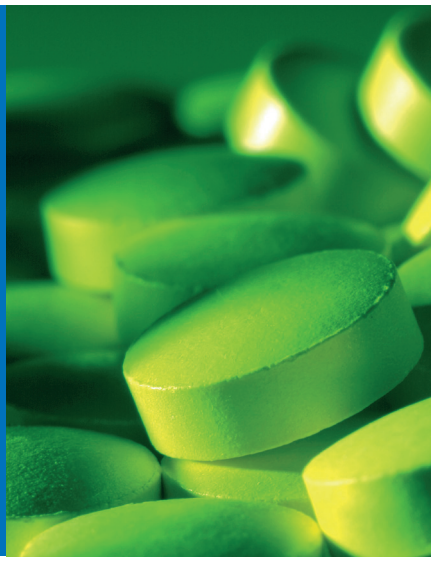
# The pharmaceutical market in Greece:

# **Facts and figures**

# 2012



**December 2012**

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# The pharmaceutical market in Greece: Facts and figures 2012

Scientific Editor:
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## Foreword by SFEE's President

It is a great pleasure for me to write the foreword to this important publication by SFEE. The Pharmaceutical Market in Greece: Facts & Figures 2012 is a comprehensive survey of the Greek pharmaceutical market, prepared by experts of the Health Economics Observatory of IOBE. It comes at an appropriate moment, when the pharmaceutical industry is going through a period of rapid changes and developments and is faced with a barrage of new laws and measures. Under the current circumstances, it is essential that decision-making with a crucial bearing on the sustainability of the National Health System is based on objective, accurate and reliable facts and data.

The survey provides an expert insight into the link between the country's economic performance and a well-functioning pharmaceutical market, which is at the centre of all efforts to promote public health.

We are strongly committed to transparency and to rigorously observing ethical principles and rules of professional conduct. To us, pharmaceuticals are not merely commodities; more importantly, they are the most socially sensitive good.

During this challenging period for the Greek society, it is all the more important to highlight the value of pharmaceuticals for human life, as well as the contribution of the pharmaceutical industry to the national economy. We are conveying the message that this industry represents growth, exports to more than 100 countries, investment and research, high-skill jobs, expertise and, last but not least, hundreds of millions of public revenue from taxes and employers' social security contributions.



The survey will be updated every year, enabling stakeholders from across the industry to share reliable and relevant information regarding current developments and their implications for the sector.

Enjoy your reading,

**Konstantinos M. Frouzis**
**President of SFEE**

## Acknowledgements

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**CEO of Cana**

## 1. Key statistics of the Greek pharmaceutical market

### Table 1: The Greek pharmaceutical market in figures*

| | | |
|---|---|---|
| **Number of companies** | Manufacturers and Importers<br>Wholesalers (2011)<br>Pharmacy cooperatives (2011) | ~100<br>135<br>27 |
| **Pharmaceutical sales** | To wholesalers/pharmacies/ (at retail prices)<br>To hospitals (at hospital prices)<br>Total sales (2011)<br>Change 2010/2011 | €5,558 mil.<br>€1,200 mil.<br>€6,759 mil.<br>-7,9% |
| **Domestic production** | At ex-factory prices (2011) | €846 mil. |
| **Exports** | Value (2011) | €859 mil. |
| **Imports** | Value (2011) | €3,003 mil. |
| **Parallel exports** | % of total sales (in value terms) (2011) | 7,1% |
| **Employment** | Number of employees (2011) | 13.600 |
| **Public pharmaceutical expenditure** | Expenditure 2011<br>Expenditure 2012<br>Change 2012/2009<br>% of GDP (2012)<br>Net public pharmaceutical expenditure per capita (2012)<br>% of public health expenditure (2011) | €3,729 mil.<br>€2,880 mil.<br>-43%<br>1,4%<br><br>€253<br>17,7% |
| **Price structure** | Ratio of ex-factory price to retail price (2012) | 67,6% |
| **Price change** | Medicines Price Index 2005/2011<br>Medicines Price Index 2010/2011 | -17,8%<br>-10,7% |
| **Generics** | % of total sales (in value terms) (2011) | 18% |
| **Generics and off-patent** | % of total sales (in value terms) (2011) | 60% |
| **R&D expenditure** | EFPIA (2012) | €84 mil. |

* The table presents summary data on the Greek pharmaceutical sector. For further details, see the main text

**Note:** Public pharmaceutical expenditure is a fraction (about 65% in 2011) of total pharmaceutical sales
See terms and definitions on p.17

## 2. Economic environment

### MACROECONOMIC INDICATORS

In 2011 the recession of the Greek economy was well deeper than initially expected. For the year as a whole, GDP contracted by 6.9%, chiefly reflecting a slump in private consumption (-7.1%). At the same time, government consumption continued to fall (-9.1%), and investment shrank for the fourth consecutive year (-20.7%). The unemployment rate increased by 5 percentage points to 17.7%.

**Table 2: Evolution of key macroeconomic indicators, Greece**

| | 2009 | 2010 | 2011 | 2012* | 2013* |
|---|---|---|---|---|---|
| **GDP in mil. €, at current prices** | 231.642 | 227.318 | 215.088 | 200.906 | 193.078 |
| **GDP per capita (in mil. €, at current prices** | 20.531 | 20.103 | 19.018 | 17.764 | 17.070 |
| **Real GDP growth (%)** | -3,3 | -3,5 | -6,9 | -6,5 | -3,8 |
| **Private consumption expenditure** | -1,3 | -3,6 | -7,1 | -7,7 | -5,9 |
| **Government consumption expenditure** | 4,8 | -7,2 | -9,1 | -6,5 | -7,2 |
| **Gross fixed capital formation** | -15,2 | -15,0 | -20,7 | -18,5 | -3,7 |
| **Exports of goods and services** | -19,5 | 4,2 | -0,3 | 0,4 | 2,5 |
| **Imports of goods and services** | -20,2 | -7,2 | -8,1 | -10,1 | -5,3 |
| **Unemployment rate** | 9,5 | 12,6 | 17,7 | 23,5 | 24,7 |
| **Harmonized Index of Consumer Prices** | 1,3 | 4,7 | 3,1 | 1,2 | 0,7 |
| **General government balance (deficit) (% of GDP)** | -15,6 | -10,3 | -9,1 | -6,6 | -4,2 |
| **General government debt (% of GDP)** | 129,4 | 145,0 | 165,3 | 169,5 | 179,3 |

**Sources:** ELSTAT and European Commission, European Economic Forecast, Spring 2012
*Estimates from the Ministry of Finance, Draft of the State Budget for 2013

The escalation of the recession stemmed from developments which affected real economic activity, as well as by the serious deterioration of the domestic social and political climate. Domestic demand came under strong pressure, as a result of, first, the full implementation of the fiscal measures taken in the second half of 2011, especially the squeeze on households' disposal income (hikes in direct and indirect taxes, cuts in pensions, single pay scale in the public sector, property levy payable via electricity bills, etc.) and, second, from rising unemployment. On the other hand, political instability and subsequent developments that led to the formation of a coalition government, the protracted discussions on the Greek government bond exchange programme and the new loan agreement, all fuelled heightened uncertainty and concerns about the country's near-term path.

The external sector of the economy dampened the fall in GDP. Reflecting a stabilisation of exports and a decline of 8.1% in imports, the current account deficit narrowed, although it still remains at an unsustainable level. Despite the public spending cuts and a reduction in the general government deficit ratio by 1.2 percentage points of GDP, the new borrowing needed to finance the deficit added to the already high debt; this, interacting with the recession, pushed the debt-to-GDP ratio even higher.

2012 was another year of recession in the Greek economy; with GDP expected to contract by -6.5%. Domestic demand continues to weaken, driving key developments of the Greek economy. Government consumption expenditure is subject to drastic cutbacks, in the context of intensified fiscal consolidation efforts. Total domestic investment declined dramatically for another year, as the pursuit of the budgetary targets puts a constraint on the implementation of public investment projects, as had been the case in the previous two years. The external sector is on track to improve its balance, however this would probably arise solely from falling imports, as exports are likely to decline in 2012, against the backdrop of slower global growth. Further factors weighing on the Greek economy in 2012 include the uncertainty surrounding the country's ability to achieve the targets amid a deep recession and a volatile economic and political environment, policy choices and developments at the EU level, particularly in terms of policy responses to the euro area crisis. For 2013, in the context of ongoing fiscal consolidation, GDP growth is likely to remain in negative territory (-3.8%). The fiscal deficit is expected to contract, but the unemployment rate and the debt ratio will deteriorate even further.



## INTERVENTIONS AND POLICY MEASURES IN THE HEALTH AND PHARMACEUTICAL SECTORS IN THE CONTEXT OF THE FISCAL CONSOLIDATION AGENDA

The healthcare and pharmaceutical sectors have borne the brunt of the fiscal consolidation effort. Pivotal interventions and legislative reforms from 2010 onwards have brought about fundamental changes in the business environment of these sectors.

## Table 3: Interventions and policy measures in the health and pharmaceutical sector from 2010 onwards

| Areas of intervention (Memorandum I, May 2010) | Law 3918/2011* | Law 4025/2011** | Law 4052/2012*** | Ministerial Decision 97018/ Oct. 2012 |
|---|---|---|---|---|
| • New pricing system for originator and generic medicines<br>• Lists: medicines for serious diseases under Law 3816/2012, negative, positive, OTC lists<br>• Promoting the use of generics<br>• Tender procedures for pharmaceutical supplies<br>• E-prescribing<br>• Lower wholesale and retail profit margins<br>• Rebate from pharmacists<br>• Rebate from pharmaceutical companies<br>• Reduction in VAT rate<br>• Merging 4 health funds into a single national health insurance provider (EOPYY)<br>• Integration of IKA hospitals into the NHS | • Establishment of an escalating percentage of pharmacies' debt to the health branches of SSFs as monthly rebate, conditional on timely payment of these debts<br>• Rebate of 4% on the value of reimbursed medicines, payable by pharmaceutical companies to SSFs 5% discount by pharmaceutical companies to NHS hospitals<br>• Wholesale profit margins: 5.4% for prescription drugs, 7.8% for nonprescription drugs (OTC) and 2% for medicines of Law. 3816/2010<br>• Expansion of the list of Law 3816 and reduction in pharmacy profit margins for products in the positive list (GG. 1666B/2011)<br>• Establishment of a negative list (Gov. Gaz. 559B/2011) | • Admission to the positive list of each pharmaceutical product is subject to an entry fee equal to 4% of the producer/ importer price (exfactory) payable exclusively by pharmaceutical companies<br>• Establishment of a second degree Appeal Board to review objections to the positive list<br>• Setting off of SSF claims on pharmaceutical companies against public hospital debts (GG. 262A/2011) | • Claw-back by the pharmaceutical companies of any overrun of the SSFs' quarterly pharmaceutical expenditure against the budget target of €240 mil per month<br>• Setting off of receivables between SSFs, hospitals and pharmaceutical companies<br>• 50% price reduction when the patent expires<br>• The first generic is priced at maximum 40% of the price of the on-patent originator<br>• The next three generics are priced at 10% lower than the previous one<br>• Wholesale profit margins: 4.9% for positive list, 5.4% for negative list and 7.8% for OTC list<br>• Mandatory e-prescribing<br>• Prescribing by active substance, until June 2012 applicable on a pilot basis for 10 active substances with the highest consumption, thereafter for all active substances<br>• Pharmaceutical companies' rebate of 9% (to cover the difference between producer price and social security price)<br>• Escalating rebate for pharmaceutical companies up to 8% depending on sales in value terms<br>• Escalating pharmacy mark-ups for medicines sold at wholesale price (WP) or special wholesale price under Law 3816, depending on WP: (i) for WP of €200-500, 8% * WP + €30; (ii) for WP of €501-1,001, 7% * WP + €30; and (iii) for WP over €1,001, 6% * WP + €30. Markup reduced to 32.4% for WP <=€200 and to 16% for medicines under Law 3816 (subsequently abolished)<br>• Escalating rebate from pharmacists to SSFs (up to 5%). | Gross profit margins for pharmacies are defined as follows:<br>a) for non-prescription drugs (OTC), 35% of wholesale price;<br>b) for non-reimbursed prescription drugs, 35% of wholesale price;<br>c) for drugs reimbursable by SSFs and with a Wholesale Price up to €200, 32.4% of wholesale price;<br>d) for reimbursable drugs with a wholesale price over €200, a fixed profit margin of €30;<br>e) drugs listed in paragraph 2 of Article 12 of Law 3816/10 and having a special wholesale price up to €200, 16% of the special wholesale price |

