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Pharmaceutical Pricing and Reimbursement Information

GREECE

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Pharma Profile

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Executive Summary

Greece is a full member of the EU since 1981. It has a total population of 11.082.751. Total life expectancy at birth is 78,1, female life expectancy at birth is 80,7 years and male life expectancy at birth is 75,4 years (OECD 2002) The main causes of mortality in Greece are: Cardiovascular diseases 31,4%, malignant tumors 23, 5%, cerebrovascular diseases 17, 5% and Respiratory system diseases 7% (2003 data, NSSG).

The economy of Greece is mainly based on services. The state continues to play a major, however diminishing, role. In the last decade there is a large ongoing privatisation programme.

The Gross Domestic Product (GDP) per capita in 2004 in PPS was \$US 19,768. The Greek economy grew with a rate of 3,5% in 2005.

The government aims at reducing the public deficit from 6,9% of GDP in 2004 in 2,6% in 2006. Recent and prospective growth performance is good. The conservatives (New Democracy) are in power since 2004. Fiscal consolidation, convergence with EU living standards, structural changes in the labour market and privatizations are the top economic priorities of the government.

Health policy lies with the Ministry of Health and Social Solidarity. The Ministry is responsible for the provision and financing of the National Health Service as well as health and social services for the poor, the elderly and the disabled.

From 2007, Greece is divided into seven Regional Health Authorities (YPE) instead of seventeen existed thus far. The population is insured through a number of insurance sick funds. The insurance funds have been under the jurisdiction of the Ministry of Labour and Social Protection since September 1995. The main groups of social insurance organizations, the size of population covered, and occupational groups covered are as follows:

- IKA (Institute of Social Insurance): 50% of the population; urban population, i.e. blue- and white-collar workers;
- OGA (Organization of Agricultural Insurance): 25% of the population; rural population (i.e. agricultural workers);
- Civil servants: 7% of the population;
- TEVE-TAE (Fund for Merchants, Manufacturers and Small Businessmen): 13% of the population; merchants, manufacturers and shop owners;
- Utilities and banks: 2.5% of the population; telecommunications, electricity and banking personnel.

Healthcare is funded mainly through the central government budget (general taxation), through the numerous state insurance funds (employers and employees contributions) and private insurance schemes. The involvement of the private sector at the healthcare delivery is extensive and has been growing rapidly over the last 10 years.

In Greece, there is universal coverage for pharmaceutical care. The main responsibility for planning and implementation of pharmaceutical policy lies with the Ministry of Health and Social Solidarity. However, several other Ministries share responsibilities for pharmaceutical issues. Pricing resides with the Ministry of Development. The Ministry of Employment and Social Protection supervises social security organizations, and the Ministry of Economy & Finance is responsible for reimbursing medicinal products for civil servants.

A medicine holding a market authorisation may not be sold in Greece until it has been granted a price. Also, this medicine must be sold at least in the country of origin or in any EU Member State other than Greece. The responsibility for pricing of pharmaceuticals lies with the Ministry of Development. Prices of pharmaceuticals are effective when published in the Price Bulletin. Recent reforms have changed the way prices are set in Greece. The government passed a new law in late 2005 (Law 3048/2005) which stipulates a new price setting system.

Three prices apply to medicinal products. The **wholesale price**, the **pharmacy retail price** and the **hospital price**.

The **wholesale price (pharmacy purchase price)** is the price the drug is purchased by the pharmacist. This price includes wholesaler's gross profit margin based on the ex-factory price of the producer or importer.

The **pharmacy retail price** derives from Pharmacy Purchase Price plus the pharmacist's profit margin and the VAT. The retail price is uniform in the whole country except for some districts where reduced VAT rates apply.

The **hospital price** derives from the Pharmacy Purchase Price reduced by 13%. Hospitals are supplied with medicines directly from the pharmaceutical companies according to their needs.

External price referencing is applied to all new pharmaceutical products including OTCs. External pricing is not applied to generic products. External pricing is used to determine the ex-factory price of pharmaceuticals.

The price of new pharmaceuticals will be determined based on the average manufacturer price level calculated by considering the average of the three lowest prices among EU-25 countries (two EU-15 countries plus Switzerland and one among the 10 new access countries).

The government passed a new law in 2006 that defines the reimbursement of medicines in Greece (Law 3457/2006). According to this new reimbursement law the expenditure for all medicines holding a marketing authorisation is covered by all sick-funds. Moreover, sick funds cover the expenditure for medicines for the uninsured and the poor. Law 3457/2006 has the following key points:

Over-the-counter pharmaceuticals and prescription-only-medicines for certain indications (eg. erectile dysfunction) are excluded from reimbursement. The later indications are commonly determined by the Ministry of Health and Social Solidarity and are published following

approval from the Central health Council (KESY). For these indications some exceptions can be made on the basis of treating an underline clinical condition following the submission of the appropriate evidence from the doctor.

A transparency committee (EDAF) will be formulated within EOF consisting of scientists drawn from the field of Pharmacy, Health Economics and Policy and Medicine. A second degree 5 member transparency committee (DEDAF) will be formulated within the Ministry of Health and Social Solidarity.

EDAF will be responsible for clustering medicines based on objective and transparent criteria such as:

- Therapeutic value
- Pharmaco-economics
- Cost of daily treatment
- Safety
- Budget impact

There are three categories of patient co-payment in Greece:

1. 0% co-payment that applies to drugs to treat cancer, epilepsy, depression, multiple sclerosis, growth hormone deficiency, insulin products for diabetics and drugs used in pregnancy.
2. 10% co-payment for chronic conditions such as osteoporosis, Parkinson's disease, Coronary Heart Disease, hepatic cirrhosis, Crohn's disease etc. This rate also applies to low-income pensioners who receive a supplementary cash benefit (EKAS) for all categories of pharmaceuticals.
3. 25% that applies to the majority of pharmaceutical products.

In 2004, health spending in Greece exceeded 9.5% of GDP, with almost 55% of total health expenditure coming from public sources. Pharmaceutical spending amounted to 17.8% of total health expenditure (1.7% of GDP). This situation, combined with the fact that the pharmaceutical market in value terms is growing by double-digit rates, as well as the government's current healthcare reform plans, create an environment of promoting efficiency in the system.

There are several developments in the Greek pharmaceutical market that are likely to intensify in the near future:

- The government aims to reinforce its cost-containment measures, by acting not only on the supply-side but also on the demand side. The latter is explicitly stated by government

officials. Attention will be paid to the control and monitoring of prescribing behaviour. To this direction, pilot projects have been initiated and effects are expected to be demonstrable shortly. Since the implementation of the bar code system for medicines from 1/1/2005 onwards, there has been an improvement in the access and availability of reliable and timely information regarding the cost, the quality of the pharmaceutical health-care provided, and the volume of the use of the latter. Among others, this minimizes possible errors in the prescription clearance procedure and facilitates the implementation of e-prescribing and Electronic Transfer of Prescriptions for an even more effective control of the system and for the provision of better service to patients over the administration and the filling of their prescriptions.

- The completion of the regulatory framework for OTC products
- The timely access of patients to new treatments
- The continuous training and education of health care professionals
- The support of the pharmaceutical industry in Greece

Table of content

Executive Summary	II
Table of content.....	VI
List of tables and figures.....	IX
List of abbreviations	X
Introduction.....	XII
1 Background.....	1
1.1 Demography.....	1
1.2 Economic background.....	1
1.3 Political context	3
1.4 Health care system	3
1.4.1 Organisation.....	3
1.4.2 Funding	4
1.4.3 Access to health care	5
1.4.3.1 Outpatient care.....	5
1.4.3.2 Inpatient care	6
2 Pharmaceutical system	8
2.1 Organisation.....	8
2.1.1 Regulatory framework.....	9
2.1.1.1 Policy and legislation.....	9
2.1.1.2 Authorities	9
2.1.2 Pharmaceutical market.....	10
2.1.2.1 Availability of pharmaceuticals.....	11
2.1.2.2 Market data	11
2.1.2.3 Patents and data protection	13
2.1.3 Market players	13
2.1.3.1 Industry	13
2.1.3.2 Wholesalers	14
2.1.3.3 Pharmaceutical outlets / retailers.....	15
2.1.3.3.1 Pharmacies.....	15
2.1.3.3.2 Other pharmacy outlets	16
2.1.3.3.3 Internet pharmacies	16
2.1.3.3.4 Dispensing doctors	16
2.1.3.4 Hospitals	16
2.1.3.5 Doctors.....	17

