Health Policy and Economics: The adoption of generic drugs in Greek healthcare system.

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Abstract: This is the first of the three studies (focused on health governance topics) related to the Greek healthcare sector that currently experiences a major reform due to economic recession. Much discussion has been raised in the country during this year (2012), regarding the introduction of "brand-generic drugs substitution", in terms of the health and economic impact for the healthcare system. Greek government in an attempt to align with European directives has voted the law (4052/2012), which adopts the use of generic drugs in every aspect of the healthcare sector.

This change is included in the Memorandum of Understanding (2012) which is the policy and structural reforms' document signed between International Monetary Fund, European Central Bank, European Commission and the Hellenic Republic. Actually, this is the policies' reform contract which the country is obliged to follow and implement until 2015.

Greece, being already since 2009 under the economic supervision of the above three Organizations, experiences a major set of simultaneous radical reforms. The public fiscal deficit and the long lasting distortions have directed the country into an economic dead-end, jeopardising its socio-economic ties. Under such pressure and within a disturbing environment, the country is obliged to implement the specific healthcare reform. Generic drugs have achieved positive feedback from their use in advanced countries so far; on the other side, longevity raises cost consequences. Good demographics do not guarantee any more the sustainability of healthcare systems in advanced countries. The percentage of 65+ ages among active population is expected to exceed up to 30% until 2050. Therefore, the increase in commercialisation of health seems to be unavoidable. The exploitation of health economics with the use of economic evaluations is necessary. Primary concern is the minimisation of health expenses and more specific the elimination of any unnecessary spending on medicines (related to prescribing and pricing) since this is a major source of leaks.

The aims of this study are first to identify the use of generic drugs as an emerging health service in the country, and second to investigate its contribution, impact and effectiveness to the public healthcare system. It refers to the public spending and not the private out-of-pocket expenses.

Keywords: generic drugs, economic evaluation, health reform, recession

1. INTRODUCTION

This study discusses the economic evaluation of the "generic-brand drugs substitution reform" and makes a policy analysis trying to identify whether this change could be performed as planned or through modifications. In the next section it is given an indication of policies from global organizations related to healthcare financing and pharmaceutical spending. Primarily, it is necessary to understand the global governance tensions as defined by international think tanks, in order to realise the new healthcare frameworks. In continuous, there is given the evidence-based information related to the specific reform (as included in appendices). Based on the global framework described, this study identifies the healthcare reform and gives an illustration of it both before and after the change. In section three, there is an effort to review and critique the change, based on various data by accommodating literature review relevant to the nature of the reform. In section four, the aim is to provide a policy analysis from the perspective of healthcare participants. There are presented some findings on the use of generics and highlights of weaknesses. In addition, the study provides a recommendation-modification. Finally in conclusions it is identified that current reform, although necessary for the healthcare system, is performed in a hostile environment since the country experiences major economic recession with questionable unclear impacts.

2. The nature and standing of the healthcare reform

2.1 The global framework on health care spending

The World Health Organisation (WHO) has recently focused its research on health systems financing, in an attempt to provide guidance in the healthcare area in times characterised both by economic downturn and rising healthcare costs *(World Health Organisation, 2010)*. Based on evidence gathered from different studies, the Organization prepared a report aiming to serve as a practical guide on ways to finance healthcare. Among others it concludes that 20-40% of all health spending, in global terms, is wasted inefficiently. Thus, improving efficiency will be the next challenge for healthcare, especially through certain actions which involve: (a) better procurement practices, (b) broader use of generic drugs, (c) better incentives for providers, as well as (d) streamlined financing and (e) efficient administrative procedures *(World Health Organisation, 2010).* Such recommendations obviously provoke industry and systems' restructuring.

According to WHO, one of the leading sources of inefficiency is the underuse of generics in combination with the high pricing of medicines *(Appendix A).* Taking into consideration that medicines account for 20-30% of global health spending *(WHO, 2010; OECD, 2011),* the possible switching from originator brands to generic equivalents is translated to enormous cost reduction for healthcare systems. Organisation's surveys have demonstrated that high-income countries can save more money in case of systematic use of generics.

However, the Organisation suggests that saved resources from use of generics should be directed to the improvement of healthcare provisions in terms of eliminating inequalities and guaranteeing service quality.

In the same manner, European Commission in the health strategy for 2008-2013, identified that health expenditures can be seen as an economic burden although it is admitted that spending on health is not just a cost but it is an investment. But one could also say that, scarcity of healthcare services is still questionable, especially when the issue is universal coverage.

Subsequently, efficiency in terms of health benefits and health outcomes is the major concern of OECD. In the context of scarce resources, governments are obliged from the one side, to adopt certain rules to maximise the accessibility to healthcare, while on the other side they need to mitigate the continuously rising costs. Pharmaceutical expenditures are in the centre of interest mostly in terms of interventions and structural policy reforms. OECD has published numerous evidence based reports *(Appendices B to H)* in an attempt to identify and reveal weaknesses that could serve as a point to start reforms. The evidence-based information presented in this study (in the Appendices section), intends to specify pharmaceuticals spending as a crucial factor for health care systems across the planet and to emphasize in the quantitative representation of what this means for the future of healthcare as a service to mankind.

With a pharmaceutical spending, which already have reached globally 700 billion USD, estimated to be more than 20% of total healthcare expenses *(OECD, 2011)*, it is a real challenge to cope with, taking additionally into account longevity, long-term treatments and expensive technology.

World Bank (2007) in one of its recent reports on health strategies raises the issue of management and performance in healthcare as a strategic action to ensure financial sustainability for healthcare systems *(Appendix I).* Moreover, it relates this action to countries' competitiveness and fiscal policies. Again, the aim placed is how to ensure equitable access to effective, quality health services that respond to the needs of the community. In addition, *European Union (2007)* shares the same values trying to establish a new healthcare strategy for its member states. Nevertheless, one of the primary targets for the sustainability of the systems is to incorporate actions that are expected to close monitor health operations in order to make changes when necessary.

2.2 Economic evidence based information

European Union (2007) in the effort of promoting a new healthcare strategy for the years 2008-2013, it claimed four main values: (a) universality, (b) access to good quality health care, (c) equity, and (d) solidarity. Nevertheless, as referred earlier, it identified in the same strategy that health expenditure can be seen as an economic burden implying any additional direct and indirect costs for the society. Consequently, it performed a number of analytical studies to examine the economic relationships between health status, health investment and economic growth and development. In regards of spending, the ultimate technical practice introduced to cope with rising costs was by regulating pharmaceuticals and changing to cost-orientated alternatives.

According to *OECD (2011)*, Greece experienced an increasing health spending per capita of 7% per year on average, during the years 2000-2009. This, by itself, compared to the average of

OECD countries, which was 4%, is a much higher growth rate. The pharmaceutical spending was one of the main responsible factors for this increase. In real terms, the pharmaceutical spending counts for the 25% of country's health expenditures, placing it as the third most expensive country in OECD countries *(Appendix G).* Moreover, more than 60% of health spending is funded by public sources.

Greece, experiences the worst post-war recession during the last four years. Public deficit in combination with external debt have created an explosive mix which penetrates in real economy jeopardising social cohesion *(Appendix J)*. Being under close economic supervision from EU, IMF and ECB, the country is obliged to apply a bulk of reforms on almost every aspect of a PESTEL analysis. Empirical evidence have shown that radical changes in uneven momentums, are risky given the fact that regions are parts of a broader complex system which demonstrate diversified impacts but with connectedness.

Being among the countries with the highest expenditures on pharmaceuticals and the first country on growth in expenditures per capita *(Appendix G, H)*, the country should have applied economic-orientated reforms in healthcare. According to *McKinsey & Company (2012)*, Greece exhibits one of the lowest levels in generic drugs penetration in the local pharmaceutical market *(Appendix K)*. The percentage is only 32% compared to other EU countries which demonstrate a minimum of 60% and above.

When referring to generics market this is consisted of three types of products:

1. Unbranded generics
2. Branded generics
3. Off-patent branded generics

These types constitute the "generics eligible market" *(Datamonitor, 2011)*. European generics market had total revenue of $38.1 billion in 2010, a market value which is expected to increase up to $49 billion by 2015 *(Datamonitor, 2011)*. Greece currently counts for a local generics market value of €1.2 billion (data of 2010) having a potential to increase (if regulations succeed) up to €2.2 billion *(McKinsey & Company, 2012)*. Its total pharmaceutical market value was estimated to approximately €4.5 billion for 2010. According to National Medicines Organization (2012) in a total of 7.500 drugs in market the 3.000 of them are generics.

2.3 Identification of the healthcare reform

On March 2012, Greek government fully adopted the *Memorandum of Understanding on Specific Economic Policy and Conditionality (2012)* which is the framework including all reforms and changes that country is obliged to implement until 2015. Among others, it has been placed the modernisation of healthcare system towards 2014, meaning a significant restructuring in the national system within just 2 years. The control of public pharmaceutical spending is the main pillar behind a series of measures and actions that is agreed to be taken *(Appendix M).* Within this decision special focus is given on (a) the pricing of medicines, (b) the monitoring of prescribing, and (c) the increasing use of generic drugs *(Appendices N, O, P).*

The target for the country is to increase the adoption of generics use from 32% to 60% by the end of 2013. This target, challenges the healthcare reform which actually is a direct intervention in how the medicines provision will be administered.

Below, there is an attempt to illustrate how the old and new systems work. This is an eco-map of health operations in terms of pharmaceuticals provision to people *(Figure 1)*.

