UNIVERSITY OF MACEDONIA

MA in the Politics & Economics of Contemporary South & Southeastern Europe

MASTER THESIS:

THE GREEK PHARMACEUTICAL INDUSTRY: PROBLEMS & FUTURE PROSPECTS

Giannaki Anastasia

Advisor: **Sophia Delipalla**
Professor UOM

Thessaloniki, October 2012

ACKNOWLEDGMENTS

First and above all, I thank God for granting me the strength to complete my master thesis. I would like to express my deep gratitude to Pr. Sophia Delipalla, for having accepted to be my master thesis advisor and providing guidance, advice and useful suggestions about this thesis. I have to acknowledge my work supervisor and also my colleagues for their assistance in many aspects that cannot list them because of limited space. Completing this thesis would have been all the more difficult were it not for the support and encouragement provided by my very close friends. Special thanks are given to the graduate secretary of the Master Department for her time, understanding and assistance in many different ways. Last but not least, I owe more than thanks to my family members, my parents and my brother, and also my partner, for their support and encouragement, especially in this specific effort. To them I dedicate this thesis.

Table of contents

ABSTRACT

The theme of the specific thesis analyses the social, constitutional and regulatory characteristics of the pharmaceutical market in Greece which is regulated extensively by the state though periodic public-controlling measures affecting both the demand and supply side for pharmaceuticals in order to restrict pharmaceutical expenditure. Pharmaceutical expenditure's steady increase, however, coupled with a period of deep recession and consequently a program of fiscal stabilization reforms which Greece is facing nowadays, are threatening the constitutional and financial viability of the pharmaceutical industry making it now more imperative than ever for a comprehensive pharmaceutical policy to be formulated and implemented which would stabilize the structure of the pharmaceutical system.

In the first part the factors which affect domestic demand together with the epidemiological and demographic factors which contributed to the health status of the Greek state will be extensively described. Moreover, the expenditure patterns of the pharmaceutical industry and its fluctuations in Greece during the last decade will be analyzed. The main features of Greece's pharmaceutical industry which are its supply structures and the existing regulatory and institutional framework will also be referred to with elaborate detail below. Furthermore, public policy's role and the measures which focus on the restructuring of the pharmaceutical market and the decrease of its expenditure will likewise be referenced to, while a brief analysis of government measures which have been adapted as part of the fiscal stabilization program in Greece will also be touched upon. Last but not least, the thesis ends with an extensive reference to the problems pharmaceutical companies face resulting from the Greek government's interventions and on a proposal for an alternative regulatory solution that would constitute an efficient and stable pharmaceutical environment for the Greek pharmaceutical industry and ensure the sustainability of future prospects.

1. INTRODUCTION

Pharmaceutical products contribute to the improvement of citizens' health in a remarkable way. Indeed, the efficient and responsible use of drugs has improved the quality of life of many people by reducing the need for surgical intervention and lengthy hospital stays. The pharmaceutical industry, on the other hand, is a substantial sector of the Greek economy as it is one of the most profitable economic activities in the Greek territory along with tourism. Moreover, the pharmaceutical industry accounts for 1% of total domestic employment as in 2007 pharmaceutical companies employed 10.000 people and both wholesale companies and pharmacies almost 32.000. Furthermore, pharmaceutical products participate with a percentage of 5% in total exports, and a percentage of almost 6% in total imports, while their account for 7% of the trade deficit[1].

The production and supply of pharmaceutical goods and services is one of the most austerely regulated sectors of the Greek economy, due to a strict public policy that regulates and affects supply, distribution, storage, pharmaceutical's quality, competition, price policy, prescription behavior, and generally demand and supply factors. The European Union through its directives determines and regulates public policy in the pharmaceutical market in Greece, a role that only the Greek government had before Greece's membership in the European Union in 1981. The Ministry of Health and Social Solidarity, which is responsible for the implementation of the policies related to the effective provision of healthcare services and regulation of the pharmaceutical market, implements a public policy focusing on the reduction in pharmaceutical spending, while boosting and contributing to the Greek pharmaceutical companies' competitiveness and productivity.

Nonetheless, drug consumption has been very extensive over the last decades and is increasing by an accelerated rate which has led to a consequent increase in pharmaceutical expenditure and contributed to fiscal imbalances. To be more accurate, pharmaceutical expenditure in Greece for the year 2010 accounted for 3% of

[1] Dragalidis Athanasios (2011), pp.10

the total GDP[2] and it continues to be increasing. The problem has become worse during the last three years as Greece has entered a deep period of recession from which it is struggling to emerge. The Greek government has already introduced important reforms and a pharmaceutical public policy which, on the one hand, affects demand and supply for pharmaceuticals, and on the other hand, preserves the competitiveness and productivity of the Greek pharmaceutical market.

2. DEMAND SIDE & EXPENDITURE PATTERNS IN GREECE

The demand for pharmaceuticals is regarded as being a complicated and dysfunctional operation as the patient cannot act independently and freely. More specifically, the pharmaceutical market is characterized by information asymmetry, agency relationship, medicinal products and services that are social goods and supplier-induced demand. Information asymmetry means that the doctor, as an expert, has the knowledge and the patient, having not the ability to handle his own health condition, follows his/her directions and prescriptions. As far as the agency relationship is concerned, it is an undoubted fact that there is an interaction between the patient and pharmaceutical professionals which is conducted through the doctor. In particular, the patient expresses the need and the doctor intermediates between him and the pharmaceutical industry professional. Furthermore, medicinal products and services are social goods in the sense that they are accessible and affordable to all through indirect financing from compulsory social health insurance funds. Last but not least, supplier-induced demand means that the doctor has the ability to over-prescribe pharmaceutical products and services to the patients and so contributes to the increase of pharmaceutical expenditure, as he/she is strongly affected by pharmaceutical companies' business strategies that focus on target sales - insurance companies, patients - so as to promote their medicines.

It is seen that demographic characteristics, such as age, gender, size of the family, and the location of residence determine the demand for pharmaceuticals.

[2] http://www.eof.gr

Undoubtedly, age is the strongest factor of all, as the order someone gets the more medicines are needed. Each person's health condition also affects the amount of pharmaceutical consumption, as does diet, smoking and alcohol habits, exercise, stress etc. Medicines and drug characteristics, that concern safety, effectiveness, and potential side effects, determine the demand for medicines. One also important demand-side factor is regarded to be the pharmaceutical company's prestige and the aggressive sales policy that they follow with a view to guiding the prescription behavior of physicians through promotional policies.

As for Greece, according to OECD's recently estimations[3], total life expectancy at birth stood at 80.6 years in 2010, almost a year higher than the OECD average (79.8) but lower than other OECD countries (e.g. Italy, Spain and Switzerland). More specifically, female life expectancy at birth has been extended in the last three decades to 82,8 years in 2010 - in comparison to 73,8 years in 1960 - while male life expectancy has been extended to 78,4 years in 2010 compared to 70,2 in 1960. This fact is due to improvements in living conditions, public health interventions and progress in medical care. However, Greece seems to have the highest rate of daily smokers among the adults of all OECD countries, with a rate of 31.9% in 2009, compared to most of the OECD countries which have achieved remarkable success in reducing tobacco consumption over the past two decades. Furthermore, the obesity rate among adults, which has increased in recent decades in all OECD countries, in Greece was 17.3% in 2009, lower than that of the United States (28.1% in 2010) but higher than the average rate for the OECD-29 countries that was 15.0%. Last but not least, "*the main causes of mortality in Greece are mainly cardiovascular diseases 31.4%, malignant tumors 23.5%, celebrovascular diseases 17.5% and respiratory system diseases 7%"*[4].

The analysis of the demand for pharmaceutical products includes, other than the description of the epidemiological and demographic factors already mentioned, the careful observation of the size of pharmaceutical expenditure. Total pharmaceutical expenditure is classified into public and private. Public expenditure is funded mainly through the central government's budget through general taxation

[3] OECD Health Data Report (2012): http://www.oecd.org/health/healthdata
[4] Areti Vardica, V. Kontozamanis (2007), pp.3-4

(ESY system), and through the numerous state health insurance funds (employer and employee contributions), while private expenditure is covered by the private insurance system. From another point of view, according to the International Classification of Health Accounts published by the OECD[5], the measurement of the pharmaceutical expenditure in Greece, which follows international healthcare standards, is a part of total pharmaceutical sales. Consequently, total pharmaceutical spending consists of public pharmaceutical expenditure that is covered by the social health insurance funds, sales to hospitals, sales of drugs to the parallel trade[6], sales of drugs to both citizens of Greece and tourists through private funding, sales of drugs to domestic or foreign citizens insured by private insurance companies, and co-payment insurance policy where "*the insured pays a specified amount of out-of-pocket expenses for health-care services such as doctor visits and prescription drugs with insurer paying the remaining cost"*[7], that is not charged to the insurance funds.

The main groups of social health insurance funds that provide insurance services to the majority of the population in Greece are as follows[8]:

- IKA (Institute of Social Insurance), covering 50% of the urban population such as white- and blue-collar workers;
- OGA (Organization of Agricultural Insurance) covering 25% of the rural population like agricultural workers;
- Civil servants' insurance fund covers 7% of the population;
- TEVE-TAE which is the Fund for Merchants, Manufacturers and Small Businessmen and covers 13% of the population;
- Utilities and banks: 2.5% of the population; telecommunications, electricity and banking personnel.

[5] http://www.oecd.org/greece

[6] **Parallel trade** occurs outside authorized distribution channels and exists when there are significant price differences between countries. It can take place when a distributor will obtain a patented or copyrighted pharmaceutical product in a low-price country and circulated it to a high-price country without the authorization of the local owner of the intellectual property right.
In 31st October 2012 the Greek government has announced the temporary ban on parallel imports on medicines that are facing important shortages to ensure the sufficient coverage for the patients' needs. The decision is applied directly towards the pharmaceutical companies, wholesale companies and pharmacists' associations and failure to comply with the specific directive is penalized strictly by imposing punishment fines which may reach even the amount of €44,000.