2.1.3.6	Patients	17
2.2	Funding	17
2.2.1	Pharmaceutical expenditure	17
2.2.2	Sources of funds	18
2.3	Evaluation.....	18
3	Pricing	20
3.1	Organisation.....	20
3.2	Pricing policies	20
3.2.1	Statutory pricing	20
3.2.2	Negotiations.....	21
3.2.3	Free pricing.....	21
3.2.4	Public procurement / tendering.....	21
3.3	Pricing procedures	22
3.3.1	External price referencing.....	22
3.3.2	Internal price referencing	22
3.3.3	Cost-plus pricing	22
3.3.4	(Indirect) Profit control	23
3.4	Exceptions.....	23
3.4.1	Hospitals-only	23
3.4.2	Generics.....	23
3.4.3	Over-The-Counter pharmaceuticals	23
3.4.4	Parallel traded pharmaceuticals	23
3.4.5	Other exceptions.....	23
3.5	Margins and taxes.....	24
3.5.1	Wholesale remuneration.....	24
3.5.2	Pharmacy remuneration	24
3.5.3	Remuneration of other dispensaries.....	24
3.5.4	Value-added tax.....	24
3.5.5	Other taxes	25
3.6	Margins and taxes.....	25
3.6.1	Discounts / Rebates.....	25
3.6.2	Margin cuts	25
3.6.3	Price freezes / Price cuts	25
3.6.4	Price reviews.....	25
4	Reimbursement	26
4.1	Organisation.....	26
4.2	Reimbursement schemes	27

4.2.1	Eligibility criteria	27
4.2.2	Reimbursement categories and reimbursement rates	27
4.2.3	Reimbursement lists	27
4.3	Reference price system	28
4.4	Private pharmaceutical expenses	28
4.4.1	Direct payments	28
4.4.2	Out-of-pocket payments	28
4.4.2.1	Fixed co-payments	28
4.4.2.2	Percentage co-payments	28
4.4.2.3	Deductibles	29
4.5	Reimbursement in the hospital sector	29
4.6	Reimbursement related cost-containment measures	29
4.6.1	Major changes in reimbursement lists	29
4.6.2	Introduction / review of reference price system	29
4.6.3	Introduction of new / other out-of-pocket payments	29
4.6.4	Claw-backs	29
5	Rational use of pharmaceuticals	30
5.1	Impact of pharmaceutical budgets	30
5.2	Prescription guidelines	30
5.3	Information to patients / doctors	30
5.4	Pharmaco-economics	30
5.5	Generics	30
5.5.1	Generic substitution	31
5.5.2	Generic prescription	31
5.5.3	Generic promotion	31
5.6	Consumption	31
6	Current challenges and future developments	32
6.1	Future developments	32

List of tables and figures

Table 1.1:	Greece - Demographic indicators 1995, 2000 - 2005	1
Table 1.2:	Greece - Macroeconomic indicators 1995, 2000 - 2005	2
Table 1.3:	Greece - Health expenditure, 1995, 2000 - 2005	5
Table 1.4:	Greece - Outpatient care 1995, 2000 - 2005.....	6
Table 1.5:	Greece - Inpatient care 1995, 2000 - 2005.....	7
Table 2.1:	Greece - Authorities in the regulatory framework in the pharmaceutical system 2006	10
Table 2.2:	Greece - Number of pharmaceuticals 1995, 2000 - 2006 ¹	11
Table 2.3:	Greece - Market data 1995, 2000 – 2005.....	12
Table 2.4:	Top 10 best selling pharmaceuticals, by active ingredient,2005	12
Table 2.5:	Greece - Key data on the pharmaceutical industry 1995 - 2005 ¹	13
Table 2.6:	Greece - Key data on pharmaceutical wholesale 1995 - 2005 ¹	14
Table 2.7:	Greece - Retailers of pharmaceuticals 1995, 2000 - 2006 ¹	16
Table 2.8:	Greece - Total pharmaceutical expenditure 1995, 2000 - 2005	18
Table 3.1:	Greece - Ways of pricing of pharmaceuticals	20
Table 3.2:	Greece - Pricing procedures.....	22
Table 3.3:	Greece – Regulation of wholesale and pharmacy mark-ups 2006.....	24
Table 3.4:	Greece - Wholesale mark-up scheme 2006	24
Table 5.1:	Greece - Development of the generic market in the out-patient sector, 2000 - 2005	31
Figure 2.1:	Greece - Flowchart of the pharmaceutical system, 2006	8

List of abbreviations

ATC	Anatomic Therapeutic Chemical classification
BMGF	Austrian Ministry of Health and Women's Issues
DG SANCO	Health and Consumer protection Directorate General
DEDAF	Second Degree Transparency Committee
EDAF	Transparency Committee
EKAS	Supplementary Cash Benefit
EKEBYL	Research Centre of Biological Materials
ESY	National Health System
GDP	Gross Domestic Product
GGE	General Government Expenditure
GP	General Practitioner
HiT	Health systems in Transition
HOM	Hospital-Only Medicine
IFET	Institute of Medicinal Research and Technology
IKA	Social Insurance Institute
KESY	Central health Council
NCU	National Currency Unit
NHS	National Health Service
NSSG	National Statistical Service of Greece
Mio.	Million
OBI	Industrial Property Organisation
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
OECD	Organisation for Economic Co-operation and Development

OGA (Organization of Agricultural Insurance):

OPP	Out-of-Pocket Payment
OTC	Over-The-Counter pharmaceuticals
PE	Pharmaceutical Expenditure
POM	Prescription-Only Medicines
PPP	Pharmacy Purchasing Price
PPPa	Purchasing Power Parity
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
QALY	Quality Adjusted Life Year
R&D	Research & Development
SHI	Social Health Insurance

TEVE-TAE (Fund for Merchants, Manufacturers and Small Businessmen):

THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
YPE	Regional Health Authority
VAT	Value Added Tax
VHI	Voluntary Health Insurance
WHO	World Health Organisation
WP	Work Package

Introduction

The Pharmaceutical Pricing and Reimbursement Information (PPRI) project is a 31 month-project (2005-2007) commissioned by the Health and Consumer Protection Directorate-General (DG SANCO) of the European Commission and co-funded by the Austrian Federal Ministry of Health, Family and Youth (Bundesministerium für Gesundheit, Familie und Jugend, BMGFJ). The project was coordinated by the main partner Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG (GÖG/ÖBIG) and the associated partner World Health Organisation (WHO) Regional Office for Europe. The PPRI project has established a network of 46 participating institutions (competent authorities and other relevant organisations) in the field of pharmaceuticals.

The PPRI project seeks to increase transparency and knowledge and facilitate the exchange of experience in the field of pharmaceuticals by

- establishing and maintaining a network of relevant institutions in the field of pharmaceuticals in the enlarged European Union (EU), in order to facilitate a regular exchange of information and allow a process of learning from each other,
- producing country reports on pharmaceutical pricing and reimbursement systems, the “PPRI Pharma Profiles”,
- developing indicators for the comparison of pharmaceutical pricing and reimbursement information,
- providing a comparative analysis on pharmaceutical pricing and reimbursement in the European Union (EU) and,

disseminating the outcomes of the project.

The PPRI Pharma Profiles are country-specific reports that provide detailed descriptions of the countries pharmaceutical systems and policies. The profiles are written by PPRI participants (country experts from competent authorities, Medicines Agencies, Social Insurance Institutions, research institutes) and edited by experts of the PPRI project coordination.

This Pharma Profile is one of the many PPRI Pharma Profiles, which all are available on the PPRI website at <http://ppri.oebig.at>. The information and data provided in the PPRI Pharma Profiles refer, in general, to the year 2006.

In order to improve readability and allow for comparisons between countries, the structure of the Pharma profiles follows a template, which was developed by the project coordination team and the PPRI participants. The template is based on a large needs assessment of both national and international stakeholders. In addition to the template a glossary was developed to facilitate the writing process and the readability. The 70-page PPRI Pharma Profile Template and the PPRI Glossary are available at the PPRI website.

1 Background

1.1 Demography

Greece, lies at the southernmost end of the Balkan Peninsula. It covers an area of 131 957 km². It is bordered to the north-west by Albania, to the north by the Former Yugoslav Republic of Macedonia and by Bulgaria, to the north-east by Turkey, to the east by the Aegean Sea, to the south by the Mediterranean Sea, and to the west by the Ionian Sea. Greece's topography is highly diverse. The numerous islands in the Aegean and Ionian Seas occupy about one-fifth of its territory. Much of the land is mountainous and rugged, less than a fourth is lowland, and about one-fifth is forested.

According to OECD data 2004 Greece has a total population of 11.062 million whereas the estimated 2005 total population is 11.082.751. In 2005, the estimated population density was 84 inhabitants per km². As a result of its geography the population is not evenly distributed. In 2005 the estimated urban population of Greece was 65,7% of the total population (NSSG, 2005).

The population is considered to be ageing and the latter is a top issue on the political agenda. Total fertility rate is diachronically decreasing. In 1990 the fertility rate was 1,39, in 2004 the fertility rate was 1,29 (OECD, 2004) and is expected to decrease further in the following decades. Total life expectancy at birth is 78,1, female life expectancy at birth is 80,7 years and male life expectancy at birth is 75,4 years (OECD 2004)

The main causes of mortality in Greece and their share in overall mortality are as follows (NSSG, 2003):

1. Cardiovascular diseases 31,4%
2. Malignant tumors 23, 5%
3. Cerebrovascular diseases 17, 5%
4. Respiratory system diseases 7%

Table 1.1: Greece - Demographic indicators 1995, 2000 - 2005

Variable	1995	2000	2001	2002	2003	2004	2005
Total population ^a	10 634.39	10 917.46	10 949.95	10987,559	11023,532	11061,735	11103,929
Population density per km ²	80,6	82,7	83,0	83,3	83,5	83,8	84
Population aged 0-14 (in % of total)	na						
Population aged 15-64 (in % of total)	67,50%	68,05%	68,04%	67,91%	67,76%	na	na
Population aged > 64 (in % of total)	na						
Life expectancy at birth, total	77,7	78,1	78,1	78,1	na	na	na
Life expectancy at birth, females	80,3	80,6	80,7	80,7	na	na	na
Life expectancy at birth, males	75	75,5	75,4	75,4	na	na	na

Sources: a OECD

1.2 Economic background

Greece is a full member of the EU. The state continues to play a major role in the economy despite an ongoing privatisation programme. The industrial base has always been relatively small compared with that of other EU countries. Industry accounts for 21-22% of GDP, with manufacturing contributing 10-12% of GDP. Monopolies existed in many sectors such as energy and telecommunications whereas other markets were tightly regulated. In 1998 the government began a programme of privatisation as part of its bid to join the EU's economic and monetary union (EMU) and has since reduced its stake substantially.

