of studies have demonstrated the health gains and cumulative benefits of such innovation (Kanavos et al., 2010). The benefits of pharmaceutical innovation should include clinical/therapeutic benefits, quality of life benefits, and socio-economic benefits. According to the international literature, there are

different criteria required by EU regulatory authorities in order to assess new technologies for pricing and reimbursement purposes. The benefits should be evident, since achieving incremental innovation requires significant investments that can be seen as a challenge for healthcare systems. Some countries like the United Kingdom, Finland and the Netherlands refer to cost-effectiveness and patients' quality of life criteria to determine the real value of a medicine while other countries, such as Austria, Belgium, Denmark, Ireland, Italy and Portugal take into account a variety of socio-economic criteria. But there are still some European countries, such as Greece, in which healthcare policies are short term and they do not yet take into consideration the overall therapeutic and economic value of the use of new technologies (Abel-Smith and Mossialos, 1994; Dickson, 1992; Jonsson, 1994; Kanavos, 2002; Valasco-Garrido et al., 2008; Mousiama et al., 2001; Liropoulos and Kaitelidou, 2000; Geitona and Kanavos, 2010).

3. Pricing and reimbursement practices in EU countries

In most countries, the pharmaceutical market is one of the most heavily regulated sectors, since governmental regulation takes into consideration healthcare market failures related to the safety, equity, accessibility and cost containment concerns. The rationale behind state intervention is focused on the fact that health policy decision makers attempt to ensure the efficient and equitable access to medicines, provide adequate incentives for innovation, and control total health /or and pharmaceutical expenditure. Measures taken for controlling the performance of pharmaceutical markets are complex and often conflicting since they are usually targeting at different and multiple actors such as the manufacturers, wholesalers, physicians, pharmacists, patients and the third-party-payers. Pharmaceutical market regulations are mainly focusing on the improvement of the effectiveness, safety and quality of pharmaceuticals, in combination with their rational use and control expenditure. Alternative regulation mechanisms include well-defined, structured and systematic actions induced by regulators in order to affect the rules and the functioning of the pharmaceutical market by changing the multiple agents' behaviour (Chen, 1999; Kanavos et al., 2010).

In economic theory terms, governmental regulation refers to the measures taken usually distinguished between the supply and demand-side. The demand side of pharmaceuticals refers to the patient/consumer, the prescriber and the pharmacist and takes into consideration that the respective healthcare provision is paid by third party payers. It is evident that in the EU countries, the share of drugs' expenditure financed by third-party payers accounts for over 75% of the total market (Mrzcek, 2002). The supply side of pharmaceutical markets is determined absolutely by all agents involved in the drugs' production.

The demand side interventions are aimed at changing the behaviour of healthcare professionals and patients. Clinical and prescription guidelines focusing on the monitoring and changing of prescribing patterns, the implementation of pharmaceutical budgets for reinforcing cost-consciousness and generics substitution are the most common measures taken for controlling the cost of prescribed treatments, promote a more rational use of medicines while maintaining the quality. As far as demand side interventions aiming at affecting patients' behaviour, cost-sharing, co-payments and co-insurance practices are included. It is noteworthy to mention that patients' and health professionals' behaviour change is primarily affected by third party payers and the reimbursement status of each product category. The definition of the amount of the price to

be paid by the third-party payer, already mentioned as reference pricing system, as well as the adoption of positive and negative lists are practices closely associated with patients' cost-sharing and co payments reimbursing mechanisms (Lopez- Casanovas and Puig-Junoy, 2000; Kanavos, 2002; Helin-Samivaara et al., 2003; Gray, 2006; Espin and Rovira, 2007; Tsiantou et al., 2009; Geitona and Kanavos 2010).

In most EU countries, supply side interventions include price regulation, direct expenditure and profit control as well as tax benefits. More analytically, price regulation refers to the administrative or statutory pricing, such as price caps, positive or negative reimbursement lists, etc. In situations of information asymmetry, as in the case of pharmaceutical products, the exercise of the price setting is complicated compared to the other goods whereas perfect information dominates in the consumption process. When price regulation is based on the product's cost plus a certain profit margin of the manufacturer's, refers to the cost-plus pricing system. Additionally, price regulation can be referred to the referencing pricing system which is based on the prices for the same product in other countries or for the same indications of similar treatments. Another price regulation mechanism derives from economic evaluations and is usually used for pricing and reimbursement decisions (Espin and Rovira, 2010; Kanavos et al., 2010).