[7] http:// www.investopedia.com

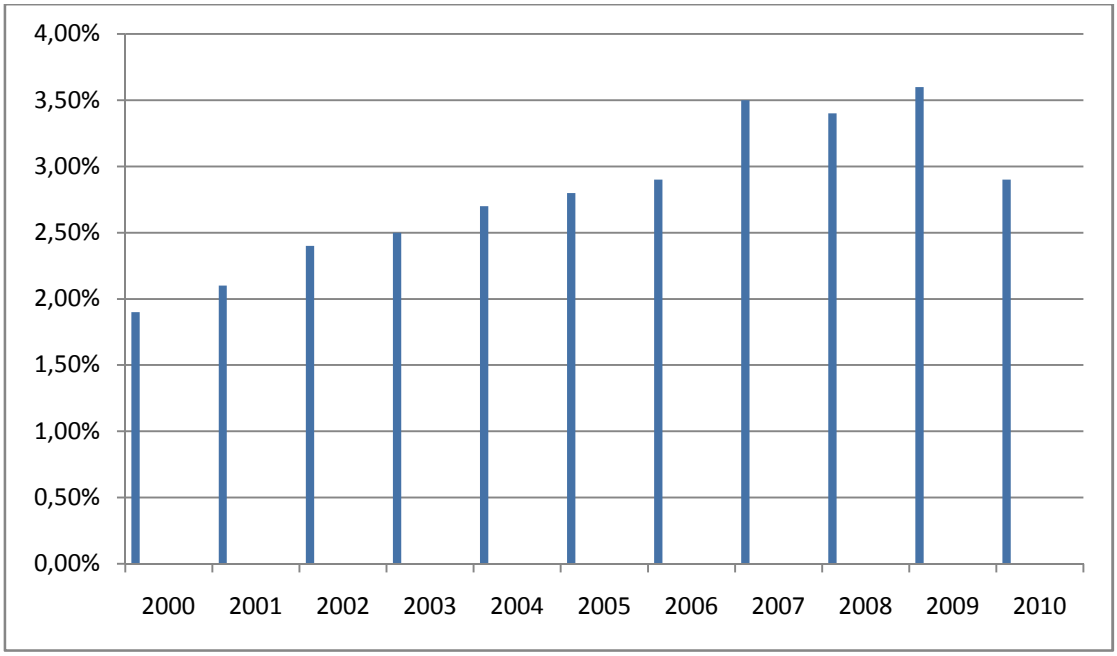
[8] Areti Vardica, V. Kontozamanis (2007), pp.2

In March 2011 a recent law for the social health insurance funds' restructuring was introduced, and more specifically Law 3918/2011, according to which the Greek government has established a social insurance body, called EOPYY, which includes the above mentioned social health insurance funds (e.g. IKA, OGA, TEVE-TAE, OPAP) and some others (e.g. ETAE). The purpose of this merger was initially the coordination of the relevant parts that could restrict the pharmaceutical expenditure in the healthcare system and afterwards the equal and fair access to a common health care system of services to all[9].

According to provisional data from the OECD Health Data 2012 report[10], pharmaceutical expenditure as part of total health spending accounted for about 2.4% of the GDP in Greece in 2010 - above the average of 1.5% in OECD countries - a percentage that represented about 1/5 of total health spending which accounted for 10.2% of the GDP in Greece in 2010. Parallel to total health expenditure fluctuations, which increased between 2000 and 2009 at a rapid rate of 6.1% per year in real terms on average, pharmaceutical expenditure as a percentage of total health expenditure in Greece has increased accordingly. The economic and financial crisis, however, led to a sudden fall in the health share of the GDP, and similarly in the decrease of pharmaceutical expenditure after the implementation of wage cutting measures and reductions in the number of workers, as well as price reductions for pharmaceuticals so as to reduce public spending on health. More specifically, a further cut in public spending by the Greek government "*has seen the health share of GDP fall by 6.5% in 2010 as part of government-wide efforts to reduce the large budgetary deficit*"[11], a fact that consequently led to the restriction of pharmaceutical expenditure. In Table 1 below the pharmaceutical expenditure patterns in Greece are depicted for the decade between 2000 and 2010.

[9] Ενδιάμεση Έκθεση της Ανεξάρτητης Ομάδας Εργασίας Ειδικών Εμπειρογνωμόνων στον Τομέα της Υγείας (2011), σελ.13
[10] http://www.oecd.org/greece
[11] http://www.oecd.org/greece

Table 1: Pharmaceutical expenditure in Greece, 2000-2010



Source: EOF 2011

3. MAIN FEATURES OF THE GREEK PHARMACEUTICAL INDUSTRY

3.1 THE INDUSTRY

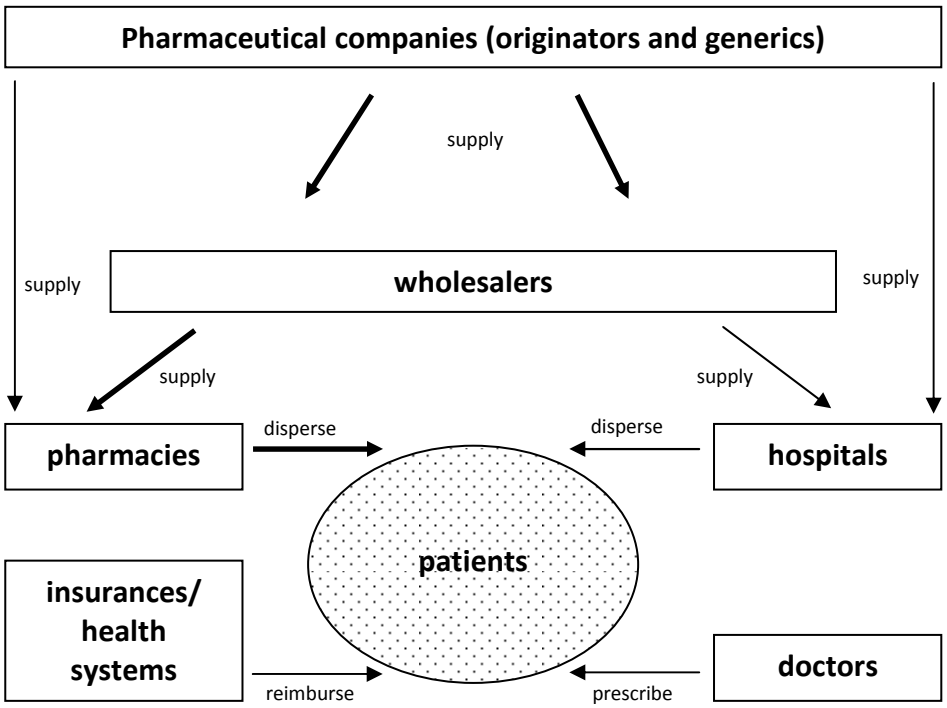
The pharmaceutical industry in Greece represents an important sector of the economy as pharmaceutical expenditure accounts for 3% of the total GDP[12] and it continues to rise. Since 1960, the industry's production business has grown significantly and in the last two decades it has reached European and global standards, a fact that has made it an important player in the global market. What also makes the Greek pharmaceutical industry valuable to the Greek economy is the fact that it is a major employer in production and marketing of medicines, as is evident in that the pharmaceutical industry accounted for almost 30% of total employment in the chemical industry and 1% of total domestic employment as pharmaceutical companies employed 15,000 people and both wholesaler and pharmacies almost 32,000 in 2007.

[12] Dragalidis Athanasios (2011), pp.10

This is a substantial contribution to domestic employment if we take into account that pharmaceutical production has been increasing at a steady rate of about 1.5% since 1994[13].

The pharmaceutical industry in Greece deals mainly with the production and sale of original pharmaceutical products and generic ones, and also distribution in both the wholesale and retail sector. The supply chain for medicines is conducted by the pharmaceutical company through wholesalers and pharmacies to the patients that represent the retail market.

Figure 1: Simplified supply chain for prescription medicines



Source: Pharmaceutical Sector Inquiry

[13] According to the Hellenic Association of Pharmaceutical Companies (SFEE): http://www.sfee.gr

More specifically, pharmaceutical companies in Greece are mainly subsidiaries of multinational corporations that promote original pharmaceutical products, Greek companies that collaborate with international pharmaceutical companies and produce generic products of the brand name or original pharmaceutical products, and packaging and manufacturing companies associate with imported pharmaceutical products. Pharmaceutical companies in Greece, manufacturers and importers, spread and supply pharmaceutical products directly to the hospitals and pharmaceutical wholesale companies and pharmacist's associations. Hospitals usually buy pharmaceuticals from pharmaceutical companies without intermediates, through a tender process, while the pharmaceutical wholesale companies and pharmacist's associations, which hold the largest share of total pharmaceutical sales (75% of the total share of pharmaceutical sales)[14], intermediate between pharmaceutical companies and pharmacies that represent the retail market.

Up to this point it is necessary to mention the distinction between the original pharmaceutical products and generics of the brand name. Original pharmaceutical products are those granted a patent for its chemical substance intended for use in chemical diagnosis, cure, treatment, and prevention of disease and there is no other similar drug patent in another country. On the other hand, generics are pharmaceutical drugs that have the same active ingredients as the original formulation, and within an acceptable bioequivalent range are identical to the brand-name drug in dose, strength, efficacy, and intended use. In Greece the manufacturing pharmaceutical companies produce original pharmaceutical products or generics of the brand name with the latter representing a low share of the medicinal market (only 12%). However, recently new legislation means that generics will become more widely prescribed in Greece as their price is 80% of the retail price of the original and that makes them cost effective for the reduction of public expenditure[15].

Similarly, there is a clear distinction between these pharmaceutical companies that produce and/or import original pharmaceutical products and those pharmaceutical companies which produce and/or import generics of the brand name. Originator pharmaceutical companies, which may consist of very large multinationals or small

[14] http://www.hellastat.eu
[15] Dragalidis Athanasios (2011), pp.28

multinational ones, implement research and development practices into new medicines, and sell high patent-protected drugs on the market. The originator pharmaceutical companies carry out "*research and development of new chemical entities and focus on the improvement of the already existing chemical entities on the market, and at sometimes intend to become involved in research into and production of biopharmaceuticals in the immediate future*"[16]. On the other hand, there are pharmaceutical companies that produce and sell generic drugs with the same or equivalent active substance as the original ones. A generic medicine enters the market as soon as the patent of the original brand-named product is expired and afterwards is sold at a lower price than the original product (80% of the retail price of the original ones). However, there are some cases where generic companies have the ability to *"enter the market earlier, most notably in cases where patent(s) of originator companies are not (considered to be) valid or where the generic company believes it has found a way to produce the medicine without infringing any patent rights"*[17].