Most industries are concentrated in Athens and Thessalonica areas. Although the contribution of agriculture, forestry and fisheries to GDP has declined in recent years, the sector is still the largest in the EU in relative terms, accounting for an estimated 6.8% of GDP in 2002, above the EU average of about 2.5%. The services sector is significant, accounting for an estimated 71.6% of GDP in 2002.

The largest sub-sector is property management, followed by trade. The transport and communications sector has grown in importance following the liberalisation of the telecoms market, while the financial services sector has also increased in recent years. Tourism is also a major contributor to economic growth.

The Gross Domestic Product (GDP) per capita in 2004 in PPS was \$US 29,578. The Greek economy grew with a rate of 3,5% in 2005. Recent and prospective growth performance is good. The Greek economy has continued to grow, boosted especially from low nominal and real interest rates and an expansionary fiscal policy stance, largely reflecting public works in preparation for the Olympic Games in 2004. The Greek economy is expected to grow in the following few years however, at a lower pace. The government aims at reducing the public deficit from 6,9% of GDP in 2004 in 2,6% in 2006.

According to OECD analysts, fiscal consolidation is the main priority. The fiscal audit, performed by the new government in close collaboration with Eurostat has revealed a very loose fiscal policy since the late 1990s, culminating in a general government deficit of 6% of GDP in 2004. The government debt-to-GDP ratio has remained stubbornly above 100%, despite uninterrupted strong growth during the past eleven years.

Convergence with EU living standards is a major medium-term policy challenge. Further policy challenges arise from the government's objective to eliminate the gap in per capita incomes with the EU-15, which widened from the late 1970s to the mid-1990s. Further structural changes in the labour market and privatizations of a number of public companies are expected in the following few years.

Table 1.2: Greece - Macroeconomic indicators 1995, 2000 - 2005

Variable (in NCU or percentage)	1995	2000	2001	2002	2003	2004	2005
GDP in NCU (million €)	102 789.968	156 513.752	167 993.925	181 003.478	196 602.393	212 734.26	228 156.254
GDP / capita in NCU	9.666 €	14.336 €	15.342 €	16.473 €	17.835 €	19.232 €	20.547 €
GDP / capita in PPPa	16 697 USD	20 939.	22 146	24 307	26 090	27 690	29 578.
Annual economic growth rate in %	na	4,5%	5,1%	3,8%	4,8%	4,7%	3,7%
General government expenditure (GGE)	na	na	21.587	22.607	25.897	27.891	29.620
GGE in % of GDP	na	na	16,2%	15,7%%	16,6%	16,7%	16,3%
Exchange rate (NCU per €), annual rate	na	1,07	1,11	1,06	0,88	0,80	0,80

GDP = Gross Domestic Product, GGE = General government expenditure, NCU = National Currency Unit, PPPa = Purchasing Power Parity

Sources: OECD Health Data Base, 2000

1.3 Political context

Greece is a parliamentary republic based on the separation and balancing of legislative, executive and judicial powers. The Constitution is the highest law in the Republic of Greece. The President of the Republic regulates the functions of the powers of the State. He is elected by Parliament for a term of five years and his office is incompatible with any other office, position, or function. The Government consists of the Cabinet which comprises the Prime Minister and Ministers. The Government determines and directs the general policy of the State, in accordance with the provisions of the Constitution and the laws. The Government must enjoy the confidence of Parliament. The members of the Cabinet and the Deputy Ministers shall be jointly responsible for the general policies of the Government. The Constitution of 1975, as revised in 1986, defines the political system of Greece as a Parliamentary Democracy with a President as head of state. In other words, the system is centred around the Parliament, one of the two legislative authorities of the country. The other is the President of the Republic.

The conservatives (New Democracy) are in power since 2004. The Greek parliament constitutes of:

- New Democracy 165 deputies
- Panhellenic Socialists Party 117 deputies
- Communist Party of Greece 12 deputies
- Left Coalition 6 deputies

General elections take place every 4 years hence; next general elections are expected in 2008.

1.4 Health care system

1.4.1 Organisation

Health policy lies with the Ministry of Health and Social Solidarity. The Ministry is responsible for provision and financing of the National Health Service as well as health and social services for the poor, the elderly and the disabled.

Greece is divided into seven Regional Health Authorities (DYPE) The population is insured through a number of insurance sick funds. The insurance funds have been under the jurisdiction of the Ministry of Labour and Social Protection since September 1995. The main groups of social insurance organizations, the size of population covered, and occupational groups covered are as follows:

- IKA (Institute of Social Insurance): 50% of the population; urban population, i.e. blue- and white-collar workers;

- OGA (Organization of Agricultural Insurance): 25% of the population; rural population (i.e. agricultural workers);
- Civil servants: 7% of the population;
- TEVE-TAE (Fund for Merchants, Manufacturers and Small Businessmen): 13% of the population; merchants, manufacturers and shop owners;
- Utilities and banks: 2.5% of the population; telecommunications, electricity and banking personnel.

A universal system of health care free at the point of use. The National Health System (ESY) was established in 1983. The system was based on the basic principles of equity and efficiency. ESY provides primary and hospital healthcare as well as emergency pre-hospital care on a universal basis without any entitlement condition regardless of professional category or region. In practice, ESY provides care through approximately 140 hospitals, 200 health centers and 1000 health posts throughout the country.

1.4.2 Funding

Healthcare is funded mainly through the central government budget (general taxation), through the numerous state insurance funds (employers and employees contributions) and private insurance schemes. The involvement of the private sector at the healthcare delivery is extensive and has been growing rapidly over the last 10 years. About 99% of the population is covered by some sort of medical insurance. Almost 90% of the population is insured under the three largest insurance schemes – these are: the Fund of Social Insurance (IKA), the Organisation of Agricultural Insurance (OGA) and the Fund of Tradesman and Small Industries (TEVE). About 40 out of 300 social insurance organisations provide coverage against sickness. The occupation of the insured determines the fund she/he is registered with. The uninsured and those in need have free access to public hospitals, outpatients departments and health centres in rural areas.

IKA, which is the largest social insurance fund, covers 55% of the population. It is responsible for the funding and provision of primary health services through an extensive network of primary healthcare facilities-polyclinics. OGA covers about 23% of the population, takes advantage of the entire ESY network (Health centres providing primary care in rural areas, and hospitals). The remaining funds provide healthcare services to their beneficiaries mainly through contracted private physicians (ambulatory care), and public or private hospitals (secondary and tertiary healthcare services). All funds cover hospital care, primary medical care, diagnostic services and pharmaceutical care.

Table 1.3: Greece - Health expenditure, 1995, 2000 - 2005

Health expenditure	1995	2000	2001	2002	2003	2004	2005
THE in NCU	na	11,780	13,429	14,345	15,776	16,399	na
THE in % of GDP	na	9.7%	10.2%	10.1%	10.2%	9.8%	na
THE per capita in NCU	na	1.080	-	-	1.433	-	-
Public HE in % of THE	na	53.9%	56.7%	55.4%	54.8%	53.9%	na
Private HE in % of THE	na	46.1%	43.3%	44.6%	45.2%	46.1%	na

GDP = Gross Domestic Product, HE= Health Expenditure, THE = Total Health Expenditure, NCU = National Currency Unit

Source: General Secretariat of Statistical Services 2006

1.4.3 Access to health care

1.4.3.1 Outpatient care

Primary Health Care (PHC) is mainly provided by the National Health System and social insurance funds settings:

a) National Health System

Care is provided by health centres and their regional surgeries in rural areas and small islands, as well as hospital outpatient departments. These services are financed through the state budget. There are 201 health centres all situated in rural and semi-urban areas and 1,478 rural surgeries, which provide free-of-charge primary medical care to all inhabitants. These settings are targeted at, and cater for the needs of mainly the rural population (most of them being OGA beneficiaries).

b) Social insurance funds

Care is provided by polyclinics (health centres) owned and operated mainly by IKA in urban areas, or private physicians and labs on contract with the funds. The rest of the social insurance funds cater for the primary health care needs of their beneficiaries through contracts with the private sector - specialty doctors, diagnostic centres and laboratories. For example, OPAD has contracts with approximately 20,000 doctors and laboratories, OAEE with 3,500 and OIKOS NAUTOU with 3,100. Private physicians or diagnostic centres on contract with insurance funds are generally paid on a fee-for-service basis. The large number of doctors on contract per insurance fund and the fee for service remuneration create conditions of induced demand and increased costs, which account for the great differences in the annual per capita cost among different insurance funds.

c) Local authority settings

This refers to a very small number of clinics and welfare units, owned and financed by municipalities. They usually provide health and social services (preventive care, prescriptions etc). Access to these services is free of charge to all citizens. Nonetheless, data by the Municipality of Athens reveal that it is primarily the uninsured and foreigners who use these services.

d) Private sector

This refers to private physicians, laboratories and diagnostic centres on contract with one or more insurance funds (services are paid by social insurance funds' resources), physicians in private practice who are not on contract with any insurance fund (services covered by out-of-pocket payments or voluntary health insurance) and private hospital outpatient departments (services covered mainly by out-of-pocket payments or voluntary health insurance).