Direct expenditures controls are also introduced in order to contain pharmaceutical expenditures through the set up of mandatory or negotiated discounts in the drug's price, as well as rebates related to a specified proportion of the sales made by a manufacturer to the purchaser over a given time period (i.e Germany, Ireland, Spain). Similar is also the payback control system which serves as a risk-sharing mechanism requiring manufacturers to return a part of their revenue, if sales exceed a previously determined target. Additionally, price-volume agreements are applied to specific new products, where the price agreed is conditional to the expected number of units sold. (i.e France, Spain). Profit control refers to a system applied in the UK for the sales of branded medicines to the NHS and tax benefits are related to the manufacturer's investment in R&D (i.e Belgium) (Kanavos, 2002; Simoens et al., 2005; Espin and Rovira, 2007).

Among other systems of supply-side regulation for price setting, the Value Based Pricing (VBP) and the External Price Referencing (EPR) systems are currently used extensively to inform decisions on pricing and reimbursement of pharmaceuticals. VBP integrates the value into the price of medicines in order to reward products that have better outcomes and to encourage future innovation in the development of new therapeutic agents. VBP can serve as a validation mechanism of new technologies, enable governments to make decisions driven by value and provide health professionals and patients the information needed to make the best treatment choices (Sorenson et al. 2008; Kanavos et al., 2010; Espin and Rovira, 2010).

External or International Price Referencing (EPR) system involves the selection of a basket of countries, which can change over time, to compare pharmaceutical prices and create a reference price (RP) for a country. It can be used for price negotiation and setting within a country as well as for reimbursement and market authorisation purposes. In addition, it provides a benchmark for negotiations between industry and health insurance organisations. Combination of both systems (VBP and EPR) can be applied for setting pharmaceutical pricing and reimbursement within a country. It is important to note that the process of selection of the above mentioned pricing systems is complex. In VBP the definition of value is the key factor and the value determination should be based on the cost effectiveness analysis (CEA) and more precisely, on the incremental cost effectiveness ratio (ICER). The greatest difference between VBP and EPR, is that VBP relies on a combination of scientific and social value judgements to inform pricing and reimbursement decisions, whereas EPR borrows these indirectly from other countries (Kanavos et al., 2010).

4. The emerging role of HTA

Health Technology Assessment (HTA) has come under focus in the last three decades and has become a crucial part of the decision making process in the healthcare sector. HTA is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value (www.eunetha.eu). HTA networks at EU level are aiming to contribute to the generation of HTAs to inform policy and healthcare decision making in European countries so that new health technologies can be adopted and obsolete technologies abandoned in a well-informed and robust manner, hence bringing about high quality, safe, accessible, sustainable, ethical and efficient health care for citizens across Europe. The partners in the EUnetHTA Collaboration share the overarching values of the European Union for health systems such as universality, access to good quality care, equity and solidarity (Valasco-Garrido et al., 2008).

In practical terms, the role of HTA is to provide informed decisions aiming at allocating resources within the healthcare sector in order to improve the efficiency in healthcare. There are many variations in the practice of HTA. In some cases, HTA is linked to reimbursement and third party payers' decision making; in others to clinical guidelines and disease management, etc. HTA is also carried out at different levels of government, and there are considerable variations in the level of stakeholder involvement, in the methodology used and in the quality of studies. In addition, in most countries economic evaluations studies are increasingly included in HTA despite their differentiations observed in the methodologies used, the type of the analysis and the data used. For this purpose specific guidelines are also available in economic evaluation studies.