There are around 350 pharmaceutical companies in Greece today that operate mainly in the production and import and/or export of pharmaceutical products, original and generics of the brand name. More specifically, as stated by a study of the statistical analysis company Hellastat, in Greece there are "*about 60 import companies, subsidiaries of multinational corporations that promote original pharmaceutical products, and around 30 Greek* companies *which mainly produce and sell or package generics of the brand name or original pharmaceutical products for the account of foreign companies"*[18]. In a study implemented by Stat Bank[19], the top 20 out of 92 pharmaceutical companies in Greece for the year 2009 have performed turnover results as follows:

[16] European Commission, Directorate General Enterprise & Industry (2009), pp.26-27
[17] European Commission, Directorate General Enterprise & Industry (2009), pp.27
[18] Ειδική Έκθεση του Συνδέσμου Φαρμακευτικών Επιχειρήσεων Ελλάδος (2011), σελ.22
[19] Stat Bank is a bank of information for the economy and business activities: http://www.statbank.gr

Table 2: Pharmaceutical companies and turnover, 2008

	PHARMACEUTICAL COMPANIES	TURNOVER IN EURO (2008)		PHARMACEUTICAL COMPANIES	TURNOVER IN EURO (2008)
1	PFIZER ΕΛΛΑΣ ΑΕ	423,576,418	**11**	ABBOTT LABORATORIES ΕΛΛΑΣ ΑΒΕΕ	174,002,787
2	SANOFI AVENTIS AEBE	401,697,807	**12**	JANSSEN - CILAG ΦΑΡΜΑΚΕΥΤΙΚΗ ΑΕΒΕ	172,221,515
3	NOVARTIS HELLAS AEBE	377,249,726	**13**	GEROLIMATOS Π. Ν. ΑΕΒΕ (ΔΛΠ)	166,826,000
4	BIANEX AE	354,449,893	**14**	BRISTOL-MYERS SQUIBB AE	162,712,185
5	ROCHE HELLAS AE	321,466,347	**15**	WYETH HELLAS AEBE	148,673,202
6	GLAXOSMITHKLINE AEBE	279,945,189	**16**	SCHERING-PLOUGH ΑΦΒ & ΕΕ	141,798,336
7	BOEHRINGER INGELHEIM HELLAS AE	256,800,663	**17**	ELPEN PHARMACEUTICAL INDUSTRY AE	120,579,287
8	ASTRAZENECA AE	253,837,720	**18**	ΦΑΜΑΡ ΕΤΑΙΡΕΙΑ ΦΑΡΜΑΚΩΝ & ΚΑΛΛΥΝΤΙΚΩΝ ΑΒΕ (ΔΛΠ)	108,997,768
9	GENESIS FARMA AE (ΔΛΠ)	220,216,863	**19**	DEMO AB & EE	90,041,798
10	FARMASERB - LILLY AEBE	194,659,702	**20**	FARMATEN ABEE	74,118,356

Source: Stat Bank (2009)

In addition, it is figured that the pharmaceutical industry is a quite competitive market as high shares of concentration exist. More specifically, the Table 3 below displays the pharmaceutical companies' shares as follows:

Table 3: Pharmaceutical companies' shares, 2009

	PHARMACEUTICAL COMPANIES	SHARE		PHARMACEUTICAL COMPANIES	SHARE
1	ΡΓΙΖΕΡ ΕΛΛΑΣ ΑΕ	6.0%-6.5%	**9**	GENESIS FARMA AE	3.5%-4.0%
2	SANOFI AVENTIS AEBE	6.0%	**10**	FARMASERB - LILLY AEBE	3.0%-3.5%
3	NOVARTIS HELLAS AEBE	6.0%	**11**	ABBOTT LABORATORIES HELLAS ABEE	3.0%
4	BIANEX AE	5.5%-6.0%	**12**	BYER HELLAS ABEE	2.5%-3.0%
5	ROCHE HELLAS AE	5.0%	**13**	JANSSEN - CILAG PHARMACEUTICAL AEBE	2.5%-3.0%
6	GLAXOSMITHKLINE AEBE	4.0%-4.5%	**14**	BRISTOL-MYERS SQUIBB AE	2.5%-3.0%
7	ASTRAZENECA AE	4.0%	**15**	WYETH HELLAS AEBE	2.0%-2.5%
8	BOEHRINGER INGELHEIM HELLAS AE	4.0%	**16**	SCHERING-PLOUGH ΑΦΒ & ΕΕ	2.0%-2.5%

Source: ICAP Group (2011)

From Table 3 above, it is observed that there is a high level of concentration in the Greek pharmaceutical market. More specifically, in some categories of production of pharmaceuticals the 3 higher selling companies together control 20% of the market share or else the 10 higher selling companies together maintain almost 52% of the market share[20]. It is noteworthy to mention that until 2000 the Greek pharmaceutical industry was supplying domestic consumption significantly by itself, but soon after the adoption of the euro, domestic pharmaceutical consumption has been expanded to the multinational pharmaceutical market.

Pharmaceutical wholesale companies and pharmacist' associations represent another component of the Greek pharmaceutical industry and as it was previously mentioned they hold the biggest share of the total sales in the Greek pharmaceutical

[20] Dragalidis Athanasios (2011), pp.14

market (75% of the total share of pharmaceutical sales). Pharmaceutical wholesale companies and pharmacist' associations that intermediate between pharmaceutical companies and pharmacies, insurance funds, doctors, and in specific cases, hospitals, "*carry stock-holding medicines and distribute a range of products able to be delivered in every geographical area within a short period of time*"[21]. There are almost 130 wholesale companies and pharmacist' associations in Greece today, a fact that generates a very antagonistic environment for the wholesale companies and provides incentives for alliances and mergers between them.

Table 4: Wholesale companies and turnover, 2008

	WHOLESALE COMPANIES	TURNOVER IN EURO (2008)		WHOLESALE COMPANIES	TURNOVER IN EURO (2008)
1	ΜΑΡΙΝΟΠΟΥΛΟΣ ΑΕ Κ.Π.	294,838,000	**6**	ΣΥΝΕΤΑΙΡΙΣΤΙΚΗ ΦΑΡΜΑΚΑΠΟΘΗΚΗ ΑΕ «ΣΥ.ΦΑ.ΑΕ»	156,771,288
2	ΣΥΝΕΤΑΙΡΙΣΜΟΣ ΦΑΡΜΑΚΟΠΟΙΩΝ ΑΤΤΙΚΗΣ ΣΥΝ. Π.Ε.	263,626,848	**7**	LAVIPHARM ACTIVE SERVICES	134,007,000
3	ΠΡΟΜΗΘΕΥΤΙΚΟΣ ΣΥΝΕΤΑΙΡΙΣΜΟΣ ΦΑΡΜΑΚΟΠΟΙΩΝ ΑΤΤΙΚΗΣ	199,809,512	**8**	ΦΑΡΜΑΓΟΡΑ ΑΕ	53,182,000
4	ΣΤΡΟΥΜΣΑΣ ΦΑΡΜΑΚΑΠΟΘΗΚΗ ΑΕ	205,450,264	**9**	ΠΡΟΜΗΘΕΥΤΙΚΟΣ ΣΥΝΕΤ.ΦΑΡΜΑΚΟΠΟΙΩΝ ΚΡΗΤΗΣ ΣΥ.Φ.Α.Κ. ΣΥΝ.Π.Ε.	78,366,002
5	ΠΕΙΦΑΣΥΝ ΠΕΙΡΑΙΚΟΣ ΦΑΡΜΑΚΕΥΤΙΚΟΣ ΣΥΝ.ΠΕ.	163,213,831	**10**	ΦΑΡΜΑΚΑΠΟΘΗΚΗ ΓΕΡΟΛΦΑΡΜ ΑΕ	63,962,000

Source: Stat Bank (2008)

[21] European Commission, Directorate General Enterprise & Industry (2009), pp.28

Last but not least, pharmacies, that represent the retail market, distribute medicinal products directly to patients or hospitals or private clinics. According to the Pan-Hellenic Pharmaceutical Association, there are in total approximately 10,500 community pharmacies in Greece nowadays, a number that is considered to be relatively high among OECD countries with respect to the population/pharmacy ratio of the country.

Table 5: Greece: Pharmacies per 1,000 inhabitants, 2004-2009

	2004	2005	2006	2007	2008	2009
PHARMACIES	83.0	83.0	86.0	84.5	91.2	92.5

Source: Hellenic Statistical Authority (2012)

3.2 THE REGULATORY FRAMEWORK

3.2.1 The regulatory bodies

The Ministry of Health and Social Solidarity is responsible for planning and implementing pharmaceutical policy and has the authority to regulate the pharmaceutical industry and the health system (including ESY policy and hospitals). The National Drug Organization (EOF) is a Drug Agency which is a division of the Ministry of Health and Social Solidarity whose tasks are mainly to issue market authorization, to classify all medicinal products, and provide pricing approval for pharmaceuticals. The Ministry of Development is a regulatory body that is responsible for the pricing of medicines. There is also the Ministry of Employment and Social Insurance which is in charge of the various social health insurance funds and the Ministry of Finance, the regulatory body that is responsible for the financial governance of the healthcare system[22].

[22] Areti Vardica, V. Kontozamanis (2007), pp.9

3.2.2 Certificating & pricing process of medicinal products

Drugs are authorized for sale in Greece once they have successfully gone through the drug approval process. This process is the means by which a drug application is reviewed by the Ministry of Health and Social Solidarity, and a department of the Ministry of Development called the General Committee of Commerce, which assess the safety, efficacy and quality of a drug, and also determine its ex-factory price. In the first stage of the approval of a new medicine, pharmaceutical companies prepare an application file in accordance with Greek and European standards and submit it to the National Drug Organization (EOF) so as to begin the process of receiving drug authorization. The National Drug Organization (EOF) evaluates the information that is given and approves the efficacy of each new drug. The applicant pharmaceutical company should then prepare an application form accompanied with a series of informative documents and evidence on the medicine. In these documents there should be specialized information about the drug's administrative characteristics, such as the proposed trade name, and the sponsor-holder, while overall summaries and overviews on chemical, clinical and non-clinical, pharmaceutical and biological documentation, as well as the name of the active substance, and product's life expectancy, both of which are required to be analyzed elaborately.

No sooner after a pharmaceutical product receives drug authorization than it enters the second stage that is the price setting process. The price setting process begins by transmitting the necessary data to the General Committee of Commerce which is the pricing regulator at the Ministry of Development that deals with the pricing process and publishes price bulletins. A three-month period is usually necessary for a decision to be forwarded to the pharmaceutical company[23].

As far as imported manufactured or packaged original drugs are concerned, the price is determined by the average of the three lowest wholesale prices among the European Union member states which are declared every year through official price figures. In the first stage of the price setting procedure, it is imperative for a medicine

[23] John Yfantopoulos (2007), pp.91

to have received the same price in the same form and content in three or more EU member countries. Afterwards companies submit an investigation sheet to the General Committee of Commerce either in paper form or electronic which should include: a) the EU member states where the specific drug is circulated, b) the name, the packaging, the active substance and its content, the classification of pharmaceuticals and the form in which this medicine is dispersed. The General Committee of Commerce takes into account the above collected data and uses them to determine the price of each medicinal product. Shortly afterwards, the values of pharmaceutical products that have been authorized in Greece are corresponded to other EU member state equivalent drug prices and converted into the corresponding currencies of the counterparts after correlating official exchange rates[24].

It should be noted, however, that there is a different way of pricing in those pharmaceutical companies that have conducted research on active substances or Greek patent formulation and produce original pharmaceutical formulations with no similar content in another country. These drugs are priced by the General Committee of Commerce in a different costing system than the imported ones and based on production and packaging costs, and also administrative, and distribution costs. In addition, the expenses of research and development and the cost of new investment are included in the estimation of the drug value.

The selling price of pharmaceutical products with the same active substance that are introduced for first time in the market are set at a maximum rate of 72% of the corresponding original medicinal products for the period of time that the national or European patent is in effect. The price of pharmaceuticals with similar active substance is set at a maximum rate of 90% of the original one, after the patent of the respective pharmaceuticals' active substance has expired. The announcement of the price of new drugs circulated in Greece is conducted through price bulletin announcements by the General Committee of Commerce and soon afterwards it is distributed to all pharmacies. If a company is going to re-price a medicine, it is obliged to resend the list of countries which circulate the original drug along with their respective codes in a short period of 45 days before the official release of the

[24] Ειδική Έκθεση του Συνδέσμου Φαρμακευτικών Επιχειρήσεων Ελλάδος (2011), σελ.17-18

Bulletin. After the pricing and possible re-pricing procedure, values for medicinal products are promoted by the General Committee of Commerce to pharmaceutical companies which have the authority to submit any objections within 4 days. The price bulletin indicates the wholesale, hospital and retail price of approved medicinal products available in Greek the market[25].