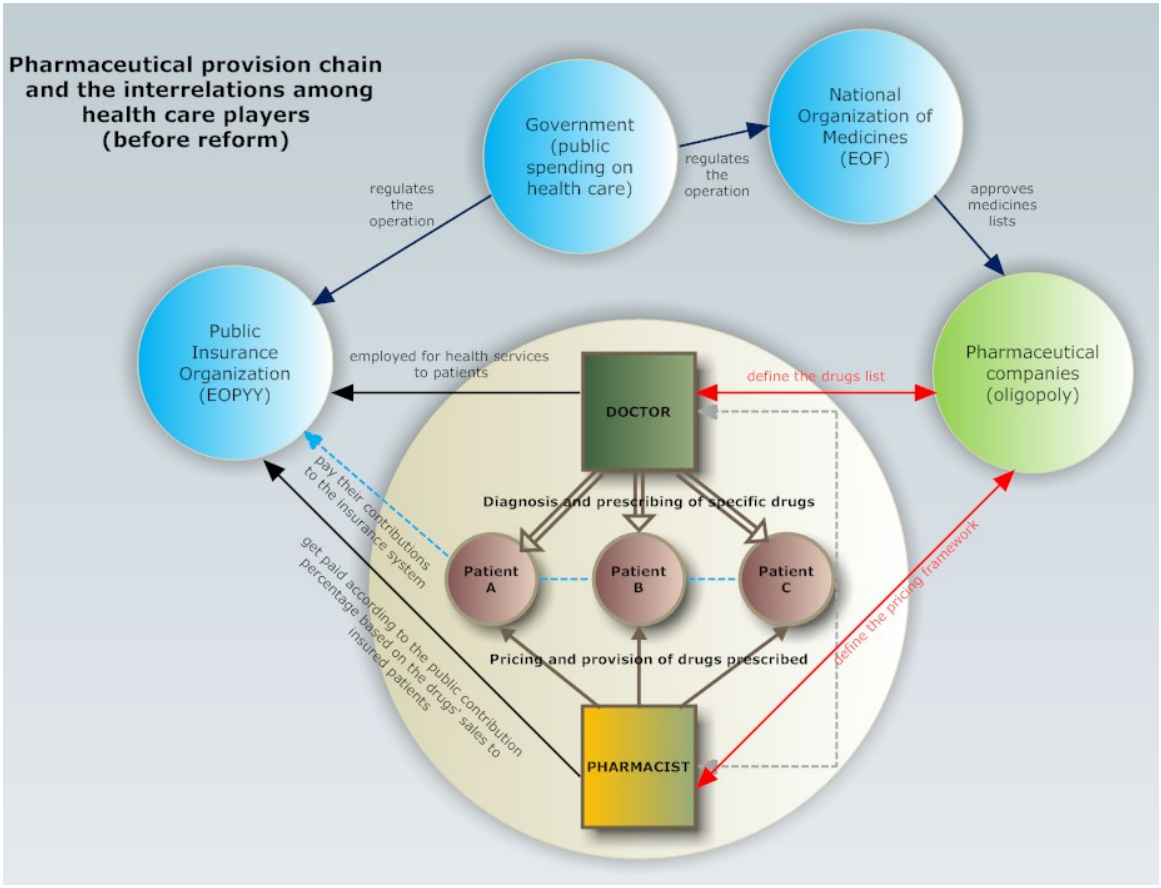

Figure 1. Eco-map of the pharmaceutical provision system – public spending (old system)

The old system provided an essential independence on pricing and prescribing to the primary system's players, which were: (a) the pharmaceutical companies, and (b) the doctors.
Government was actually isolated in identifying the health needs and approve the budgets originated from the Public Insurance Organization (EOPYY), who had a relative independence in administration and budgeting. The system was rather a flabby one, with lack of controls and absence of appraisals.

For example, doctors acted as decision making agents by defining which type of drug will be given to the patient. This practice though has global and old characteristics. Doctors' behaviour in terms of prescribing is based on information and incentives *(Hellerstein, 1998)*. Such behaviour incorporates the supplier induced demand. When decisions are originated from asymmetric information and agent problem this creates social and health costs. Thus, the decisions are not cost-effective. Nevertheless, in common practice, pharmacists often substitute branded drugs prescribed by doctors with generics that are considered equivalent *(Hellerstein, 1998)*.

In the new law there is an intervention to monitor the prescribing of medicines, and increase the use of generics in order to decrease the healthcare spending *(Hellenic Republic, 2012).* In the next diagram *(Figure 2)*, it is clearly demonstrated the change of roles and controls, as placed by government. Nevertheless, such changes reveal weaknesses mostly originated from the inability of public services to support effectively the altered operations. This stems from luck of budgets which are necessary to protect the new legal framework.

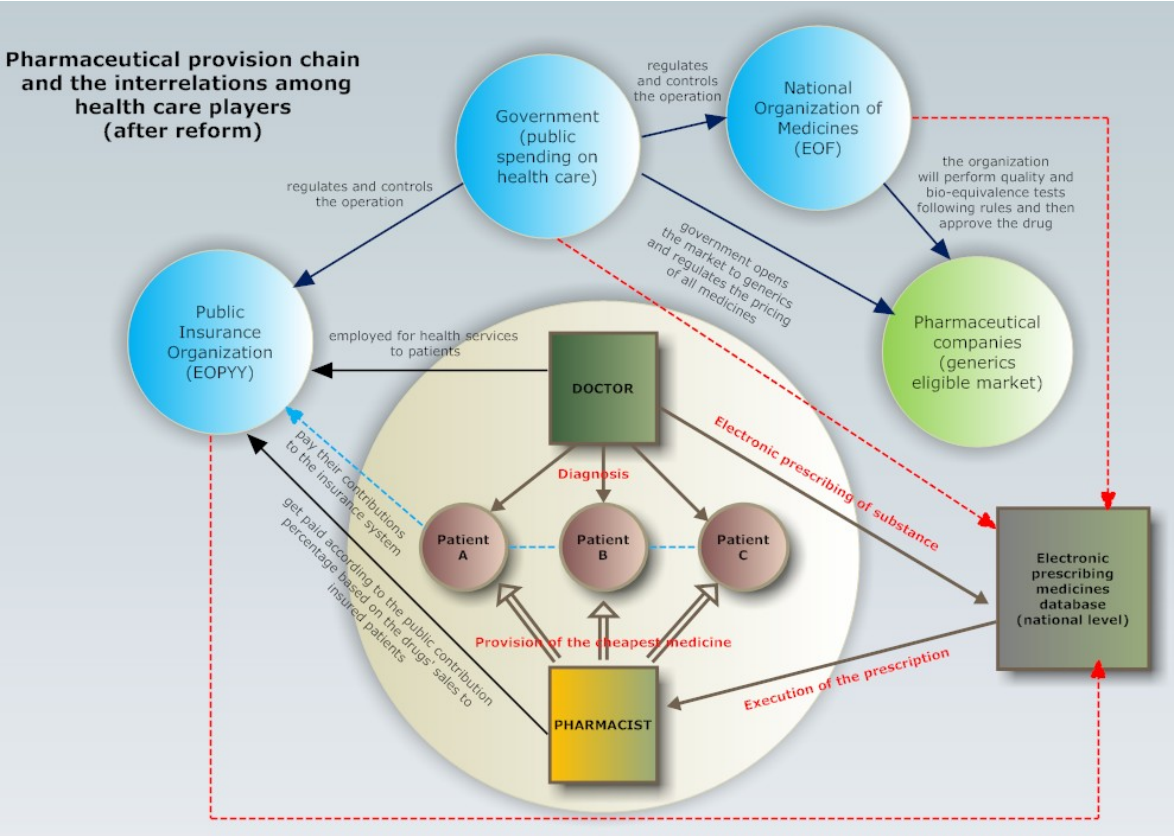

Figure 2. Eco-map of the pharmaceutical provision system – public spending (reformed system)

The reformed system introduces a close monitored process where prescribing and pricing is under continuous scrutiny. At this stage, primary market system's players are: (a) the government, (b) the National Medicines Organization, (c) the doctors, (d) the pharmaceutical companies, and (e) the pharmacists. Pharmacists are the ones who will decide the generic in the new system following the government rules. As experienced in the case of Norway, pharmacists demonstrate heterogeneity in drugs decision which stems from their professional specialties *(Dalen et al, 2011)*.

2.4 Understanding the broader context and its influences

During 1984, in USA took place the greatest reform which changed the structure of pharmaceutical industry. The country adopted the law which facilitated the entry of generic drug products after patent expiration of branded ones *(Grabowski and Vernon, 1992).* The difference in the new law was stated in a simple rule. The generics had to prove only bioequivalence to the branded while prior to that date they were obliged to follow the Food and Drug Administration (FDA) requirements which were costly and tight.

This seemingly slight change created a butterfly effect in the local economy changing pricing policies, market values, competition and strategies.

The motive for this enactment was that on 1984 a large number of patents were expired or they were closed to that *(Appendix L).* Taking into consideration that during those years, technology was not in the same state like nowadays, branded medicines usually covered whole substances creating almost monopolistic characteristics. The entry of generics altered the nature of pharmaceutical market by removing barriers and obstacles.

Comparing to what previously mentioned, the penetration of generics is supported through time from pharmaceuticals and governments for various reasons. At least this seems to hide mutual benefits. A mix of demographics, financing, and market values are usually at the upfront operating as initial motives for changes.