HTA bodies are responsible for assessing the economic, social, organisational and ethical implications of a given technology which usually refers to drugs, medical devices and procedures. They aim to improve the quality and safety of healthcare in a context of continuous medical progress, by advising decision makers, producing guidelines for health professionals, certifying healthcare organisations, developing diseases' management and informing health professionals, patients and the public. Today, HTA is used to assess new technologies before or after their establishment on the market. The challenges that lie ahead include the need to provide advice in a timely and transparent manner, by using multi-disciplinary approaches and taking into consideration stakeholders' issues. HTA analyses must not be restricted to individual product medical added value but they should make reviews beyond it. HTA studies on innovative technologies should be used at the national level in the formulation of national health policies, given that costs and values differ among countries.

It is well known that most European Union member states have established responsible bodies for publishing pricing and reimbursement (P&R) guidelines, since price setting remains a national health policy issue. In this context, the establishment of HTA agencies worldwide is targeting to inform decisions aimed at allocating resources within the healthcare sector (Zentner et al., 2005; Yfantopoulos, 2008; Kanavos et al., 2010a; Wilsdon and Serota 2011). Decisions about third party payers and stakeholders are the most important target for HTA agencies in order to improve the allocative efficiency of healthcare. The criteria used for assessment and the role of global HTAs in P&R as well as in market access decisions are presented in the Table 1.

Table 1. Criteria used in global HTA

Country	Relative Effectiveness	Budget Impact	Cost-Effectiveness	Cost/QALY	Cost/QALY with threshold	Influence on price, reimbursement & market access*	Pharmaceutical innovation
<i>Australia</i>	•	•	•	•		Price & access	•
<i>Brazil</i>	•	•	•			Access only	
<i>Canada</i>	•		•	•		Access only	•
<i>England</i>	•		•	•	•	Access only	•
<i>France</i>	•					Price, reimbursement & access	•
<i>Germany</i>	•		•			Reimbursement & access	
<i>Italy</i>	•					Price & reimbursement (limited)	
<i>Netherlands</i>	•	•	•	•		Price, reimbursement & access	•
<i>New Zealand</i>	•	•	•	•		Price & access	
<i>Poland</i>	•	•	•	•		Price & access	
<i>Scotland</i>	•		•	•	•	Access only	•
<i>South Korea</i>	•	•	•	•	•	Price & access	
<i>Spain</i>	•		•	•		Access only	
<i>Sweden</i>	•		•	•		Reimbursement & access (limited on price)	
<i>Turkey</i>	•	•	•	•		Price & access	

Source: Wilsdom and Serota, 2011.

*Market access refers to restrictions imposed on the product

In the UK the National Institute for Clinical Excellency (NICE), established in 1999, undertakes a more-rigorous approach to economic evaluation. The role of NICE is to make recommendations to health professionals on the economic appraisal of new and existing technologies, the development of clinical guidelines and the specification of audit technologies. Nowadays, NICE contribution is very significant, since it has made restrictive or negative rulings on 63% of all drugs examined data. In 2003, the Institute for Quality and Efficiency in Health Care (IQWiG) was established in Germany aiming to evaluate the current state of medical knowledge on diagnostic and therapeutic schemes for selected group of diseases, the quality and efficiency of services provided by the statutory health insurance and drugs' effectiveness. IQWiG is also responsible for the development of evidence based guidelines and recommendations for disease management as well as for the dissemination of information on evidence-based therapies. IQWiG contribution is substantial since it reported no proven benefit in 73% of all drugs examined.

Adversely, the role of the SBU in Sweden, established in 1987 and in 1992 commissioned as an independent public authority, does not make any decisions concerning approval or reimbursement of drugs, and does not have a supervisory function. However, despite its relative lack of power, SBU has made a substantial contribution to improvements in the healthcare system. In a survey carried out in 2002, 81% of physicians stated that they obtained a practical benefit from SBU reports. Additionally, SBU projects on the pre-operative routines and the management of mild head injury led to annual savings of about €24 million and €4 million respectively. Furthermore, the report concerning the non evidence that calcium and vitamin D supplements prevent osteoporosis among women under the age of 80, revealed a potential saving of €3.2 million (www.sbu.se).

