

Policy Article

The pharmaceutical policy reforms in Greece during the economic crisis, 2010-2015

ABSTRACT

In the decade 2000-2009 Greece had the higher rate of public pharmaceutical expenditures as a percentage out of the total public health expenditure and the bigger per capita consumption of public pharmaceutical expenditure among the EU countries. At the end of this decade, Greek governments confronted with this “paradox” and tried to reduce it unsuccessfully. In order to finance its debt, Greece took a financial package of 110 billion € from Troika of the European Commission (EC), European Central Bank (ECB), and International Monetary Fund (IMF) under strict conditions and adopted austere policies designed by Troika all over the public finance sector in order to reduce its debts. Our aim is to provide an overview of new legislation starting from the first memorandum until the first quarter of 2014 and to record the impact of pharmaceutical reforms in all over the pharmaceutical chain. The legislation of this period had the reduction in public pharmaceutical expenditures as a primary endpoint. The new laws focus on new drug pricing policies, profit control regulations, and demand regulations. The economic targets in order to decrease public pharmaceutical expenditures were achieved but not without cost, all the parts in the pharmaceutical chain were affected, especially the last link the patients.

Key words: Greece, Economic crisis, Reform, Public pharmaceutical expenditures, Out-of-pocket expenditures.

1. INTRODUCTION

Health care expenditure in Greece in 2000 was the 8,0 % of the gross domestic product (GDP) or 1.451,0 \$ per capita, and the pharmaceutical expenditure was accounted 18,9% of health care expenditure or 274,7 \$ per capita. Ten years later, in 2009, the health care expenditure was the 10,2 % of the GDP, or 2.997 \$ per capita, with the pharmaceutical expenditure representing a significant and a fast-growing component of health spending, the 27,8% of the total health care expenditure, or 828,7 \$ per capita. Over this decade, the total health expenditure dynamics were growing much faster in Greece than in the EU countries (6.1% vs. 4.8% per year in real terms) [1].

Total health care expenditure and pharmaceutical expenditure compared to GDP and per capita pharmaceutical expenditure are frequently used as indicators in order to have an aspect about the quantitative data among countries. Furthermore, comparisons among countries should be interpreted with caution and only if influencing factors such as the level of income and methodological

issues about categorization of drug expenditures as: public, private, hospital, outpatient, prescribed, or over the counter (OTC), are taken into account.

This boom in pharmaceutical expenditure has been one of the most multidimensional and controversial issues in political and economic debates, framing a very complex situation regarding the future of public pharmaceutical expenditure financing.

Pharmaceutical expenditure can be considered an investment in order to improve the health status, and this increase is a worldwide phenomenon with wide variation in growth between countries. The rate of this increase in Greece led the government before 2010 to revise the components that affected pharmaceutical expenditure, mainly with price regulations, but without any success, mainly due to political particularism and administrative weaknesses.

In Greece, insured citizens participate in covering the cost of drugs with a co-payment rate set at 10% or 0% (for patients with chronic conditions) and 25% (for others) on the retail price. The only products that were not reimbursed were the over-the-counter (OTC) and the “lifestyle” drugs [2].

Greece, in all over the pharmaceutical chain market, had heavily restricted competition; for example, there are restriction on the number of retail pharmacies in every municipality, and Greece was in the 80th position among 177 countries in the corruption perception index, which ranks the countries based on how corrupt their public sector is perceived to be [3].

The pharmaceutical spending reflects the quantity and prices of pharmaceutical. The reasons behind the increasing pharmaceutical expenditure in Greece from 2000 to 2009 were attributed to: the aging population; the growing prevalence of chronic disease; the growth in insurance coverage for prescription drugs; the doctor's over-prescribes; the adoption of more expensive treatment combinations; epidemiological factors; the introduction of new, more effective, and more expensive drugs; the high rate of replacement of old off-patent medicines by newer, more expensive ones for the same indications; direct-to-consumer advertising; taxes such as value-added tax (VAT); the absence of cost-containment strategies, general inflation and the abolishment of the positive list in 2006 (list that included all the reimbursable pharmaceuticals).

2. ECONOMIC ADJUSTMENT PROGRAMME

In May 2010, Greece signed with Troika (International Monetary Fund IMF, European Central Bank ECB, and European Commission EC), the Economic Adjustment Programme (memorandum of understanding), an austere policy transformation in order to reduce the public sector's expenditures, which were considered as the cause of the country's high public debt.

The Greek parliament voted the first memorandum in 6th of May of 2010, (Measures for the implementation of the support mechanism for the Greek economy by the member states of the Eurozone and the International Monetary Fund), which posed a frame for measures to reduce public spending and increase competitiveness in all over the public finance sector for a financing package of 110 billion € and supporting economic policies [4,5].