Table 1.4: Greece - Outpatient care 1995, 2000 - 2005

Variable	1995	2000	2001	2002	2003	2004	2005
Total number of doctors	na	47.521	na	50.347	52.225	53.943	na
Number of doctors per 1,000 inhabitants	3,8 (1993)	4,35	na	-	4,74	4,86	na
Total number of outpatient doctors	na	24.035	na	26.750	27.998	29.215	na
<i>thereof General Practitioners³</i>	na	757	na	937	1.153	1.260	na
<i>thereof dentists</i>	na	12.362	na	13.107	13.079	13.316	na
Number of out patient doctors per 1,000 inhabitants	na	2,2	na	na	2,54	2,63	na
Number of out-patient clinics departments ("ambulatories")	na	180	na	188	187	189	na

na = not available

Source: General Secretariat for Statistical Services

1.4.3.2 Inpatient care

All beneficiaries of the Social Insurance Funds have free access to public hospitals and to a large number of private hospitals contracted by each fund. The number of private contracted hospitals varies among the funds, depending mainly on the number of beneficiaries and their distribution across the country. Some funds, like IKA, provide part of hospital care in their own hospitals, but the majority of the population relies on the services provided by public hospitals. It is estimated that 75% of hospital days are allocated to public hospitals, with the remaining 25% to private ones. Child births in private maternity hospitals are preferred due to the improved infrastructure of the latter, and accounts for a major part of hospitalization in the private sector.

The uninsured and the poor have access only to public hospitals. Uninsured citizens can acquire access to private hospitals and clinics, if they are willing and able to pay. In any case, any citizen – whether covered by a health insurance fund or not – can choose a private hospital but they must bear most of the cost if the hospital is not a contracted one.

Table 1.5: Greece - Inpatient care 1995, 2000 - 2005

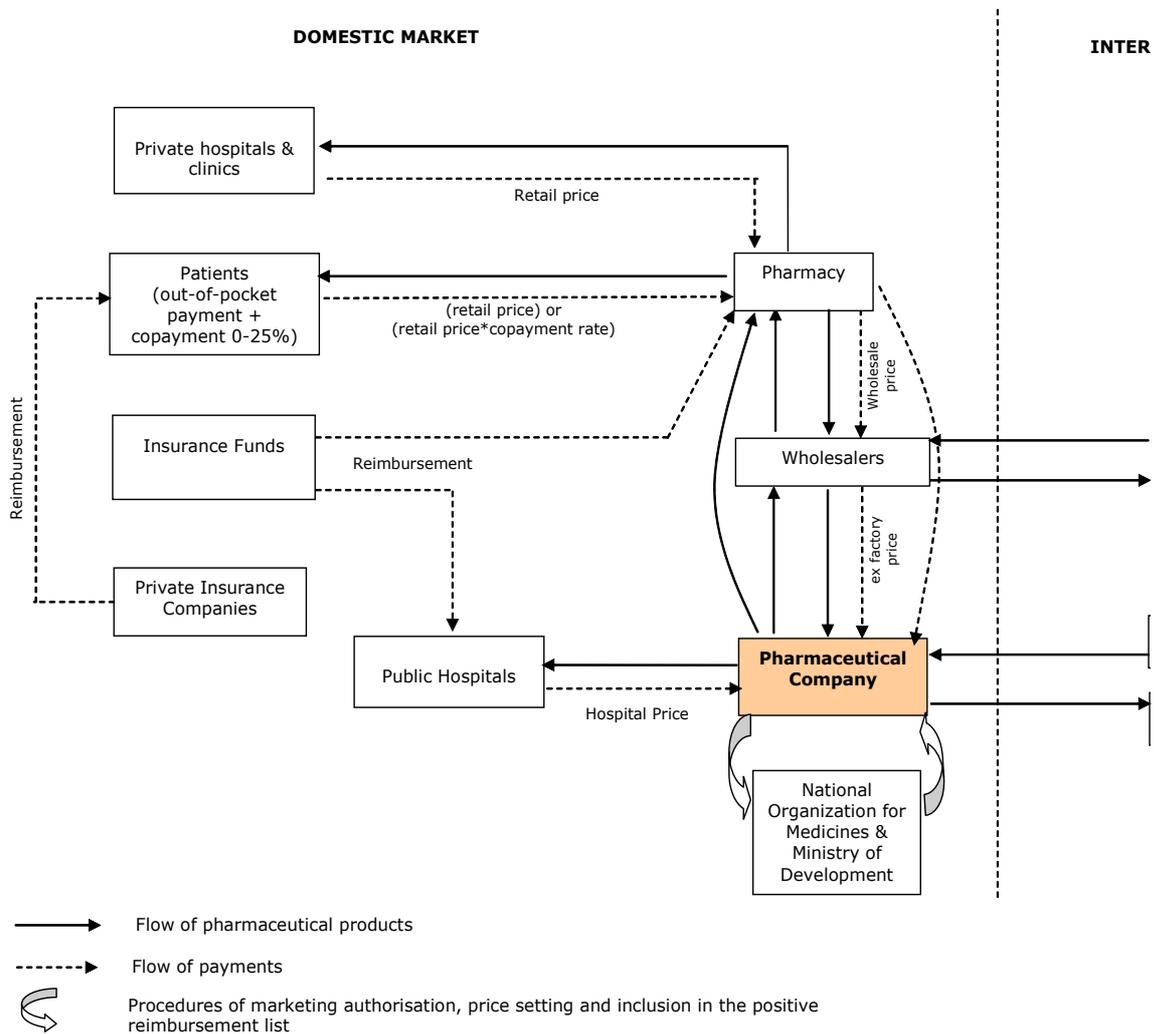
Variable	1995	2000	2001	2002	2003	2004	2005
Number of inpatient doctors	na	23,486	na	24,424	na	23,597	na
Number of inpatient doctors per 1,000 inhabitants	na	2.21	na	-	na	2.14	na
Number of hospitals	na	140	na	141	na	141	na
Number of acute care beds	na	51,500	na	51,762	na	51,781	na
thereof in private sector	na	5	na	6	na	6	na
Acute care beds per 1,000 inhabitants	na	4.72	na	na	na	4.7	na
Average length of stay in hospital	na						

Source: NSSG

2 Pharmaceutical system

2.1 Organisation

Figure 2.1: Greece - Flowchart of the pharmaceutical system, 2006



Source: Institute of Economic and Industrial Research (IOBE)

2.1.1 Regulatory framework

2.1.1.1 Policy and legislation

2.1.1.2 Authorities

In Greece, there is universal coverage for pharmaceutical care. The main responsibility for planning and implementation of pharmaceutical policy lies with the Ministry of Health and Social Solidarity. However, several other Ministries share responsibilities for pharmaceutical issues. Pricing resides with the Ministry of Development. The Ministry of Employment and Social Protection supervises social security organizations, and the Ministry of Economy & Finance is responsible for reimbursing medicinal products for civil servants.

The Greek healthcare system is characterized by a large number of regulatory bodies, whose roles sometimes conflict. The Ministry of Health and Social Solidarity (YYKA) regulates the pharmaceutical industry and other aspects of the health system, including ESY policy and hospitals. The Ministry of Commerce is responsible for pricing decisions. Budgetary oversight of the health system is the responsibility of the Ministry of Economy and Finance. With the exception of OPAD, which the Ministry of Economy and Finance regulate, most health insurance funds are under the supervision of the Ministry of Employment and Social Protection. The Ministry of Rural Health and Food is responsible for health services in the countryside. The Ministries of Defence, Agriculture and Merchant Marine are involved in the provision of care to, respectively, military personnel and dependents, the rural population and seamen. The recent reforms will help improve the pharmaceutical industry. For example, a General Secretariat of Medicinal Products will be formed in order to unify the decision-making procedures in a single agency; EOF will be modernized to conform to EU standards; and relations between the government and industry will be governed by cooperative agreements. In exchange for participation, the government will ensure “medium term market stability.” The Industrial Property Organization (OBI) handles intellectual property applications.

The National Medicines Agency (EOF) is responsible for issuing marketing and licensing approvals for pharmaceuticals. Note that pricing approval (see following section) is also required. EOF modernization process currently underway will affect the approval process and promote operational efficiency. The key divisions of EOF are:

Scientific Board of Approvals: Issues opinions on the issue of authorizations, amendments, revocations, and suspensions of marketing authorizations for products under the authority of EOF. This board is comprised of several divisions, including conventional medicinal products, biological medicinal products, blood products, radioactive medicinal products, special foods, veterinary medicinal products and veterinary vaccines.