3. Review and critique of the economic evaluation and reform

The economic evaluation was depended on a cost-minimisation analysis which in theoretical terms assumes that outcomes are equivalent. More specific, the initial acceptance is that both branded and generics have the same results on patients. Based on this principle, the next target is to decrease the cost.

In developed countries there have been performed various economic evaluations not only based on cost minimisation but also in other techniques such as cost-effectiveness, cost-utility and cost-benefit analysis. So far, these have demonstrated that benefits are higher than costs, regarding generics use, but, influences and future impact has to be under scrutiny for each region separately respecting its specialties and local characteristics. At least, there should be given an adequate transition period for the healthcare system's participants to accept and comply towards amendments. For example, cost-effectiveness could be adopted during a certain transition period to measure the cost per unit of effect in Greek health care system. But, as *Hutubessy et al (2003)* have highlighted, this technique is slow and costly, although it is considered crucial in decision making on health issues.

3.1 Social factors

Changes that were instructed in other countries, in response to economic evaluations, secured the adequate time and space in respecting regional factors such as demography and epidemiology as well as cultures and practices in healthcare. For example in Turkey, where the healthcare system has experienced similar reforms since 2006, there were prioritised three pillars: (a) universal coverage, (b) enhancing equity, and (c) solidarity. The country for the last 5 years is still under alignment to the new system, with good results. Similarly to Greece, Turkey has reformed the system due to health care financing reasons *(Yildirim and Yildirim, 2011)*.

When a new branded medicine is nominated for approval it is necessary to perform a well-controlled set of tests in order to get its license. This includes a number of animal and human studies, efficacy tests, placebo processes and side effects tracking. Also the bioavailability test is required *(Lewek and Kardas, 20110).* On the contrary, generic drugs are required to be tested only to a bioequivalence study. Bioequivalence study means that the drug should be given to 18-24 healthy adult volunteers, who are objects of research during their medication period. In this period medical inspectors observe and register consequences, analyse impacts and study the effects of the drug. This study demonstrates some weaknesses though. First, bioequivalence studies are done in controlled environments where medical conditions are appropriate and controllable. Second, there is also the concern on formulation differences. A generic drug must meet the same standards with the branded in terms of, strength, purity, quality and identity. Such characteristics in combination with dose formulation and route of administration are not examined in the specific test.

It is true that generic drugs lack the number and extent of clinical trials. This is the reason why still in some cases, like antiepileptic and psychotic drugs there are doubts about generics efficacy and in addition there is a risk of possible adverse events *(Wilner, 2004).* The fact is that bioequivalence examines usually the active ingredients of a generic drug while inactive ingredients are not necessarily under control and may differ. Therefore, the concern of medical community stands for the so called "inter-changeability effects" in terms of extensive use to patients *(Wilner, 2004).* In social terms generics do not stand equally in all cases and it is possible to create inequalities. Coverage is not weighted mostly due to economic restraints.

3.2 Economic factors

The generic drugs' industry represents a separate sector in the market with its own characteristics and specialties. Growth in the generic pharmaceutical industry is likely to become more robust in the coming years *(McCurry, 2012).* According to *McKinsey & Company (2012),* the wide adoption of generics in Greece is expected to boost local market and provide new opportunities in the economy. Benefits are expected to work both wise for the country. From the one side, this is the expected decrease in healthcare spending on medicines, while on the other side the entrance of new companies and the enrichment of drugs supply chain is expected to increase market's value. This, in an extent implies added value and growth for country's gross domestic product (GDP).

There is another perspective though, equally concerned. Generics industry, which is based on replication and low-cost reproduction of formulas, may affect negatively research-based industry *(Lofgren, 2002).* Research and Development in response, is expected to alter their primary aims by involving more commercial characteristics and constraints in their strategies.

Moreover, since the reform places pricing restraints to pharmaceutical companies, this indirectly supports the imports of generics instead of creating a positive framework for local production which probably, would trigger more local powers. When placing restraints to final pricing, this enables importers to establish links with low-cost production countries, and import the generics. Greece belongs to Eurozone, which is considered a strong but costly economy. Consequently, the import of bulk quantities prerequisites that the National Medicines Organization will have to test and approve them, which in an extent demands additional public costs.

Lofgren (2002) has identified that the extensive use of generics creates growth in the local market when there is a relative pricing freedom. Wherever there are control systems, generics do not benefit the economy but only the healthcare spending. This sounds controversial to the current reform which clearly places profit margins and pricing policies.

3.3 Political factors

The development of generics' market operates as leverage for pharmaceutical industries. Sometimes this proved to be a key driver for enhancing international competitiveness, such in the case of US-base pharmaceutical firms. Obviously, creating a decentralised liberated market, this entails an open economy. This leads to investments and cultivation of entrepreneurial mindset. However, the question is (a) what is the impact of the reform in market terms and (b) if this reform is expected to unleash regional powers or just swift of the global players.

Keeping the players in competition is a matter of politics and governance. In countries with more mature generics market, competitors already start to forge alliances in order to gain competitive advantages and differentiate from the others *(Pharmaceutical Technology Group, 2012).*

Governments as payers are still powerful though, and can regulate market's characteristics through their behaviour as a group in a complex adaptive environment. Since health represents a significant budget for the country, it may serve as a vehicle for doing politics.

The pharmaceuticals industry demonstrates a dynamic which evolves and moves from monopolistic pricing to competitive pricing. According to *Reiffen and Ward (2005)* pricing is related to the number of competitors and drug characteristics are related to the entry process in the market. Therefore, the above relations could be considered as governance elements affecting the politics of health in the country. Through interference to these two relations government can regulate and affect directly the market for the benefit of healthcare system. Another element is the market size which defines the estimation on potential revenues for the generics market. The expected amount of revenues affects and forms the policies that the generic drugs manufacturers follow to enter the market. This should be under consideration for every government who intends to leave this market with no intervention. According to *Lankford (2012),* big pharmaceuticals that produce wide-accepted generics have the power to negotiate directly with the governments and define pricing policies according to the healthcare plans.

4. Policy Analysis and recommendations

In this section there is an attempt to perform an analysis and make recommendations based on the policy analysis triangle *(Figure 3)* used as a compass of highlighting and discussing the relevant issues. Taking into consideration the series of questions that the triangle poses, there is a need to identify and reveal possible weaknesses with the help of both the literature review and the empirical experience, as derived from the country's healthcare transformation through time.

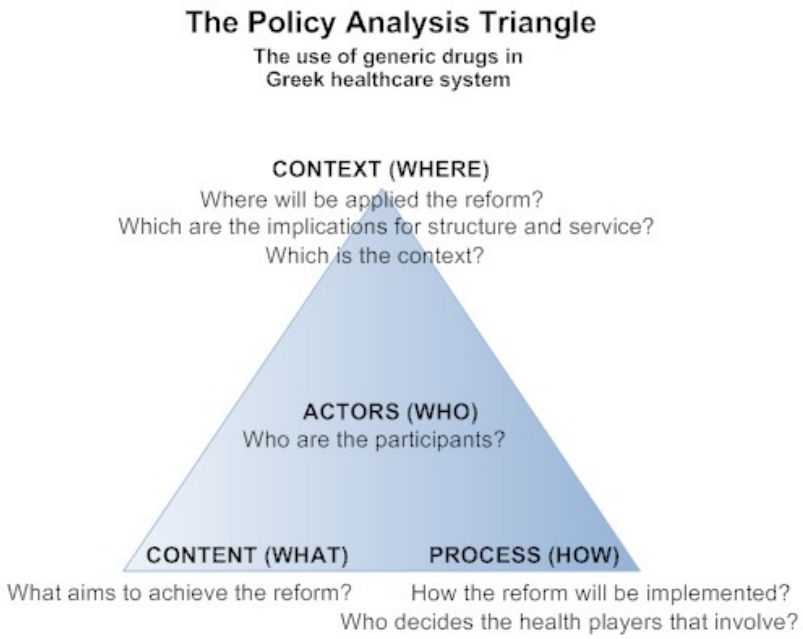

Figure 3. The Policy Analysis Triangle

The study on healthcare literature in combination with evidence-based information raised some concerns regarding the specific reform such as: (a) which are actually the aims of the reform, (b) how these are intended to be achieved, and (c) who are willing to participate in this effort. Beyond this, (d) there is a need to recognise if the context is ready and the momentum appropriate for change with minimum impact.

Obviously the reform was motivated by cost-minimization evaluation, setting purely financial orientated standards. Is this wise though to apply only one type of economic evaluation when this comes to public health and safety of the society?
Following are discussed some policy concerns.

4.1 Concerns on safety issues

As declared previously, the wide adoption of generics has already been regulated since March 2012. Although this regulation follows global trends, it seems questionable whether it will stand through the hard economic times that the country experiences. Reforms demand extra resources as they raise a dynamic of change. Nevertheless, income tunnels are tightly controlled from country's loaners. This includes healthcare extra provisions as well. Generic drugs have to cope with a risk issue regarding their efficacy and impact. Their operations environment is not clear in terms of guaranteed results. Moreover, it is worth to mention that according to *European Medicines Agency (2010)* although the bioequivalence study follows regulated guidelines, aspects related to generic substitution are subject to national regulations in European Union. This means each country decides for its own and places its requirements. Another issue is that bioequivalence studies refer to chemical products and not the biologics which are considered as an emergent sub sector in generics *(Berndt et al, 2005)*. In a blurred surrounding safety cannot be guaranteed unless the government is committed for continuous scrutiny of generics' imports and qualitative controls.