The economic adjustment program and the following legislation applied schedules with clear policies and economic targets in which the health and pharmaceutical sectors were invited to contribute greatly.

Subsequently, the reforms adopted throughout the distribution of the pharmacy chain (industry, wholesalers, retailers, prescribers, and patients) focused in product price control, reference price control, and profit control. Analytically, the new policies that were adopted include: new drug's pricing system, positive-negative list, list with expensive drugs for serious diseases, the broad use of generic drugs, e-prescription, decrease of profit for all the drug sellers, rebate and clawback, VAT's decrease in drugs, pooling of insurance funds, and integration of social insurance institute (IKA) hospitals into the National Health Service (NHS) [6,7]. These reforms have had a great impact on Greek health [8,9].

Until January 2014 the Greek parliament voted seven laws and over twenty-two ministerial orders, which included measures pointing on the direction of public pharmaceutical expenditure minimization.

3. POLICY REFORM

3. 1 Pricing policies

The Ministerial decision 57408/2013, Greek Government Gazette 1446/B/14/06/2013, set the framework for drug pricing issues [10].

For drugs that have been approved and invoiced for the Greek pharmaceutical market and are not circulated to other EU countries, the price will be determined by the estimated cost, which includes the costs of production and packaging for any format and packaging, and the cost of distribution, management, and dissemination, which are updated by respective biennial tables that are calculated based on the respective average costs of the branch. There are not considered as costs: The default interest, personal taxes (income taxes, etc.), costs for breaches provisions applicable, prices of active substance higher from any supplier than the selling price of the research firm, commissions and other expenses of third parties that are not associated with the production and distribution of pharmaceutical products. For the pricing of drugs that have been developed for research on active substances in Greece and have been authorized by EOF, the value of new investments in research and the development cost of active substances will be taken into account. Cases of biosimilar formulated drugs were excluded.

For the audit of drug costing by the pharmaceutical industry, companies are required to keep books for drugs that are produced and packed. This book will record each form of drug, the quantity and values of the raw and auxiliary materials, other materials used in packing, and other production costs. Moreover, the quantity of the drugs produced and their value according their ex-factory prices must be recorded. At the end of the year the total industrial cost of the drug produced must be recorded.

For the pricing of reference drugs, research is conducted from the appropriate department of the National Organization for Medicines, which stands for what in Greek is called EOF to EU member states, where data are renounced to the appropriate authorities or official and prestigious European

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institutions. Necessary data for determining the drugs price are: The name of the drug, the active substance, the content of active substance, the formulation, packing, categorization by anatomical therapeutic chemical (ATC) classification, the responsible marketing prices (ex-factory price, hospital price, wholesale price, retail price) and the expiring date of the first patent of the active substance. To determining the price, the drug must be registered and priced in at least three European Union (EU) states. The prices of the reference drugs are under the protection of the first patent invention of the active substance, resulting from the average of the three lowest corresponding prices EU members.

The price of pharmaceutical products with similar active substances and pharmaceutical forms, which are introduced in the market after the expiration of the first national or European patent active substance of the medicinal product reference, set at a level reduced by at least at sixty percent (60%) compared with the retail price of the relevant medicinal product reference, just before the expiration of the first national or European patent's active substance. Generic products may not receive a price greater than 80% of the price received by the reference products after the end of patent protection.

3.3 Profit control regulations

For pharmaceutical products produced in Greece, the maximum net profit for the producer is determined to be up to 8.5% of the total estimated cost, excluding depreciation, interest, and profit to third parties for jobbing [10].

For pharmaceutical companies which handle drugs in Greece with the new legislation, prospectively adopted the following measures: Clawback from pharmaceutical companies when exceeding the amount of the quarterly pharmaceutical expenditure of the Social Insurance Fund (SIF) (monthly expenditure of 240 € million). A discount rate of 5% from pharmaceutical companies for all NHS hospitals. Rebate 4% from pharmaceutical companies for each prescription drug in SIF. Price reduction of 50% for every drug with patent expiration [11,12].

The monthly pharmaceutical expenditure of the SIF cannot overlap 1/12 of the annually budget. The excess amount will be requested from the SIF by the marketing authorization holders of the pharmaceutical products.

From 01.01.2013, a temporary fee was set for 2011 at 15% of retail sales on pharmaceutical products, which were included in the positive list of prescription drugs reimbursed by the SIF. If one pharmaceutical product didn't pay this fee, it automatically was removed from the prescription list and reimbursement by SIF to the prescribed but not reimbursed by SIF.