Nowadays, a number of countries in Europe actively use health economic evaluations and have established HTA bodies. They have also set up pharmaco-economic guidelines to be used in the decision-making process. Some of these countries are the UK, Netherlands, Finland, Portugal, Sweden, Denmark, Ireland, Switzerland, France, Italy, Estonia, Poland, Hungary etc. The administrative structure of the healthcare system affects significantly the type and the function of HTA in each county. In highly de-centralised countries, such as in Sweden, there are more than one body while in others HTA decisions are taken at national level. It is worth to mention that the lack of a systematic process for the selection of technologies for evaluation as well as the no evident link between regulatory and HTA bodies refer among the most significant drawbacks.

In summary, a global perspective of HTA may offer a predictable environment for long-term investment to the industry, clarity of roles & responsibilities to decision makers and assessments based on the added therapeutic value to patients. International collaboration among various HTA agencies should be reinforced through the already existing network of competent national and international agencies. The enforcement of the EUnetHTA Collaboration is very useful since it provides systematic information on the use of best available evidence, common methodological and process standards as well as common review processes.

5. Medicinal market regulation in Greece

Drugs' market regulation operates under the guidance of the Ministry of Health and Social Solidarity (MoH) in accordance to the EU legislation. The process regarding drugs' market authorisation is operating under the responsibility of the National Drug Organization (EOF), and pricing process under the responsibility of the Pricing Committee at the MoH. For drugs' approval, pharmaceutical companies are required to submit the product's dossier to the National Drug

Organization (EOF) and for pricing setting to the Ministry's respective Committee. The pricing Committee is responsible for the price determination as well as for the drugs' price bulletins publication. Prices' setting takes into account the wholesale prices of imported and locally manufactured or packaged products as well as various other criteria.

In Greece, health authorities have always applied regulatory controls on the supply-side with emphasis on prices' reductions targeting to control the growth of pharmaceutical expenditure. Short-term measures taken to reduce pharmaceutical expenditure failed to deal with rising healthcare budgets and most importantly hampered innovation. In that sense, technology up to now has been considered as a cost driver increasing health service intensity, excess inflation and the cost of treatment, since the overall benefits of pharmaceutical innovation are not yet taken into consideration.

Last two decades, three major reforms (1998, 2006 and 2010) have been implemented targeting at pharmaceuticals' control. The first reform refers to the introduction of a positive reimbursement list and a reference pricing system based on the lowest price among the 15 EU countries. Although based on legislation the principle criterion for the inclusion of a drug in the list was its therapeutic value, which was based on the severity of the disease, the product's effectiveness/safety ratio, the availability of alternative treatments and the target population, the only inclusion criterion was the daily treatment cost. In order for a product to be included in the positive list, its average cost of daily treatment should be equal to or lower than the reference price of each therapeutic category. Both measures didn't achieve their goals and the country reference pricing system has been judged by the Council of State as unconstitutional. More importantly, positive list failed because it restricted patients' access to new and more effective drugs, given that it took years to update the list with negative impact on long-term innovation. Drugs withdrawals from the market and shortages have been reported while parallel trade and exports increased. Also, patients' co-payments had not a significant impact on controlling expenditures due to low prices of pharmaceuticals in the country.

The second major reform, in 2006, refers to the abolishment of the existing positive list aiming at the reimbursement of all medicines except OTCs and lifestyle drugs (not defined till 2011). In addition, a new pricing system was introduced based on the average of the three lowest European prices, of which two were calculated from the former 15 European Member States plus Switzerland and one from the new EU members (Yfantopoulos, 2008). Also, the 2006 reform introduced a rebate system paid by the pharmaceutical companies to the Social Security Funds (SSF). Again, the above cost containment measures didn't achieve their goals since the rebate system partially operated and pharmaceutical expenditures were continuously increasing due to the inability of controlling the volume of prescribed drugs as well as changing physicians' prescribing behaviour (Geitona and Xaplanteris, 2010).

It is worth mentioning that the 1998 and 2006 reforms appeared inefficient given that pharmaceutical expenditures were continuously increasing, regardless of the introduction or the abolishment of the positive list. The reasoning behind the expenditure rise is that the supply side measures taken were solely focused on prices' control and measures targeting at the demand side were totally missing.