The price decisions for all pharmaceutical products are made by the Ministry of Development which determines four different prices for a pharmaceutical product: the ex-factory price, the wholesale price, the retail or pharmacy price, and the hospital price. More accurately, the ex-factory price is the price at which pharmaceutical companies sell to wholesalers, which for imported products is set at the lowest ex-factory European price, while for the locally manufactured and/or packaged product it is determined by taking into account production and distribution expenses, plus any discount. On the other hand, the wholesale price is the price at which wholesalers sell to pharmacists/retailers. *"This includes the wholesaler's profit and compulsory discounts to pharmacists. For wholesalers, the gross profit margin is fixed at 8.43%, based on the net price of the producer or importer (the wholesaler purchase price) or at 7.78% on the wholesale price (the pharmacy purchase price)"*[26]. The pharmacy or retail price is calculated on the basis of the wholesale price, when one adds the retailer's profit margin (35% above the wholesale price) and value-added tax (VAT). Moreover, the hospital price is the sale price of the medicinal products to public hospitals, social security institutions and pharmacies of private clinics, which is based on the wholesale price, reduced by 13%. Lastly, the price of a generic medicine is determined separately at 80% of the retail price of its equivalent branded pharmaceutical product.

[25] Ειδική Έκθεση του Συνδέσμου Φαρμακευτικών Επιχειρήσεων Ελλάδος (2011), σελ.18
[26] John Yfantopoulos (2007), pp.92

4. THE ROLE OF PUBLIC POLICY

The government aims to constrain and control the growth of pharmaceutical expenditure by taking measures both on the supply-side and the demand-side. As far as the supply-side cost containment measures are concerned, in 1998 the Greek government introduced a positive list with reimbursement drugs and set the lowest reference pricing system among the EU-15 member states according to article 20 of Law 2458/1997. Inclusion on the positive list for a drug was necessary if it was to be reimbursed by the various social insurance funds. Firstly, the necessary prerequisite for a medicinal product to be included on the list was to have been granted a market authorization from the Ministry of Health and Social Solidarity. Some of the criteria for inclusion on the list were the drug's therapeutic impact, its pharmaco-economic efficiency, the average cost of daily treatment, the target population, the safety, the effect in pharmaceutical expenditure and other criteria that are occasionally imposed by the Ministry of Health and Social Solidarity. The moment a drug has been included on the positive list and published in the press and the official newspaper of the Greek government, it could be reimbursed by the social health insurance funds[27].

Unfortunately, the positive list and the lowest reference pricing system among European countries are measures that have proven to be ineffective as pharmaceutical companies responded with regular alterations in the packaging of drugs, increased parallel exports and imports, and implemented promotional strategies focusing on supply-induced demand by influencing physicians to prescribe new medicines that were more expensive with higher profit margins for them. In addition, the positive list's measure did not has the expected results as there were long delays and the bureaucracy involved in the procedure for inclusion of a drug on the list caused considerable problems for the regular circulation of pharmaceutical companies' new medicines on the market. More specifically, the inclusion procedure of medical products on the positive list should not exceed 90 days according to the community directive. Greece was beyond this limit, despite a two-year improvement concerning the inclusion procedure delay, and it continued to be one of the EU countries with the longest delays. Data refer that *"over the period 1998 to 2003, according to OECD*

[27] Xenophon Contiades, Christina Golna, Kyriakos Souliotis (2007), pp.123

data, the annual rate of growth of pharmaceutical expenditure in Greece was 7.9%, which is among the highest in the OECD countries (average 6.1%)"[28]. Indeed, pharmaceutical expenditure, after a short reduction in amount, continued to grow at the same rate as before the implementation of the specified cost containment measures.

The Greek government introduced Law 3408/2005 and Law 3457/2006 in an attempt to comply with European Union rules and control growth of pharmaceutical expenditure. More specifically, a new pricing system was implemented in late 2005 (Law 3048/2005) that was derived from the average of the three lowest European prices, two from the former EU-15 member states before 1st May 2004 plus Switzerland and one from the new EU-10 member states after May 2004, to which import expenses and compulsory discounts were added. It should be noted that the new pricing system called 'external price referencing' *"was applied to all new pharmaceutical products including over-the-counter drugs (OTCs)*[29] *and determined only the ex-factory price of pharmaceuticals - producer or importer"*[30]. Moreover, according to Law 3408/2005, the price of generic products was set at 80% of the price of the original product. The wholesale price was based on the ex-factory price of the producer or importer plus a gross profit margin of 8.43%. At the pharmacy level there was a gross profit margin of 35% on top of the wholesale price, while hospital prices of medicinal drugs were reduced by 13% compared to the wholesale price. The price of medical products where a patent has expired would have a discount of 20%.

However, although, the particular pricing system based on the average of the three lowest prices of EU-25 member states had provided fair terms of competition due to the equalization of the price setting procedures, it changed the perfectly competitive stage for the Greek pharmaceutical industry. Until then, the Greek pharmaceutical companies set the prices of their products by themselves, after negotiations with the state, making a substantial profit from selling them to the Greek and foreign markets. Regionally manufactured original pharmaceutical products *"now obtain the same price and follow the same procedures as the respective imported*

[28] John Yfantopoulos (2007), pp.87
[29] **OTC** medicines : drugs that are usually sold to a consumer without a prescription from a physician
[30] Areti Vardica, V. Kontozamanis (2007), pp.22

original medicinal products"[31]. Such a prospect provides opportunities for growth to the indigenous pharmaceutical industry, but, on the contrary, increases the competition among locally manufactured products and imported ones which stand for a share of sales in the Greek territory.

According to the Law 3457/2006, the 1998 reimbursement list was enacted as it restricted the inclusion of medicines in the reimbursement system of the social insurance funds. Then, the Greek government aimed at completing compensation for all medicines except OTCs and lifestyle drugs in the reimbursement system so as to provide extended access to medicines to all. Lastly, the new legislation has established a rebate pricing system according to which pharmaceutical companies - manufacturer and/or importer - were obliged to pay a rebate price back to the social health insurance funds. A '*rebate price is the difference between the price reimbursed by the social insurance funds and the reference price for the therapeutic cluster while the rebate amount is calculated by multiplying the rebate price by the quantity of drugs purchased by therapeutic cluster"*[32].

Needless to say, the abolition of the list and the introduction of the rebate pricing system did not have the expected positive results again. Pharmaceutical expenditure continued to increase despite abolishing the 1998 reimbursement list, while the promising rebate system plan has never been accomplished as pharmaceutical companies had never implemented the rebate system granting the National Insurance Funds a rebate payment.

An innovative cost containment measure implemented by the government was the bar code system for medicines acting on the demand-side. The measure was introduced on 1st January 2005 and its main purpose was to control and monitor the prescribing behavior that increases pharmaceutical expenditure. After the implementation of the bar code system, the access to information related to pharmaceutical healthcare services had been improved and there was even more effective control of the prescribing system that minimized possible errors and provided better service to the patients.

[31] Areti Vardica, V. Kontozamanis (2007), pp.21
[32] John Yfantopoulos (2007), pp.96

Together with the innovating bar code system, the Authenticity Band was introduced. The Authenticity Band *"is pasted on each medicinal product package, which ensures the product's authenticity and provides a means of reimbursement by insurance funds and companies"*[33]. The EOF Agency after the approval process of a medicine assigns a code to the drug which represents its identity in Greece or any other market. From 1st January 2005, the authenticity brand bore a bar-code, and today a second bar-code has been included to the authenticity brand providing direct access to information for any medicinal product marketed in Greece and also safeguarding to pharmaceutical products from dangerous to human health imitation drugs (fake drugs).

5. PROBLEMS OF THE SECTOR

Pharmaceutical companies recognize the public authorities' responsibility to protect public health and safety while the latter struggle to constrain pharmaceutical expenditure's growth and confront various administrative and management problems, such as administrative burdens and workforce deficiency. However it cannot be ignored that pharmaceutical companies bear all the cost of their daily operations derived from the drug authority and price setting processes or high finance costs in the form of fees, and indirect costs related to the competitive pharmaceutical market. In addition, the existence of delays in almost all stages of drug authorization and price setting processes, which far exceeds the statutory schedule, is a common known fact that negatively affects the Greek pharmaceutical companies' growth. All these discrepancies and many other problems that will be analyzed below constitute a severe environment for the Greek pharmaceutical industry nowadays. Socially responsible companies are aware of these problems that require now more than ever the efficient cooperation of the representatives of both public management and pharmaceutical entrepreneurships.

[33] Areti Vardica, V. Kontozamanis (2007), pp.18

As far as the drug authorization process is concerned, there are various indications showing a significant delay in the drug authorization process which usually exceeds the 210 days set by law and in many cases may even reach the period of two years. Such a delay creates disastrous problems for pharmaceutical companies as it shifts the introduction of a new medicine on the market and provokes worries about the preservation of the scheduled sales pharmaceutical companies have planned. The lack of personnel in the regulatory body that leads to operational weaknesses is regarded as being the main factor that contributes to these restraints. More specifically, the lack of staff in the EOF offices in order to evaluate applications for approved marketing authorization is an essential factor that affects the efficient operation of the organization. There seems to have been significant deficiencies in the EOF's workforce level resulting from the recently massive retirement of experienced executives with extensive experience which have been accompanied by the necessary planning measures for cutting down on graduate recruitment that the economic recession has forced[34].

In addition, the existence of technical inadequacies in the EOF Agency contributes to essential delays and operational weaknesses in a drug's licensing and price setting processes. The EOF's failure to ensure the efficient operation of the approval process due to the shortage of technical support highlights the existence of bureaucracy and the substantial operational problems of the organization**.** There is the absence of an electronic document management system which would restrict the possible delays during each stage of the ratification process and also improve the evaluation process of dossiers deposited in all the stages of the approval process[35].

The price reference system derived from the average of the three lowest European prices (except for Malta, Estonia, Sweden and Denmark prices) that determines the ex-factory price of pharmaceuticals - producer or importer - is quite a disputable option as it does not focus on countries with similar economic and financial profiles thereby generating doubts as to its fairness. For instance, the price reference system does not take into account the differentiation of important macroeconomic parameters of the relevant countries such as the level of GDPs, the health profiles,

[34] Ειδική έκθεση Συνδέσμου Επιχειρήσεων και Βιομηχανιών (2011), σελ.23-26
[35] Ειδική έκθεση Συνδέσμου Επιχειρήσεων και Βιομηχανιών (2011), σελ.26

currency exchange rates, etc., when it is time for the reference price of the medicines to be calculated. Moreover, the viability of such a pricing model that is based on the gathering of medicines' prices is under question as it is likely that some countries which participate in the reference price process may not refer the possible disclosed discounts on pharmaceutical companies' medicines or the rebate in insurance funds (a percentage of pharmaceutical products' sales that is given back to social health insurance funds). Consequently, it is necessary the international price reference system for medicines be based on the prices of EU countries with similar economic and financial prospects to Greece and take into account the possible discounts which affect the final price of a medicine[36].

