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Short article

Reforms in the Greek pharmaceutical market during the financial crisis

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ABSTRACT

Introduction: Following the financial crisis of 2008, Greece has been facing severe fiscal problems associated with high public debt and deficit. Given their significant contribution to public sector expenditure, part of the effort to reduce public expenditure has involved a focus on pharmaceutical markets.

Methods: Our aim is to provide an overview of recent policy changes in the Greek pharmaceutical market as a response to the crisis. We also discuss other potential measures that can be implemented. The recommendations are relevant to European countries facing debt crises, but also to any other country, as improving efficiency makes funds available to be used on other interventions.

Results: In 2010 and 2011, following the debt crisis and the agreement with the IMF, EU and ECB, the Greek government introduced several policy measures aimed at cost-containment. These changes included (a) price cuts, (b) the re-introduction of a positive list, (c) changes in the profit margins of pharmacies and wholesalers, and (d) tenders for hospital drugs. As a result, public drug expenditure decreased from €5.09 billion in 2009 to €4.25 billion in 2010 and €4.10 billion in 2011.

Conclusion: As the need to cut expenditure becomes more urgent, seeking efficiency is possibly the only option for countries that do not wish to compromise quality of healthcare and public health. However, efficiency and cost containment are not only about introducing new policies, but also about the enforcement of existing laws and fighting corruption.

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1. Introduction

Since the financial crisis of 2008, some of the Eurozone countries have been facing severe fiscal problems. Greece, Portugal and Ireland have received financial help from the IMF, EU, and ECB, the so-called troika. As the main problem in these countries is associated with high public debt and

deficit, one of the main challenges is to reduce public sector expenditure. Health expenditure accounts for a significant part of the governmental budget and GDP (10.6% of GDP in Greece, 11.3% in Portugal and 9.7% in Ireland in 2010 [1]). Part of the effort to reduce public spending has involved a focus on pharmaceutical markets, given the significant contribution of pharmaceuticals to total health expenditure (24.8% in Greece [2007], 20.6% in Portugal [2008] and 17.5% in Ireland in [2009]) and its high public share (79% in Greece [2007], 55.9% in Portugal [2006], and 74.6% in Ireland [2008]) [2].

One way to reduce expenditure and generate savings for public funds would be a blunt resort to cuts. This would, however, lead to a reduction in access to medicines and, consequently, to lower quality of care. Therefore, the great challenge is to increase efficiency, which can help

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generate savings without compromising the health care system's goals [3].

As Greece is the country that currently faces by far the most severe financial problems, this paper focuses on recent policy changes in the Greek pharmaceutical market as a response to the crisis. Furthermore, we discuss other potential measures that could be implemented in order to increase efficiency without compromising health outcomes. The recommendations are also relevant to other European countries facing debt crises, since improving efficiency releases funds that are then available to be used for other interventions, given the relative scarcity of resources, regardless of the fiscal situation.

2. The Greek pharmaceutical market before the crisis

In the last five years before the crisis, total pharmaceutical expenditure in Greece nearly doubled, from 4.329 billion Euros in 2004 to 7.788 billion in 2008 [4]. In the same time period, the pharmaceutical expenditure of the public system (i.e. social health insurance funds) increased from 2.4 billion in 2004 to 4.53 billion in 2008 and reached the all-time peak of 5.1 billion in 2009. Per capita pharmaceutical expenditure increased from under €200 in 2000 to almost €700 in 2008. According to OECD data, this was the highest in the EU in 2008 (see Fig. 1).

Reasons behind the large per capita pharmaceutical expenditure in Greece include (a) the general absence of demand-side measures such as promoting generics, electronic prescribing and prescription monitoring that resulted in low generic market penetration post-patent expiry [5], relatively high generic prices [6], and high prescription volume [7]; (b) the weak enforcement of existing regulations; and (c) the abolishment of the positive list in 2006. In addition, non-regressive pharmacy and wholesaler mark-ups also contributed to the increase in expenditure when older, cheaper drugs were replaced by newer, more expensive drugs.

With the exception of generic pricing policies (according to which generic prices could not exceed 80% of the originator price), there were no policies encouraging generic uptake in Greece. Physicians had been prescribing exclusively by brand name, and – unlike some other countries – substitution was not present at the pharmacy level. As a result, generic market share by volume was 26% in Greece in 2010, which is low compared to other EU countries such as Germany (65%), the UK (60%) or the Netherlands (56%) [8]. Although originator prices in Greece are among the lowest in the EU, potential savings are foregone since generic uptake is very slow – i.e. 7% after the first year of generic entry (EU-average: 30%) and 21% after the second (EU-average: 45%). Furthermore, in the period from 2000 to 2006, the average time to generic entry following loss of exclusivity was 15 months, the highest among the EU-15 [9].