4.2 Concerns on healthcare system's participants

The new status changes the roles of participants and as a result is expected to create new interrelationships and commercial links among them. For example doctors are now obliged to prescribe substances and not specific medicines. Pharmacists have the responsibility to decide the final medicine. Nevertheless, it is assumed that any medicine which includes the requested substance and has been approved by the National Medicines Organization is expected to produce the same results to the patient. But as *Hellstrom and Rudholm (2010)* highlighted, uncertainty concerning product quality of generic drugs delay their prescription, until their impact is confirmed. This implies that doctors and pharmacists need a certain period of time to guarantee the medicine's consequences to the patient.

On the other side, Greek Government has regulated and gives authority to National Medicines Organization (EOF) to test and control all generic drugs in order to license them before their circulation. According to *Kesselheim et al (2006)*, usually there is a gap between branded drugs' patents which expired (market exclusivity) and active generic substitution. This is a policy issue which involves close monitoring from the government and the National Medicines Organization. Health care system should be ready to benefit from lower prices when patents are expired, meaning ready-to-import generics waiting for being prescribed by pharmacists. Also, the administration of intellectual property rights should be discrete since their protection is the motive for research, new drugs development and innovation, a chain which ends to the users of the system. It is questionable though whether, an organization which does not have the full equipment and the trained staff to exercise such tests and perform market evaluation, will undertake such responsibilities effectively. Furthermore this organization is public and the country is obliged to terminate 150,000 public employees until the end of 2015 *(Memorandum of Understanding on Specific Economic Policy and Conditionality, 2012).*

Public health and public education are the two major areas where significant cuts are planned to take place during the next two years. The funding of the system tends to decrease in ultimate amounts and resources will be shrinked towards 2015. Under such an environment, still there might be moral hazards mostly stem from strict budget policies and decrease in available cash budgets. Any opportunity costs could not be identified for the system, since the specific economic evaluation did not include more types of evaluation in its research. Opportunity costs are identified when alternatives exist.

Pharmaceutical companies though expect huge growth mostly from generic drugs and bio-similars, in global level up to 2017 *(Pharmaceutical Technology Europe, 2012)*.

In their recent study *Rizzo and Zeckhauser (2009)* concluded that generic drugs alter the consumer behaviour of patients who prefer to adjust their prescription portfolios to lower priced drugs in general. Patients still buy branded drugs when necessary but tend to search for cheaper ones since they are market-driven avoiding centralised approaches.

On the other side, in Greece, people have not yet acquired the suitable mindset to accept generics as equivalent. Patients have access to branded medicines, and according to the new law, they could choose to use them since they will be willing to pay the difference in cost. This raises inequalities as wealthier patients have access to branded products. While lower prices of generics benefit healthcare spending, the prescription of uncontrolled generics may create unwanted reactions to patients which may end to unplanned expenses.

4.3 Recommendation

In addition the new legal framework does not present any methods on how to measure and monitor health inequalities. Actually, it switches the supply induced demand from the doctor to the pharmacist. Nevertheless, the new prescription system will be electronic, and this is an initiative to register information that could be proved useful.

It is well-understood that country does not have any flexibility in altering the reform. Greece experiences unfamiliar situations and it is not the intention of this study only to critique. Therefore, the recommendation is based on a two-pronged strategy immediately to be implemented:

(1) To assign an upgraded role to the ***National Medicines Organization (EOF),*** beyond its scientific mission, and equip it with any available and necessary resource to perform administrative controls and health equity audits *(move resources and staff from other public services and centralise the scientific with the operational audits).*

(2) To bring together the primary system's participants and agree on a framework where health equity audits will take place in terms of pharmaceuticals' use in the country and their impact on a day-to-day analysis *(reports should be prepared on monthly basis for the country and this will have direct affect to the medicines' policy of the country).*

In the next figure are given the steps that could be followed in order to prepare the common framework *(Figure 4).*

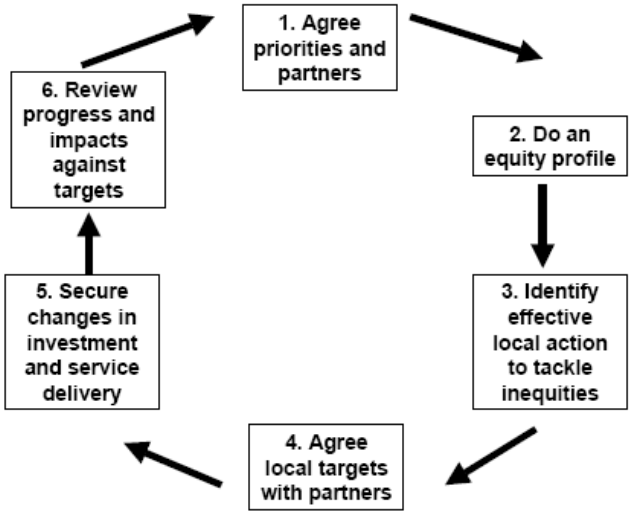

Figure 4. The steps in health equity audit

(Source: Hamer, Lucy et al (2003) Health Equity Audit Made Simple: A briefing for Primary Care Trusts and Local Strategic Partnerships. *NHS Health Development Agency, Working Document*, p. 19.)

The recommendation introduced aims to provide answers in the question of which will be the impact in the new healthcare map of the country (for pharmaceuticals use) due to this reform.
The country demonstrates its own specialties which stem from social, cultural and political aspects. In such a case, it is expected that any increase in healthcare demand may lead to healthcare discounts and distortions which in extent may lead to losses instead of savings in the system and the society.

Conclusions

Any change in health care systems' policies incorporate balancing of trade-offs. When radical interventions are imposed, like in the case of Greece, thorough attention should be given in the overall impact in order to avoid negative non-reversible outcomes. By adopting non-tested policies, especially in healthcare, this may jeopardise country's wellbeing and affect its economic productivity and prosperity. The business of making generics hides huge opportunities and has a gradual progress over the last decade both in European and global level.

Nevertheless, keeping people healthy is the next challenge for any advanced economy. A possible obstacle in this is the healthcare paradox; meaning the lack of money in investing in health solutions that were financed for research and development. Strategies like result-based financing and healthy-life years for citizens could be parameters of a broader concern.

From the industrial age mankind has transited to knowledge era. Health capacity and health capital though, is expected to define the forefront years and reveal regional weaknesses in the globalised matrix. The future competitive advantage for the regions is expected to be the health welfare. This study concludes that it is not certain whether the adoption of generic drugs will benefit the citizens of the country, in overall terms. Although this strategy has succeeded in advanced European and outside economies, current reforms in the country seem that do not provide a fertile ground and raise precipitant inequalities. Mostly this is due to that the restructure provoked is not a rational derivative of a progress rather than an outside impose due to economic recession.

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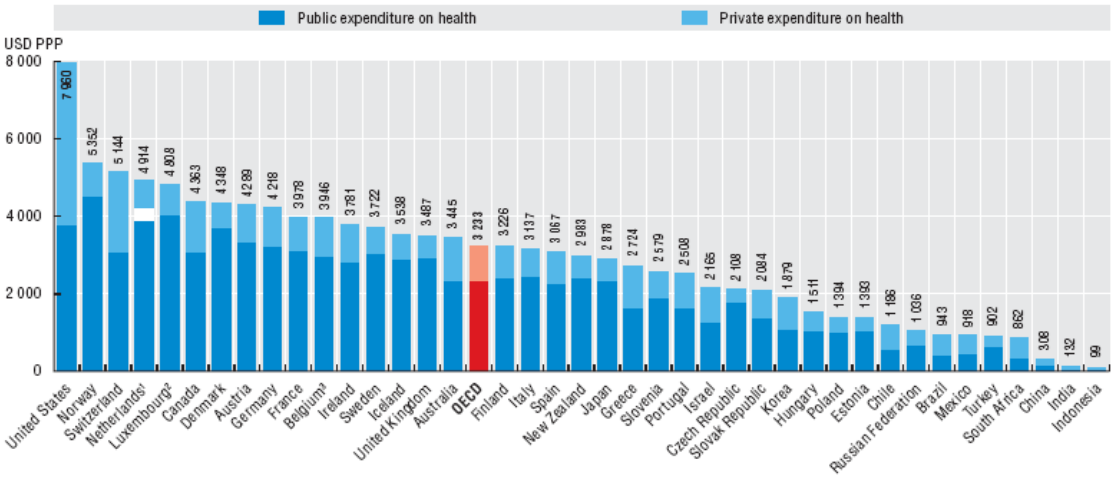
APPENDIX A
More health for the money: The ten leading sources of inefficiency