* Law 3918/2011, "Structural reforms in the health system and other provisions".
**Law 4025/2011, "'Restructuring of social care units, provisions on rehabilitation centres, restructuring of the National Health System, and other provisions".
***Law 4052/2012, "Prescribing by active substance and reimbursement based on reference price"

| Ministerial Decision 104744 Oct. 2012 | Ministerial Decision 104747 Oct. 2012 | Law 4093/2012 | Legislative Act, GG 229/2012 | Decision, GG 3057/2012 |
|---|---|---|---|---|
| • Establishment of a positive list with ATC4 classification and reference prices.<br>• Entry of new products in the positive list subject to assessment of efficacy, safety, quality, costeffectiveness and wider socio-economic impact<br>• A reference price (RP) is defined per therapeutic class as the lowest daily treatment cost (DTC) among all reference drugs (patent protected or not) and the average of all generics in the class, i.e. RP = weighted average DTC among 1...i on-patent products, 1...n non-patent products, 1...m generics<br>• Products included in the positive list with DTC ≤ €0.4 are reimbursed at retail price even if it exceeds the reference price<br>• New entries in the list are subject to a one-off entry fee of €2,000 | • Establishment of a list of diseases qualifying for reduced patient copayment for medicines administered<br>• EOF supplements Positive Reimbursement List based on ATC classification, including the copayment level per medicine/SKU | • Calculation of claw-back on a bi-annual basis, with the possibility of setting off against equal amounts owed to EOPYY or NHS hospitals<br>• Prescriptions by brand name cannot exceed 15% of the total value of prescriptions by each physician.<br>• As from 1.1.2014 EOPYY will charge patients with €1 per prescription and €25 per admission to NHS hospitals<br>• Rebate 5% from the pharmaceutical companies for sales to EOPYY pharmacies<br>• Rebate 5% from pharmacies for sales of medicines in the list of Law 3816 | • Introduction, as from 1.1.2013, of an extraordinary levy of 15% on 2011 retail sales of products in the positive list, with the possibility of setting off against the claw-back paid in 2012. Non-payment of the levy entails transfer of the product to the negative list. **(Exempted are companies that have paid or set off the claw-back for 2012 by 10.12.2012)**<br>• Retroactive effect of the rebate of pharmacists as from January 1, 2012, for all medicines except those in the list of Law 3816. | Mandatory INN prescription; as an exception, prescription by brand name is permitted for pharmaceuticals that cause allergies and reactions, or used by transplant and immunocompromised patients, blood derivatives, insulins, vaccines , biotechnology and combination products and drugs with narrow therapeutic range. Further exceptions refer to medicines for epilepsy, psychosis, schizophrenia, asthma and chronic, degenerative and autoimmune diseases. Prescribing by both brand name and active substance is possible in cases of patients suffering from chronic diseases who are sufficiently and effectively adjusted to a treatment regimen. All exceptions will be posted on EOF's website. Prescriptions by brand name cannot exceed 15% of the total annual prescriptions by each physician and must be duly reasoned. Penalties will be imposed on physicians noncomplying with this ceiling. |

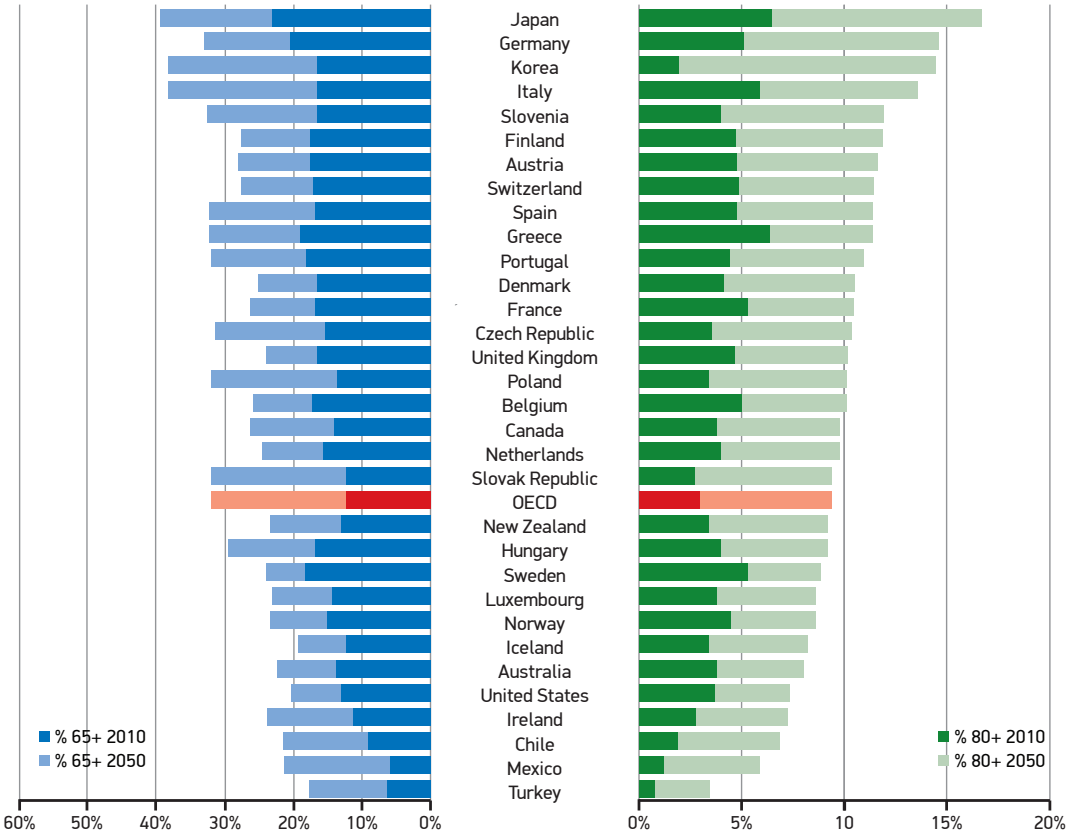
## 3. Greek demographics and health profile of population

### DEMOGRAPHIC TRENDS

Demographics are a crucial determinant of pharmaceutical expenditure, as they affect demand for health services. Higher life expectancy, due to the advances of medical science and the development of innovative medications, explains to a large extent the strong upward trend of pharmaceutical expenditure.

In OECD countries as a whole, life expectancy at birth increased by almost 10.3 years in 45 years (1965 to 2010). In Greece, where life expectancy is higher than the OECD average, there have also been life expectancy gains, of a cumulative 2.6 years over the last decade.

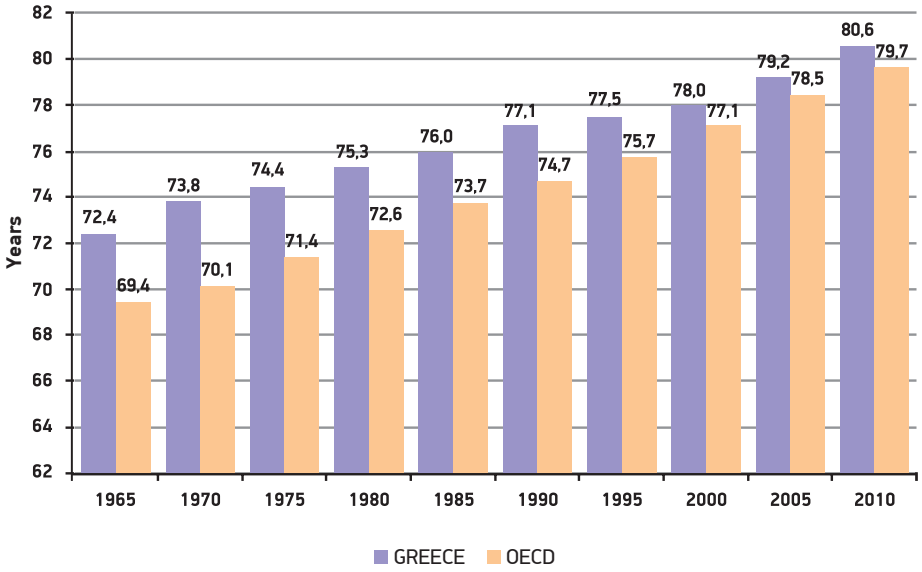
**Figure 1: Projected shares of the population aged 65+ and 80+ in the OECD and other selected countries, 2010-2050**




**Source:** OECD Labour Force and Demographic Database, 2010

Higher life expectancy, along with the projected increase in the population aged over 65, who typically use more health services, will have a significant impact on health costs in the future.

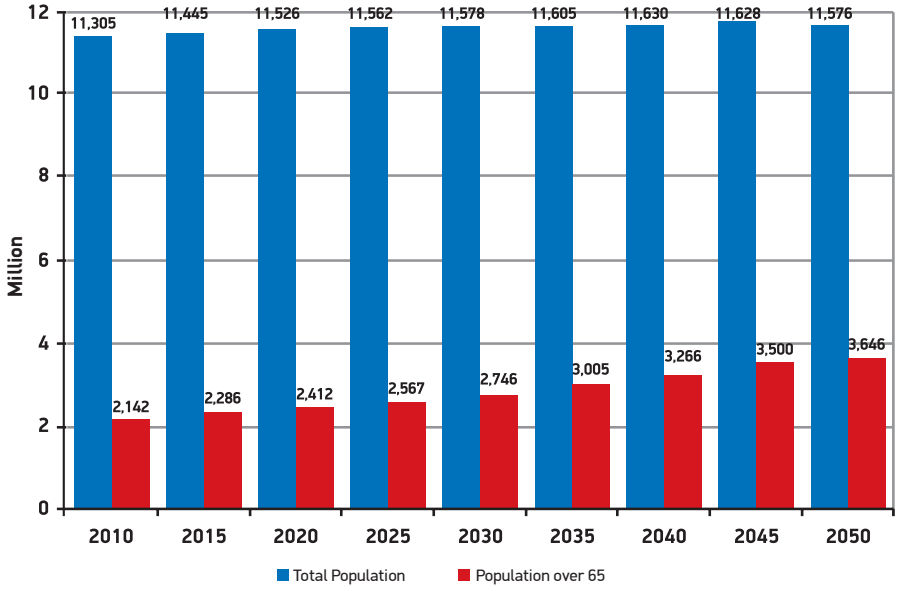
## Figure 2: Evolution of life expectancy at birth in Greece and in the OECD countries






**Source:** OECD, Health Data 2012

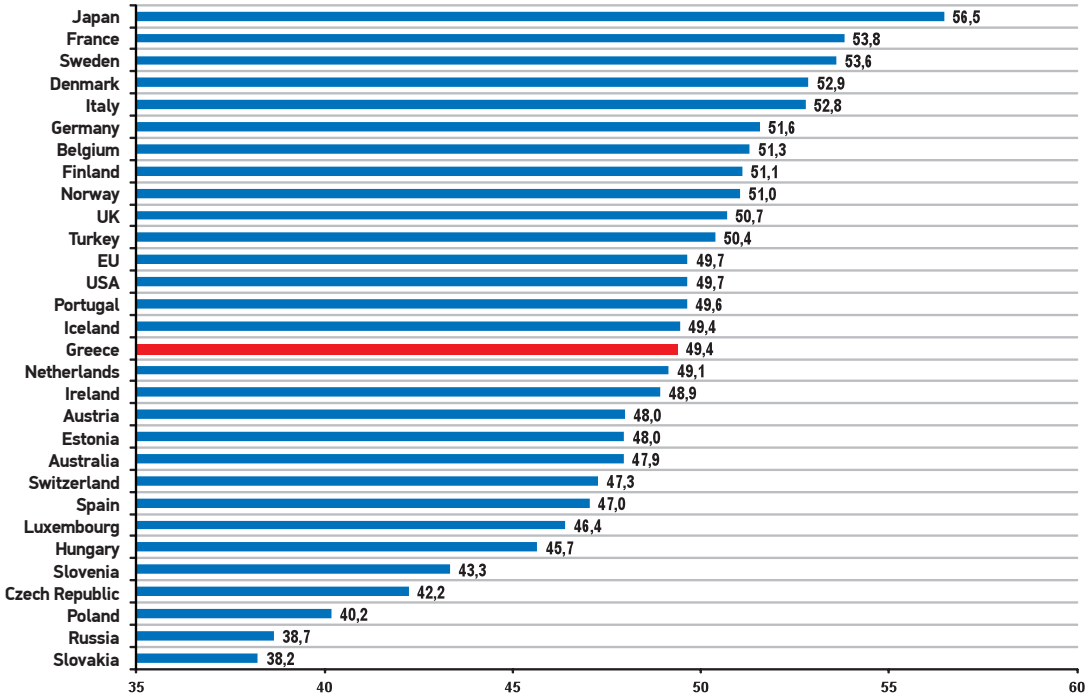
## Figure 3: Population projections for Greece, 2010-2050




**Source:** Eurostat, 2012

A measure of changes in the age structure of population is the dependent population ratio, i.e. the ratio of the population aged 0-14 and 65 and over to total active population (aged 15-64). This indicator is on an upward trend in advanced economies, reflecting rising life expectancy and declining birth rates.[1].

## Figure 4: Dependent population ratio, 2010




**Source:** OECD, Health Data 2012

Japan has the highest dependent population ratio, while Greece's ratio is lower than the EU average or the US. In comparison with the larger EU countries (France, Germany, UK), Greece has a better (i.e. lower) dependent population ratio, while compared with other Mediterranean countries its ratio is higher than that of Spain and lower than that of Portugal. However, what is important is that nearly half the population is dependent on the other half, and this proportion tends to deteriorate, signalling growing pressures on social security systems already experienced in many advanced countries.