Prescribing guidelines and electronic monitoring of prescribing are still in their infancy. In addition, there are no financial or non-financial incentives in place to encourage physicians to prescribe efficiently. The absence, until recently, of a negative or positive list, means that any

drug was reimbursed. Thus, high volume is also among the main reasons that have contributed to high spending. The increase in volume took place gradually in the relatively good economic times, possibly as prescribers observed that higher volume did not lead to any consequences. In 2007, for example, Greece demonstrated the highest per-capita consumption of antibiotics of all OECD countries [4,10].

It is also worth mentioning that high mark-ups in the supply chain contribute to high expenditure. In particular, as mark-ups were not regressive in Greece, the launch of new expensive pharmaceutical products had a multiplying effect on expenditure, as opposed to other countries, where regressive mark-ups limit the additional contribution to costs on behalf of the supply chain. As a result of high pharmacy margins, there is a large number of pharmacies in Greece. In fact, at 1200 inhabitants per pharmacy, Greece has the highest concentration of pharmacies in the EU (EU-average: 3300 inhabitants per pharmacy) [11]. The number of wholesalers is also much higher than the EU average, which raises questions regarding efficiency in the provision of pharmaceuticals. There are 130 wholesalers in Greece [12], as opposed to 20 in the UK, 9 in the Netherlands, 2 in Finland and 3 in Denmark [13].

Corruption has also contributed to high pharmaceutical spending in Greece. There are claims that some physicians in Greece may be incentivised to unnecessarily prescribe particular medicines or brands [14]. There have also been cases of unusually high prescription volume [15,16] and prescriptions for people who had already died [17]. Cases of “abusive” prescribing have been included in the annual report of the General Inspector of Public Administration [18]. However, it is difficult to quantify the effect on total spending due to the unrecorded nature of such activities. Nevertheless, corruption seems to be widespread in health-care in Greece and is not restricted only to pharmaceuticals. For example, informal payments by patients towards physicians for hospital treatment, despite universal health insurance, occur very frequently [19]. Unfortunately, corruption affecting the pharmaceutical market can occur at various levels, and decisions made at the highest level can also encourage the waste of resources.

3. Policy changes

Following the debt crisis and the memorandum of agreement with the troika, the Greek government urgently introduced several cost-containment measures. The most important measures included (a) price cuts, (b) the re-introduction of a positive list, i.e. a list that includes all reimbursable pharmaceuticals, (c) changes in profit margins for pharmacies and wholesalers and (d) tenders for hospital drugs.

According to the market decree of 27th April 2010, significant price cuts applied to the wholesale price of pharmaceuticals. Price cuts were in the range of 0–27% with a weighted average of 21.5%² [20]. A second reduc-

² Price cuts took place as follows: for pharmaceuticals with a wholesaler price up to €1 there was no change in price. The reduction for pharmaceuticals priced between €1.01 and €5 was 3%, between €5.01 and €20