Source of inefficiency	Common reasons for inefficiency	Ways to address inefficiency
1. Medicines: underuse of generics and higher than necessary prices for medicines	Inadequate controls on supply-chain agents, prescribers and dispensers; lower perceived efficacy/safety of generic medicines; historical prescribing patterns and inefficient procurement/distribution systems; taxes and duties on medicines; excessive mark-ups.	Improve prescribing guidance, information, training and practice. Require, permit or offer incentives for generic substitution. Develop active purchasing based on assessment of costs and benefits of alternatives. Ensure transparency in purchasing and tenders. Remove taxes and duties. Control excessive mark-ups. Monitor and publicize medicine prices.
2. Medicines: use of substandard and counterfeit medicines	Inadequate pharmaceutical regulatory structures/mechanisms; weak procurement systems.	Strengthen enforcement of quality standards in the manufacture of medicines; carry out product testing; enhance procurement systems with pre-qualification of suppliers.
3. Medicines: inappropriate and ineffective use	Inappropriate prescriber incentives and unethical promotion practices; consumer demand/expectations; limited knowledge about therapeutic effects; inadequate regulatory frameworks.	Separate prescribing and dispensing functions; regulate promotional activities; improve prescribing guidance, information, training and practice; disseminate public information.
4. Health-care products and services: overuse or supply of equipment, investigations and procedures	Supplier-induced demand; fee-for-service payment mechanisms; fear of litigation (defensive medicine).	Reform incentive and payment structures (e.g. capitation or diagnosis-related group); develop and implement clinical guidelines.
5. Health workers: inappropriate or costly staff mix, unmotivated workers	Conformity with pre-determined human resource policies and procedures; resistance by medical profession; fixed/inflexible contracts; inadequate salaries; recruitment based on favouritism.	Undertake needs-based assessment and training; revise remuneration policies; introduce flexible contracts and/or performance-related pay; implement task-shifting and other ways of matching skills to needs.
6. Health-care services: inappropriate hospital admissions and length of stay	Lack of alternative care arrangements; insufficient incentives to discharge; limited knowledge of best practice.	Provide alternative care (e.g. day care); alter incentives to hospital providers; raise knowledge about efficient admission practice.
7. Health-care services: inappropriate hospital size (low use of infrastructure)	Inappropriate level of managerial resources for coordination and control; too many hospitals and inpatient beds in some areas, not enough in others. Often this reflects a lack of planning for health service infrastructure development.	Incorporate inputs and output estimation into hospital planning; match managerial capacity to size; reduce excess capacity to raise occupancy rate to 80–90% (while controlling length of stay).
8. Health-care services: medical errors and suboptimal quality of care	Insufficient knowledge or application of clinical-care standards and protocols; lack of guidelines; inadequate supervision.	Improve hygiene standards in hospitals; provide more continuity of care; undertake more clinical audits; monitor hospital performance.
9. Health system leakages: waste, corruption and fraud	Unclear resource allocation guidance; lack of transparency; poor accountability and governance mechanisms; low salaries.	Improve regulation/governance, including strong sanction mechanisms; assess transparency/ vulnerability to corruption; undertake public spending tracking surveys; promote codes of conduct.
10. Health interventions: inefficient mix/ inappropriate level of strategies	Funding high-cost, low-effect interventions when low-cost, high-impact options are unfunded. Inappropriate balance between levels of care, and/or between prevention, promotion and treatment.	Regular evaluation and incorporation into policy of evidence on the costs and impact of interventions, technologies, medicines, and policy options.

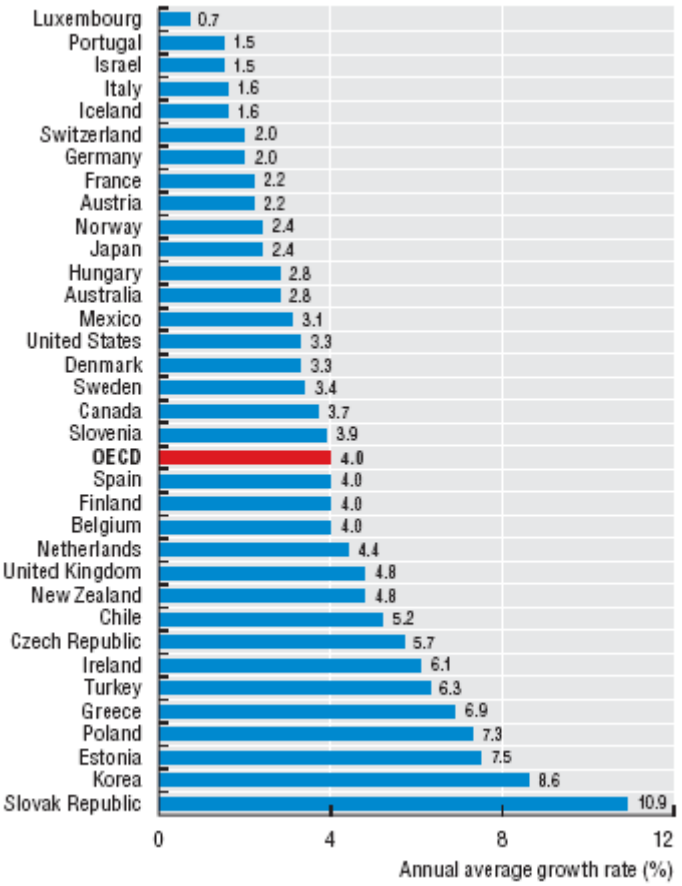
(Source: World Health Organisation (2010) Health Systems Financing: the path to universal coverage. *The World Health Report*, p. 63).

APPENDIX B
Total Health Expenditure per capita (public and private; 2009 data)



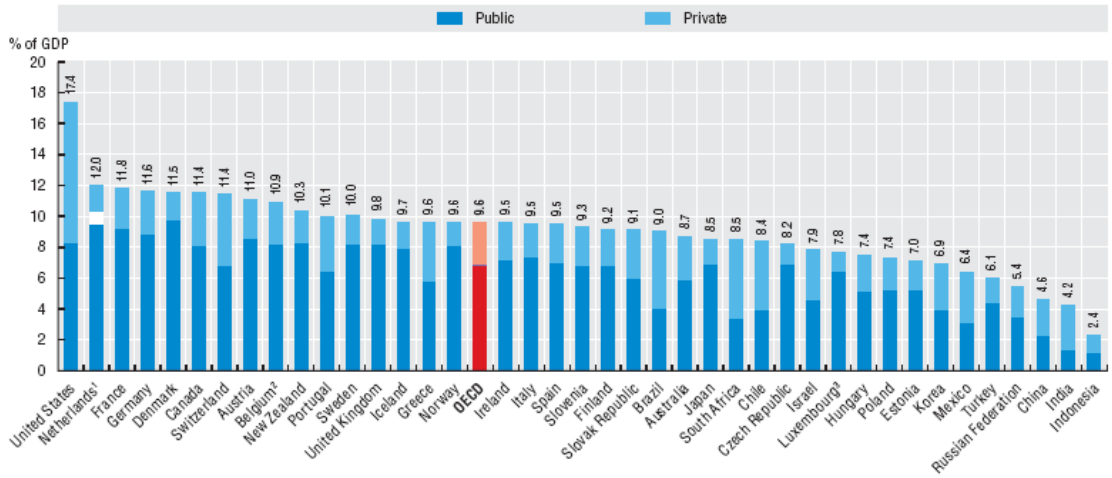
(Source: OECD (2011) Health at a Glance 2011: OECD Indicators. OECD Publishing, p. 149, http://dx.doi.org/10.1787/health_glance-2011-en)

APPENDIX C
Annual average growth rate in health expenditure per capita in real terms, 2000-09 (or nearest year)



(Source: OECD (2011) Health at a Glance 2011: OECD Indicators. OECD Publishing, p. 149, http://dx.doi.org/10.1787/health_glance-2011-en)

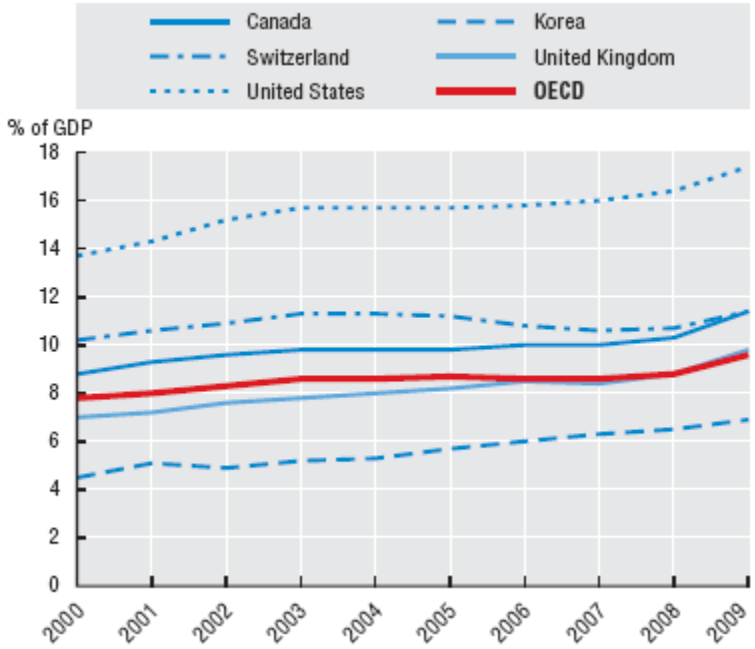
APPENDIX D
Total Health Expenditure as a share of GDP
(public and private; 2009 or nearest year)



1. In the Netherlands, it is not possible to clearly distinguish the public and private share related to investments.
2. Total expenditure excluding investments.
3. Health expenditure is for the insured population rather than the resident population.