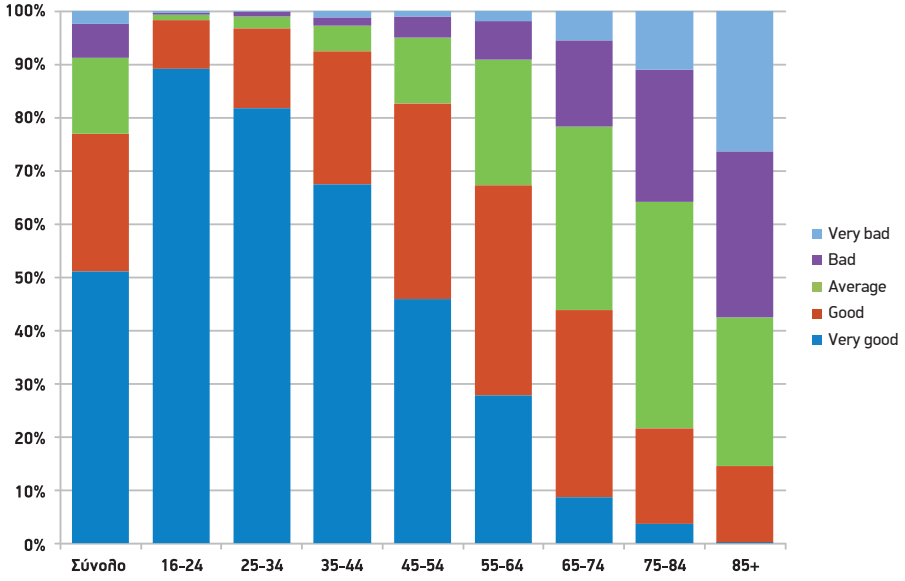


[1]For instance, in Greece there were 114.7 thousand live births in 2010 (down by 2.7% from 2009) and 109 thousand deaths (up by 0.6% from 2009). Characteristic of the demographic changes is that compared with 1960, births per 1,000 population declined by 37.0%, while the number of deaths per 1,000 population increased by 44.4% over the same period.

## HEALTH PROFILE OF GREEK POPULATION

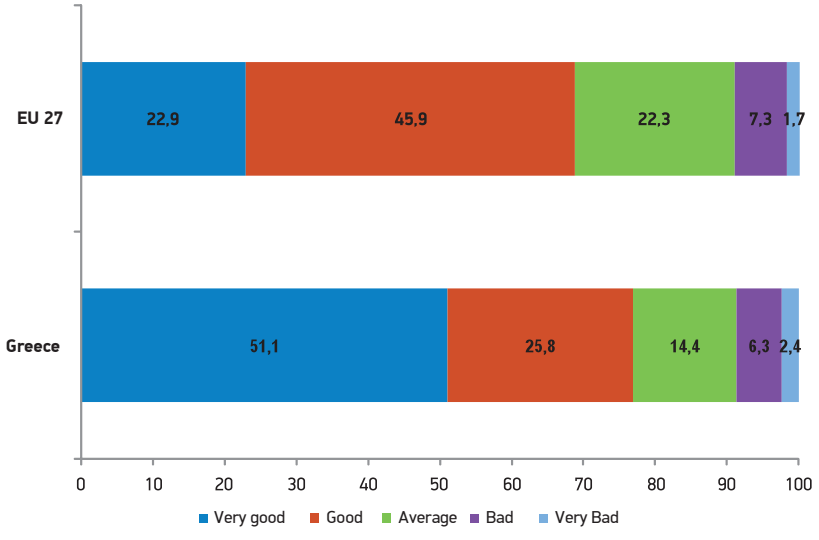
Greek citizens are overall satisfied with their health status, with only 8.7% reporting that their state of health is bad or very bad. Good or very good state of health is reported by 77% of the population, which is above the EU-27 average. It should be noted that the health of an individual depends on many factors, such as his/her lifestyle, but also, and significantly, on the medical care and health services he/she receives.

### Figure 5: Self-reported health status by age group in Greece, 2010




**Source:** Eurostat, Statistics on Income and Living Condition 2012

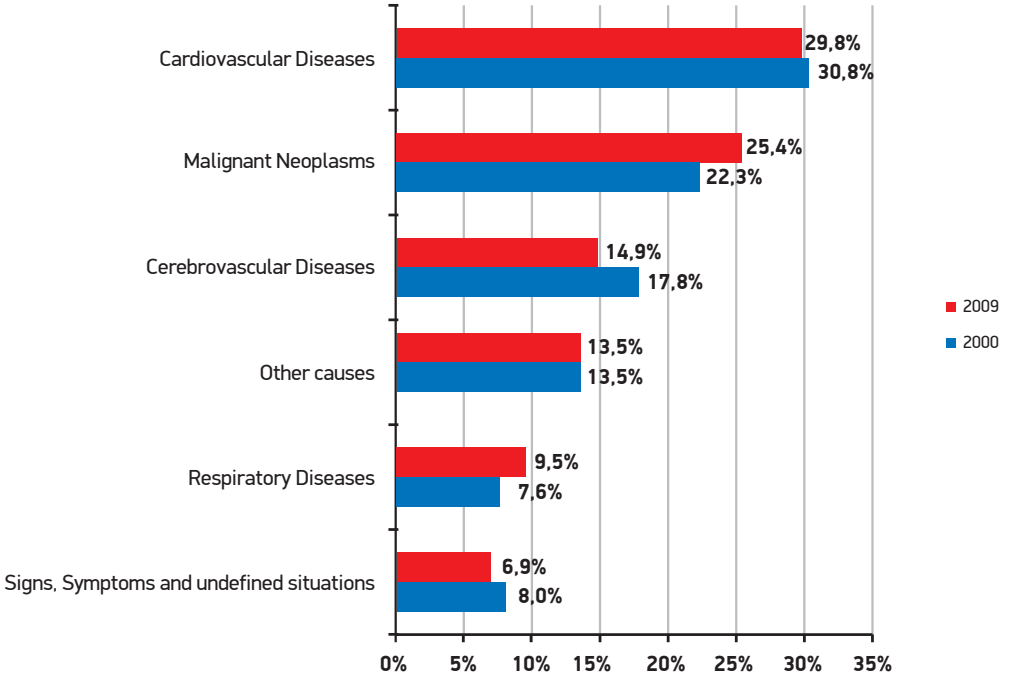
### Figure 6: Self-reported health status in Greece and in the EU 27, 2010




**Source:** Eurostat, Statistics on Income and Living Condition 2012

Based on 2009 data, the major causes of death in Greece were cardiovascular diseases, with a share of 29.8% in total deaths, and malignant neoplasms, with 25.4%, followed by cerebrovascular diseases (14.9%) and respiratory diseases (9.5%). These four causes together account for 79.5% of total deaths, while there is also a relatively high proportion (6.9%) of deaths due to "signs, symptoms and ill-defined conditions". Meanwhile, deaths from road traffic accidents decreased by 39.2% from 2,037 in 2000 to 1,258 in 2010.

**Figure 7: Causes of deaths in Greece**




**Source:** ELSTAT, 2012

## 4. The demand side: health and pharmaceutical expenditure in Greece

### HEALTH AND PHARMACEUTICAL EXPENDITURE IN GREECE

**Data on pharmaceutical expenditure are often confused with the data on total pharmaceutical sales released by the National Organisation for Medicines (EOF).**

EOF compiles monthly data on the sales of medicines by pharmaceutical companies to hospitals, wholesalers and pharmacies. By contrast, pharmaceutical spending – according to the OECD's International Classification of Health Accounts, with which Greek statistics have been harmonised – is the total cost of out-patient medicines. **Pharmaceutical expenditure is therefore only a fraction of total pharmaceutical sales.**

In more detail, pharmaceutical sales can be broken down into the following components:

(a) public pharmaceutical expenditure, incurred by social insurance funds (part of this expenditure is refunded by pharmaceutical companies to the government, in the form of VAT payments, at a rate 6.5%, and other refunds/rebates);

(b) sales of pharmaceutical supplies to hospitals (invoiced at hospital price = wholesale price minus 13%);

(c) sales of pharmaceutical products that are re-exported (parallel exports);

(d) sales of pharmaceutical products to Greek citizens or tourists at their own cost;

(e) sales of pharmaceutical products to Greek citizens or foreigners which are reimbursed by private insurance companies;

(f) patient copayment, which does not imply a cost for social security funds.

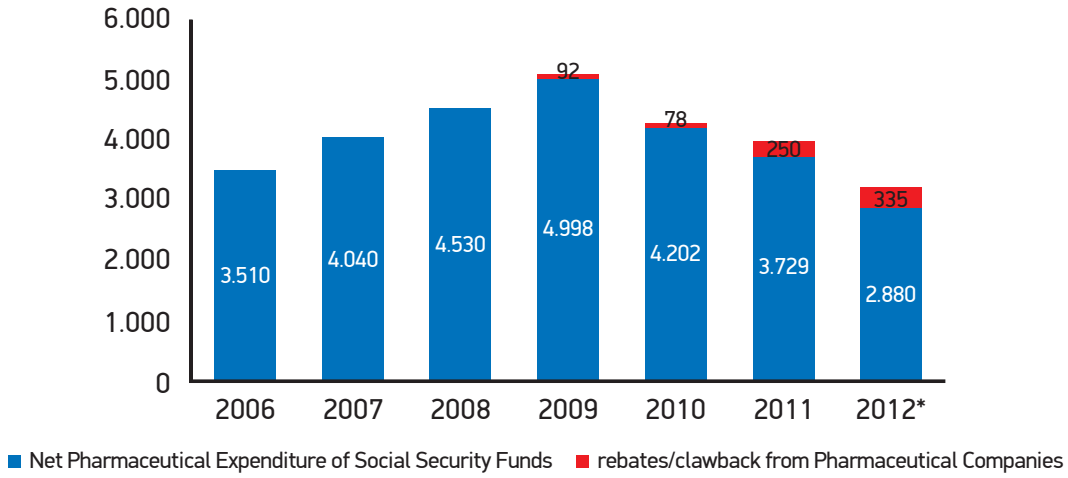
Regarding point (b), it should be noted that pharmaceutical sales to hospitals are included in hospital expenditure, so they would be counted twice if included in the analysis as an additional expenditure item.

Regarding points (c), (d) and (e), it should be noted that these sales are not part of public pharmaceutical expenditure; on the contrary, they generate revenue for the government, in the form of VAT, income tax, payroll tax, social security contributions, etc.

**Total pharmaceutical expenditure** in Greece in 2011 is estimated at €5.07 billion, accounting for 24.1% of total health expenditure and 2.4% of GDP.

**Public pharmaceutical expenditure** followed an upward trend until 2009, in line with developments in overall health expenditure and GDP. However, in 2010-2011 it fell sharply by 22% to reach **€3.98 billion** in 2011, corresponding to 1.8% of GDP and 30% of public health expenditure. It is worth pointing out that: (a) the size of public pharmaceutical expenditure does not take into account the rebates/discounts from pharmaceutical companies to social security funds, which for 2011 are estimated at €250 million and further reduce the size of public pharmaceutical expenditure to €3.73 billion or 1.7% of GDP, fairly close to the target for 2012, i.e. €2.88 billion or 1.4% of GDP; and (b) the remaining (non-pharmaceutical) public health expenditure is not subject to formal and accurate recording and measurement, thus making it difficult to identify any overspending and/or mismanagement.

**Figure 8: Public pharmaceutical expenditure 2006-2012 (in € billions)**




**Source:** General Secretariat for Social Security
**Note:** Data on rebates/claw-back from pharmaceutical companies are only available for the years 2009-2011.
*The figures for 2012 are estimates.

**Net public pharmaceutical expenditure is the final amount paid by social security funds, net of all rebates and claw-back payments.** The latter include for 2009-2010, a rebate of 3% applicable on sales values; for 2011, a rebate of 3%-4% plus an entry-fee in 2011; and for 2012, a rebate of 9% applicable on sales values, an escalating rebate of up to 8% on sales volumes, plus a bi-annual claw-back payment in the event of an overrun in public pharmaceutical expenditure above a monthly ceiling of €240 million paid by pharmaceutical companies.

[2]Official data were last released by ELSTAT in 2007. For subsequent years, total pharmaceutical expenditure figures are only estimates, which complicates both comparisons with the official data for earlier years (see note to Table 4) and, obviously, the design and implementation of effective policies in the areas of health care and pharmaceuticals.