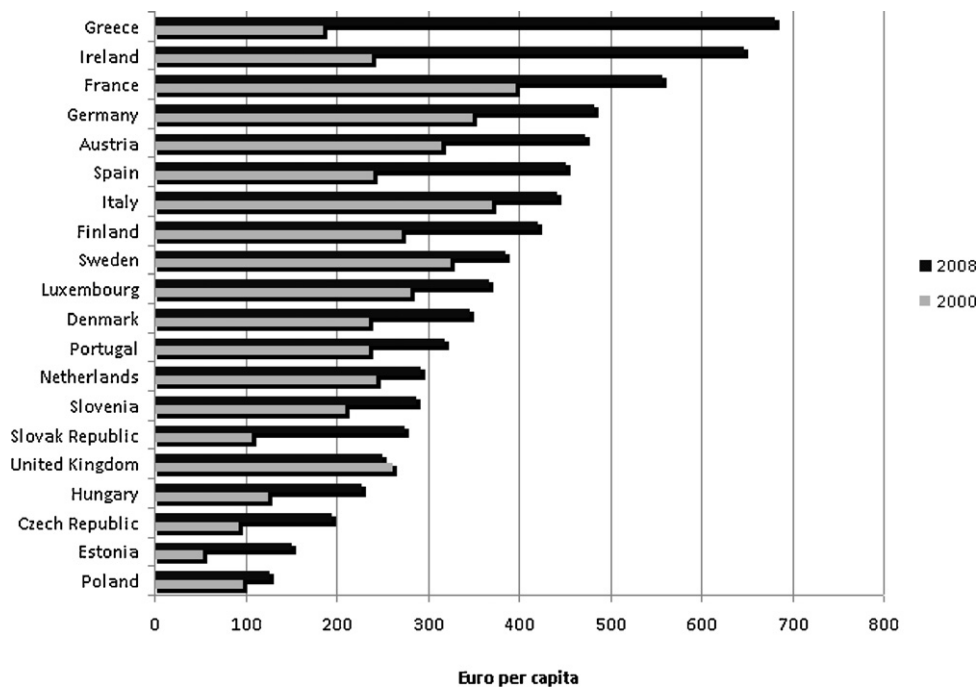


Fig. 1. Per capita pharmaceutical expenditure in the EU.

Source: Kanavos P, Vitoros S, Nicod E, Irwin R, Casson M. European Parliament Report: differences in costs of and access to pharmaceutical products in the EU. Brussels: Policy Department, Economic and Scientific Committee A DG Internal Policies; 2011.

tion of the wholesale price took place on 1 July 2011, with a weighted average of 10.2% [21]. Reductions in wholesale prices are automatically translated into reductions in public (retail) prices, as wholesale prices are proportionate to retail prices. Furthermore, the price cap for generics was decreased from 70% to 63% and later to 40% of the corresponding originator's price before patent expiry, while originator prices are now to be cut by 50% upon the entry of the first generic competitor in the market. Given that generic manufacturers are not burdened by R&D and clinical trials costs, this horizontal cut in generic prices is not expected to deter generic entry in the short run, as the per-unit cost of producing pharmaceuticals is very low, and generic manufacturers can operate at very low prices, as shown in the case of tendering in outpatient markets (evidence presented in Section 4).

Another development, in late 2011, was the reintroduction of a positive list, which had been abolished in 2006. Initially, drugs were included on the positive list if the producer would pay a 4% rebate on the difference between the price and the average cost of treatment in a therapeutic cluster. Therefore, the reintroduction of the list did not fully promote efficiency and was based on cash flows rather than on need, budget impact, or effectiveness. According to the latest policy changes, a drug is included in the positive list if it has been granted reimbursement in other EU countries using Health Technology Assessment (HTA). This

does indirectly take cost-effectiveness into account, but the criteria for inclusion on the positive list could have been more transparent and adaptable to the particular needs of the Greek pharmaceutical market and its patients. The idea was to set a reference price per therapeutic class when determining which products will be included in the positive list. However, due to difficulties in calculating the price at the cluster level, this approach was dropped in practice.

Pharmacy mark-ups are currently 35%, but are expected to be reduced. Also, a rebate from pharmacists to social insurance funds has been implemented for products whose price exceeds 2000 Euros. The rebate varies progressively from 1.5% to 8%, depending on the price of the product [22]. In addition, wholesaler margins have been decreased from 7.8% to 5.4% for prescription drugs [23]. Despite the high concentration of pharmacies, the ministry of health has announced that 1000–1200 new pharmacy licences will be issued to further increase competition on the pharmacy market. While such an initiative will increase access to care from the patient's perspective, it will not reduce prices of pharmaceuticals as retail prices on the pharmacy level are a fixed function of ex-manufacturer prices. Moreover, as pharmaceutical consumption in terms of volume is already very high, more pharmacies may lead to supplier induced demand. Thus, it is questionable whether the measure will contribute to efficiency gains or losses in the supply chain.

In the hospital market, priority has been given to generics over originators by means of tendering. The first tender for hospital drugs took place on 28th July 2011 for the procurement of ciprofloxacin in three hospitals. The tender led to a reduction in the cost of this product from €1.5

it was 20%, between €20.01 and €50 it was 23%, between €50.01 and €100 it was 25%, and for pharmaceuticals priced above €100 it was 27%.

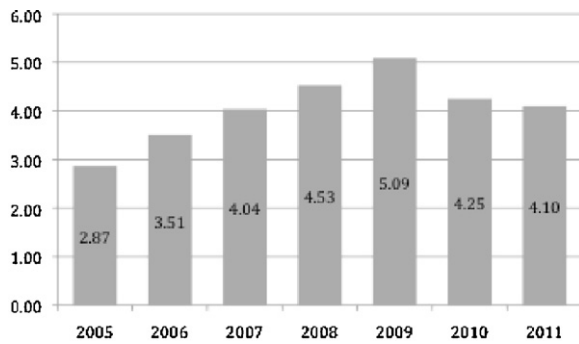


Fig. 2. Annual pharmaceutical expenditure of the Greek Public Health Insurance Funds, 2005–2011 (billion Euros).