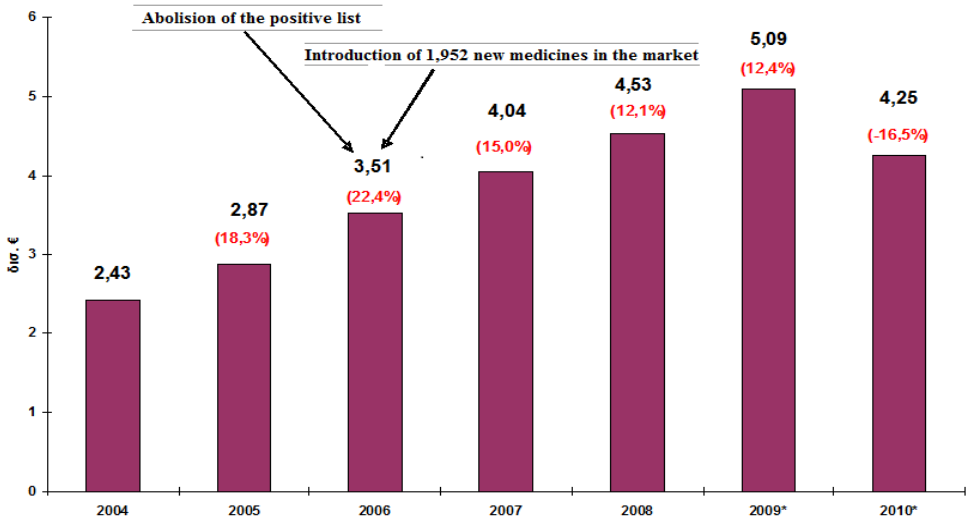
In addition, the diversity of the Greek pharmaceutical industry's distribution channels is not taken into consideration when calculating the ex-factory price of pharmaceutical products. To be more accurate, the supply chain for medicines in Greece is conducted by the pharmaceutical company through wholesalers and pharmacies' associations to the patients that represent the retail market. The lack of wholesalers in many EU member states generates a discrepancy in the calculation of the ex-factory price that in any case appears not to be representative. The reason for this is that pharmaceutical companies in some counties maintain important administrative resources for the efficient operation of distribution channels with wholesale companies and communication with relevant services, a fact that creates significant administrative costs that should be calculated before price setting.

Moreover, there is an important delay in the procedure of price issue bulletins according to which prices are given to new medicines so as to enter the market for the first time. By law, a minimum number of five price issue bulletins are scheduled to be published by the Greek government annually. In practice, however, the government failed to issue price bulletins periodically and a gap in the scheduled price issue bulletins has been appearing. For instance, the law for pricing of medicines was amended in November 2005 and the first price bulletin was finally issued in 2006. Thus, such a delay not only affected pharmaceutical companies negatively as their profits were constrained, but also led to the introduction of a relatively high number of

[36] Ενδιάμεση Έκθεση της Ανεξάρτητης Ομάδας Εργασίας Ειδικών Εμπειρογνωμόνων στον Τομέα της Υγείας (2011), σελ.63

new drugs in the price issue of 2006 that resulted in an increase in pharmaceutical expenditure[37].

Table 6: Pharmaceutical expenditure patterns, 2004-2009



Source: ΓΓΚΑ & Φαρμακευτικής Οίκου Ναύτου (2004-2009)

There is difficulty in the development and establishment of a strategic policy in the pharmaceutical industry due to a lack of a stable legal framework to support business planning, which could increase pharmaceutical companies' productivity. The industrial activities in Greece have been adversely affected due to recent economic circumstances and steadily reduced owing to uncertainty and continual amendments in public policy options regarding reductions in drug prices, management policies in favor of generic drug consumption, lack of incentives from the state that boost domestic production (e.g. tax exemptions for research and development), and finally the EOF's inability to provide substantial support to the pharmaceutical industry. All the factors mentioned above have contributed to the hampering of the efficient planning and development of the sector, are steadily shrinking the Greek pharmaceutical companies' productivity, with a detrimental impact in employment in the sector.

The long accumulated debts that are incurred mainly by hospitals and social health insurance funds and the delay of their repayment create significant liquidity

[37] Yiannis Stournaras (2011), pp.3

problems for pharmaceutical companies and set barriers for future development and implementation of production and investment programs. The accumulation of pharmaceutical companies' requirements have created serious cash flow problems - especially for those pharmaceutical companies that produce in the Greek territory and do not have any support from multinational groups. This has forced them to increase borrowing so as to deal with their obligations. The attempt of the Greek government to repay the high levels of debt owed by Greek hospitals to suppliers and pharmaceutical companies began in March 2009. By the end of 2010 the two interested parties - the state and pharmaceutical companies - had reached an agreement on the repayment of the sizable accumulated hospital debt for the period 2007-2009 through the issuing of three-year zero coupon bonds of a total value of €5.2 billion. Through a system of government guarantees and certification of invoices, the Postal Savings Bank began the process of repaying the €5.2 billion owed to the industry[38]. According to Law 3867/2010 the Greek government took up the 2005-2010 accumulated debt of the Greek state hospitals (almost €1.1 billion in March 2011) and paid hospital suppliers in the form of domestically issued bonds called zero coupon bonds or 'Pharma-Bonds'[39]. These financial instruments are bonds that are considered to have international security identification and suspended in the case of a government's weakness to print money to fund its deficit. They are negotiable on the Athens Exchange Market and added on to other Greek debt. The government guarantees that bondholders who choose to discount these bonds at the banks will crystallize a 19% discount versus their original claim. In the case of Greece, the Pharma-bonds operate similarly to money, and can be deposited with a bank which can use them as collateral for real cash.

However, debt continued to be accumulated due to the worsening economic environment from the recession. An implementation of a 'haircut' in zero coupon Pharma-bonds by the Greek government in March 2012 - in an attempt to alleviate the country's sovereign debt and restrict public deficit - have made the titles of these three-year Pharma-bond holders' suffer a reduction of 62.80% of par nominal value and consequently their profits incurred huge losses. Without a doubt, the holders of these three-year Pharma-bonds, the pharmaceutical companies, will not have the

[38] http://www.researchandmarkets.com/reports/
[39] http:// www.investopedia.com

ability to recover the amount of the depreciated value of their bonds. This fact has negatively affected the already severe climate in the Greek pharmaceutical industry and it further threatens foreign business and trust-confidence in pharmaceutical companies in Greece. For instance, Swiss Roche which specializes in oncology medication widely declares it will stop supplying a number of Greek public hospitals, while a number of other multinationals, including Germany's Bayer, are reported to have introduced cash-on-delivery policies in the case of Greece[40].

The Hellenic Association of Pharmaceutical Companies (SFEE) is a professional non-profit association whose purpose is to protect and pursue the interests of its members[41]. The SFEE has collected and presented all the data related to the state's unsettled debts to its member pharmaceutical companies for invoices issued from 01.01.2010 to 31.03.2012. The main points emerging from the analysis of the data indicate the level of sales, incoming revenues, and state's debt to the pharmaceutical companies for invoices issued from 01.01.2010 to 31.12.2010 which are depicted in the following table[42]:

Table 7: Pharmaceutical companies' sales, incoming revenues & state's debt, 2010-2012

Period	**Sales** (in euro)	**Incoming Revenue** (in euro)	**Total public debt** in 31.03.2012
01.01.2010-31.12.2010	1.4 billion	1.2 billion (88%)	170.0 million
01.01.2011-31.12.2011	1.2 billion	404.2 million (34%)	781.1 million
01.01.2012-31.03.2012	255.4 million	2.1 million (0.83%)	253.2 million
01.01.2010-31.03.2012	**2.9** billion	**1.6** billion **(57.9%)**	**1.2** billion

Source: Hellenic Association of Pharmaceutical Companies, (2012)

[40] http://www.bloomberg.com

[41] Regular members of the SFEE may be entities engaged in the production or marketing and promotion of medicinal products

[42] Ειδική Έκθεση του Συνδέσμου Φαρμακευτικών Επιχειρήσεων Ελλάδος (2012) , σελ.1-7

- The level of pharmaceutical companies' sales during period 01.01.2010 to 31.12.2010 amounted to €1.4 billion. By the end of 31.03.2012, the amount of revenue of pharmaceutical companies for invoices issued from 01.01.2010 to 31.12.2010 amounted to €1.2 billion. In other words, on 31.03.2012 the amount of the government's debt to pharmaceutical companies for invoices issued from 01.01.2010 to 31.12.2010 amounted to €170 million, and consequently 88% of the invoices from 2010 have been paid.
- For the period 01.01.2011 to 31.12.2011 the level of sales by pharmaceutical companies to the state amounted to €1.2 billion. The amount of revenue from the 2011 invoices was €404.2 million, which represented the 34.1% repayable amount of total government debt for the year 2011. Finally, on 31.03.2012 the amount of debt to pharmaceutical companies for invoices issued from 01.01.2011 to 31.12.2011 amounted to €781.1 million.
- As for sales, incoming revenues, and public debt for invoices issued for the period 01.01.2012 to 31.03.2012 the data shows that the level of sales amounted to €255.4 million, the revenue accounted for just €2.1 million - only 0.83% of the government debt has been paid - and the amount of state debts for issued invoices amounted to €253.2 million.

To summarize, by the end of 31.03.2012 the total sales of pharmaceutical companies to the state for the period 01.01.2010 to 31.03.2012 amounted to €2.9 billion, the total revenue from the state for the same period amounted to € 1.6 billion - just 57.9% of the total public debt has been repaid - and the total unsettled government debts to pharmaceutical companies for invoices issued from 01.01.2010 to 31.03.2012 amounted to €1.2 billion. It is noteworthy to say those ESY hospitals' present total debts of €676.1 million representing a 52.8% of the total unsettled government debt to pharmaceutical companies.

The report has also recorded important data concerning accumulated debts before and after 2010 for invoices issued between pharmaceutical companies and IKA (EOPYY) and military hospitals. On the one hand, IKA (EOPYY), the social health insurance fund displays high debts of nearly €454.9 million of which €10.7 million is related to debt before 2010. Furthermore, military hospitals have paid only 34.7% of

their total obligations to pharmaceutical companies amounting to €125 million, from which €59.5 million represents debts before 2010. Conclusively, all the fore mentioned above contribute to a negative climate between pharmaceutical companies and the state which exacerbates their already damaged collaboration from the recession.