Pharmaco-vigilance Committee: Evaluates the adverse drug reactions and makes suggestions on correcting or amending the Summaries of Products Characteristics and Patient Information Leaflets.

Scientific and Ethics Committee of Clinical Studies Authorization: Oversight of the clinical trials sector.

Pharmacopoeia Committee: Responsible for the Hellenic Pharmacopoeia.

Medical Devices Committee: Issues guidance on medical devices.

Second Degree Scientific Board: Appeal board for initial EOF decisions.

The Institute of Medicinal Research and Technology (IFET): A subsidiary of EOF that performs statistical and econometric analysis, research programs, and agency computerization. IFET is also responsible for ensuring distribution of certain specialty pharmaceutical products under EOF authority (on its own behalf or on behalf of third parties) in order to ensure availability when the market might be insufficient for that purpose.

Research Centre of Biological Materials (EKEBYL): Subsidiary with responsibility for certification, quality control, and research regarding medical devices.

The table below summarises the authorities involved in the pharmaceutical market in Greece.

Table 2.1: Greece - Authorities in the regulatory framework in the pharmaceutical system 2006

Name in local language (Abbreviation)	Name in English	Description	Responsibility
YKKA	Ministry of Health and Social Solidarity	Regulatory body	Overall planning and legislative authority In charge of the reimbursement legislation/decision
EOF	National Medicines Agency	Medicines Agency (subordinate to the Ministry of Health)	In charge of market authorisation, classification, vigilance
YPAN	Ministry of Development	Regulatory body	In charge of Pricing
Ministry of Employment and Social Insurance		Regulatory body	In charge of the various sick funds
Ministry of Finance		Regulatory body	Responsible for funding

2.1.2 Pharmaceutical market

The supply side of the pharmaceutical sector is determined by the pharmaceutical companies operating in Greece, as well as by wholesalers and pharmacies. In 2003, the number of pharmaceutical companies was estimated at 270 (locally producing and importing). At the same time, 130 wholesale companies operated in Greece, of which 115 were private and 15 were pharmacists' associations (estimate of the Hellenic Union of Wholesalers). The number of pharmacies was 9,350 (provisional data from the Hellenic Union of Pharmacists).

Pharmaceutical companies are either subsidiaries of multinational companies or greek companies, some of which specialise in the production of generics. The major R&D companies offer huge technological and managerial know-how to the country and apply modern production and management practices. Moreover, the pharmaceutical industry promotes R&D by providing grants to universities, research institutes and researchers, while it invests in keeping the medical society updated on the latest scientific information.

2.1.2.1 Availability of pharmaceuticals

Table 2.2: Greece - Number of pharmaceuticals 1995, 2000 - 2006¹

Pharmaceuticals	1995	2000	2001	2002	2003	2004	2005	2006
Authorised	8346	12523	13639	15016	16390	16648	na	na
On the market	3535	4033	4188	4097	4280	4295	na	na
POM	na	na	na	na	na	na	na	na
Reimbursable	na	na	na	na	na	na	na	na
Generics	na	na	na	na	na	na	na	na
Parallel traded	na	na	na	na	na	na	na	na
Hospital-only	na	na	na	na	na	na	na	na
Others (please include further lines if necessary)	na	na	na	na	na	na	na	na

Na = not available; POM = Prescription-Only Medicines

Source: National Medicines Organization (EOF)

2.1.2.2 Market data

Sales of medicinal products to Public Hospitals and Wholesalers / Pharmacies exhibit an increasing trend over the period of 1987-2003, with a Mean Annual Growth Rate of 4.5%. Nevertheless, a reduction in the sales' rate of increase –both in volume and value - can be observed over the last three years. Pharmaceutical sales, including parallel exports, amounted to 443 millions € of packages, of which 12.5% was distributed to public hospitals and 87.5% to wholesalers and pharmacies.

Table 2.3: Greece - Market data 1995, 2000 – 2005

Pharmaceutical industry in million NCU / €	1995	2000	2001	2002	2003	2004	2005
<i>Prescriptions</i>							
No. of annual prescriptions by volume	Na	na	Na	na	na	na	na
No. of annual prescriptions by value	Na	na	Na	na	na	na	na
<i>Pharmaceutical sales</i>							
Sales at ex-factory price level (.000) €	Na	1782092	2174703	2609798	3020819	3469203	na
Sales at wholesale price level	Na	1358818	1652199	1983512	2252835	2638861	na
Sales at pharmacy retail price level	Na	In-cluded above					na
Sales at hospitals	Na	423274	522504	626286	767984	853342	na
Sales of generics	Na	na	Na	na	na	na	na
Sales of parallel traded pharmaceuticals	Na	na	Na	na	na	na	na
<i>Exports and imports</i>							
Total pharmaceutical exports *	59	283	346	274	556	682	928
Total pharmaceutical imports*	630	1332	1309	874	1929	2250	2730

* Please indicate if this is finished products and / or raw material

Source: EOF, IFET, National Statistical Service of Greece 2005

Source: Eurostat (CN, codes 29.36-29.39, 29.41 & 30.01-30.06) 2005

Table 2.4: Top 10 best selling pharmaceuticals, by active ingredient, 2005

Position	Pharmaceutical, by active ingredient
1	ATORVASTATINE
2	CLOPIDOGREL
3	OLANZAPINE
4	OMEPRAZOLE
5	SALMETEROL
6	RIVASTIGMINE
7	ALMODIPINE BESYLATE
8	DONEPEZIL HYDROCHLORIDE
9	ADALIMUMAB
10	BUDESONIDE FORMETEROL

Source: IMS 2005

2.1.2.3 Patents and data protection

The National Organization for Medicines acts within the scope of pharmaceutical legislation. Therefore, EOF: a) does not examine whether a patent protects a pharmaceutical product or not, but b) examines whether the data protection period has been elapsed, according to Directive 2004/27/EC, Art. 10 para. 1.

The Hellenic Industrial Property Organisation (O.B.I.) is the only legally qualified institution for the protection of inventions and the granting of patents. The Courts are competent for the protection of patent rights, in case of violation, contest etc.

With regard to parallel imports of patented products, Article 2 of the Annexe IV of the Adhesion Act of the new member states has been transposed to the national law.

There is not any explicit provision in the Hellenic legislation concerning compulsory licensing or “government use” on patented medicines. Anyway, in case of serious public health risk, general provisions concerning urgent and provisional measures could be used.

2.1.3 Market players

2.1.3.1 Industry

Manufacturing of medicinal products in Greece is one of the most important sub sectors of the chemical industry. It represents almost 1/3 of the chemical industry, both in terms of the number of employees and production units operating in Greece and in terms of value added, sales and investment (IOBE, 2005).

Pharmaceutical companies are either subsidiaries of multinational companies or Greek companies, some of which specialise in the production of generics. The major R&D companies offer huge technological and managerial know-how to the country and apply modern production and management practices. Moreover, the pharmaceutical industry promotes R&D by providing grants to universities, research institutes and researchers, while it invests in keeping the medical society updated on the latest scientific information.

Table 2.5: Greece - Key data on the pharmaceutical industry 1995 - 2005¹

Pharmaceutical industry	1995	2000	2001	2002	2003	2004	2005
Total no. of companies	90	69	61	63	62	91	na
- research-oriented	na	Na	na	na	na	na	na
- generic producers	na	Na	na	na	na	na	na
- biotech	na	Na	na	na	na	na	na
Number of persons employed	5.667	4.756	4.412	4.719	4.668	4.951	

Source: Institution for Economic and Industrial Research 2005

The supply side of the pharmaceutical sector is determined by the pharmaceutical companies operating in Greece, as well as by wholesalers and pharmacies. In 2003, the number of pharmaceutical companies was estimated at 270 (locally producing and importing). At the same time, 130 wholesale companies operated in Greece, of which 115 were private and 15 were pharmacists' associations (estimate of the Hellenic Union of Wholesalers). The number of pharmacies was 9,350 (provisional data from the Hellenic Union of Pharmacists).

Domestic production increased to € 437 million in 2003, compared to € 431 million in 2002, exhibiting however a declarative rate. The mean annual growth rate for the period 1998-2003 is 7.8%.

Based on the available data in 2005, the pharmaceutical industry employed 4,412 employees in 61 production units, accounting for 25.7% of the chemical industry and 1.6% of total manufacturing sector. Over the period 1993-2001, the number of persons employed in the pharmaceutical industry was reduced by 32%. This fact can be attributed to the reduction in the number of production units by 36.5%, which in turn was fuelled by a decline in the rate of increase of domestic production of pharmaceutical products, due to the price setting mechanism, which favours imported products against domestically produced. It is estimated that more than 11,200 employees work on the production and marketing of medicines, rendering the pharmaceutical industry one of the most vital and dynamic sectors of the National Economy.

The highest share of investment expenditure in the pharmaceutical industry is devoted to the replacement of existing capital equipment (on average 39.8%), with the exception of the year 2000, when the highest share was invested on the increase in production capacity for products already being manufactured (37%). It is remarkable that investments which aim to expand production capacity for the production of new products are reduced over the period under investigation, and the respective share on total investments is very low over 2002-2004 (3%). On the other hand, investments on safety and environmental protection increase over time.