Pharmaceutical companies must have stocks per code of drug for three months in relation to sales of the immediately preceding year.

The marketing authorization holder may request the deletion of the medicinal product from the official list of medicines if he furnishes a certificate that informs the EOF three (3) months earlier to stop circulation.

The drug wholesalers with the new legislation determined the percentage of the gross profit for the non-prescription drugs to be up to 7.8% on the ex-factory price, for the prescription drugs that are not reimbursed by SIF as 5.4% on the ex-factory price, for the reimbursed drugs from the SIF as 4.9% on the ex-factory price, and finally for the reimbursed drugs that patients can receive from

hospital pharmacies or private pharmacies without any co-payment for the treatment of serious disease, as a percentage of 2% of hospital price, which is the special wholesale price.

For pharmacies, the percentage gross profit is determined as a percentage as follows: For non-prescription or over-the-counter (OTC) drugs, up to 35 % of the wholesale price. For prescription drugs that are not reimbursed by social insurance funds, 35% on the wholesale price. For the reimbursed drugs by SIF and with wholesale price up to 200 € a 32.4 % for the wholesale price. For the reimbursed drugs by SIF with wholesale price or special wholesale price exceeding 200,00 € the profit of the private pharmacies is equal to the fixed amount of 30,00 €. For the reimbursed drugs that patients can receive from hospital pharmacies or private pharmacies without any co-payment for the treatment of serious diseases,¹⁵ and have special wholesale prices up to 200 € the profit rate of the private pharmacy is fixed at 16% of the special drug price [10]

4. PATIENTS DEMAND REGULATIONS

4.1. Denying or limiting reimbursement

The new legislation includes measures which decrease the demand from the citizens as: Adoption of a negative list which includes prescribed and non-prescribed drugs that are not reimbursed from the SIF, and the insured must pay to obtain it.¹¹ Mandatory electronic prescribing.¹³ Establishment of second degree committee positive list of prescription drugs, which includes the prescribed drugs that are reimbursed from the SIF.² Recommendation of the positive drug's list, based on the anatomical therapeutic chemical classification (ATC4) system of WHO in the fourth level using reference values in which the referring price is the reimbursement price for the SIF [14].

The e-prescription system adapts and integrates the corresponding reference price, retail price, and total involvement of the patient for each drug of the positive list, all into the consideration of doctors, pharmacists, and the insured.¹⁴ For every therapeutic category, a reference price is defined as the reimbursement price for the SIF for all of the products of this category. Moreover, the SIF covers the reference price and if the patient chooses a more expensive drug, it must pay the difference from the retail price. From 1.1.2014, every prescription performed at pharmacy must be paid extra with the amount of 1 euro [14].

For the e-prescriptions only the active substances are referred to, and pharmacies must allocate the cheapest available drug with the prescribing active substance. In the case that the insurance requests a more expensive drug he must pay more than his participation, that is, the difference between the insurance price and the retail price of the drug.¹² Compulsory for the physicians to prescribe based on the international name of the active substance, the international nonproprietary name (INN) [12].

4.2 Other regulations

The new legislation includes and other regulations as: Offsetting requirements SIF from pharmaceutical companies with hospital's debts [2]. Just before the patent expiration of one drug, the

price of the first generic drug will be determined at 40% of the original.¹² Each subsequent triplet generic will be 10% cheaper than the previous one [12].

For the medicinal products that are used for the treatment of serious diseases, which are only licensed for hospital use, wholesale prices and retail prices are determined as follows: On the hospital drug's price, a 2 % gross profit is added for the drug seller; in this way, the special wholesale price is formed. In the resulting price, 30.0 € is added as a profit for private pharmacies. At this final price VAT is added [12].

5. THE IMPACT OF POLICY REFORM

5.1 Parallel exports

The reduction in drug price may lay one drug cheapest than the country which the drug is produced. This difference in price makes highly profitable not only for re-exports in other European countries but also for the export of drugs that were produced in Greece. The drugs' exports made within the EU are perfectly legitimate according to Greek legislation, as far as adequacy is ensured in the domestic market. In September 2010, an upsurge with a lack of drugs was reported in the Greek market to protect public; health the control mechanisms were activated directly in the temporary ban on parallel exports of drugs that were lacking in Greek market, and fines were imposed on companies that violated the relevant laws [16]. When the first results started to show a partial lifting of the temporary ban, followed by parallel exports for 12 drugs [17].

In this lack of some drugs in Greek market contributed great and the fact that the multinational pharmaceutical companies began to reduce the quantities offered in Greece in order to reduce their 'risk' on the Greek economy and to push the government for higher drug prices. Parallel exports in 2010 was 626 million €, in 2011 486 million € and in 2012 420 million € [18].