In 2010 and Greece being under the economic crisis and EU and IMF inspection, the government adopted tough austerity measures in order to:

- Cut government spending,
- Reduce the size of the public sector,
- Decrease tax evasion - increase tax collection,

- Control health spending - reform healthcare and pension systems
- Improve competitiveness through structural reforms to the labor and product markets.

In this context, the government legislated in 2010 a third reform on pharmaceuticals. This time the government implemented both supply and demand side measures in order to reduce pharmaceutical spending. Again, a new positive reimbursement list was introduced by classifying the drugs in ATC4 clusters and the drug's daily treatment cost should not exceed the average cost of each therapeutic category which was comprised by branded and generic products. Any excess would be paid back as a rebate for enlistment. More importantly, in the criteria of the reimbursement list there was a provision for accepting a 20% price premium for innovative medicines with the submission of pharmacoeconomics studies. In addition, this reform included numerous cost-containment measures targeting to control NHS hospitals' pharmaceutical expenditure through the introduction of hospital formularies, therapeutic protocols/guidelines, patients' electronic prescribing, drug tenders, changing of physicians' prescription patterns and generic substitution. Also, the creation of an integrated information technology (IT) system intra and across hospitals as well as the establishment of a HTA body have been announced. More analytically, a set of measures have been legislated targeting at hospital spending control such as the centralised public procurement of medical supplies, the modernisation of hospital accounting and billing systems, bookkeeping of medical supplies and monitoring activity in NHS facilities, timely invoicing etc. As about the establishment of the HTA body it aimed to evaluate new technologies in health, therapeutic interventions, clinical practices, and disease management.

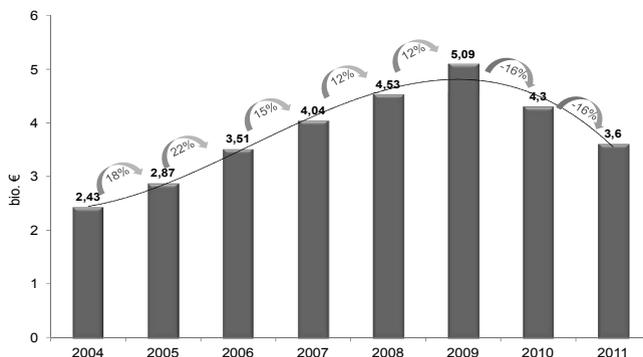
Similar measures have also been applied to social security funds (SSF) for the reduction of their expenses with emphasis given in the creation of an integrated electronic processing system for controlling the prescriptions and diagnostic tests within all SSFs. As of 2011 the 4 key SSFs covering 90% of the Greek insured population were unified to form EOPYY with increased negotiating power.

It should be mentioned that although the implementation of these measures has not yet been completed, it seems to be successful in controlling spending (figure 1), since total pharmaceutical expenditure decreased more than € 2 billion in 2010-2011, both outpatient and hospital, exceeding the troika target which was €2 billion . However, other cost drivers within the hospital sector remained uncontrolled and offset major savings coming from drugs and other supplies (Figure 2).

Outpatient drug spending evolution

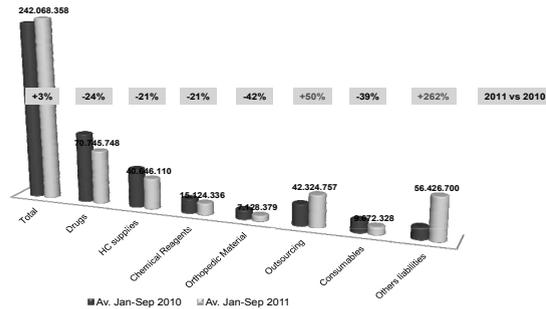
2004-2009: Average increase of € 0,5bn per year

2010-2011: Average decrease of € -0,7bn per year



Source: Ministry of Health, ESY.net, 2011

Average Hospital Spending per cost category
 2011 drug savings vs 2010 are squandered due to increased costs of outsourcing and other liabilities



Source: Ministry of Health, ESY.net, 2011

In addition, the price premium never operated and cost-effectiveness criteria have been excluded from the list, although they had already been announced by the MoH. Hopefully, in November 2011 the Greek HTA agency began to operate, the so called National Centre for Evaluation of Quality and Technology in Healthcare. It is expected that investment in HTA would offer long term benefits related to improvements in healthcare access and outcomes as well as rationality in resources allocation. Potential benefits of the HTA in Greece should be:

- Establishment of cost-effective prescribing policies
- Reinforcement of decision making based on costs and benefits rather than cost cutting
- Help purchasers to set priorities
- Providers' choice of the most cost-effective treatment techniques -practices
- Recommendations can be used as criterion for reimbursement acceptance
- Maximization of health gains from a finite budget or/and maximize of outcomes to input constraints
- Reallocation of resources from less to more productive uses.