Source: The authors, with data from the General Secretariat of Social Insurance; 2012.

million the year before to €0.222 million [24]. Another tender took place on 14th November 2011 for two products: the cost of ciprofloxacin and omeprazole decreased from €5.2 million to €0.42 million and from to €1.287 million to €0.17 million, respectively [25]. These very large reductions in costs demonstrate the foregone potential savings that could have been achieved if the tenders had been implemented directly after the corresponding law was drafted in 2006.

A plan in 2011 to introduce prescribing by INN, i.e. prescribing by the name of the chemical substance rather than by drug brand name, which would have boosted generic market shares and therefore also efficiency, was initially withdrawn. In early 2012 the plan was re-introduced. The ministry of health announced that prescribing by chemical substance would be mandatory and that pharmacists would have to dispense the cheapest generic available. As a result of fierce opposition by physician associations, the 2012-bill was amended. Physicians are allowed to prescribe a particular brand, in which case patients will have to pay the price difference (if any) between the prescribed brand and the price of the reimbursed generic out-of-pocket. Generic prescribing would increase the use of less costly generics and thereby increase efficiency. However, as the amendment gives the option to physicians to prescribe a particular brand, this may induce cost-shifting from the public system to patients and thus reduce patient access.

As a result of recent policy interventions, pharmaceutical expenditure has been reduced significantly. In particular, the annual public drug expenditure was €4.10 billion in 2011, down from 5.09 billion in 2009 and €4.25 billion in 2010 [26]. This represents a total decrease of 19.5% in two years (see Fig. 2). However, expenditure is still higher than it was in 2006 (3.51 billion) and 2007 (4.04 billion) and 42.8% higher than in 2005 (2.87 billion).

Fig. 3 demonstrates the breakdown between public and private health expenditure from 2002 to 2010. We observe that the steep increase in public health expenditure did not substitute private expenditure in years prior to 2009 when expenditure was rising. Similarly, the decrease in public health expenditure in 2010 did not lead to a significant increase in private health expenditure (which appears to

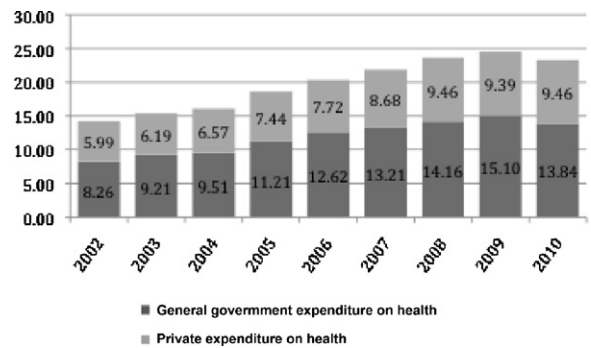


Fig. 3. Annual public and private expenditure on health in Greece, 2002–2010 (billion Euros).

Source: The authors, from the WHO Global Health Expenditure Database; 2012.

be relatively stable). Therefore one might conclude that – at least until the end of 2010 – lower public expenditure did not increase out-of-pocket spending. In addition, the decrease in public pharmaceutical expenditure was mainly a result of significant price cuts for originators and generics, higher generic market penetration and lower wholesaler markups.

4. Policy options towards efficiency

Given that Greek originator prices are already relatively low, one of the main goals should be to increase efficiency in the generic markets. Though evidence has shown that generic competition does not always reduce originator prices [27–29], a high generic market penetration in combination with low generic prices will achieve further savings. Potentially, this issue could be addressed by mandatory generic prescribing (without the option that physicians currently have to prescribe a particular brand).

Because in the past there have been safety concerns with the use of some generics in Greece, a prerequisite for an increase in generic market share is the strict enforcement of bioequivalence controls to ensure high quality of generics. Any reported deviations in drug quality between generics and branded originals would make physicians and patients reluctant to prescribe and consume generic products. Currently, all generics in the market have presented a bioequivalence report and are approved by the National Organisation for Medicines (EOF). However, in order to reassure physicians and patients, the authorities must make regular checks at the point of production and also perform additional quality assurance. The EMEA could help local authorities by providing technical expertise and suggestions on the frequency, location and methods of quality assurance.