## Table 4: Health and pharmaceutical expenditures in Greece (in € millions, unless otherwise indicated)

| | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| GDP | 135.044 | 145.098 | 155.192 | 170.865 | 183.583 | 193.050 | 208.893 | 222.771 | 232.920 | 231.642 | 227.318 | 215.088 | 200.906 |
| GDP per capita in € | 12.385 | 13.251 | 14.124 | 15.500 | 16.596 | 17.386 | 18.737 | 19.941 | 20.756 | 20.554 | 20.088 | 18.934 | 17.623 |
| Total health expenditure | 10.803 | 12.914 | 14.278 | 15.378 | 16.155 | 18.726 | 20.263 | 21.832 | 23.525 | 24.554 | 23.186 | 21.079 | .. |
| Health expenditure per capita (€) | 991 | 1.179 | 1.299 | 1.395 | 1.460 | 1.686 | 1.818 | 1.954 | 2.096 | 2.179 | 2.049 | 1.856 | .. |
| Health expenditure as % of GDP | | | | | | | | | | | | | |
| Public health expenditure | 8,0% | 8,9% | 9,2% | 9,0% | 8,8% | 9,7% | 9,7% | 9,8% | 10,1% | 10,6% | 10,2% | 9,8% | .. |
| Public health expenditure per capita (€) | 6.444<br>591 | 7.832<br>715 | 8.264<br>752 | 9.208<br>835 | 9.552<br>864 | 11.256<br>1.014 | 12.569<br>1.127 | 13.175<br>1.179 | 14.102<br>1.257 | 15.140<br>1.343 | 13.772<br>1.217 | 12.647<br>1.113 | ..<br>.. |
| Public as % of total health expenditure | 59,6% | 60,6% | 57,9% | 59,9% | 59,1% | 60,1% | 62,0% | 60,3% | 59,9% | 61,7% | 59,4% | 60,0% | .. |
| Public Health Expenditure as % of GDP | 4,8% | 5,4% | 5,3% | 5,4% | 5,2% | 5,8% | 6,0% | 5,9% | 6,1% | 6,5% | 6,1% | 5,9% | .. |
| Total pharmaceutical expenditure | | | | | | | | | | | | | |
| Total pharmaceutical expenditure per capita (in €) | 2.042<br>187 | 2.324<br>212 | 2.684<br>244 | 3.137<br>285 | 3.554<br>321 | 4.026<br>363 | 4.600<br>413 | 5.414<br>485 | 5.834<br>520 | 6.346<br>563 | 5.403<br>477 | 5.073<br>447 | ..<br>.. |
| Pharmaceutical expenditure as % of health expenditure | 18,9% | 18,0% | 18,8% | 20,4% | 22,0% | 21,5% | 22,7% | 24,8% | 24,8% | 25,8% | 23,3% | 24,1% | .. |
| Pharmaceutical expenditure as % of GDP | 1,5% | 1,6% | 1,7% | 1,8% | 1,9% | 2,1% | 2,2% | 2,4% | 2,5% | 2,7% | 2,4% | 2,4% | .. |
| Private pharmaceutical expenditure | 764 | 822 | 879 | 972 | 1.129 | 1.157 | 1.090 | 1.374 | 1.304 | 1.256 | 1.123 | 1.094 | .. |
| Private pharmaceutical expenditure per capita | 70 | 75 | 80 | 88 | 102 | 104 | 98 | 123 | 116 | 111 | 99 | 96 | .. |
| Public pharmaceutical expenditure | 1.278 | 1.502 | 1.805 | 2.165 | 2.425 | 2.869 | 3.510 | 4.040 | 4.530 | 5.090 | 4.280 | 3.979 | 3.215 |
| Public pharmaceutical expenditure per capita | 117 | 137 | 164 | 196 | 219 | 258 | 315 | 362 | 404 | 452 | 378 | 350 | 282 |
| Rebate from pharmaceutical companies | .. | .. | .. | .. | .. | .. | .. | .. | .. | 92 | 78 | 250 | 335 |
| Net public pharmaceutical expenditure | .. | .. | .. | .. | .. | .. | .. | .. | .. | 4.998 | 4.202 | 3.729 | 2.880 |
| Net public pharmaceutical expenditure per capita | | | | | | | | | | 444 | 371 | 328 | 253 |
| Net public pharmaceutical expenditure as % of GDP | 0,9% | 1,0% | 1,2% | 1,3% | 1,3% | 1,5% | 1,7% | 1,8% | 1,9% | 2,2%* | 1,8%* | 1,7%* | 1,4%* |

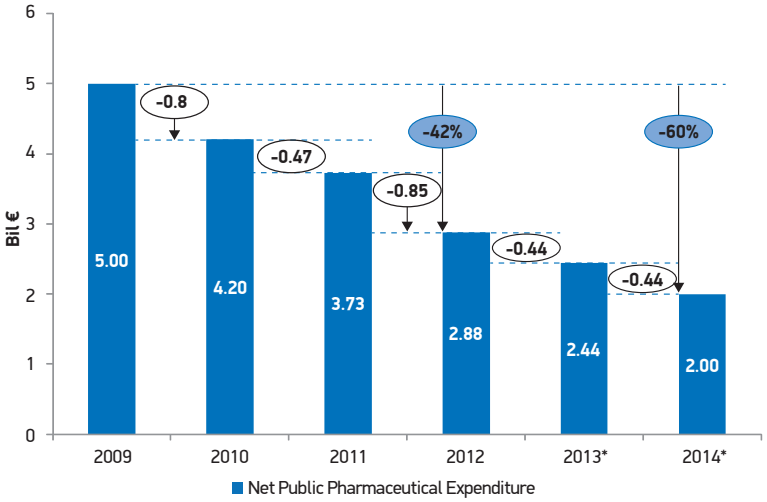
**Sources:** OECD Health Data 2012, ELSTAT 2009, Ministry of Health, General Secretariat for Social Security 2012, IOBE estimates

* Percentages refer to net public pharmaceutical expenditure.

**Note:** Data for the years to 2007 are from the OECD and ELSTAT. Health expenditure figures for 2008 to 2010 are estimates by the OECD, while those for 2011 are estimates by IOBE. Data on public pharmaceutical expenditure come from the Ministry of Health, General Secretariat for Social Security. Data on rebates are provided by SFEE. Total pharmaceutical expenditure for 2008-2011 was estimated by IOBE from data on sales to pharmacies and wholesalers as released by EOF, minus the value of parallel exports.

***The figures for recent years are indicative and in no way substitute for the official figures to be released by ELSTAT based on the System of Health Accounts being developed in collaboration with the National Kapodistrian University of Athens***

## Figure 9: Public pharmaceutical expenditure: post-Memorandum developments and prospects

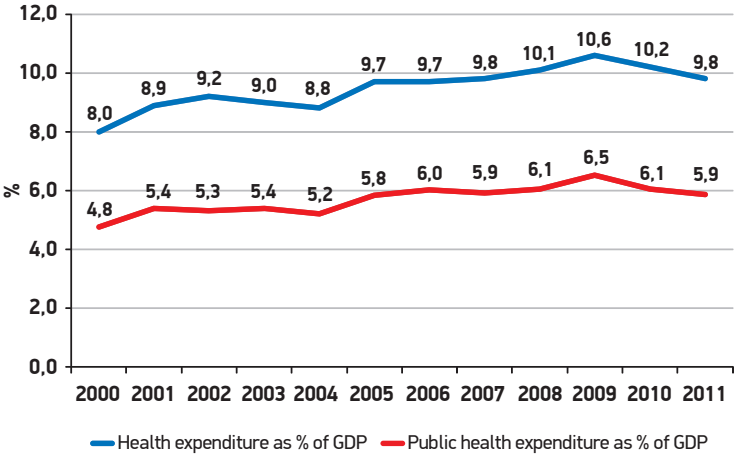



**Source:** Table 4 in this publication and targets of the Medium-Term Fiscal Strategy 2013-2016

The cumulative decrease of €1.27 billion in (net) public pharmaceutical expenditure in the period 2009/2011 resulted from reforms in the pharmaceutical market (changes in the pricing system, increases in rebates to social security funds, reduction in regulated wholesale and retail margins, reduction in the VAT rates, etc.). Furthermore, total health expenditure is estimated to have fallen both as a percentage of GDP and in per capita terms. **Total health expenditure per capita in Greece is 11% lower than the OECD average and comparable to the levels observed in other countries of the European South, while public health expenditure per capita is 27% below the OECD average.**

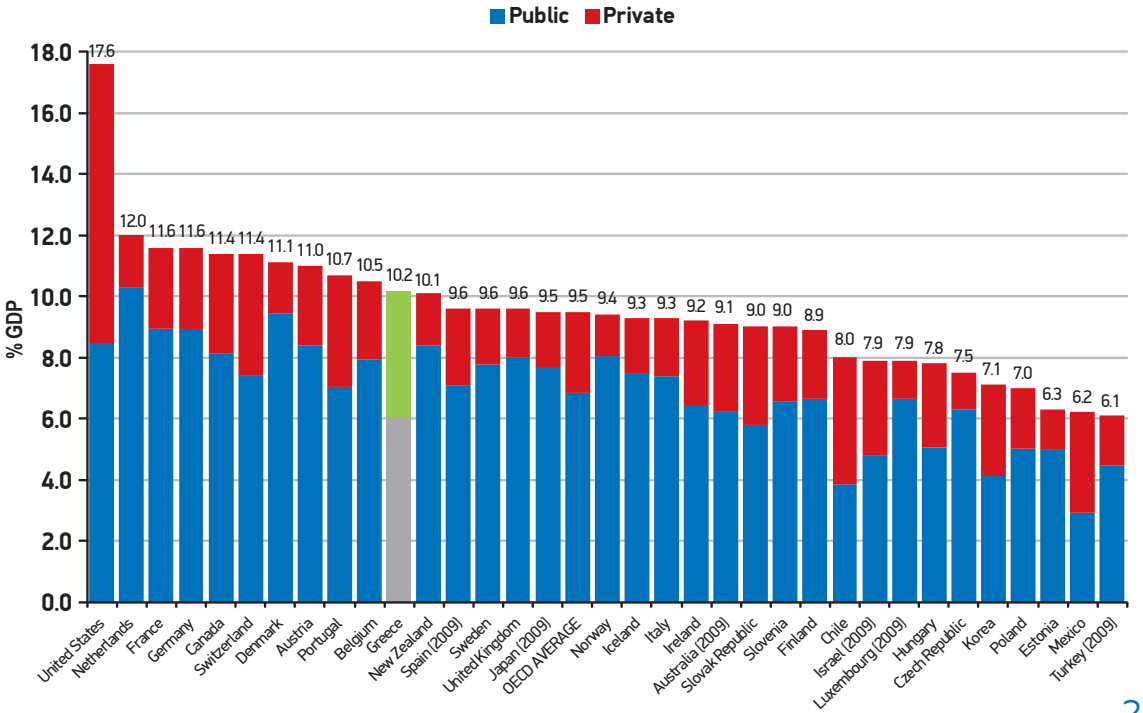


## Figure 10: Total and Public Health expenditure in Greece as a percentage of GDP, 2000- 2011




**Source:** OECD, Health Data 2012. For 2011, IOBE estimate

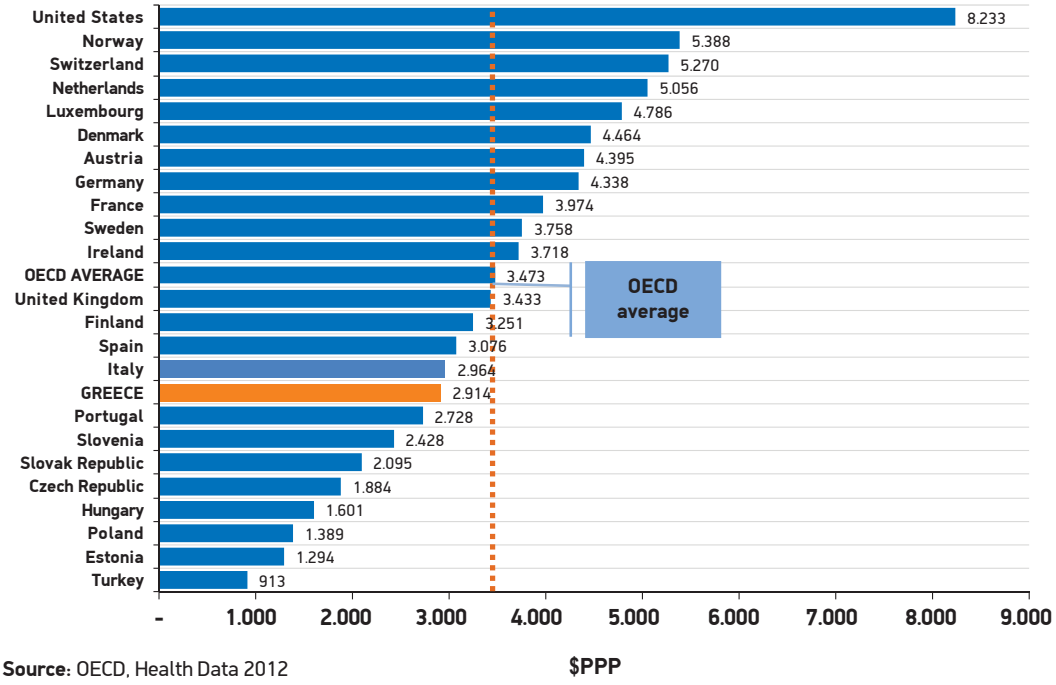
## Figure 11: Health expenditure in OECD countries as a percentage of GDP, 2010