Furthermore, the Greek HTA Centre may provide consultations regarding the short- and long-term social and economic consequences of the use of new technologies and make recommendations on their effective and efficient use mainly for reimbursement purposes. It is believed that with the 2010-11 measures taken, the government will meet IMF proposed targets and savings, rationalize healthcare investments and ensure economic sustainability especially of the insurance organizations. By this way, the NHS primary goals such as the improvement in the quality of healthcare delivery, the universal access and the increase in the productivity of healthcare sector will be achieved

6. Concluding remarks

In a time of political and financial turmoil, benefits could be obtained through the pooling of resources and experiences among various countries. In this paper an overview of the rewarding innovation regulatory systems has been presented, systems that are widely used in the EU and specific OECD countries based on the assumption that clinical and social value judgements among countries could be suited in another country. However, it has been seen that each EU country has

a specific set of requirements and local adaptations of HTA which are not as straight forward, as they seem. Different countries utilize different levels of complexity and processes as well as different advantages, limitations and impact key variables such as price/reimbursement, coverage and access, assessment of value and rewarding of innovation (Kanavos et al.,2002).

For this purpose, recent major pharmaceutical reforms in Greece have been critically discussed in this paper, taking into consideration the dynamic and complex environment among cost containment measures and the implementation of health technology assessment in combination with some of the critical factors that influence today's key decision makers, such as the economic crisis, increasing austerity as well as political and international pressures.

In brief and critically thinking, it should be mentioned that the implementation of cost containment measures were necessary in the country in order to stabilize or/and reduce health care & pharmaceutical expenditure. The above measures applied were usually short term and based on price cuts rather than on value assessment and volume controls, and were mostly restricted to medicinal products.

The traditional criteria in terms of safety, efficiency, effectiveness and equity are almost always used in the pricing and reimbursement mechanisms but they very seldom provide incentives and reward innovation. If a product offered superior or/and marginal therapeutic benefit, it was difficult to justify a price premium relative to its competitors. In that sense, the allocation of health resources was always based on the maximum investment required with unknown or never assessed benefits, since reimbursement price was negotiated on the basis of a variety of factors, excluding pharmacoeconomic criteria. By this way, the therapeutic value of a product could not be rewarded, since economic evaluation and HTA was out of any consideration.

The 2010 -11 reform regarding the creation of HTA agency in Greece seems to be very promising since it would speed up decision making and lead to the development of evidence based policies. Hence the existence of real-world evidence would demonstrate the value of medicines and other new technologies in the real world. It is believed that Greek government and IMF expectations will be fulfilled due to long term targeting and acceptance of value based pricing and reimbursement practices. Hence, long-term economic accountability may sustain entrepreneurship and reinforce innovation and employment which are imperative at a time of economic recession and uncertainty that Greece is facing nowadays.

Bibliographical references

- Abel-Smith B. and Mossialos E., (1994), "Cost containment and health care reform: a study of the European Union", *Health Policy* 28(2):89-132.
- Chen P., (1999), "Setting price controls while facing variable or uncertain market conditions", *International Economic Review* 40(3):617-634.
- Dickson M., (1992), "The pricing of pharmaceuticals: an international comparison", *Clin Ther* 14(4):604-610.
- EFPIA (European Federation of Pharmaceutical Industries and Associations) (2011) <http://www.efpia.org>.
- Espin J., and Rovira J., (2010), "External Reference Pricing", *WHO/HAI*, December.
- Espin J., and Rovira J., (2007), "Analysis of differences and commonalities in pricing and Reimbursement systems in Europe", *Escuela Andaluza de Salud Pública*, Granada, Spain.