Last but not least, there is an insufficient research and development effort in Greece compared to the US, European and emerging economies such as Brazil, China and India. According to EFPIA Figures, "*the pharmaceutical industry is the high technology sector with the highest value-added per person employed, well ahead of the average value for high-tech and manufacturing industries, and also the sector with the highest ratio of R&D investment to net sales as it amounts to approximately 3.5% of total EU manufacturing value added and 19.1% of the total worldwide business R&D expenditure*"[43]. Research and development in the pharmaceutical industry requires significant economic and scientific resources so as for new innovative medicines to be developed. However, Greece which has been in a deep recession for four years now has seen the pharmaceutical sector's investments be grounded to a halt. This situation in combination with the existence of bureaucratic and organizational problems in the structure of the industry has affected research and development negatively and devaluates any future prospect for pharmaceutical companies' development. Available data from EFPIA Agency's annual report for the year 2010 have shown the Greek pharmaceutical companies to have spent only €84 million in research and development, a percentage far lower than the European pharmaceutical industry's average rate.

[43] European Federation of Pharmaceutical Industries & Associations (2012), pp.10

6. PUBLIC POLICY MEASURES AFTER THE IMPLEMENTATION OF THE MEMORANDUM

The economic crisis has deteriorated the already harsh environment in the pharmaceutical industry and constrained every effort for development. The restrictive measures taken by the Greek government, after implementation of the Memorandum, have a direct impact on the pharmaceutical market. The government after committing to fiscal consolidation involving the Greek economy subsequently imposed a series of measures that led to a continuing pressure for price cutting and reduction in the consumption of medicines on the pharmaceutical sector.

More specifically, after the imposition of the memorandum in Greece and the enforcement of its subsequent obligations, it was imperative that the Greek government should drastically reduce pharmaceutical consumption and expenditure. A re-pricing policy was conducted for 6,383 pharmaceutical products in order for pharmaceutical expenditure to be reduced by 14.46% in April 2010 while the following year (February 2011) a re-pricing policy was conducted for 3,437 pharmaceutical products with an estimated reduction of about 11.34% in pharmaceutical expenditure. According to estimations, after the implementation of a series of cost-containment measures, including price reductions, pharmaceutical expenditure was reduced by €1 billion in 2010, while in the next two years a new reduction in pharmaceutical expenditure by almost €1 billion is anticipated[44].

However, such horizontal interventions on the reduction in pharmaceutical prices has led to a sharp decline in pharmaceutical companies' profits, but simultaneously, pharmaceutical expenditure as a share of the GDP has continued to increase rapidly making it now more than ever imperative that the specified measures be reassessed. Consequently, the roots of the problem should be focused, as was mentioned before, on other cost-containment measures that would mainly affect supply-induced demand and excessive spending and mismanagement in the healthcare system. In addition, there are many who support that this price-cut policy on

[44] Dragalidis Athanasios (2011), pp.27-28

pharmaceuticals will have negative consequences for the Greek pharmaceutical industry in the long run, as there are worrying concerns regarding the increase of parallel exports which could create important shortages in certain medicines, and/or substitution of cheap medicines by more expensive ones.

Therefore, through the enforcement of the memorandum and the implementation of price cutting measures, the reduction in the price of pharmaceutical products has continued, and pharmaceutical company profit margins have been reduced respectively. More specifically, the new way of pricing and the cost-containment measures that the government has imposed in an attempt to restrict pharmaceutical expenditure has affected an ex factory price lower than it was before - with approximately a 24.5% decrease between 2010 and 2011. Other measures, which according to an Independent Working Group of Experts in the Healthcare system's estimations will reduce medical prices and save €1 billion along with the new price calculating system of drugs based on European Union member country prices, are as follows[45]:

- Reduction in the profit margins of the wholesalers - from 7.8% to 5.4%.
- Reduction in the profit margins of pharmacists - decreased by 4.5% on average.
- Reduction of VAT on medicines from 11% to 6.5%.
- Application of positive and negative lists.
- Implementation of compulsory rebate - claw back - on pharmaceutical companies' profits (4% of sales based on the wholesale price).
- Expansion of electronic prescription of medicines in all social health insurance funds.
- Widespread consumption of generic medicines.
- Implementation of treatment protocols.
- Removal of the upper and lower price variation percentage of medicinal products that was introduced in September 2009.

[45] Ενδιάμεση Έκθεση της Ανεξάρτητης Ομάδας Εργασίας Ειδικών Εμπειρογνωμόνων στον Τομέα της Υγείας (2011), σελ.54-55

The prices of the original pharmaceutical products that, as was already mentioned, are calculated based on the average of the three lowest ex-factory prices of European Union member countries, is formed at 80% of the initial value when their patent has expired - become off-patent - and the respective generic enters the market. The price for generic drugs is formed at 72% of the price of the existing original medicine with a standing patent. The final price of a medicine is comprised by the ex-factory price to which is added the wholesaler's gross profit (5.4%), the gross profit margin of the pharmacies (retailers) that is 35% of the wholesale price (or 24.34% of retail price) and also a value-added tax (VAT) increase by 6.5%. Compulsory discounts are finally imposed on the wholesale price that are determined at 5.12% rate for prescription drugs and 7.24% for non-prescription ones (MISYFA)[46].

Nevertheless, the introduction of such restructuring actions established in the Greek pharmaceutical market, has not served its purpose in some cases while at times has generated substantial problems and warps in the pharmaceutical industry. In particular, the implementation of the positive list on 15th November 2011 - that contains medicinal products subject to medical prescription reimbursed by the social health insurance funds - will lead to the reduction of pharmaceutical prices and introduction of more drugs for disease treatment in the categories of percentage co-payment in Greece. However, such continual price reductions will force pharmaceutical companies, on the one hand, to substitute the already cheap drugs by new, more expensive ones, and on the other hand, to increase parallel exports generating serious threats regarding the availability of medicines in the Greek market.

Furthermore, the introduction of a new negative listing including medicinal products subject to medical prescription but not reimbursed by the social health insurance funds, downgrades the economic status of patients with relation to healthcare who have difficulties paying for medication from their own pockets and as well for people with disabilities and chronic disease. More accurately, by 1st March 2012 the negative list contains low cost drugs widely available, such as antipyretics, analgesics, drugs for weight loss and drugs for smoking cessation, and also medicinal

[46] Dragalidis Athanasios (2011), pp.28

drugs received by people with disabilities and chronic diseases[47]. However, this list may put an end to inexpensive drugs as pharmaceutical companies could replace the cheap drugs with more expensive ones thereby in the long run generating two classes of citizens in the healthcare system. Moreover, as far as the pharmaceutical treatment of people with disabilities and chronic diseases is concerned, although the specified drugs are not expensive enough to affect their income dramatically, their use is so widely common that it leads to the economic bleeding of their income and endangers the lives of this most vulnerable group.

The rebate amount from pharmaceutical companies' total sales - a percentage of pharmaceutical products' sales that is given back to the social health insurance funds - that has been set at 4% of the retail price of the prescribed medication and 5% of the hospital price in 2008 and later amended to 9% of the ex-factory price has proven to be an unfair and unsubstantiated measure to the majority of the pharmaceutical industries in Greece. According to Law 3408/2005 (Article 13 par 3) the rebate amount is defined as the difference between the price reimbursed by the social insurance funds and the reference price for the therapeutic cluster. The rebate amount is calculated by multiplying the rebate price by the quantity of drugs purchased per therapeutic cluster and is paid compulsory by the pharmaceutical manufacturer or distributor. Moreover, in a recently published directive by the Ministry of Health and Social Solidarity (no 1504/2012) pharmaceutical companies are obliged to an additional claw back rebate payment towards insurance funds depending on the volume of each medicinal product's total sales per three months. The following table demonstrates the fluctuations of the new-entry claw back rebate payment:

[47] http://www.eof.gr

Table 8: Claw Back Rebate System, 2012

Total sales/pharmaceutical product (per three months)	**Claw back rebate**
400,000€-800,000€	2%
800,000€-1,500,000€	4%
1,500,000€-2,500,000€	6%
Over 2,500,000€	8%

The majority of the pharmaceutical companies in Greece, in any case, are unified against the outlined legislated measures on the grounds that such actions have been set on a wrong direction which will only contribute to profit reductions without affecting pharmaceutical expenditure[48].

7. SUGGESTIONS & FUTURE PROSPECTS

7.1 Pharmaceutical product's efficient prescription

Overall, the rapid expansion of pharmaceutical expenditure as a share of the GDP in Greece is more or less connected to increase in demand for pharmaceuticals - due to demographic characteristics and supply-induced demand - rather than increase in pharmaceutical products' prices. More specifically, many physicians affected by pharmaceutical companies' promotional strategies over-prescribe medicines and/or specifically promote more expensive drugs thereby contributing to supply-induced demand for pharmaceuticals. The decrease in pharmaceutical expenditure therefore could be resolved with effective and direct expansion of electronic prescribing throughout the healthcare system of the country rather than price reduction of pharmaceutical products, original and generic. The implementation of the electronic prescription of medicines and its expansion to all social health insurance funds

[48] Stat Bank's Conference "Health - Medicine 2012"

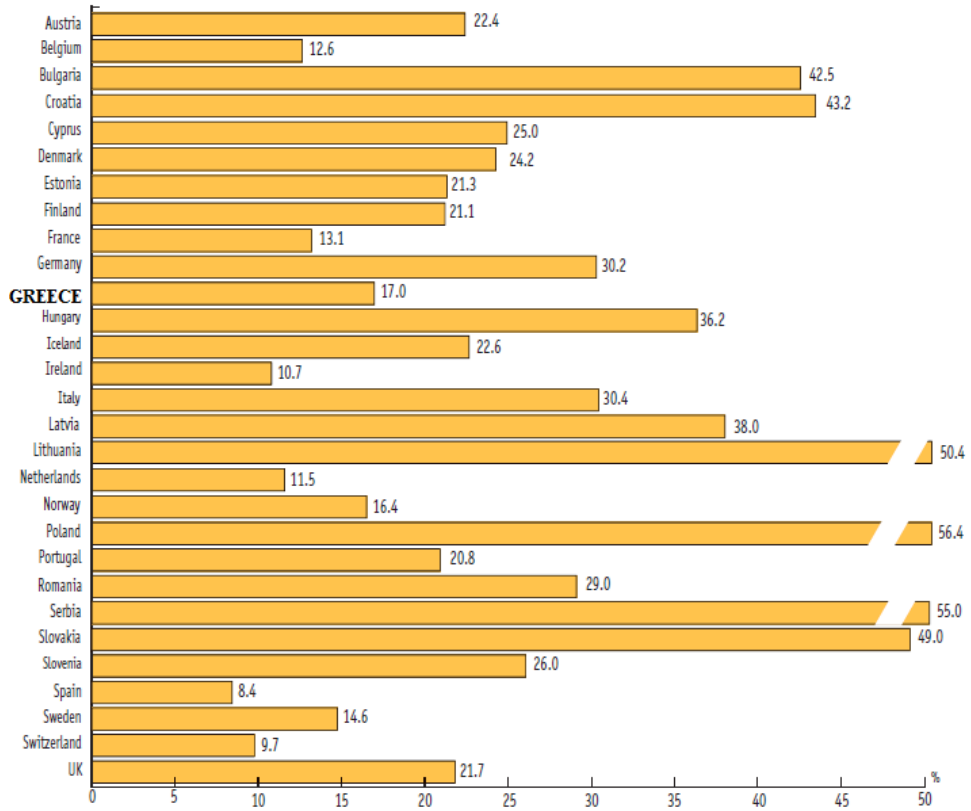
became feasible through several pilot programs in the social health insurance funds and hospitals. From 24th January 2011[49], the electronic register and prescription of medicines has been first enforced in OAEE social health insurance fund and later implemented by the other insurance funds (IKA, OPAP, OGA) and hospitals. The physicians should prescribe medicines and services through an electronic prescription database in order to observe and control consumption of medicines. In this way, the Ministry of Health and Social Solidarity is attempting to control and observe the number of medicines each doctor can prescribe and consequently control over-prescription behavior and reduce pharmaceutical consumption and expenditure. Nevertheless, structural discrepancies in the system and the non-compliant attitudes of many physicians were manifested, a fact that devaluated the importance and effectiveness of the prospective measure. Therefore, the government must correct any disability and malfunction of the conservative prescription system and also oblige every relevant party to comply with the law and set up prescription control mechanisms; otherwise it should impose strict punishment on them.