**Source:** OECD, Health Data 2012.

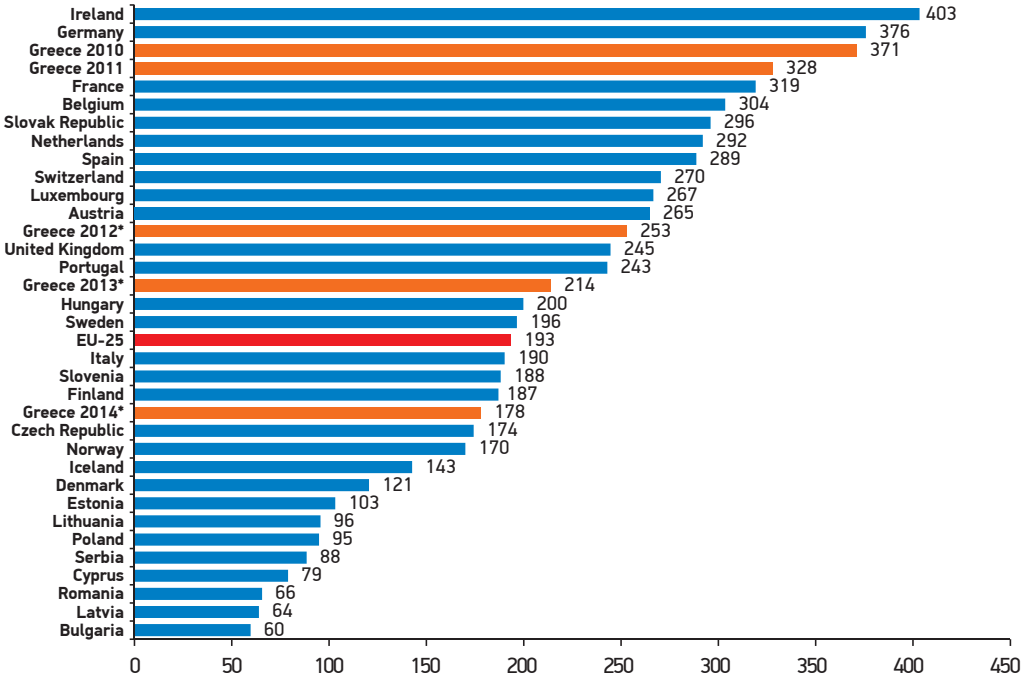


## Figure 12: Health expenditure per capita in OECD countries, in US$ PPP (Purchasing Power Parity) 2010




**Source:** OECD, Health Data 2012

## Figure 13: Net public pharmaceutical expenditure per capita in the EU-25, in € PPP (Purchasing Power Parity), 2010

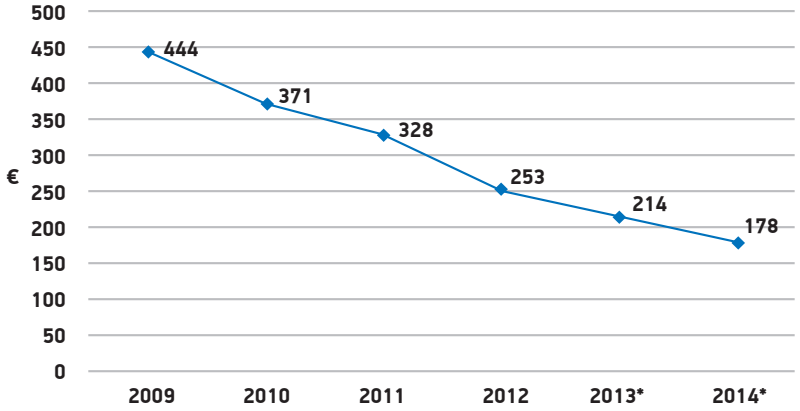





**Source:** OECD, Health Data 2012, data editing by IOBE

Figure 13 above shows net public pharmaceutical expenditure per capita in the EU countries in 2010 and additionally for Greece, its evolution until 2012 and projections up to 2014 (ceteris paribus). **It can be observed that, ranked in terms of expenditure, Greece fell to 3rd place in the EU in 2010 (€371), then to 11th in 2012 (€253) and finally to 18th place in 2014 (€178), 8% below the EU-25 average.**

## Figure 14: Net public pharmaceutical expenditure per capita in Greece, in €

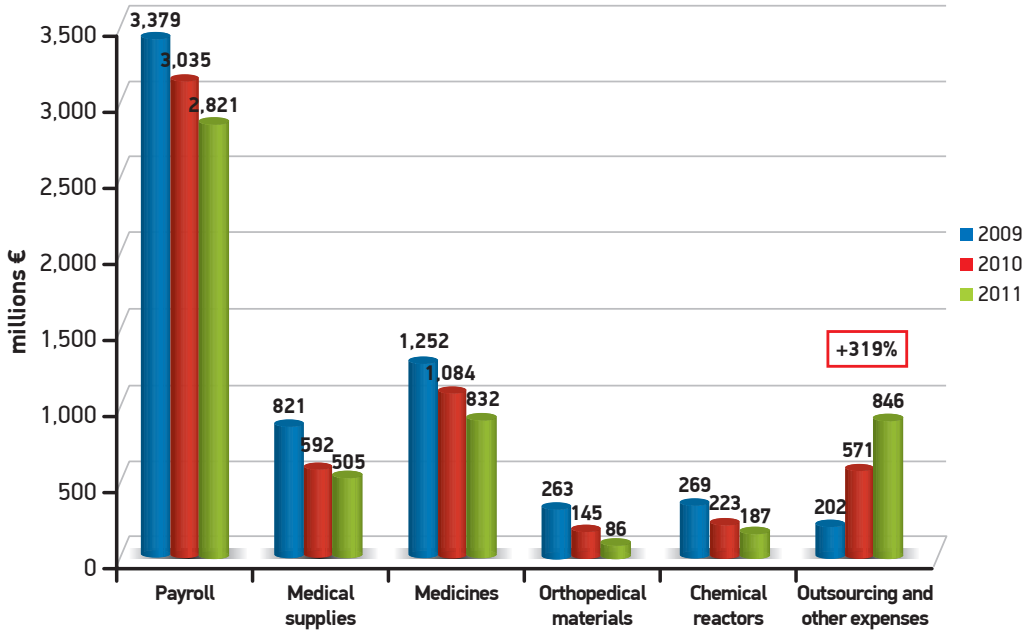



**Source:** IOBE, 2013
* Projections

Net (after rebates and claw-backs) public pharmaceutical expenditure per capita **dropped by 43% between 2009 and 2012** and is projected to decline further by 17% (relative to 2009) by the end of 2014.

The decline in public health expenditure in Greece is also reflected in the data of hospital expenditure. Notably, during the period 2009-2011 hospital pharmaceutical expenditure (as well as payroll costs and costs for the procurement of medical and other supplies) decreased dramatically, by 33.5%. In contrast, however, it should be noted that spending on **outsourcing and other expenses increased by 318.8% during the same period,** hugely offsetting the gains and savings achieved from the other cost centres of the National Health System.

**Figure 15: Breakdown of NHS hospitals' expenditures, 2009-2011**

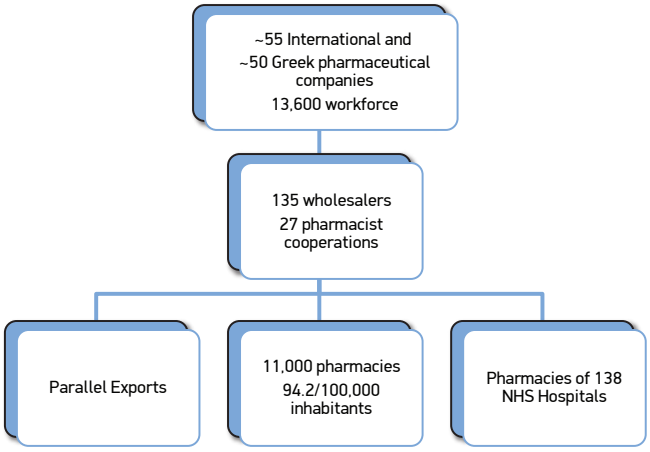



**Source:** ESYNET, 2012

## 5. The supply side: the pharmaceutical industry and the economy

The production and distribution of pharmaceuticals is one of the most dynamic sectors of the Greek economy. In 2011, according to the Labour Force Survey conducted by ELSTAT, approximately 13,600 workers were employed in the manufacture of basic pharmaceutical products and pharmaceutical preparations, making the pharmaceutical industry a vital factor in fostering job creation and growth in Greece.

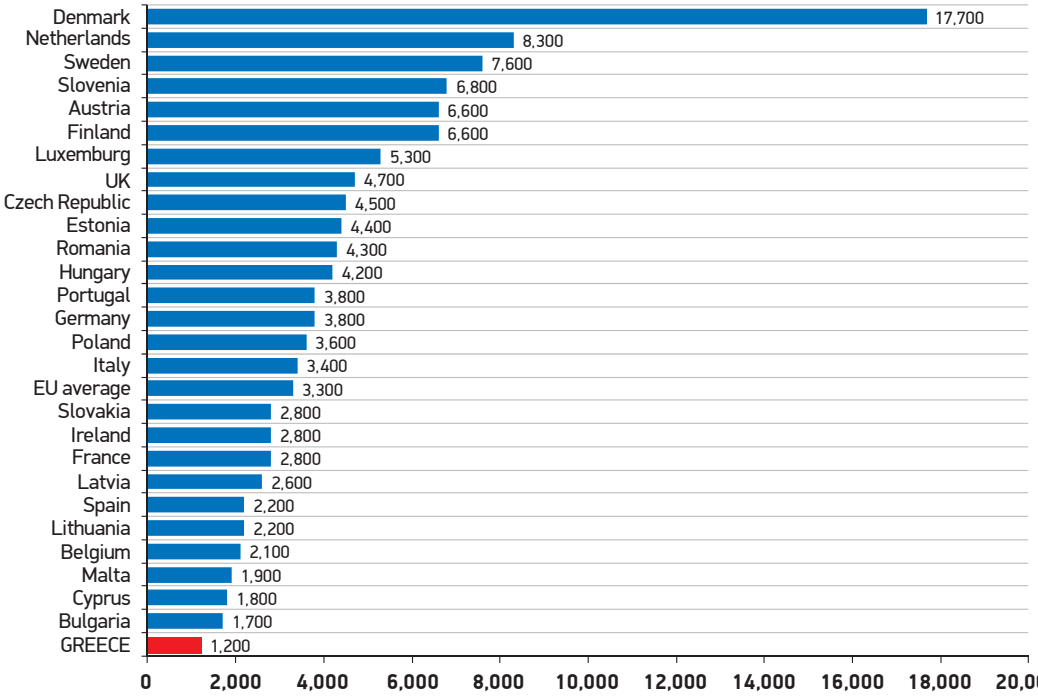
The supply of pharmaceutical products in Greece is defined by the pharmaceutical companies that are active in the sector (engaging in the manufacturing or marketing areas) and the distribution chain. More analytically, medicinal products with the exception of those distributed through hospitals, for which no wholesaler intervenes, follow this course: pharmaceutical company - wholesaler - pharmacy.