- EUnetHTA Collaboration (2011), *www.eunethta.eu*.
- Geitona M., Kanavos P., (2010), "Coloctal cancer management and prevention policies in Greece", *Eur J Health Econ*, 10(1):27-33.
- Geitona M., and Xaplanteris L., (2010), "Data Collection and Conduction of Pharmacoeconomic Studies in Greece", *European Psychiatric Review* 3(1):21-5.
- Gray J., (2006), "Changing physician prescribing behaviour", *Can J Clin Pharmacol* 13(1):81-84.
- Helin-Salmivaara A., Huupponen R., Klaukka T. and Hoppu K., (2003), "Focusing on changing clinical practice to enhance rational prescribing-collaboration and networking enable comprehensive approaches", *Health Policy* 66(1):1-10.
- IMS Health 2011, *www.imshealth.com*.
- Ioannides-Demos L.L., Ibrahim J.E. and McNeil J.J., (2002), "Reference-based pricing schemes: effect on pharmaceutical expenditure, resource utilisation and health outcomes", *Pharmacoeconomics* 20(9):577-91.
- Jonsson B., (1994), "Pricing and reimbursement of pharmaceuticals in Sweden", *Pharmacoeconomics* 6(1):51-60.
- Kanavos P.,(2002), "Pharmaceutical regulation in Europe", *Commonwealth Fund Harkness Report*, Harvard Medical School and London School of Economics.
- Kanavos P., Nicod E., van den Aardweg S. and Pomedli S., (2010a), "The impact of health technology assessments: an international comparison" *Euro-Observer*, 12:4.
- Liaropoulos L., Kaitelidou D., (2000), "Health Technology Assessment in Greece", *International Journal of Technology Assessment in Health Care* 16(2): 429-448.
- Lopez-Casasnovas G. and Puig-Junoy J., (2000), "Review of the literature on reference Pricing", *Health Policy* 54(2):87-123.
- Morgan S., Lopert R. and Greyson D., (2008), "Toward a definition of pharmaceutical innovation", *Open Medicine* 2:1.
- Mousiama T., Ioakimidou S., Largatzi E., Kaitelidou D.,and Liaropoulos L., (2001), "Health Technology Assessment in the area of prevention" *International Journal of Technology Assessment in Health Care* 17(3): 338-357.
- Mrazek M.F., (2002), "Comparative approaches to pharmaceutical price regulation in the European Union", *Croat Med J* 43(4):453-61.
- OECD Health Data, (2010) Directorate for Employment, Labour and Social Affairs, *http://www.oecd.org*.
- Simoens S., De Bruyn K., Bogaert M. and Laekeman G., (2005), "Pharmaceutical policy regarding generic drugs in Belgium", *Pharmacoeconomics* 23(8):755-66.
- Tsiantou V., Zavras D., Kousoulakou H., Geitona M., Kyriopoulos, J. (2009) "Generic medicines: Greek Physicians' perceptions and prescribing practices", *Journal of Clinical Pharmacy and Therapeutics*, 34, 547-554.
- US Department of Trade, (2004), "Pharmaceutical Price Controls in OECD countries: implications for U.S consumers, pricing, research, development and innovation", *International Trade Administration*, Washington DC. *www.ita.doc.gov*.

- Valasco-Garrido M., Kristensen B., Nielsen C., Busse R., (2008), "Health Technology Assessment and Health Policy-Making in Europe", *World Health Organization, Observatory Studies Series No 14*.
- Vogel R.J., (2002), "Pharmaceutical patents and price controls", *Clin Ther* 24(7):1204-1222.
- Wilsdon T., and Serota A., (2011), "A comparative analysis of the role and impact of Health Technology Assessment", *CRA report*, London.
- Yfantopoulos J., (2008), "Pharmaceutical pricing and reimbursement reforms in Greece", *Eur J Health Econ* 9:87–97.
- Zentner A., Valasco-Garrido M. and Busse R., (2005), "Methods for the comparative evaluation of pharmaceuticals", *GMS Health Technol Asses 1: Doc09* PMID: PMC3011319.