7.2 Generic medicines

The consumption of generic medicines in the Greek pharmaceutical market is ranked among the lowest in the EU and is seen as have never being implemented before a pharmaceutical policy focused on the development of generics as a measure of controlling supply costs. This is in contrast to the production side profile of Greece where *"almost 97% of generics sold are attributed to Greek pharmaceutical companies, whereas multinational companies hold 90% of the branded sales, and in addition, there is small number of large multinational companies involved in the Greek generic market but with small shares of sales"*[50].

[49] Law 3918/2011
[50] V.Tsiantou, D.Zavras, H.Kousoulakou, M.Geitona, J.Kyriopoulos (2009), pp.2

Figure 2: Share (estimate-in %) accounted for by Generics in Pharmaceutical Market Sales Value (at ex-factory prices), 2010



Source: EFPIA 2012

A possible reason for this situation is that the Greek regulatory framework does not encourage the development of this sector in the Greek pharmaceutical industry and physicians are not given incentives to use generics until nowadays. For instance, although *"physicians are permitted to prescribe by the generic brand name, they are not allowed to prescribe by a product's International Non-proprietary Name (INN)"*[51]. In addition, Greece is regarded as having one of the lowest pharmaceutical price listings in the EU - according to the European Commission's estimates. This makes original Greek pharmaceutical products and services relatively inexpensive, making the use of generic medicines not as widespread and necessary.

Furthermore, it is commonly observed that Greek physicians and patients are suspicious and skeptical about the quality of the generic medicines specifically that

[51] http://www.cbi.eu/marketinfo

which concerns their efficiency and safety in comparison to branded products[52]. Additionally, a main possible reason for the poor generic penetration is *"the lack of a price regulation strategy aiming at the creation of a competitive environment between brand name and generic drug producers"*[53]. It is also commonly observed that many pharmaceutical companies of original pharmaceutical products have introduced defense policies against the production of generic products as a result of the reduction in their profit margins and the worsening of the economic environment by means of producing alternatives to generics products, extending the patent of the original products, buying or establishing companies that produce generics so as to keep their market share stable, and lastly by obstructing generic companies' entry into the market by contributing to the complication of the patent granting process.

But what actually is a generic medicine? It is a medicinal product that is comparable to the brand name drug in the way that it contains the same active ingredients as the original formulation and has the same therapeutic effects. Generic medicine is legally released once the original product's patent expires or with the characterization "International Non-proprietary Name (INN)" or by the generic brand name, called 'Branded Generic'. Generic drugs are less expensive than the branded original ones, as the Law 3984/2011 defines the prices of generic medicines to represent 63% of the value of their respective originator products at the retail level. The development of generic medicines in the Greek pharmaceutical market needs to be supported by a generic medicines policy, which will encourage and create incentives for physicians, pharmacists and patients to prescribe, dispense and consume generic medicines, respectively. According to Greece's last measures as imposed by the memorandum, the branded generics are going to gradually substitute the original ones with 30% of the market share by the end of 2012 so as to offer important savings and release important funds to the country.

It is also noteworthy to mention that the majority of pharmaceutical companies in Greece have a positive attitude towards generics and believe that it is worth operating in this sector, because generics in Greece is a growing market. Moreover, Greek physicians are willing to substitute an original drug with a generic product if

[52] V.Tsiantou, D.Zavras, H.Kousoulakou, M.Geitona, J.Kyriopoulos (2009), pp.6
[53] V. Tsiantou, D. Zavras, H. Kousoulakou, M. Geitona, J. Kyriopoulos (2009), pp.2

there is quality control regarding the generic medicine's production. The fact that many drugs are going to soon be off-patented provides the opportunity for generics to be introduced into the domestic market. Greek pharmaceutical companies that have the experience of brand generic production may implement a prescribing system that uses branded generics which are more economical than the original ones, thereby contributing in this way to the reduction of pharmaceutical expenditure. But it is necessary for the state to give instructions and directions to the relevant parties - doctors and pharmacists - for them to be both qualified and informed about the use of cheaper generics. Having considered all the above, we would support that the expansion of generic medicines in Greece should become a priority for the state and generic promotional policy should be introduced in the country on a permanent basis with the parallel implementation of a long term policy for education and training of physicians and pharmacists on the appropriate prescription and use of generic or cheaper drugs.

7.3 Positive and negative listing amendments

The introduction of the positive and negative list measures is a good way to reduce pharmaceutical expenditure and confront its increase. However, evidence from the past has shown that the positive list measure had led to the opposite results than the expected ones mainly that of the reduction of pharmaceutical expenditure, while it introduced bureaucratic and economic barriers before the patients regarding accessible medicines. Therefore, the positive list must be improved by involving constructive discussion and cooperation between pharmaceutical companies and the Greek government.

To this point it is needed to be mentioned that free access to medical care is a privilege of all. The state has the authority and obligation to put an end to uncontrolled prescribing that increases pharmaceutical spending; however, by the introduction of negative listing and the further exclusion of specified vulnerable groups from it puts their lives in danger. A full report justifying the individual physician's decision on usage of negative listed drugs accompanied by the medicinal

product's prescription and also regular check-ups for chronically ill patients might be a possible solution in the prevention of such unpleasant phenomena[54].

7.4 Research and Development

R & D is important for the pharmaceutical industry as it boosts investments, provides new employment positions and contributes to the increase in a country's GDP. In addition, it is observed that R & D costs have increased over the last years. For these reasons, the pharmaceutical companies focus on "*cooperation with third parties, either to gain access to specialized knowledge, and/or to reduce costs*"[55]. Indeed, it is commonly seen at the international level that many pharmaceutical companies focus in mergers and partnership with research institutions nowadays so as to accomplish research and investment in the emerging field of biotechnology and also production to third world companies and the expansion of activities in relevant sectors. According to Theodore Kolletis, the President of Pan-Hellenic Organization of Greek Pharmaceutical Companies, research and development of new pharmaceutical products in Greece today is indeed conducted but at a lower rate than that of European pharmaceutical companies[56]. The fact that many drugs are going to be off-patented during the next period offers the opportunity to Greek pharmaceutical companies to become specialized in the already active substances and develop them into new forms. A long-term public policy must be implemented that will provide the appropriate framework for a steady collaboration between pharmaceutical companies and research institutions and universities towards the development of the pharmaceutical industry. The government should set as its first priority the preservation of interaction between pharmaceutical companies and research institutions and universities, and provide incentives to those pharmaceutical companies that are involved in such activities by offering them economic and fiscal incentives, such as tax reduction and subsidies.

[54] Stat Bank's Conference "Health - Medicine 2012"
[55] European Commission, Directorate General Enterprise & Industry (2009), pp.94

[56] Περιοδικό 'Χρήμα' (2009), Τεύχος 357

7.5 Public policy's re-organization

There is undoubtedly absence of a steady and coordinated pharmaceutical public policy as related to drug licensing and pricing processes that promotes long-term planning and guarantees the development of a healthy business environment in the Greek pharmaceutical market. It is estimated that in Greece with governments changing every four years, the people in charge of the Ministry of Health and Social Solidarity are replaced respectively. Such a policy, however, does not provide a stable and positive environment for business and any other activity. It is imperative first of all for the Ministry of Health and Social Solidarity to be solely responsible with concern to certificating and pricing of medicines so as to coordinate all relevant parties. Indeed, recently the transition from the Ministry of Development to the Ministry of Health and Social Solidarity of all powers related to drug licensing and pricing processes and pharmaceutical policy has been achieved. In addition, a long term pharmaceutical public policy should be planned and implemented towards providing a stable and viable business environment for the pharmaceutical companies in Greece no matter what political party is in power at the specific time[57].

The EOF Agency needs to be re-organized and re-structured with regard to drug licensing and pricing process policy. An intra-coordinated healthcare policy that focuses mainly on the reduction of red tape and operational and organizational improvements through the restructuring of the EOF Agency's function, the strict implementation of the legislated processes and punishment in cases of non-compliance should be set as a priority for the Greek state.

More specifically, as far as the drug authorization process is concerned, it is commonly known that a significant delay exists which may extend to a period of two years. The law, however, indicates that the process of drug authorization should not exceed the period of 210 days for the efficient and competitive operation of the pharmaceutical market. It is substantial now more than ever for a re-designated plan of action to be introduced promptly focusing at first on a comprehensive analysis and

[57] Ενδιάμεση Έκθεση της Ανεξάρτητης Ομάδας Εργασίας Ειδικών Εμπειρογνωμόνων στον Τομέα της Υγείας (2011), σελ.55

mapping of the current agency's situation and a subsequent application of a new operating business model with a detailed description of the involved processes.

Moreover, assessment and evaluation of the specific needs of administrative and scientific personnel in the EOF Agency should be set as a matter of prior concern for the proper function of the pharmaceutical market. More specifically, the lack of staff in EOF offices due to the massive retirement of experienced personnel involved in evaluating applications for approval, marketing authorization and calculation of drug prices is a major problem for the efficient operation of all approval stages. It is necessary that the EOF increase its workforce's power by adding new employees with extensive experience in the field and/or training the already existing ones. In addition, training programs for public administrative executives who are responsible for calculating the price of medicines during the price setting process is an imperative prerequisite for the accomplishment of the complex approval process[58].

In addition, the existence of substantial shortages in the computerization system and technologically up-to-date equipment in the health care system increases excess spending and mismanagement and subsequently increases the total health expenditure. The EOF should be upgraded technologically to support the new operational model by the installation of an electronic document management system for all stages of the licensing process. The EOF Agency should implement a workflow management system based on the data that would result from the operational and organizational re-designation of the agency so as for any discrepancies and mismanagement to be monitored and detected per stage. Also, the EOF Agency should adopt a fully electronic document management system to improve the evaluation process of dossiers deposited in all stages of approval and utilize the EOF's existing electronic information infrastructure which does not seem to efficiently support the actions of approval process[59].