**Source:** ELSTAT, Ministry of Health and Panhellenic Association of Pharmaceutical Wholesalers

At the same time, direct sales from companies to pharmacies are permitted. In some occasions the dispense of products from physicians or directly from pharmaceutical companies to the patient is allowed by the Social Insurance Fund. The wholesale segment of the market feature private wholesalers and pharmacist cooperatives. In 2011, 135 wholesalers (data from the Panhellenic Association of Pharmaceutical Wholesalers) and 27 pharmacist cooperatives operated in the domestic market. It should be noted that the population density of pharmacies in Greece is the highest among EU Member States, with a ratio **of one (1) pharmacy per 1,200 inhabitants, compared with the EU-27 average of one (1) pharmacy per 3,300 inhabitants.**

## Figure 16: Pharmacy density (population per pharmacy) in the EU 27, 2010




**Source:** German Pharmacies, Figures, Data, Facts 2011



### EOPYY pharmacies

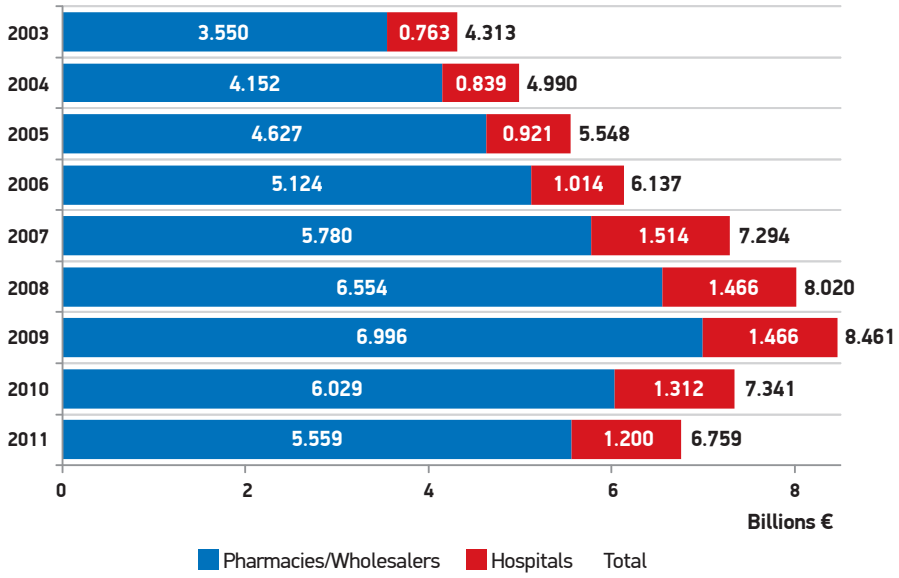
The majority of medicinal products that are high cost or are used for the treatment of serious diseases, as defined in Law. 3816/2010, are provided exclusively by the pharmacies of EOPYY or public hospital pharmacies. EOPYY initially operated five pharmacies in the Attica region and one in Thessaloniki, supplying pharmaceuticals without copayment by the insured and without the need for a confirmation of the prescription by the relevant social security fund. Currently, 19 pharmacies of EOPYY are in operation, while there are plans for increasing their number to 30 nationwide. In other parts of the country, the insured can obtain high cost medicines for the treatment of serious diseases (Law 3816/2010) from EOPYY's local health units, after placing an order. Under a decision published in Government Gazette 1003/B/2.04.2012, the list of Law 3816/2010 was split into two distinct lists: one for pharmaceutical products that are only available from hospitals and EOPYY pharmacies and one for the remaining pharmaceuticals, which are also available from private pharmacies. Products in the former list, i.e. those exclusively available from EOPYY pharmacies, are sold at the hospital price, increased by 5% (plus VAT), while those in the second list are subject to the prices as regulated by the Ministry of Health. It is worth noting that the Panhellenic Pharmacists Association filed for cassation before the Council of State (the Supreme Administrative Court) on June 2012, claiming that EOPYY pharmacies distort competition in the market.

## SALES[3]

The 2011, total pharmaceutical sales amounted to €6.7 billion, of which 82.2% were channeled to wholesalers and pharmacies (including parallel exports which in 2011 accounted for 8.7% of the value of non-hospital sales), while the remaining 17.8% were sold to hospitals.

Sales to pharmacies and hospitals were on an upward path until 2009. Over the last two years, the reduction in medicine prices and other measures aimed at curbing public pharmaceutical expenditure in the context of fiscal consolidation have led to a sharp decline of 20% in pharmaceutical sales.

### Figure 17: Pharmaceutical sales in Greece, 2003-2011 (in billion €)

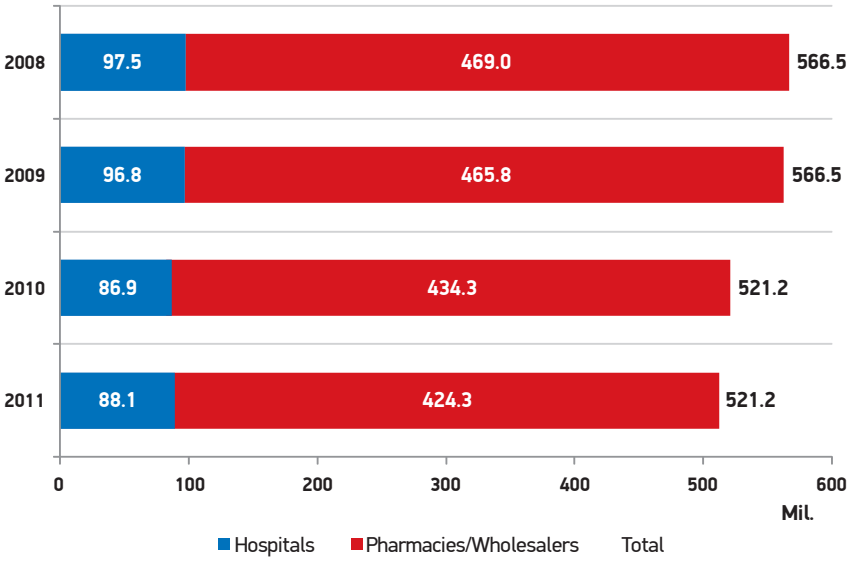



**Source:** EOF 2012



[3]Total pharmaceutical sales are recorded on a monthly basis by the National Organisation for Medicines (EOF) and comprise the value of sales by pharmaceutical companies to hospitals (at hospital prices) and to wholesalers/pharmacies (at retail prices). Volume data on sales are also available (number of packages/boxes or standard units).

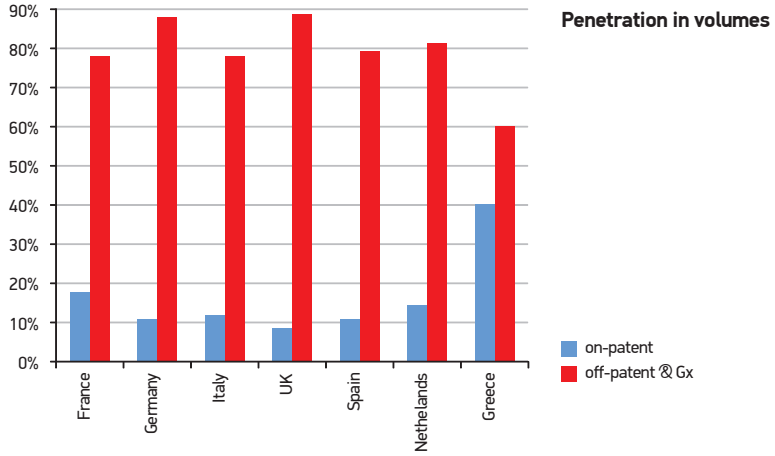
## Figure 18: Pharmaceutical sales in Greece, 2008-2011, number of packages



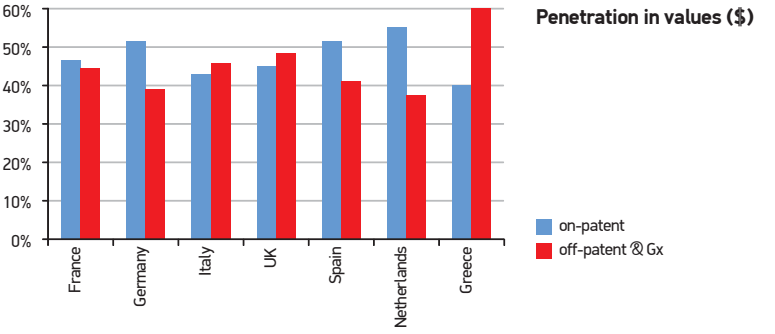

**Source:** EOF 2012

Medicinal products authorised on the market can be classified according to their patent protection status. Non-patent protected medicines include branded products the patent of which has expired (off-patent) and generics (Gx). In Greece, the penetration rate of non-patent protected products reaches 60% in volume terms, which is lower than in other European markets. Unlike what is the case in other countries, when measured in value terms penetration figures do not differ across protected and non-protected products; this implies that the prices of non-patent protected medicines in Greece are higher than in other European countries. By contrast, the prices of patented products are among the lowest in the EU, which is attributable to the pricing method.

## Figure 19: Penetration of on- and off-patent and generic pharmaceuticals in selected countries, 2011




| | France | Germany | Italy | UK | Spain | Netherlands | Greece |
|---|---|---|---|---|---|---|---|
| on-patent | 17.0% | 10.5% | 11.9% | 8.8% | 10.3% | 13.3% | 40.0% |
| off-patent & Gx | 79.1% | 87.6% | 78.3% | 89.0% | 79.0% | 80.9% | 60.0% |




| | France | Germany | Italy | UK | Spain | Netherlands | Greece |
|---|---|---|---|---|---|---|---|
| on-patent | 47,7% | 50,8% | 42,8% | 45,9% | 51,7% | 55,4% | 40,0% |
| off-patent & Gx | 44,6% | 39,3% | 45,5% | 48,8% | 40,3% | 38,0% | 60,0% |

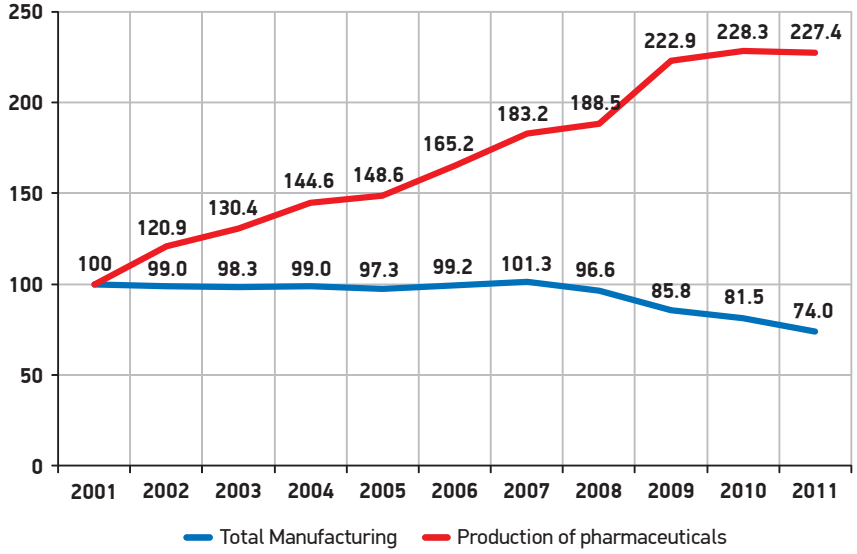
**Source:** IMS, 2012
**Note:** The penetration of generics is estimated at about 18% in value terms



## PRODUCTION

The pharmaceutical industry has recorded strong growth over the last decade, with the volume of its output more than doubling. It is one of the fastest growing sectors of domestic manufacturing, at a time when Greece's total industrial production is on a declining path. This is attributed primarily to heavy investment in production facilities and overall capacity expansion. Although the economic crisis has moderated the dynamic performance of the industry, slowing the growth of domestic production, the losses posted by the industry in the last two years have been smaller than those for the overall manufacturing sector.

## Figure 20: Manufacturing production index and the pharmaceutical sub-index (2001=100)

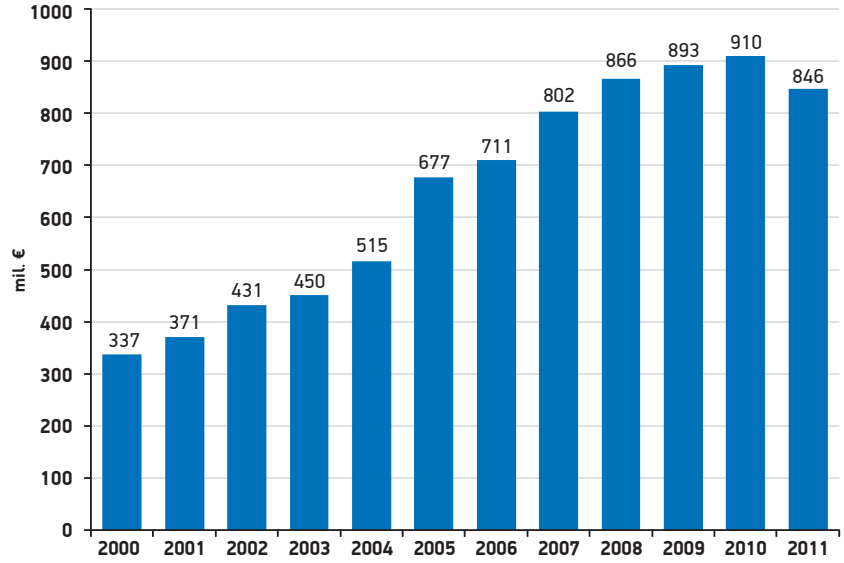



**Source:** IOBE calculations based on data from ELSTAT

In **value terms**, pharmaceutical production in Greece was €846.2 million in 2011, about 7% lower than in 2010. The domestic pharmaceutical industry **has a growing share in domestic industrial production**; in terms of this share, Greece ranks high among OECD countries in terms of the share of manufacturing of pharmaceutical products in overall industrial production.