5.2. Panhellenic pharmaceutical association

The Greek pharmaceutical industry, which includes 29 Greeks and 38 subsidiaries of multinational companies, is a highly productive, dynamic, and innovative sector that sustains and improves lives, with a particular contribution to the domestic economy, employment growth, and exports to more than 85 countries. Greek pharmaceutical companies provide significant R&D investments, develop expertise, and produce generic drugs (drugs with substantially similar trademark-branded generics), faithfully applying the standards of quality assurance (QA) and the rules of good manufacturing (GMP). According to the European Federation of Pharmaceutical Industries and Associations (EFPIA) Greek pharmaceuticals invested 84 million € in R&D [19]

Comment [u3]: need to include practice

The Panhellenic Pharmaceutical Association stated that it is the result and not a component of the problem of public pharmaceutical expenditure. Moreover, pricing as a tool for reducing pharmaceutical expenditure has long been exhausted, and drug prices in Greece are now at the lowest possible level.

The existing pricing methodology is characterized by the association as opaque and ineffective leading to significant delays and errors. Moreover, the association requests the integration of the claw back into tiered rebate sales.

The association requested prescription based on the drug's trade name. The measure of mandatory prescription based on active substance plus the mandatory replacement with the cheaper drug with the same active substance is an option with disastrous results for the protection of public health such, as containment of pharmaceutical expenditure and the growth of the domestic pharmaceutical industry. This has led the domestic pharmaceutical industry to dissolve and the simultaneously create a monopoly of imported drugs. Finally, they estimate that the per capita pharmaceutical expenditure in Greece could be reduced to 170 € for 2014 [20].

5.3. The panhellenic pharmacy society

According to one study, at the end of 2012, in about 4,000 pharmacies, the economic crisis hit 95.6% of the pharmacies in the country. The main problems for the pharmacies according to the research are: ' State's gambling debts' 67,5%, liquidity problems 46,2%, reduce turnover 27,5% the direct payment from customers 9,4%, payments for the wholesalers 7,8% a possible eventual closure 5,4% and problems in cooperation with banks for 4,4%. The average reduction in turnover in 2012 compared with the previous year is expected to reach 28.47%; it is worth noting that one in four pharmacies expects a drop in turnover of more than 40%. 9 out of 10 pharmacies believe that the government measures for the health sector are in the wrong direction; finally when pharmacists were asked about the issues that should be given weight by the Panhellenic Pharmaceutical Association, 74.5% answered "liquidity-payments" from the government [21].

The panhellenic pharmacy society recognizes extreme social phenomena after the reforms in the pharmaceutical sector in the era of recession and characterizes as irresponsible all those behind these policies in which the insured pay 4 and 5 times more than before the crisis. Because pharmacists were the daily recipients and witnesses of the anger and complaints of the insured because of the increased shareholdings that they were forced to pay in order to obtain their medications, the Panhellenic Pharmaceutical Association suggested to their members to print and put in a prominent position the following statement: "Dear insured, the amount you pay for your drugs is not decided by the pharmacist but is automatically obtained from the electronic health ministry without the possibility of intervention by the pharmacist. For any clarification, a pharmacist is available. Panhellenic Pharmaceutical Association" [22]

5.4 Association of pharmaceutical companies, SFEE

The association of pharmaceutical companies, members of the European Federation of Pharmaceutical Industries and Associations (EFPIA), requested the government to promote policies that will ensure a stable and viable business environment for pharmaceutical companies while ensuring patient access to existing and new innovative treatments. Moreover, they requested government transparency, stopped surprises in pricing and reimbursement policies, and stopped causing problems in patient access to treatment [23]. Finally, they requested an amount of 3 billion as the ultimate limit below which the unimpeded access of policyholders and patients to drugs cannot be guaranteed [23-26]

They also requested from the government to reimburse faster the pharmaceuticals that provide the public hospitals. Worth noting that the total public debt (public and military hospitals) for pharmaceuticals companies was in 2012 $\approx$ 67 million in 2013 $\approx$ 810 million and in 28/02/2014 $\approx$ 193 aggregate at 1,070 billion [26].

5.5 Social pharmacies

The economic crisis has plunged many social groups in Greece into a social crisis at least,²⁷ others argue for a humanitarian crisis [28].

Between 2007 and 2012 Greeks lost the 1/3 of their total household income, about 4.400,00 € per capita, 4 times bigger than the average of Eurozone countries, and that affected access to health care and may have resulted in poorer health status and increased health inequalities [29].