2.1.3.2 Wholesalers

In Greece, there are 130 wholesale companies operated in Greece, of which 115 were private and 15 were pharmacists' associations (2005).

Table 2.6: Greece - Key data on pharmaceutical wholesale 1995 - 2005¹

Wholesalers	1995	2000	2001	2002	2003	2004	2005
Total number of wholesale companies	na	na	na	na	na	130	132
Total number of outlets	na	na	na	na	na	130	123

¹ as of 1 January

na = not available

Source: Source: Institution for Economic and Industrial Research 2005

2.1.3.3 Pharmaceutical outlets / retailers

2.1.3.3.1 Pharmacies

Outside of hospitals and clinics, pharmacists have a monopoly on the sale of both prescription and OTC drugs. Government approval is needed to open a pharmacy, and each pharmacist may own only one store – a measure that bars chains from the Greek market. Medicinal products are dispensed to citizens exclusively by the legally operating private pharmacies. The terms and conditions for the foundation and operation of pharmacies are included in the current pharmaceutical legislation, compliance to which is supervised by the Ministry of Health and Social Solidarity

In 2006, there were 8,732 pharmacies operating in Greece. Furthermore, a significant increase in the number of pharmacists has been indicated. In 1960, the number of pharmacists was 1,582, in 1971 1,776, in 1981 4,682, in 1996 8,646 and in 1999 11,416. This increase is attributed partly to the number of graduates from Greek universities and partly to the significant flow of graduates from universities abroad. The number of graduates in the academic years 1992-93 and 1995-95 was 228 and 334 respectively. It is estimated that the number of graduates has reached 900, 35-40% of them being from universities abroad.

In examining the pharmacy sector in Greece, it was found that on average there is one pharmacy for every 1,143 people, the highest ratio in the EU. The picture, however, is completely the opposite, if the number of pharmacists per pharmacy is considered, which is 1:1, unlike other countries e.g. the Netherlands, where it is higher, i.e. 13 pharmacists per pharmacy.

License to practice pharmacy is awarded by the Central Health Council. The Competent Prefecture of the country grants a pharmacy license to operate. Population restrictions apply to those holding license from January 1st, 1997 onwards. In particular, a) one license for population up to 3,000 inhabitants, b) one license for every 3,000 inhabitants for population from 3,001-10,000 inhabitants, c) one license for every 2,500 inhabitants for population from 10,001 to 100,000 inhabitants and d) one license for every 2,000 inhabitants for population bigger than 1,000,001 inhabitants. Another prerequisite for the establishment of a pharmacy is the minimum distance from existing pharmacies. That is, at least 100 meters from another pharmacy, 120 meters from two corporate pharmacies, 160 meters from three, 200 meters from four, 250 meters from five or more corporate pharmacies.

Table 2.7: Greece - Retailers of pharmaceuticals 1995, 2000 - 2006¹

Retailers	1995	2000	2001	2002	2003	2004	2005	2006
Number of community pharmacies ²	na	8,732						
No. of private pharmacies	8909	8997	na	na	na	9400	na	na
No. of public pharmacies	na							
Number of hospital pharmacies for outpatients	na	na	na	na	na	na	144	na
Number of other POM dispensaries: _____	na							
Total number of POM-dispensaries ¹	8909	8997	na	na	na	9400	na	na
No. of internet pharmacies	na							
No. of OTC dispensaries, like drugstores: _____	na							

OTC = Over-The-Counter Pharmaceuticals, POM = Prescription-Only Medicines; na = not available; No. = number
¹ as of 1 January

² incl. branch pharmacies

Source: Institution for Economic and Industrial Research & General Secretariat for Statistical Services

2.1.3.3.2 Other pharmacy outlets

There are no other pharmacy outlets in Greece.

2.1.3.3.3 Internet pharmacies

Internet Pharmacies are not allowed in Greece by law.

2.1.3.3.4 Dispensing doctors

Not available.

2.1.3.4 Hospitals

Hospitals purchase medicines according to the needs of each of their clinics. The procurement procedure is carried out by the in-hospital pharmacy. A special hospital scientific committee approves of a new drug to be ordered. Also, public hospitals dispense medicinal products to the poor at no charge. Moreover, hospitals exclusively dispense a range of products to outpatients that are fully reimbursed by social insurance funds. Pharmaceutical companies are allowed to offer an additional discount up to 5% on the wholesale price to wholesalers. This discount is unlimited should the buyer be the state, public hospitals and foundations supervised by the Ministry of Health and Social Welfare.

2.1.3.5 Doctors

Currently, neither cost containment nor efficiency is actively pursued through incentives provided to doctors to prescribe rationally. On the contrary, the medical care payment system gives doctors skewed incentives to offer more services. Specialist doctors working in hospitals and health centers are paid on a salary basis and contracted doctors in ambulatory settings on a fee-for-service. Service in the public centers, though poorly paid, is used by the doctors, in some cases, to recruit patients for their private practices. Thus, they have powerful financial incentives to minimise the time and effort devoted to salaried institutional practice and to spend time instead in private work, whether permitted or not.

There are no proxy-demand measures such as budget ceilings on doctors, promotion of generic prescribing, utilisation reviews, prescribing practices monitoring or prescribing guidelines to facilitate cost-effective prescribing. Thus far, only one guideline for the treatment of hypertension has been issued to doctors but there is no evidence on doctors' adherence to it. All the attempted policy changes in Greece have focused on drug pricing and the positive list. However, evidence from other European countries suggests that pressure on price without pressure on volume actually does not contain overall expenditure but instead causes the "balloon effect" and may also lead to the misallocation of resources. It also appears that Greek doctors are mainly updated on new treatments and medical developments by pharmaceutical industry representatives. Many doctors are sponsored the costs of attending conferences and seminars by pharmaceutical companies. Moreover, most doctors do not prescribe according to practice guidelines or evidence-based practice.

2.1.3.6 Patients

Patients do not play a significant immediate role in the Pharmaceutical Policy. Patient information is made through internet channels and press.

2.2 Funding

2.2.1 Pharmaceutical expenditure

As recorded by the National Statistical Service of Greece, pharmaceutical expenditure in 2004 amounted to €2.9 billion, exhibiting an increase of 12.6% between 2000-2004. 77,9% of total pharmaceutical expenditure concerned public and 22,1% concerned private expenditure. Private expenditure is the sum of co-payments paid by patients plus out-of-pocket payments for pharmaceuticals bought either under prescription or not (OTC).

Table 2.8: Greece - Total pharmaceutical expenditure 1995, 2000 - 2005

Pharmaceutical expenditure	1995	2000	2001	2002	2003	2004	2005
TPE in NCU (in billion €)	na	1812	2068	2380	2749	2916	na
TPE in % of Total Health Expenditure	na	15,4%	15,4%	16,6%	17,4%	17,8%	na
TPE per capita in NCU	na	166	na	na	249	na	na
Public PE in % of THE	na	70,5%	72,6%	75,3%	77,6%	77,9%	na
Private PE in % of THE	na	29,5%	27,4%	24,7%	22,4%	22,1%	na

NCU = National Currency Unit, GDP = Gross Domestic Product, TPE = Total Pharmaceutical Expenditure, PE = Pharmaceutical Expenditure

Source: General Secretariat of Statistical Services

2.2.2 Sources of funds

In Greece, there is universal coverage for pharmaceutical care through the various sick funds. Also, the government funds pharmaceutical care for the uninsured and the poor. Moreover, out of pocket payments hold a significant percentage of pharmaceutical spending.

2.3 Evaluation

The government aims to reinforce its cost containment measures, by acting not only on the supply-side but also on the demand side. Attention is paid to the control and monitoring of prescribing behaviour. To this direction, pilot projects have been initiated and effects are expected to be demonstrable shortly. Since the implementation of the bar code system for medicines from 1/1/2005 onwards, there has been an improvement in the access and availability of reliable and timely information regarding the cost, the quality of the pharmaceutical healthcare provided, and the volume of the use of the latter. Among others, this minimizes possible errors in the prescription clearance procedure and facilitates the implementation of e-prescribing and Electronic Transfer of Prescriptions for an even more effective control of the system and for the provision of better service to the patients over the administration and the filling of their prescriptions.

EOF monitors the manufacturing, import, and sales of medicinal products at monthly intervals in order to detect any product shortages and record prescription and expenditure tendencies.

EOF also grants companies the Authenticity Band. 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. EOF provides a significant social contribution, through its coverage of basic market needs shortages of medicinal products.

As of 1-1-2005, the authenticity brand bears a bar-code. Today, a second bar-code has been incorporated to the authenticity brand offering direct access to a number of important details regarding each package of any medicinal product marketed in Greece.

The ability to monitor the health care system with regards to the use of pharmaceutical products by tracking production, storage, distribution and dispensing of the latter is improving, resulting in better services provided to the public.

In some insurance funds doctors are monitored. It is expected that by June 2007 all insurance funds will have set up prescription control mechanisms. Also, Budget Impact Analysis mechanisms are expected to be applied early 2007.