A policy that has been very successful in achieving lower generic prices in the outpatient (retail) markets is tendering. Evidence from the Netherlands showed that prices of high-volume products such as omeprazole, simvastatin and amlodipine decreased by up to 88%, 85% and 85%, respectively, following the introduction of tendering for particular molecules [30]. This is also the case in Germany, where tendering in addition to reference pricing has led to

substantial shifts in market shares [31]. If the authorities are unable to use tenders to cover the entire market, this procurement mechanism could at least be used for high-volume in- and outpatient products. In the first instance, this will generate direct savings for any generic dispensed, without compromising patient access. In the long run, however, the measure could reduce the number of generic manufacturers, which would relax generic competition and therefore lead to fewer drugs for which at least one generic alternative is available on the market.

Although an internal reference price was planned to be introduced as means of determining which drugs would be included in the reimbursement list, this approach was later dropped. However, this is a policy option that has been used extensively across the EU. The effect of internal reference pricing on generic prices remains ambiguous. While empirical evidence from Germany has shown that internal reference pricing leads to price reductions in the first instance and thereafter generates a downward trend in prices [32], other studies indicate that the internal reference price also works as a price floor, below which no producer has an incentive to decrease their price [33]. In the UK, which has lower generic prices than other EU countries [33,34], free generic pricing has been effective, as well. In any case, it seems that internal reference pricing may only work if there are a sufficient number of competitors in the market.

As prescription volume is a factor that contributes to increased expenditure, drug budgets [35] – e.g. at the physician, at the regional, or at the national level – could help control costs. In addition, clinical guidelines and prescribing targets, e.g. a compulsory percentage of generic prescriptions among all prescriptions made by a physician, should be adopted to influence prescribing patterns. These approaches would, however, require the implementation of credible enforcement mechanisms.

Health Technology Assessment or Value-Based Pricing may also be used as instruments to divert funding from less cost-effective products towards therapies with higher levels of therapeutic value. However, this requires a mechanism similar to NICE in the UK, which is not easy to create. For a relatively small market like Greece with a time constraint for reforms, this may only be an option for the long run [36]. For the time being, limiting external price referencing to EU countries that employ HTA (adjusting for purchasing power parity and exchange rate fluctuations) for reimbursement purposes could be an option that could easily be implemented by using compliance with the external reference price as criteria for the positive list.

5. Discussion and policy implications

Pharmaceutical markets in Greece have been very inefficient for a long time, and the waste involved in public health expenditure has greatly contributed to the Greek debt crisis. The country faced years of missed opportunities, with the peak being in 2006–2009, when per-capita pharmaceutical expenditure rose steeply, without any action being taken to prevent this from happening.

One of the main post-troika actions taken to reduce pharmaceutical expenditure was to reduce originator

prices via market decrees. As eleven EU-27 countries use Greece as a reference country [37], price cuts in Greece led to lower originator prices in other countries as well [38]. As a result, some companies have threatened to withdraw their products from the Greek market following the recent price cuts [39] or may delay launch in the near future [38]. Until now, product withdrawal only took place only at a very small scale. In addition, parallel exports have led to local shortages of some drugs [40], resulting in a ban on exports of particular products. Such bans can swiftly resolve these problems, but authorities have to make sure that the policy measure is enacted early enough, before shortages are actually observed.

Measures taken have led to a significant decrease in spending. However, there is room for improvement and action has to be taken to further increase efficiency, as discussed in this paper. Apart from designing policies, implementation and enforcement are also of great importance, as this may often be the weak link in achieving policy goals. Interestingly, a mandatory rebate of 4% (with a total amount of approximately €140 million) from the pharmaceutical industry to public health insurance funds was not enforced in the years 2006 and 2007 [41]. In addition, corruption at various levels of the public sector may have played a key role in unnecessary expenditure, as Greece ranks in the 80th place among 182 countries globally in the Corruption Perceptions Index [42]. Fighting corruption at all levels should therefore also be an absolute priority in the efforts to increase efficiency.

As the need to cut expenditure becomes more urgent, seeking efficiency is possibly the only option for countries that do not wish to compromise quality of healthcare and public health. Given that Greek originator prices are already low, it seems to be more reasonable to focus primarily on total volume, as well as generic uptake and generic prices. While this would partly allow to further decrease costs without compromising patient access, it has to be acknowledged that any type of cost cutting in health care may convert public expenditure to private expenditure; at least to some extent. Whether this is directly intended by a policy measure or this occurs through unforeseen imperfections in regulation, appropriate measures need to be implemented to protect those who are unable to bear additional private expenditure on healthcare. One way to achieve that could be a special committee that decides on exemptions for vulnerable groups on a case-by-case basis. In any case, the need for further reforms and increased efficiency remains, while policy makers should be very careful not to compromise patient access and outcomes in order to prevent a public health disaster, especially for vulnerable and low income patients.

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