In all countries, low-income individual are more likely to report unmet care needs than those with high incomes. This gap was particularly large in Greece, Hungary, and Italy [30].

The out-of-pocket expenditure as a percentage of total health expenditure in Greece was in 2009: 28.0% in 2010: 28.8% and in 2011: 30.5 % [1].

In Greece in the era of crisis, mainly through social structures of the municipalities and other voluntary organizations, have developed structures of social solidarity (social outpatient, pharmacies solidarity) in order to confront the survival problems of homeless, uninsured, unemployed, precarious workers, socially vulnerable groups, poor with the demand for help to grow explosively during the time. [30-31].

6. MACROECONOMIC EFFECTS

In 2010, the first year of the adoption of the measures, the total health expenditure was the 9,5 % of GDP or 2.623,9 \$ and the pharmaceutical expenditure was 738,8 \$ per capita; in the second year, 2011, the total health expenditure was the 9,1% of GDP and the pharmaceutical expenditure was 2,6% of the GDP or 673,4 \$ per capita [32].

According to the Fourth Review of IMF, after the implementation of the measures in 2010, the decrease in public pharmaceutical expenditure contributed greatly to the decrease in public health expenditure as a share of GDP in 2012. This was achieved mainly due of lower reimbursement costs for pharmaceuticals. The IMF review estimated that in 2013, public health expenditure was projected to reach 5.3 % of GDP (6.3 percent of the GDP average for EU countries) from 5.8 % in 2012 to 7,1 % in 2010 [33].

An assessment of the progress made by Greece until March 2014 with respect to the second economic adjustment programme, refers as success story the reduction of public spending on pharmaceuticals from 3.9 billion € in 2010 to about € 2.5 billion in 2013. Moreover, important challenges are before us as the improving financing mechanism and financial flows across the system, stronger monitoring, and control mechanisms [34].

For the first time since 1948, with a country-specific definition for the term "primary surplus" Greece recorded a primary surplus of €1.5 billion, around 0,8% of GDP, in 2013 [35-37]

7. CONCLUSION

The continuous increasing for many years of public pharmaceutical expenditures has contributed greatly to the Greek debt crisis. In post-troika period, Greece took measures without any positive economic impact in the public finance. Only after the implementation of containment measures which were defined by troika as negative lists, new reference pricing system, generic drug introduction, price control, profit reduction, in all over the pharmaceutical distribution chain started the decreasing of public pharmaceutical expenditure.

At the macroeconomic level, we observe that with the implementation of these reforms and with Draconian austerity measures in the pharmaceutical sector, a reduction in pharmaceutical expenditures was achieved, but at the same time created a new economic, social, and political framework, with all the stakeholders of the pharmaceutical sector, producers, imports, wholesalers, pharmacists, and patients affected.

On the one hand, the use of new and more expensive drugs contributes to increased the pharmaceutical expenditure; however, new and more expensive drugs are also more effective and reduce other costs such as hospitalization expenditures by reducing the need for hospital admission or minimizing hospital stay.

The poor are getting poorer, and the scenario gets from bad to worse; there is an undetermined number of citizens who do not have adequate access to healthcare services in Greece. We observe a society in transition and the rights of citizens that have been mastered after many years, as insurers' small copayment rates for their drugs are undermined. Today, even the insured must pay higher copayment rates for their drugs; if we take into account the increased per diem hospital reimbursement, the increased insurance contributions, the fees for visits to outpatient hospital departments, and the income gap of the last years, large social groups confront inequalities in health.

Beyond political and legislative reforms pharmaceutical policy requests "culture reform". A minimum of realism is needed from all stakeholders in the policy-making agenda to create the conditions for all citizens, especially the unprivileged, to have access to drugs in one European country that respects its citizens.

The country that gave birth to democracy, culture, philosophy, the county of Asklepios according to the mythology and Hippocrates, the legendary "father of medicine", for the first time after the second world war, and the civil war goes through not only a financial crisis but a crisis in values, of institution, of application of the laws and regulatory standards [38].

Greece now hasn't many options, driven by a huge loan and with no specific political movement to provide political guidance seems impossible to repay its debt, national central bank still exists, but without power to determine monetary policy, in Eurozone level this power belongs to ECB. Greek citizens are suffering paying the price of their choices at all levels. The financial recession is inevitably followed by a health recession with an unknown impact of those regulations on the health of future generations.

Behind numbers there are people and health is a precious human right and obligation all over the world, and all who have the responsibility in a dynamic process of policy-making must analyse the impacts of major policies and policy proposals from a health perspective, taking into account health in

all policies (HiAP), and study the consequences of their public policies on health promotion in order to protect not only health but also well-being and happiness [39].

COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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