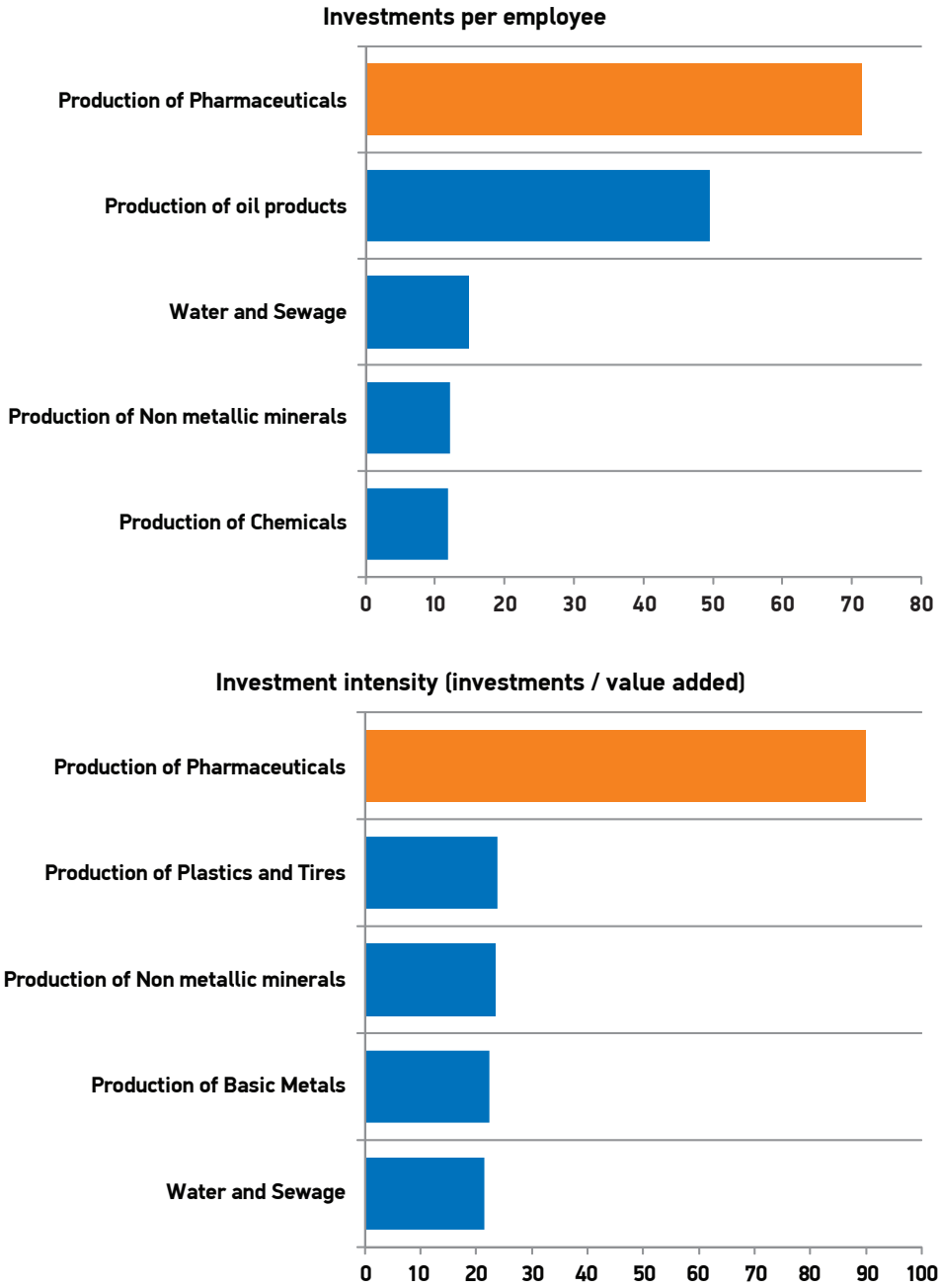
## Figure 21: Domestic production of pharmaceuticals, 2000-2011 (in € millions)




**Sources:** ELSTAT 2012 and Eurostat, PRODCOM database

The domestic pharmaceutical industry is characterised by high labour productivity and, within domestic manufacturing, is the sector with the highest investment intensity.

**Figure 22: Structural indicators of pharmaceutical manufacturing, 2009**




**Source:** Eurostat, Structural Business Statistics, IOBE calculations

## EMPLOYMENT

The European pharmaceutical industry is a high-tech sector offering employment to 660,000 people (Source:EFPIA, The Pharmaceutical Industry in Figures, 2012). In Greece, 13,600 people were employed in the manufacturing of basic pharmaceutical products and pharmaceutical preparations in 2011, according to the Labour Force Survey of ELSTAT (2012). However, adding also the commercial activities of pharmaceutical companies, employment in the sector as a whole is much higher.

Overall, workers employed directly in the healthcare sector exceed 140,000. However, it is worth noting that, in comparison with the OECD average, Greece has a high number of doctors per capita and a low number of nurses per capita.

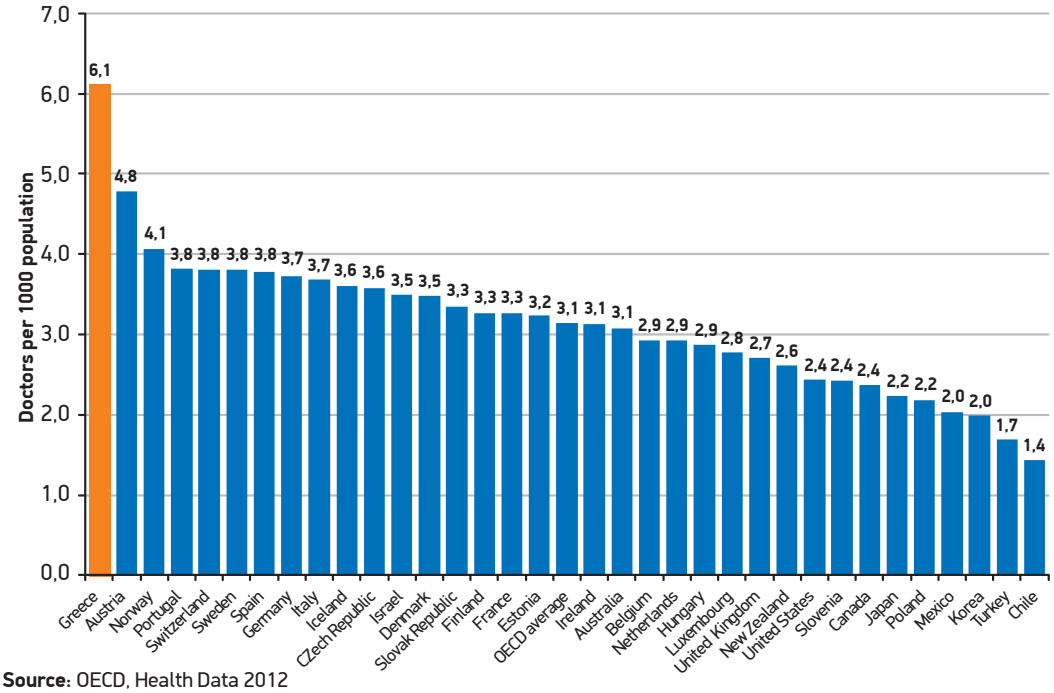
### Table 5: Employment in the health sector

| | 2007 | 2008 | 2009 | 2010 |
|---|---|---|---|---|
| Physicians | 62,207 | 67,540 | 69,030 | 69,265 |
| Specialized Physicians | 38,463* | 39,189* | 41,239 | 41,628 |
| Dentists | 14,429 | 14,694* | 14,774 | 14,661 |
| Pharmacists | 10,031* | 10,228* | 10,458* | 10,700* |
| Nursing staff** | 37,718 | 38,291** | 37,306** | |

**Source:** OECD, Health Data 2012
* IOBE estimates
** Including registered nurses and nursing aides

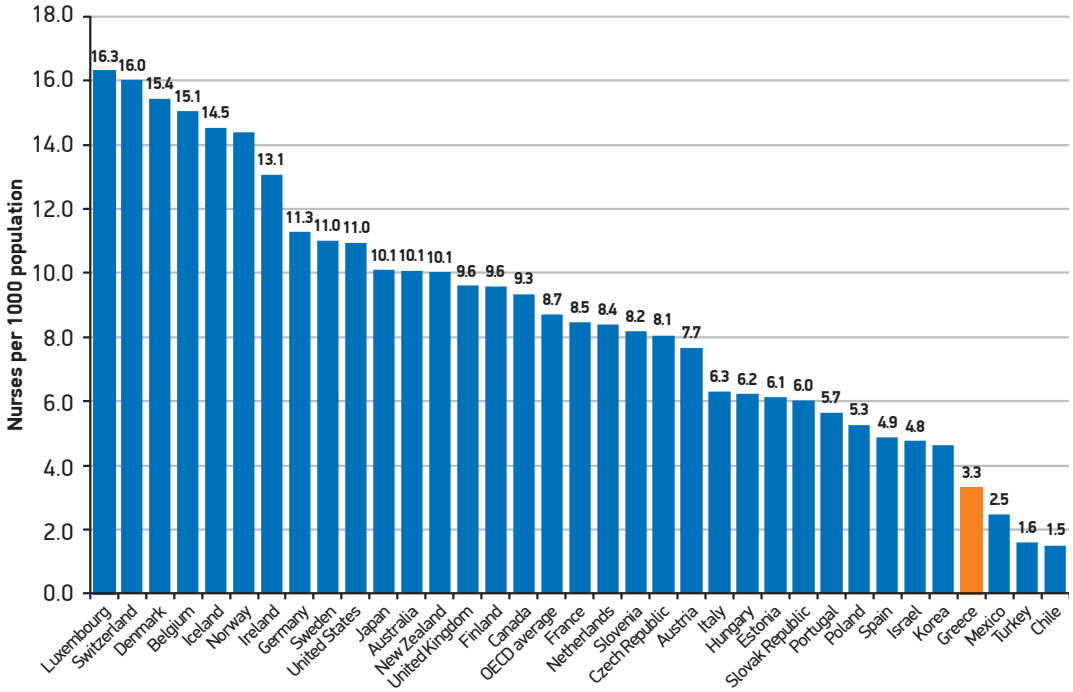


### Figure 23: Practicing physicians per 1,000 population in OECD countries, 2010




**Source:** OECD, Health Data 2012

## Figure 24: Nurses per 1,000 population in OECD countries, 2010



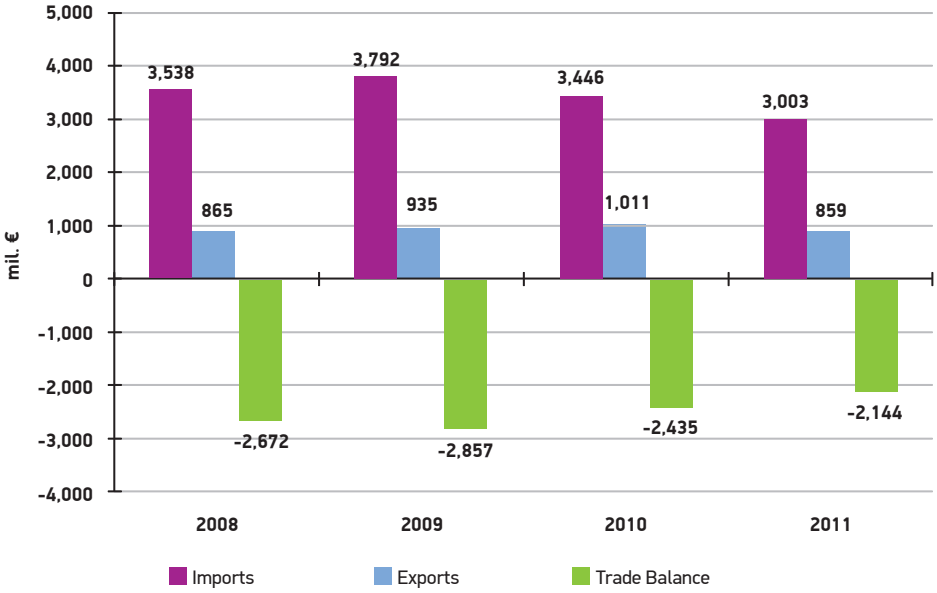



**Source:** OECD, Health Data 2012

## EXTERNAL TRADE

The pharmaceutical industry is an important driver of developments in Greece's external trade. Imports and exports of medicinal products amounted to €3.0 billion and €859 million respectively in 2011. Compared with 2010, imports of pharmaceutical products fell by 12.9% and exports by 15%. The pharmaceutical trade deficit exceeds €2 billion, but has a tendency to decline over the last few years.