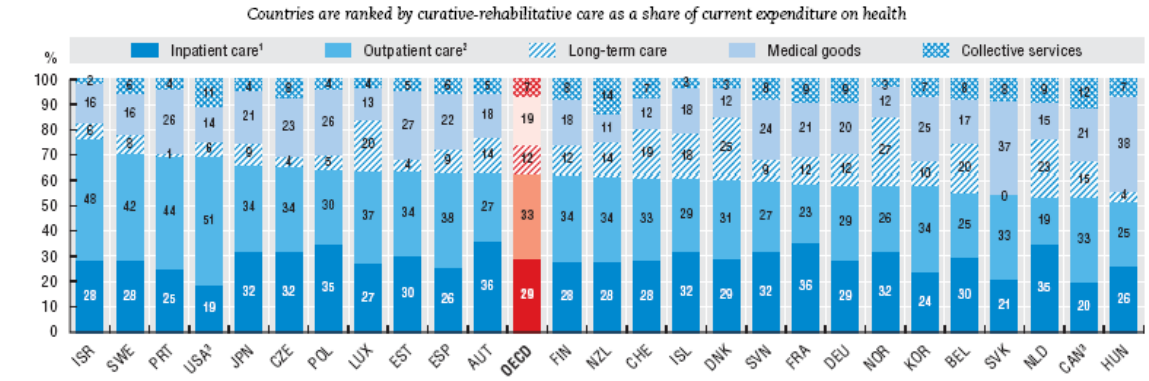
(Source: OECD (2011) Health at a Glance 2011: OECD Indicators. OECD Publishing, p. 151, http://dx.doi.org/10.1787/health_glance-2011-en)

APPENDIX E
Total health expenditure as a share of GDP, selected OECD countries, 2000-09



(Source: OECD (2011) Health at a Glance 2011: OECD Indicators. OECD Publishing, p. 151, http://dx.doi.org/10.1787/health_glance-2011-en)

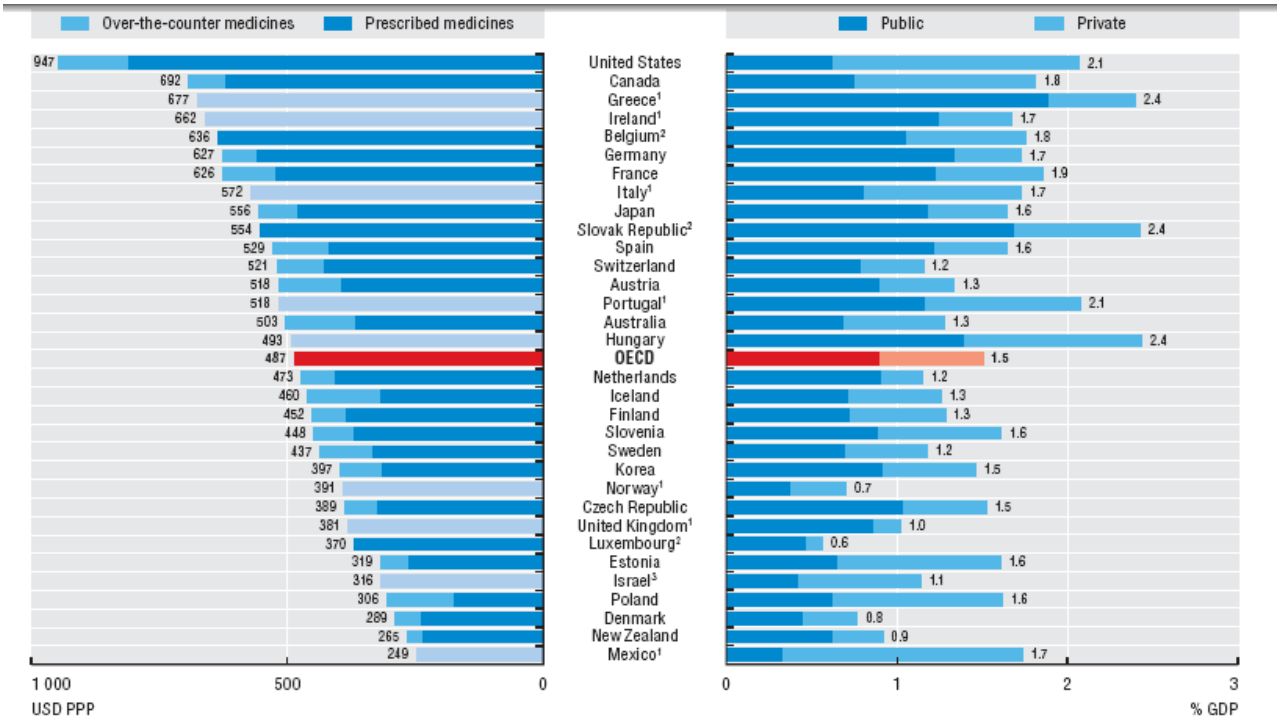
APPENDIX F
Current health expenditure by function of health care, 2009



1. Refers to curative-rehabilitative care in inpatient and day-care settings.
2. Includes home-care and ancillary services.
3. Inpatient services provided by independent billing physicians are included in outpatient care for the United States and Canada.

(Source: OECD (2011) Health at a Glance 2011: OECD Indicators. OECD Publishing, p. 153, http://dx.doi.org/10.1787/health_glance-2011-en)

APPENDIX G
Expenditure on pharmaceuticals per capita and as a share of GDP, 2009 (or nearest year)

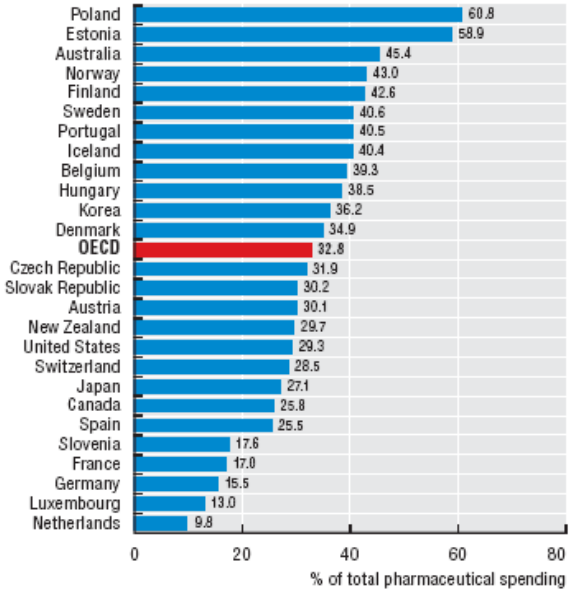


(Source: OECD (2011) Health at a Glance 2011: OECD Indicators. OECD Publishing, p. 155, http://dx.doi.org/10.1787/health_glance-2011-en)

APPENDIX H
Evidence-based information on pharmaceutical expenditures

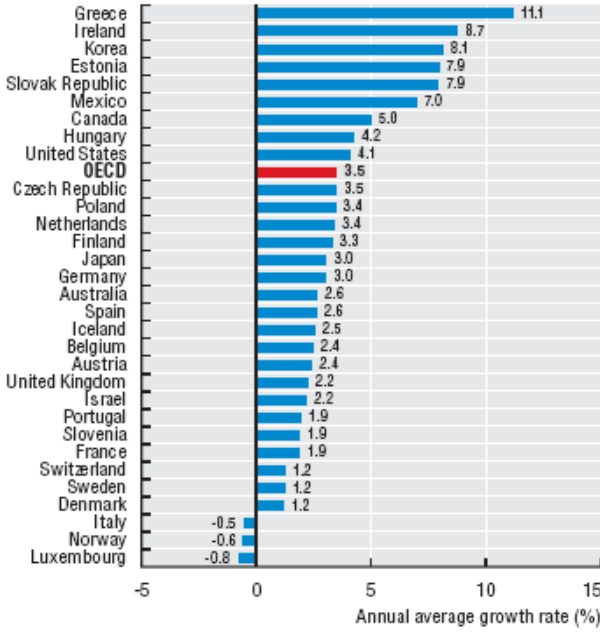
APPENDIX H1

Out-of-pocket expenditure as a share of total pharmaceutical expenditure, 2009 (or nearest year)



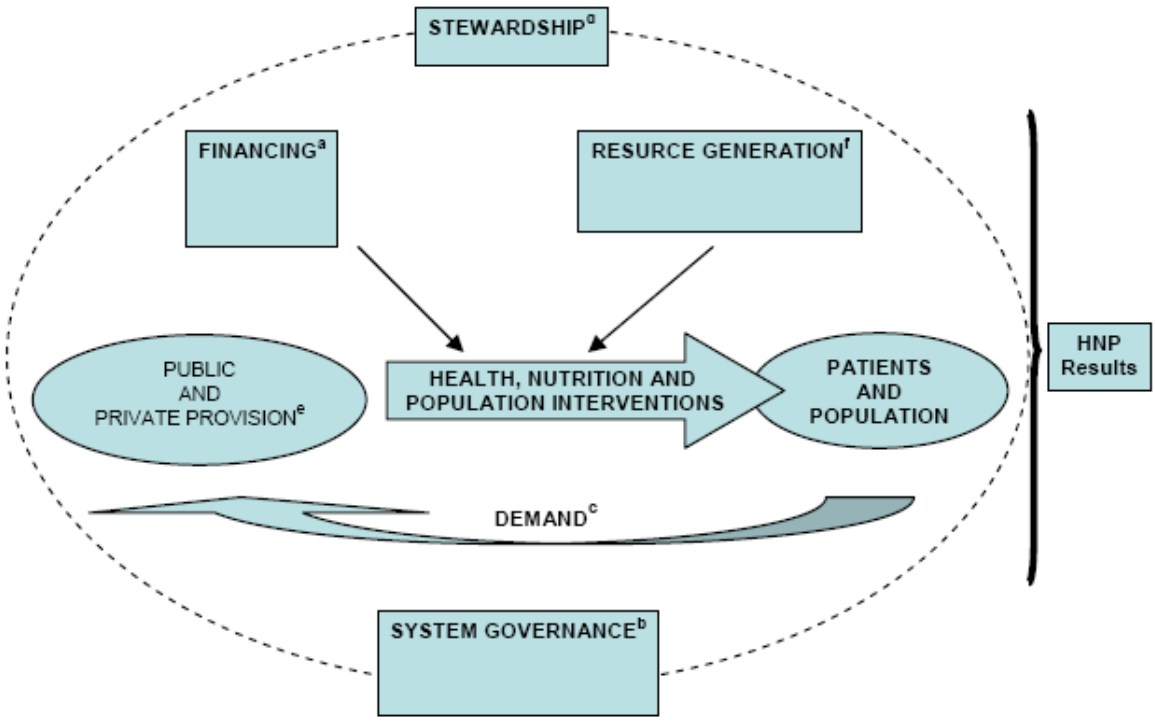
APPENDIX H2

Growth in real per capita pharmaceutical expenditure, 2000-09 (or nearest year)