3 Pricing

3.1 Organisation

A medicine holding a market authorisation may not be sold in Greece until it has been granted a price. Also, this medicine must be sold at least in the country of origin or in any EU Member State other than Greece. The responsibility for pricing of pharmaceuticals lies with the Ministry of Development. Prices of pharmaceuticals are effective when published in the Price Bulletin. Recent reforms have changed the way prices are set in Greece. The government passed a new law in late 2005 (Law 3048/2005) which stipulates a new price setting system.

3.2 Pricing policies

Table 3.1: Greece - Ways of pricing of pharmaceuticals

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Not applied	Not applied	Not applied
Statutory Pricing	The price of new pharmaceuticals is determined based on the average price calculated by considering the average of the three lowest prices among EU-25 countries (two EU-15 countries and one among the 10 new access countries)	gross profit margin 8,43% based on the ex-factory price of the producer or importer	gross profit margin 35% on top of the wholesale price
Price Negotiations	Not applied	Not applied	Not applied
Discounts / rebates	4% rebate based on the turnover each pharmaceutical company incurs to social insurance funds	Not applied	Not applied
Public Procurement	➤ Vaccines, narcotics		
Institution in charge of pricing	➤ Ministry of Development, advised by the Pricing Committee		
Legal Basis	➤ Law N.3408/2005 article No 13		

3.2.1 Statutory pricing

The key elements of the new pricing policy are as follows:

1. The price of new medicinal products will be determined based on the average price calculated by considering the average of the three lowest prices among EU-25 countries (two EU-15 countries and one among the 10 new access countries).
2. Locally manufactured original medicinal products will now obtain the same price and follow the same procedures as the respective imported original medicinal products. Thus far, the Greek state treated locally manufactured products different compared to imported ones. The equalization of procedures for both locally produced and imported products establishes fair terms of competition and is expected to provide opportunities for growth to the indigenous pharmaceutical industry.
3. The price of medicinal products for which there is proof that the patent expires, will be reduced by 20%.
4. The price of generic medicinal products will be determined based on 80% of the initial price of the original product, as applied to this day.
5. Hospital prices of the medicinal products are reduced by 13% compared to the wholesale price.

Three prices apply to medicinal products. The **wholesale price**, the **retail price** and the **hospital price**.

The **wholesale price (pharmacy purchase price)** is the price the drug is purchased by the pharmacist. This price includes wholesaler's gross profit margin based on the ex-factory price of the producer or importer.

The **pharmacy retail price** derives from Pharmacy Purchase Price plus the pharmacist's profit margin and the VAT. The retail price is uniform in the whole country except for some districts where reduced VAT rates apply.

The **hospital price** derives from the Pharmacy Purchase Price reduced by 13%. Hospitals are supplied with medicines directly from the pharmaceutical companies according to their needs.

3.2.2 Negotiations

There are no price negotiations in Greece taking place.

3.2.3 Free pricing

Non applicable.

3.2.4 Public procurement / tendering

Tendering in Greece applies for very specific segments like military hospitals, vaccines and narcotics.

3.3 Pricing procedures

Table 3.2: Greece - Pricing procedures

Pricing procedure	In use: Yes / no	Level of pricing	Scope
Internal price referencing	No		
External price referencing	Yes	Manufacturer price	All pharmaceuticals and OTC products
Cost-plus pricing	Yes	Manufacturer price	Only for locally produced pharmaceuticals
Other, e. g. indirect profit control	No		

3.3.1 External price referencing

External price referencing is applied to all new pharmaceutical products including OTCs. External pricing is not applied to generic products. External pricing is used to determine the ex-factory price of pharmaceuticals.

The price of new medicinal products will be determined based on the average price calculated by considering the average of the three lowest prices among EU-25 countries (two EU-15 countries plus Switzerland and one among the 10 new access countries).

Pharmaceutical companies submit an application to the Directorate of Medicinal Products Prices within the Ministry of Development. Attached to this application is a check-sheet containing the details of the package (form, pack size, strength) and the prices of the product that apply in the European countries. The pricing law provides for significant fines for companies that submit incorrect data. The Directorate of Medicinal Products Prices cross-checks the submitted prices and calculates the wholesale price. Then, hospital and retail price are calculated based on certain mark ups.

3.3.2 Internal price referencing

Internal price reference is indirectly applied for the pricing of generics. Generic prices are set at 80% maximum of the price of the respective originator.

3.3.3 Cost-plus pricing

Cost plus pricing applies only to locally developed originators. In particular, prices are built based on production costs and distribution expenses plus a profit margin.

3.3.4 (Indirect) Profit control

Not applicable in Greece.

3.4 Exceptions

The law provides for exceptions and in particular, in cases when the Ministry of Health regards a product as absolutely necessary to Public Health.

3.4.1 Hospitals-only

Hospital prices of pharmaceuticals are reduced by 13% compared to the wholesale price of POM.

3.4.2 Generics

The prices of generics are set at the 80% of the retail price of the respective originator.

3.4.3 Over-The-Counter pharmaceuticals

The prices of OTC products in Greece are also regulated. The criteria used for calculating the price of an OTC product are the same as those for ethical products. OTCs can only be sold by pharmacies and not by any other kind of outlet, such as supermarkets.

3.4.4 Parallel traded pharmaceuticals

There is no special treatment of parallel traded pharmaceuticals with regards to pricing and reimbursement.

3.4.5 Other exceptions

Not applicable.

3.5 Margins and taxes

Table 3.3: Greece – Regulation of wholesale and pharmacy mark-ups 2006

	Wholesale mark-up			Pharmacy mark-up		
	Regulation (yes/no)	Content	Scope*	Regulation (yes / no)	Content	Scope*
Greece	Yes	linear mark-up of 8,43% on top of the manufacturer price	All pharmaceuticals	Yes	linear mark-up of 35% on top of the pharmacy purchase price	All pharmaceuticals

Source: Pricing Law 14/89

3.5.1 Wholesale remuneration

Wholesalers' gross profit margin is 8.43% based on the ex-factory price of the producer or importer. This margin applies to all pharmaceutical products.

Table 3.4: Greece - Wholesale mark-up scheme 2006

Ex-Factory Price in €	Maximum Mark-up in % of Ex-factory price	Wholesale price in €
Any	8,43%	-

Source: Market Decree 14/89

3.5.2 Pharmacy remuneration

The pharmacist's gross profit margin is 35% on top of the wholesale price. This margin applies to all pharmaceutical products.

3.5.3 Remuneration of other dispensaries

Non applicable.

3.5.4 Value-added tax

The **VAT rate** is 9% for all products on top of the Pharmacy Purchase Price plus the pharmacist's gross profit margin (standard rate in the country 19%).

3.5.5 Other taxes

There are no other taxes for pharmaceutical products or dispensing fees.

3.6 Margins and taxes

3.6.1 Discounts / Rebates

Discounts are strictly regulated and can be given on certain circumstances. Specifically, the following discounts can be given:

- 5% additional discount may be offered from wholesalers to pharmacists as long as this is documented.
- 4% of the wholesalers price for Pharmacists in towns with population less than 5000 inhabitants. In order for wholesalers to be able to offer this discount importers/producers of pharmaceutical provide wholesalers with an additional 0,4% discount.
- Unlimited discount can be given to public hospitals by manufacturers

3.6.2 Margin cuts

3.6.3 Price freezes / Price cuts

The price of medicinal products for which there is proof that the patent expires, will be reduced by 20%.

3.6.4 Price reviews

The pricing system stipulates that prices of new pharmaceutical products will be annually reviewed and accordingly adjusted for the first four years after price fixing. The Directorate retains the right to extend the review period beyond the first 4 years in special circumstances.

4 Reimbursement

4.1 Organisation

The government passed a new law that defines the reimbursement of medicines in Greece (Law 3457/06). According to this new reimbursement law the expenditure for all medicines holding marketing authorisation is covered by all sick-funds. Moreover, sick funds cover the expenditure for medicines for the uninsured and the poor. Law 3457/06 has the following key points:

Over-the-counter pharmaceutical and Prescription-Only-Medicines for certain indications are excluded from reimbursement. The later indications are commonly determined by the Ministry of Health and Social Solidarity and are published following approval from the Central health Council (KESY). For these indications some exceptions can be made on the basis of treating an underline clinical condition following the submission of the appropriate evidence from the doctor.

A transparency committee (EDAF) will be formulated within EOF consisting of scientists drawn from the field of Pharmacy, Health Economics and Policy and Medicine. A second degree 5 member transparency committee (DEDAF) will be formulated within the Ministry of Health and Social Solidarity.

EDAF will be responsible for clustering medicines based on objective and transparent criteria such as:

- Therapeutic value
- Pharmaco-economics
- Cost of daily treatment
- Safety
- Budget impact

According to law 3457/06 the calculation of the rebate value is made on a product by product basis. For each product a rebate price is determined by the Transparency committee (EDAF). In order to calculate the rebate price for each product the Transparency Committee clusters all prototype medicines based on the above criteria. All new medicines will be categorised in a cluster within 30 days from marketing approval. In turn, EDAF communicates the clusters to the pharmaceutical companies which have the right to appeal against the EDAF's decision within 30 days. Subsequently, DEDAF will examine the appeal and will issue the final decision.