The adoption of fast track methods in drug the authorization process would be an essential measure to avoid bureaucracy. For instance, the EOF Agency might put

[58] Ειδική Έκθεση του Συνδέσμου Φαρμακευτικών Επιχειρήσεων Ελλάδος (2011), σελ.37-38
[59] Ειδική Έκθεση του Συνδέσμου Φαρμακευτικών Επιχειρήσεων Ελλάδος (2011), σελ.38-39

aside some assessments for folders that have already been approved in the past in order to create conditions for faster customer services. In particular, this proposal would be enforceable if it is applied to a generic drug dossier's evaluation for which the pharmaceutical company has already been granted a consent form and is asking for additional licenses proving that they establish proper documentation. The implementation of such a plan would provide valuable benefits for the pharmaceutical companies as it would facilitate their strategies concerning the time that is needed for a new medicinal product to enter the market[60].

Sustainable cooperation between the EOF and the business community that might be accompanied by re-educational activities of both EOF's executives and the pharmaceutical industry's managers are two substantial options for the effective operation of the agency. More specifically, it is necessary for government institutions to indulge in constructive cooperation with the business community so as to support and supplement the EOF's complex regulatory and supervisory role. Therefore it is proposed that a joint association between the relevant parties - the government institutions and pharmaceutical companies - be established to promote specific proposals for the designation of a new business planning model for the EOF Agency.

Furthermore, the comprehensive re-assessment of the price setting system is necessary in order for the pharmaceutical market to operate properly. Such a prospect requires the simplification of the price setting process by the relevant departments and identification of a reliable system of data concentration in order for the chances of errors and discrepancies to be eliminated[61]. Moreover, the price reference system derived from the average of the three lowest European prices that determines the ex-factory price of pharmaceuticals -producer or importer - should be based on the prices of EU countries with similar economic and financial possibilities as that of Greece and take into account the differentiation in important macroeconomic parameters of relevant countries, such as the level of GDP, the health profile, and currency exchange rates, and the possible discounts which may affect the final price of a medicine[62].

[60] Ειδική Έκθεση του Συνδέσμου Φαρμακευτικών Επιχειρήσεων Ελλάδος (2011), σελ.40
[61] Ειδική Έκθεση του Συνδέσμου Φαρμακευτικών Επιχειρήσεων Ελλάδος (2011), σελ.41-43
[62] Ενδιάμεση Έκθεση της Ανεξάρτητης Ομάδας Εργασίας Ειδικών Εμπειρογνωμόνων στον Τομέα της Υγείας (2011), σελ.63

8. CONCLUSION

The production and sale of pharmaceuticals is one of the most important sectors of the Greek economy as pharmaceutical expenditure accounts for 3% of the total GDP, while the pharmaceutical industry participates with a percentage of 1% in total domestic employment as its employees numbered 42.000 people for the year 2007 - 10.000 people in pharmaceutical companies and almost 32.000 in both pharmacies and wholesale companies. Furthermore, pharmaceutical products account for 7% of the trade deficit as it participated with a percentage of almost 5% in total exports, and a percentage of almost 6% in total imports for the year 2009. Until the year 2000 the Greek pharmaceutical industry sufficiently supplied an important part of domestic consumption. However, no sooner after Greece joined the European Monetary Union (EMU) and adopted the euro currency, than the rising competition among the international pharmaceutical companies and the domestic ones resulted in the restriction of the Greek pharmaceutical industry's domestic consumption share - from 55.4% in 1990 it decreased to 30.9% in 1999 and 17.6% in 2004. During the last five years the pharmaceutical industry has performed satisfactorily in the fields of production and sales if one considers the deteriorating global economic circumstances. The steady increase in pharmaceutical expenditure, though, together with the deep period of recession and the consequent program of fiscal reforms which Greece is facing nowadays, are endangering the constitutional and financial viability of the pharmaceutical industry.

The Greek pharmaceutical industry has significant growth opportunities in the generic market as in a short period of time from now, generic medicines are going to be used extensively - on the grounds of fiscal stabilization reforms - and that the patents of many original pharmaceutical products will have expired by 2013. It is noteworthy to say that the necessary infrastructure and expertise in Greece for the sufficient and successful operation of the generic market exists, but there is still room for improvement. It is imperative that an innovative public policy which may simplify the approval process and provide operational and organizational changes to the regulatory bodies associated with the pharmaceutical industry's function be implemented. Furthermore, emphasis should be given to research and development through collaboration between pharmaceutical companies and research institutions

and universities, while economic and fiscal incentives, such as tax reduction and subsidies, should be provided to those pharmaceutical companies that are involved in such activities.

The undertaking for the establishment of a strong pharmaceutical industry in the generic market in Greece can be successfully realized by the Greek pharmaceutical industry considering its low share in the Greek pharmaceutical market - in comparison to the EU average - and also the emerging demand for generic products in European and developing countries that offers great opportunities for the business expansion of generics in the specific economies.

REFERENCES

Foreign bibliography

1. Institute of Pharmaceutical Research and Technology (IFET), Areti Vardica and V. Kontozamanis, Pharmaceutical Pricing and Reimbursement Information, "Greece: Pharma profile", Final Version, June 2007
2. European Commission, Directorate General Enterprise & Industry, "Competitiveness of the EU Market and Industry for Pharmaceuticals", Volume II: Markets, Innovation & Regulation, Final report, Rotterdam, December 2009
3. The European Federation of Pharmaceutical Industries and Associations (EFPIA), "The Pharmaceutical Industry in Figures", Key Data 2012
4. John Yfantopoulos, "Pharmaceutical pricing and reimbursement reforms in Greece", Eur J Health Econ, 2008, 9: 87–97
5. Xenophon Contiades, Christina Golna, Kyriakos Souliotis, "Pharmaceutical regulation in Greece at the crossroad of change: Economic, political and constitutional considerations for a new regulatory paradigm", Health Policy 82, 2007, 116–129
6. V. Tsiantou, D. Zavras, H. Kousoulakou, M. Geitona, J. Kyriopoulos, (2009): "Generic medicines: Greek physicians' perceptions and prescribing practices", Journal of Clinical Pharmacy and Therapeutics (2009) 34, 1-8
7. S. Jacobzone, "Pharmaceutical policies in OECD countries: Reconciling social and industrial goals", OECD Labour Market and Social Policy Occasional Papers, No. 40, OECD Publishing, 2000, http://dx.doi.org/10.1787/323807375536
8. V. Kontozamanis, E. Mantzouneas, C. Stoforos, "An overview of the Greek pharmaceutical market", Eur J Health Econom 2003, 4: 327–333
9. Clause E. Barfield, Mark A. Groombridge, "Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy Article", Fordham Intellectual Property, Media and Entertainment Law Journal, Volume 10, Issue 1, 1999, Article 8

Greek bibliography

1. Ίδρυμα Οικονομικών και Βιομηχανικών Ερευνών (ΙΟΒΕ) (Foundation For Economic & Industrial Research), Ε. Βίτσου, "Η Αγορά Φαρμάκου στην Ελλάδα", Παρατηρητήριο Οικονομικών της Υγείας, Ετήσια Έκθεση 2009
2. Σύνδεσμος Φαρμακευτικών Επιχειρήσεων Ελλάδος (ΣΦΕΕ) (Hellenic Association of Pharmaceutical Companies), "Έκθεση του Συνδέσμου Φαρμακευτικών Επιχειρήσεων Ελλάδος για τα χρέη του δημοσίου προς τις εταιρείες-μέλη του: Πωλήσεις, εισπράξεις και χρέη από 01.01.2010 έως 31.03.2012", Αθήνα, Απρίλιος 2012
3. Ίδρυμα Οικονομικών και Βιομηχανικών Ερευνών (ΙΟΒΕ) (Foundation For Economic & Industrial Research), "Δαπάνες υγείας και πολιτικές υγείας στην Ελλάδα την περίοδο του μνημονίου", Αθήνα, Σεπτέμβριος 2011
4. "Ενδιάμεση Έκθεση της Ανεξάρτητης Ομάδας Εργασίας Ειδικών Εμπειρογνωμόνων στον Τομέα της Υγείας", Αθήνα, Απρίλιος 2011
5. ICAP, "Κλαδική μελέτη: Φαρμακαποθήκες", Αθήνα, Ιούλιος 2009
6. Ίδρυμα Οικονομικών και Βιομηχανικών Ερευνών (ΙΟΒΕ) (Foundation For Economic & Industrial Research), Ε. Βίτσου, "Διαχρονική Ανάλυση Μεταβολής των Τιμών Φαρμάκων κατά την περίοδο 1998-2008", Τομέας Οικονομικών της Υγείας
7. Σύνδεσμος Επιχειρήσεων και Βιομηχανιών (ΣΕΒ), "Επιχειρηματικότητα χωρίς εμπόδια: Νέα προσέγγιση για τη δημιουργία ευνοϊκού επιχειρηματικού περιβάλλοντος - Ειδική έκθεση για τις διαδικασίες έγκρισης διάθεσης φαρμακευτικών προϊόντων: α) Διαδικασία αδειοδότησης, β)Διαδικασία τιμοδότησης", ΣΕΒ, Απρίλιος 2011
8. Piraeus Bank, Δαγκαλίδης Αθανάσιος, "Κλαδική μελέτη 15 - Παραγωγή & Εμπορία Φαρμάκων", Ιούνιος 2011
9. Hellenic Republic, Hellenic Statistical Authority, "Living conditions in Greece", Piraeus 2012
10. Έρευνα της STAT BANK για τις μεγαλύτερες επιχειρήσεις φαρμάκων, Οικονομικά Αποτελέσματα 92 φαρμακευτικών επιχειρήσεων για τα έτη 2007-2008
11. Yiannis Stournaras, Shaping the Future of Healthcare in Greece, Financial Times, June 21, 2011

12. Σπύρος Ασημακόπουλος, "Οικονομικές πολιτικές στην αγορά του φαρμάκου", Διπλωματική Εργασία, Πανεπιστήμιο Πατρών, Σχολή Επιστημών Υγείας, Τμήμα Φαρμακευτικής, Πάτρα 2010
13. Περιοδικό 'Χρήμα', Αφιέρωμα: Αγορά Φαρμάκου, Νοέμβριος 2009, Τεύχος 357
14. Περιοδικό 'Χρήμα', Αιμίλιος Νεγκής, Αφιέρωμα: Αγορά Φαρμάκου, Μάιος 2011, Τεύχος 372

Other sources

1. Hellastat, "Ανάλυση αγοράς 2009 - Φαρμακευτικές επιχειρήσεις", http://www.hellastat.eu
2. OECD Health Data 2012, "How Does Greece Compare", http://www.oecd.org/health/healthdata
3. CBI Market Survey: "The Pharmaceutical products market in Greece", CBI Market Database Information, Publication date: February, 2010 http://www.cbi.eu/disclaimer
4. Σύνδεσμος Φαρμακευτικών Επιχειρήσεων Ελλάδος http://www.sfee.gr
5. Research and Markets Brochure: "Greece Pharmaceuticals and Healthcare Report Q3 2009" http://www.researchandmarkets.com/reports/1055026
6. http://www.eoppy.gov.gr
7. http://www.eof.gr
8. http://www.investopedia.com
9. http://www.statbank.gr
10. http://www.bloomberg.com