(Source: OECD (2011) Health at a Glance 2011: OECD Indicators. OECD Publishing, p. 155, http://dx.doi.org/10.1787/health_glance-2011-en)

APPENDIX I
Health System Functions and Other Determinants of Good System Performance



Source: Based on the *World Health Report, 2000*, WHO.
a. Includes funding (public, out-of-pocket, and DAH), contributions, pooling, and payment mechanisms.
b. Includes financial management and procurement and "other" systems.
c. Influenced by preferences, beliefs and behaviors.
d. Oversight.
e. Service delivery.
f. Includes human resources, pharmaceuticals, and medical equipment.

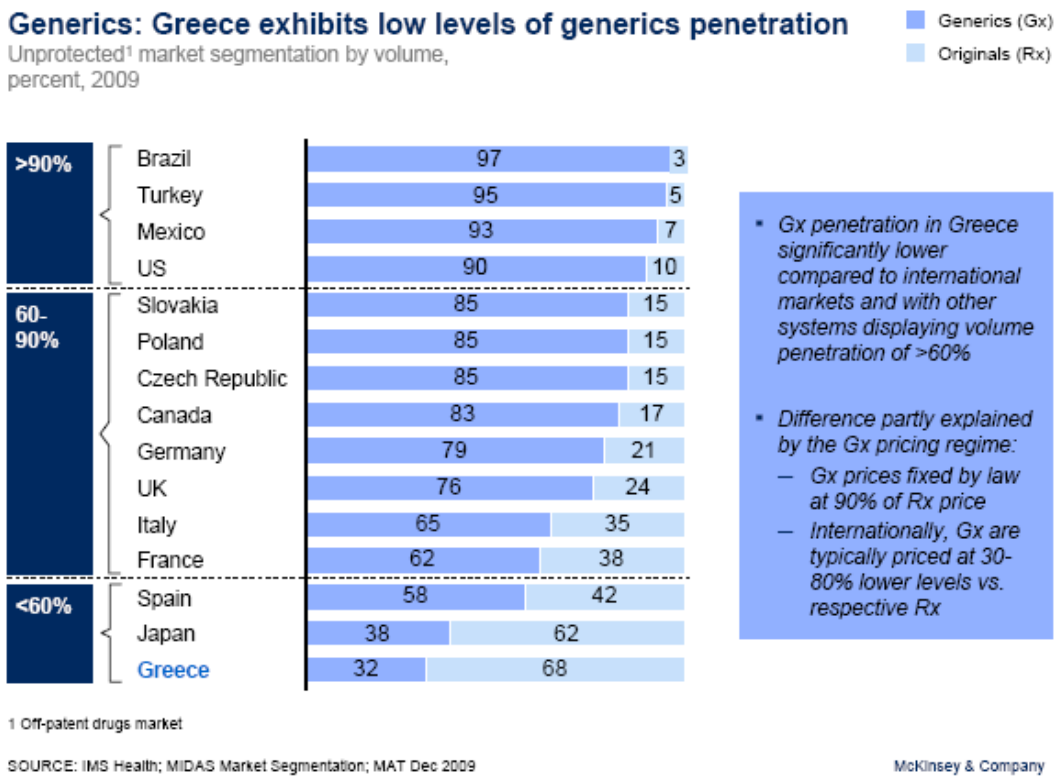
(Source: World Bank (2007) Healthy Development: The World Bank Strategy for Health, Nutrition and Population Results, p. 89)

APPENDIX J
Country statistical profile: Greece 2011-2012

	Unit	2003	2004	2005	2006	2007	2008	2009	2010
Production and income									
Gross domestic product (GDP)	Bln USD curr. PPPs	250.3	266.5	272.8	302.1	316.2	338.0	330.6	318.7
GDP per capita	USD current PPPs	22 702	24 088	24 572	27 095	28 250	30 077	29 303	28 189
Gross national income (GNI) per capita	USD current PPPs	22 567	23 917	24 184	26 513	27 408	29 097	28 501	27 415
Household disposable income	Annual growth %	4.7	3.1	1.9	5.4	9.2	-1.8	2.7	..
Economic growth									
Real GDP growth	Annual growth %	5.9	4.4	2.3	5.2	4.3	1.0	-2.0	-4.5
Net saving rate in household disposable income	%	-6.2	-6.9	-9.7	-9.5	-3.0	-8.3	-3.2	..
Gross fixed capital formation	% of GDP	11.8	0.4	-6.3	10.6	5.5	-7.5	-11.2	-16.5
Economic structure									
Real value added: agriculture, forestry, fishing	Annual growth %	-8.8	10.7	-0.2	-11.1	-7.8	10.1	9.3	12.3
Real value added: industry	Annual growth %	3.9	0.0	9.7	-5.3	1.1	0.8	0.4	-11.6
Real value added: services	Annual growth %	3.5	3.0	3.0	4.7	2.2	5.7	1.1	-5.0
Government deficits and debt									
Government deficit	% of GDP	-5.7	-7.4	-5.3	-6.0	-6.7	-9.8	-15.6	-10.4
General government debt	% of GDP	112.3	114.8	121.2	115.6	112.9	116.1	131.6	147.3
General government revenues	% of GDP	39.0	38.1	38.6	39.2	40.0	39.9	37.3	39.1
General government expenditures	% of GDP	44.7	45.5	44.0	45.2	46.6	49.7	52.9	49.5
Expenditure									
Public expenditure on health	% of GDP	5.3	5.1	5.8	6.0	5.8	..	..	..
Private expenditure on health	% of GDP	3.6	3.5	3.8	3.7	3.8	..	..	..
Public social expenditure	% of GDP	19.8	19.9	21.0	21.3	21.3	..	..	..
Private social expenditure	% of GDP	1.9	1.8	1.7	1.6	1.5	..	..	..
Public pension expenditure	% of GDP	11.0	11.1	11.7	11.8	11.9	..	..	..
Private pension expenditure	% of GDP	..	..	..	..	0.0	0.0	0.0	..
Net official development assistance (Aid)	% of GNI	0.21	0.16	0.17	0.17	0.16	0.21	0.19	0.17

(Source: OECD (2012) OECD Factbook statistics, Country Statistical Profiles. Key tables from OECD, http://dx.doi.org/10.1787/csp-grc-table-2011-1-en)

APPENDIX K
Generic drugs penetration in Greek pharmaceutical market



(Source: McKinsey & Company (2012) Greece 10 Years Ahead: Defining Greece's new growth model and strategy, p. 61)

APPENDIX L
Generic drugs in USA pharmaceutical market (patent expiration)

Generic Name	Pioner Brand Name	Manufacturer	Year of Patent Expiration	Date of Generic Entry
Thioridazine	Mellaril	Sandoz	N.A.	May 1983
Indomethacin	Indocin	Merck	1981	May 1984
Tolazamide	Tolinase	Upjohn	N.A.	October 1984
Methyldopa	Aldomet	Merck	1984	November 1984
Chlorpropamide	Diabinese	Pfizer	1984	November 1984
Ibuprofen	Motrin/Rufen	Upjohn/Boots	1985	July 1985
Lorazepam	Ativan	Wyeth	1985	September 1985
Diazepam	Valium	Roche	1985	September 1985
Propranolol	Inderal	Ayerst	1985	September 1985
Metoclopramide	Reglan	Robins	1985	July 1985
Flurazepam	Dalmane	Roche	1985	February 1986
Doxepin	Sinequan/Adapin	Pfizer/Pennwalt	1986	April 1986
Haloperidol	Haldol	McNeil	1986	June 1986
Clonindine	Catapres	Boehringer Ingelheim	1986	July 1986
Verapamil	Calan/Isoptin	Searle/Knoll	1986	September 1986
Perphen/Amitryptyline	Triavil/Etrafon	Merck/Schering	1986	September 1986
Cephalexin	Keflex	Lilly	1987	April 1987
Clorazepate	Tranxene/Azene	Abbott/Endo	1987	June 1987

SOURCE.–Food and Drug Administration Approved Drug Product List (Orange Book) (1981–87) for year of patent expiration; PMA Patent Status of Medicinals; IMS America, Inc., U.S. Drug Store and Hospital Market (1983–87) for date of generic entry.
NOTE.–N.A. = not available.