For each cluster a reference price is calculated. The reference price is then calculated as the difference of the pharmacy retail price of a medicine from the reference price weighted to account for wholesalers and pharmacists' margins. Rebate prices are published along with the price bulletin. Subsequently, Sick funds are charged for the whole amount of the retail price of pharmaceuticals and claim, in turn, the rebate price from the pharmaceutical companies. The

specific article of the law has not yet been implemented. Currently, a transitional period applies, in which pharmaceutical companies have to pay back at the end of each year a specific amount of money based on the turnover the latter incur to social insurance funds.

4.2 Reimbursement schemes

In line with the EU Transparency Directive, law 3457/06 postulates that reimbursement of all approved prescription medicines is determined by the transparency committee EDAF. The latter cluster all new approved medicines in clusters after 30 days from marketing approval. Within 5 days EDAF communicates its decision to the pharmaceutical companies which, in turn, retain the right to appeal against EDAF's decision within 30 days. In this case DEDAF examines the appeal and issues its final decision within 60 days. Reimbursement for vaccines falls under the law for Preventive Medicine according to which all Vaccines which are included in the National Immunization plan are fully reimbursed. However, the law has not yet been implemented and presently all prescription medicines are reimbursed.

4.2.1 Eligibility criteria

All medicines with an approved price are eligible for reimbursement.

4.2.2 Reimbursement categories and reimbursement rates

Table 4.1: Greece - Reimbursement of pharmaceuticals

Reimbursement category	Reimbursement rate	Characteristic of category
	100%	Pharmaceuticals treating cancer, epilepsy, depression, multiple sclerosis, growth hormone deficiency, insulin for diabetics and pharmaceuticals used in pregnancy
	90%	Pharmaceuticals for chronic conditions such as osteoporosis, Parkinson's disease, coronary heart disease, hepatic cirrhosis and Crohn's disease – and for people with low pensions
	75%	Standard rate of reimbursement

4.2.3 Reimbursement lists

Since April 1998 Greece had operated a positive list of drugs eligible for reimbursement. The list was uniform for all sick funds operating in the country and the criteria used to determine reimbursement were based on proven therapeutic efficacy and safety, cost of daily treatment equal or less than the reference price of the pharmaco-therapeutic category that a drug belongs (categories were based on the ATC/WHO classification, reimbursement by at least two EU countries

countries and on additional information as and when required. The list was abolished in May 2006.

According to the new law for pharmaceutical policy in Greece (Law 3457/06) all drugs granted a price are reimbursed. Specific product categories are excluded from reimbursement such as Over-the-Counter Pharmaceuticals and pharmaceuticals that correspond to life style indications.

4.3 Reference price system

Law 3457/06 stipulates for a reference price system in the reimbursement procedure. The details for clustering pharmaceuticals will be defined by the Transparency committee (EDAF) based on the following criteria.

- Therapeutic value
- Pharmaco-economics
- Cost of daily treatment
- Safety
- Budget impact

4.4 Private pharmaceutical expenses

Not available.

4.4.1 Direct payments

Self-medication pharmaceuticals and life style products have to be paid directly by the patient.

4.4.2 Out-of-pocket payments

Out-of-pocket payments are incurred by the patient directly to the Pharmacist during the purchase of a prescription medicine.

4.4.2.1 Fixed co-payments

Not applicable in Greece.

4.4.2.2 Percentage co-payments

There are three categories of percentage co-payment in Greece.

- 0% co-payment that applies to drugs to treat cancer, epilepsy, depression, multiple sclerosis, growth hormone deficiency, insulin products for diabetics and drugs used in pregnancy.
- 10% co-payment for chronic conditions such as osteoporosis, Parkinson's disease, Coronary Heart Disease, hepatic cirrhosis, and Crohn's disease. This rate applies also to low-income pensioners.
- 25% that applies to the majority of pharmaceutical products.

4.4.2.3 Deductibles

Not applicable in Greece.

4.5 Reimbursement in the hospital sector

Public hospitals are reimbursed by social insurance funds on a per diem basis. The per diem fees include all the resources consumed during a hospitalization (medicines, examinations, surgical operations etc). Traditionally, per diem fees have been kept below average per diem costs.

4.6 Reimbursement related cost-containment measures

4.6.1 Major changes in reimbursement lists

In May 2006 the positive list which was in effect since 1998 was abolished

4.6.2 Introduction / review of reference price system

There is ongoing discussion on determining the final reference pricing policy. Previous reference pricing was based on the ATC/WHO classification system (see section 4.3).

4.6.3 Introduction of new / other out-of-pocket payments

There have not been any changes to out-of-pocket payment in the past few years.

4.6.4 Claw-backs

Not applicable

5 Rational use of pharmaceuticals

5.1 Impact of pharmaceutical budgets

There are no pharmaceutical budgets in the Greek Health care system.

5.2 Prescription guidelines

There are presently no prescription guidelines that apply in Greece.

5.3 Information to patients / doctors

The "Marketing directives" as stated in [Directive 2001/83/EC](#) are implemented in Greece, monitored by EOF.

5.4 Pharmaco-economics

As mentioned, the reimbursement system provides for the implementation of a rebate system where drugs are grouped into therapeutic clusters and a reference price is calculated for each cluster. Pharmaceutical companies will return the weighted difference between their products' price and the reference price to social insurance organizations. The proposal states that rebate levels can be adjusted based on pharmaco-economic evidence in order to reward cost-effective therapies.

5.5 Generics

Currently, there are not any legal regulations on the use of generics. The latter are not officially seen as a cost-containment tool. However, the government has recently applied 20% price cuts for products which patents have expired and have at least one product with the same active ingredient marketed for more than one year with a market share greater than 5%. This has resulted in savings for the Health-care system. In 2003, the generic market accounted for almost 10% (both in volume and value terms) of total pharmaceutical market, while its mean annual growth rate for the period 1996-2003 is estimated at 8.7%.

Table 5.1: Greece - Development of the generic market in the out-patient sector, 2000 - 2005

Generic market share	2000	2001	2002	2003	2004	2005
Volume (number of prescriptions per year)	na	na	na	na	na	na
Value	131.000	148.000	190.000	212.000	na	na

Na = not available

Source: Institute for Economic and Industrial Research

5.5.1 Generic substitution

At present there is no official policy for generic substitution in Greece.

5.5.2 Generic prescription

Doctors are not obliged to write prescriptions generically. Also, there is no profit from prescribing generic pharmaceuticals. Furthermore, doctors prescribe both prototypes and generic products by a "brand' name.

5.5.3 Generic promotion

Generic promotion strategies among doctors, patients and pharmacists do not apply in Greece.

5.6 Consumption

Consumption of Pharmaceuticals in Greece is regulated by EOF.

6 Current challenges and future developments

6.1 Future developments

In 2004, health spending in Greece exceeded 9.5% of GDP, with almost 55% of total health expenditure coming from public sources. Pharmaceutical spending amounted to 17.8% of total health expenditure (1.7% of GDP). This situation, combined with the fact that the pharmaceutical market in value terms is growing by double-digit rates, as well as the government's current healthcare reform plans, create an environment of promoting efficiency in the system. Regarding P&R, the government's objectives are to better strengthen measures that affect the demand side (eg. Prescribing physicians, monitoring of prescription control), whilst maintaining control on the supply-side.

Regarding pharmaceuticals, the policy gradually implemented, provides for the timely access to new treatments (mainly through the abolition of the positive reimbursement list), the strict control of the demand side (through effective measures to control pharmaceutical expenditures) and the promotion of cost-effectiveness in the provision of pharmaceutical care.

The government aims to reinforce its cost containment measures, by acting not only on the supply-side but on the demand-side as well. The latter is explicitly stated by government officials. Attention is paid to the control and monitoring of prescribing behaviour. To this direction, pilot projects have been initiated and effects are expected to be demonstrable by the end of 2005. Moreover, with the application of bar coding on medicines packs from 1/1/2005, an improvement of the access to reliable and timely information regarding the cost and the quality of the pharmaceutical healthcare provided is anticipated. Also, bar code will facilitate the implementation of e-prescribing and Electronic Transfer of Prescriptions for an even more effective control of the system and for the provision of better service to the patients over the administration and the filling of their prescriptions.

There are several developments in the Greek pharmaceutical market that are likely to intensify in the near future:

- The government aims to reinforce its cost containment measures, by acting not only on the supply-side but also on the demand side. The latter is explicitly stated by government officials. Attention will be paid to the control and monitoring of prescribing behaviour. To this direction, pilot projects have been initiated and effects are expected to be demonstrable shortly. Since the implementation of the bar code system for medicines from 1/1/2005 onwards, there has been an improvement in the access and availability of reliable and timely information regarding the cost, the quality of the pharmaceutical healthcare provided, and the volume of the use of the latter. Among others, this minimizes possible errors in the prescription clearance procedure and facilitates the implementation of e-prescribing and Electronic Transfer of Prescriptions for an even more effective control of the system and for the provision of better service to the patients over the administration and the filling of their prescriptions.

- The completion of the regulatory framework for OTC products
- The timely access of patients to new treatments
- The continuous training and education of health care professionals
- The support of the pharmaceutical industry in Greece