(Source: Grabowski, G. Henry and Vernon, M. John (1992) Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act. *Journal of Law & Economics*, XXXV, p. 348)

APPENDIX M
Directives in controlling pharmaceutical spending
(Structural fiscal reforms in Greece)

Controlling pharmaceutical spending

In order to achieve EUR 1 billion of reduction in outpatient pharmaceutical spending in 2012, the Government will simultaneously implement a set of consistent policies comprising changes in pricing, prescribing and reimbursement of medicines that enhance the use of less expensive medicines, control prescription and consumption and prosecute misbehaviour and fraud. The Government defines a consistent set of incentives and obligations for all participants along the medicines supply chain (including producers, wholesalers, pharmacies, doctors and patients) to promote the use of generic medicines.

The Government will revise the co-payment system in order to exempt from co-payment only a restricted number of medicines related to specific therapeutic treatments. **[Q1-2012]**

(Source: IMF-EU-ECB (2012) Memorandum of Understanding on Specific Economic Policy Conditionality, p. 13).

APPENDIX N
Directives in adopting the use of generic medicines
(Structural fiscal reforms in Greece)

Increasing use of generic medicines

A comprehensive set of measures is adopted simultaneously to promote the use of generic and less expensive medicines. The aim of these measures is to gradually and substantially increase the share of the generic medicines to reach 35 percent of the overall volume of medicines sold by pharmacies by **end-2012**, and 60 percent by **end-2013**. This will be achieved by:

- reducing the maximum price of the generic to 40 percent of the price of the originator patented medicine with same active substance at the time its patent expired. This is set as a maximum price; producers can offer lower prices, thus allowing an increased competition in the market. **[Q1-2012]**
- automatically reducing the prices of originator medicines when their patent expires (off-patent branded medicines) to a maximum of 50 percent of its price at the time of the patent expiry. Producers can offer lower prices, thus allowing an increased competition in the market. **[Q1-2012]**
- creating dynamic competition in the market for generic medicines through price reductions of at least 10 percent of the maximum price of each generic follower. **[Q4-2012]**
- associating a lower cost-sharing rate to generic medicines that have a significantly lower price than the reference price for reimbursement (lower than 40 percent of the reference price) on the basis of the experience of other EU countries, while increasing substantially the co-payment of more expensive medicines in the reference category and of new molecules. **[Q1-2012]**
- allowing the reimbursement of newly patented medicines (*i.e.* new molecules) only after at least 2/3 of the EU countries are already reimbursing them and on the basis of a proper assessment of their cost-effectiveness carried out in other European countries. **[Q1-2012]**
- excluding from the list of reimbursed medicines those which are not effective or cost-effective on the basis of the experience of other countries. **[Q1-2012]**
- making it compulsory for physicians to prescribe by international non-proprietary name for an active substance, rather than the brand name. **[Q1-2012]**
- mandating the substitution of prescribed drugs by the lowest–priced product of the same active substance in the reference category by pharmacies (compulsory "generic substitution"). **[Q1-2012]**

The Government takes further measures to ensure that at least 40 percent of the volume of medicines used by public hospitals is made up of generics with a price below that of similar branded products and off-patent medicines. This should be achieved, in particular by making compulsory that all public hospitals procure pharmaceutical products by active substance, by using the centralised tenders procedures developed by EPY and by enforcing compliance with therapeutic protocols and prescription guidelines. **[Q2-2012]**

The Government, pharmaceutical companies and physicians adopt a code of good conduct (ethical rules and standards) regarding the interactions between pharmaceutical industry, doctors, patients, pharmacies and other stakeholders. This code will impose guidelines and restrictions on promotional activities of pharmaceutical industry representatives and forbids any direct (monetary and non-monetary) sponsorship of specific physicians (sponsorship should be attributed through a common and transparent allocation method), based on international best practice. **[Q1-2012]**

The Government simplifies administrative and legal procedures, in line with EU legal frameworks, to speed up the entry of cheaper generic medicines. **[Q2-2012]**

(Source: IMF-EU-ECB (2012) Memorandum of Understanding on Specific Economic Policy Conditionality, p. 15-16).

APPENDIX O
Directives in pricing of medicines
(Structural fiscal reforms in Greece)

Pricing of medicines

The Government continues to update, on a quarterly basis, the complete price list for the medicines in the market, using the new pricing mechanism based on the three EU countries with the lowest prices. **[Q1-2012]**

The Government introduces an automatic claw-back mechanism (quarterly rebate) on the turnover of pharmaceutical producers which guarantees that the outpatient pharmaceutical expenditure does not exceed budget limits. **[Q1-2012]**

Starting from **Q1-2012**, the pharmacies' profit margins are readjusted and a regressive margin is introduced - *i.e.* a decreasing percentage combined with flat fee of EUR 30 on the most expensive drugs (above EUR 200) - with the aim of reducing the overall profit margin to below 15 percent.

Government produces an implementation report on the impact of the new profit margins by **Q1-2013**. If it is shown that this new model to calculate profit margins does not achieve the expected result, the regressive margin will be further revised.

Starting from **Q1-2012**, the wholesalers' profit margins are reduced to converge to 5 percent upper limit.

(Source: IMF-EU-ECB (2012) Memorandum of Understanding on Specific Economic Policy Conditionality, p. 13).

APPENDIX P
Directives on prescribing and monitoring
(Structural fiscal reforms in Greece)

Prescribing and monitoring

The Government

- takes further measures to extend in a cost-effective way the current e-prescribing to all doctors, health centres and hospitals. E-prescribing is made compulsory and must include at least 90 percent of all medical acts covered by public funds (medicines, referrals, diagnostics, surgery) in both NHS facilities and providers contracted by EOPYY and the social security funds. **[Q1-2012]**
- introduces a temporary and cost-effective mechanism (until all doctors are able to use the e-prescription system) which allows for the immediate and continuous monitoring and tracking of all prescriptions not covered by e-prescription. This mechanism will make use of the web-based e-prescription application established by IDIKA, which allows the pharmacies to electronically register manual prescriptions from a specific doctor to a specific patient. For medicines to be reimbursed by EOPYY (and other funds), pharmacies must register in the web-based application all manual prescriptions. For this service, doctors who prescribe manually will be charged a monthly administrative fee by EOPYY to compensate the pharmacies. The introduction of this temporary mechanism would ensure that all prescriptions are electronically recorded, allowing for the full and continuous monitoring of doctors' prescription behaviour, their compliance with prescription guidelines. **[February 2012]**
- continues publishing prescription guidelines/protocols for physicians. Starting with the guidelines for the most expensive and/or mostly used medicines the government makes it compulsory for physicians to follow prescription guidelines. Prescription guidelines/protocols are defined by EOF on the basis of international prescription guidelines to ensure a cost-effective use of medicines and are made effectively binding. **[Q1-2012]**
- enforces the application of prescription guidelines also through the e-prescription system, therefore discouraging unjustified prescriptions of most expensive medicines and diagnostic procedures. **[Q1-2012]**
- produces (Ministry of Health and EOPYY together with the other social security funds until they merge) detailed monthly auditing reports on the use of e-prescription in NHS facilities and by providers contracted by EOPYY and other social security funds (until they merge). These reports are shared with the European Commission, ECB and IMF staff teams. **[Q1-2012]**
- implements (Ministry of Health and EOPYY together with the other social security funds until they merge) an effective monitoring system of prescription behaviour. They establish a process to regularly assess the information obtained through the e-prescribing system. **[Q2-2012]**
- produces regular reports, at least on a quarterly basis, on pharmaceutical prescription and expenditure which include information on the volume and value of medicines, on the use of generics and the use of off-patent medicines, and on the rebate received from pharmacies and from pharmaceutical companies. These reports are shared with the European Commission, ECB and IMF staff teams. **[Q1-2012]**
- provides feedback and warning on prescription behaviour to each physician when they prescribe above the average of comparable physicians (both in NHS facilities and contracted by EOPYY and other social security funds until they merge) and when they breach prescription guidelines. This feedback is provided at least every month and a yearly report is published covering: 1) the volume and value of the doctor's prescription in comparison to their peers and in comparison

to prescription guidelines; 2) the doctor's prescription of generic medicines vis-à-vis branded and patent medicines and 3) the prescription of antibiotics. **[Q2-2012]**

- enforces sanctions and penalties as a follow-up to the assessment and reporting of misconduct and conflict of interest in prescription behaviour and non-compliance with the EOF prescription guidelines. Continuous or repeated non-compliance with the prescription rules will lead to the termination of the contract between the doctor and the EOPYY and the doctor's permanent loss of his/her capability/right to prescribe pharmaceuticals which are reimbursed by the government/EOPYY in the future. **[Q1-2012]**
- continuously updates the positive list of reimbursed medicines using the reference price system developed by EOF. **[Q1-2012]**
- selects a number of the most expensive medicines currently sold in pharmacies, to be sold in hospitals or EOPYY pharmacies, so as to reduce expenditure by eliminating the costs with outpatient distribution margins, and by allowing for a strict control of the patients who are being administered the medicines. **[Q1-2012]**

If the monthly monitoring of expenditure shows that the reduction in pharmaceutical spending is not producing expected results, additional measures will be promptly taken in order to keep pharmaceutical consumption under control. These include a prescription budget for each doctor and a target on the average cost of prescription per patient and, if necessary, across-the-board further cuts in prices and profit margins and increases of co-payments. **[Q2-2012]**

In compliance with EU procurement rules, the Government conducts the necessary tendering procedures to implement a comprehensive and uniform health care information system (*e-health system*). **[Q1-2012]**

(Source: IMF-EU-ECB (2012) Memorandum of Understanding on Specific Economic Policy Conditionality, p. 14-15).