## Figure 25: Pharmaceutical trade balance (in € millions)

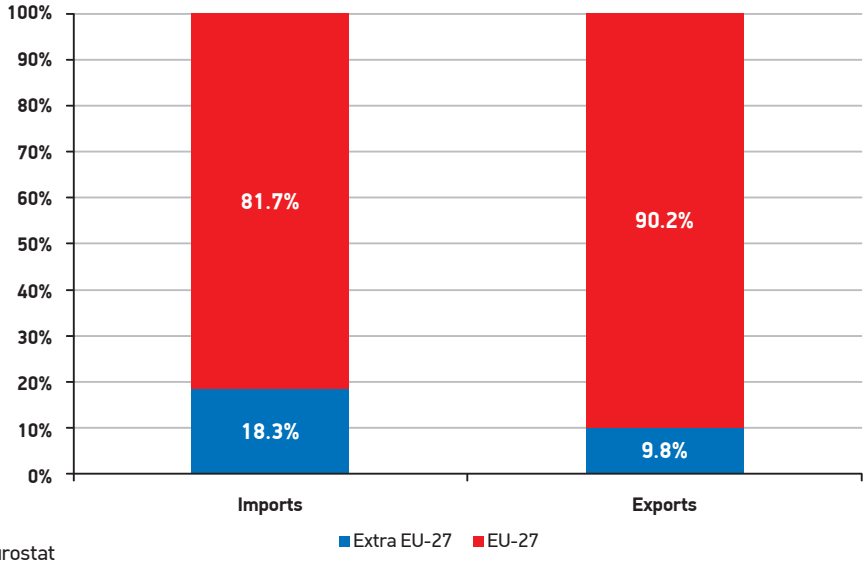



**Source:** Eurostat

Of the total amount of pharmaceutical imports to Greece in 2011, 81.7% came from other EU countries, while the remaining 18.3% came from outside the EU. A similar pattern can be seen in exports, with 90.2% of Greek pharmaceutical exports directed towards other EU markets.



## Figure 26: Intra- and extra EU trade in pharmaceuticals per geografical region, 2011

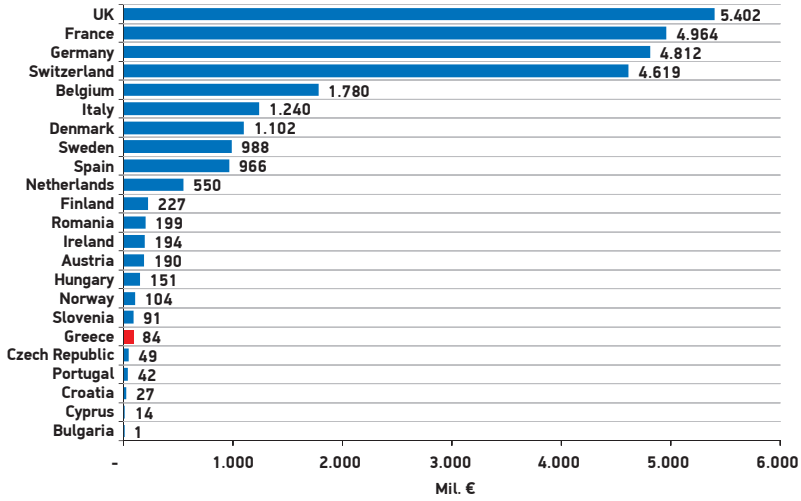



**Source:** Eurostat

## RESEARCH AND DEVELOPMENT (R&D)

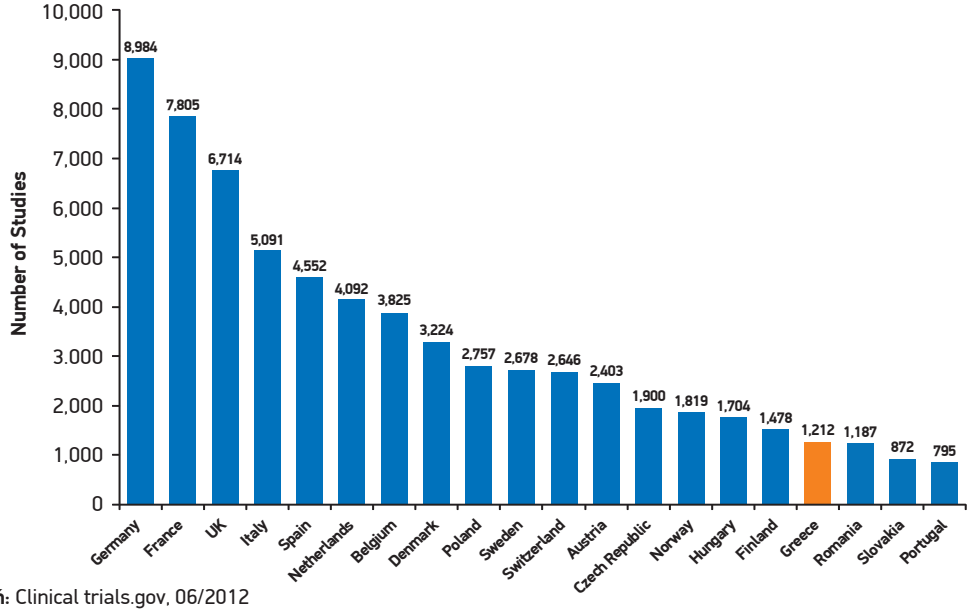
Although R&D of innovative medicines is a key driving force for growth in the pharmaceutical market, Greece has one of the lowest rankings among EU countries in this area, as it has yet to create an appropriate environment for attracting and hosting clinical trials. This is an area with a strategic growth potential that can have a multiplying effect on the national economy, contributing to the employment of high-skilled staff and helping to restore conditions for higher domestic added value in the future.

### Figure 27: Pharmaceutical R&D expenditures in Europe




**Source:** EFPIA, The Pharmaceutical Industry in Figures, 2012

### Figure 28: Number of clinical trials (all phases and stages)




**Πηγή:** Clinical trials.gov, 06/2012

## FINANCIAL DATA ON PHARMACEUTICAL COMPANIES

The financial condition of the pharmaceutical industry has deteriorated over the last three years, which is reflected in lower sales and negative financial results. It should be noted that the significant reduction of the receivables of pharmaceutical companies is due to the repayment of public sector arrears for the period 2007-2009 with zero-coupon Greek government bonds. These bonds were subject to a haircut of 53.5% on their nominal value and were exchanged for new bonds maturing 30 years later. As a result, **the pharmaceutical companies incurred a loss of €1 billion**.

### Table 6: Aggregate balance sheet data of pharmaceutical companies

| | 2009 | 2010 | 2011 | 2009/10 | 2010/11 |
|---|---|---|---|---|---|
| Number of firms | 106 | 106 | 106 | | |
| Fixed assets | 1,011,362,621 | 1,101,116,101 | 1,192,267,137 | 8.2% | 7.6% |
| Net fixed assets | 527,349,778 | 590,100,267 | 590,981,447 | 10.6% | 0.1% |
| Depreciation | 484,012,843 | 511,015,834 | 601,285,690 | 5.3% | 15.0% |
| Current assets | 5,449,787,727 | 5,234,871,201 | 3,690,933,000 | -4.1% | -41.8% |
| Accounts receivable | 4,129,674,394 | 4,169,951,820 | 2,631,648,564 | 1.0% | -58.5% |
| Inventories | 1,051,517,565 | 898,199,895 | 833,055,652 | -17.1% | -7.8% |
| Securities | 12,648,325 | 719,356,623 | 395,738,530 | 98.2% | -81.8% |
| Cash & cash equivalents | 268,595,769 | 166,719,487 | 226,228,784 | -61.1% | 26.3% |
| **Total assets** | **5,995,976,579** | **5,844,531,248** | **4,306,080,437** | **-2.6%** | **-35.7%** |
| Equity | 1,164,310,694 | 852,090,961 | 785,157,744 | -36.6% | -8.5% |
| Long-term accounts payable | 1,107,036,865 | 777,349,881 | 731,042,464 | -42.4% | -6.3% |
| Short-term accounts payable | 3,724,629,020 | 4,215,090,406 | 2,789,880,229 | 11.6% | -51.1% |
| Total accounts payable | 4,831,665,885 | 4,992,440,286 | 3,520,922,693 | 3.2% | -41.8% |
| **Total liabilities** | **5,995,976,579** | **5,844,531,248** | **4,306,080,437** | **-2.6%** | **-35.7%** |
| **Turnover (sales)** | **5,631,656,128** | **4,987,065,353** | **4,742,251,628** | **-12.9%** | **-5.2%** |
| Cost of goods sold | 3,853,142,786 | 3,601,157,954 | 3,185,113,038 | -7.0% | -13.1% |
| Gross profit | 1,778,513,342 | 1,385,907,400 | 1,557,138,590 | -28.3% | 11.0% |
| **Net profit** | **361,191,749** | **-167,846,229** | **-80,994,680** | .. | .. |

**Source:** IOBE calculations based on data from firms' financial statements. Amounts are expressed in euros

## Table 7: Consolidated common-size statement of pharmaceutical companies

| | 2009 | 2010 | 2011 |
|---|---|---|---|
| Fixed assets | 16.9% | 18.8% | 27.7% |
| Net fixed assets | 8.8% | 10.1% | 13.7% |
| Depreciation | 8.1% | 8.7% | 14.0% |
| Current assets | 90.9% | 89.6% | 85.7% |
| Accounts receivable | 68.9% | 71.3% | 61.1% |
| Inventories | 17.5% | 15.4% | 19.3% |
| Securities | 0.2% | 12.3% | 9.2% |
| Cash & cash equivalents | 4.5% | 2.9% | 5.3% |
| **Total assets** | **100.0%** | **100.0%** | **100.0%** |
| Equity | 19.4% | 14.6% | 18.2% |
| Long-term accounts payable | 18.5% | 13.3% | 17.0% |
| Short-term accounts payable | 62.1% | 72.1% | 64.8% |
| Total accounts payable | 80.6% | 85.4% | 81.8% |
| Total liabilities | 100.0% | 100.0% | 100.0% |
| **Turnover (sales)** | **100.0%** | **100.0%** | **100.0%** |
| **Cost of goods sold** | **68.4%** | **72.2%** | **67.2%** |
| Gross profit | 31.6% | 27.8% | 32.8% |
| Net profit | 6.4% | -3.4% | -1.7% |

**Source:** IOBE calculations based on data from firms' financial statements

## 6. Pricing of Medicinal Products

### PRICING SYSTEM

In recent years, Greece has used various systems of international reference pricing for pharmaceutical products. During 2005-2008, a fixed reference system applied, whereby the price of a medicinal product was determined at the average price in the three countries with the lowest prices, of which two were chosen from among the EU-15 countries plus Switzerland and the third was one of the 10 countries that joined the EU on 1 May 2004 (Law 3408/2005, Government Gazette 272 A).

In September 2009, the pricing method was changed and it was decided that the ex-factory price for new pharmaceuticals in Greece would be equal to the average of the three lowest prices in the other member countries of the EU-27 (Law 3790/2009) which released official price data. The list of EU countries with available official data was made public in the first Drug Price Bulletin of each year.

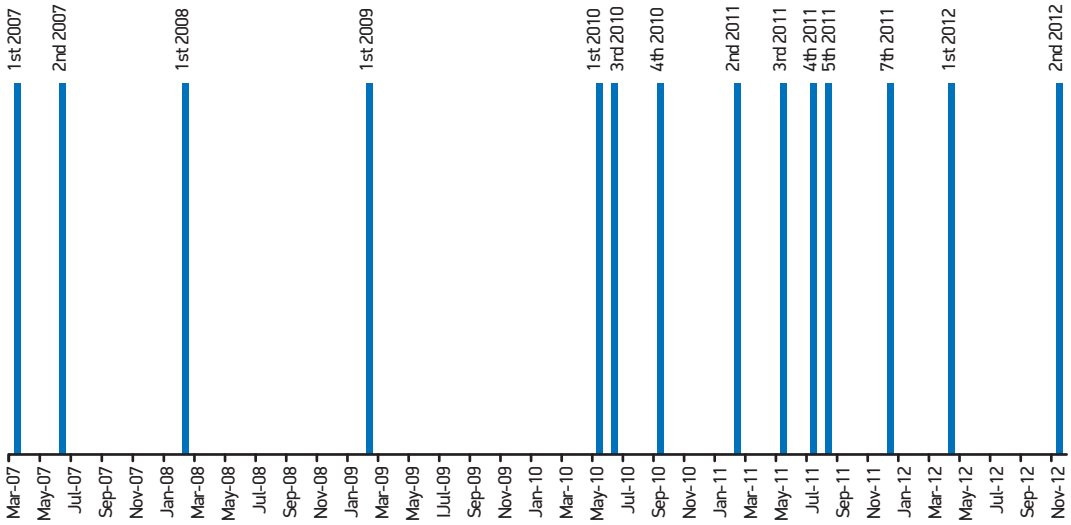
Before being priced in Greece, a medicinal product should have been priced, for the same form and strength, in **at least three (3) of the EU countries**. As four EU countries (Malta, Estonia, Sweden and Denmark) out of the total 26 reference countries did not publish reliable data on prices, pricing had to be based on the average of the three lowest prices among the other 22 EU countries.



The national legislation, in line with relevant EU law, provides for the issuance of a Drug Price Bulletin (DPB) by the competent authority every 3 months. The tables below show the dates and frequency of issuance of DPBs from mid-2007 to the latest release on 2 November 2012. That DPB re-priced 12,202 formulations, of which 803 are medicines for serious conditions, 806 are OTC, 493 are on the negative list and 10,100 are on the positive list, as far as their reimbursement status is concerned.

Tables 8 and 9 show the frequency of issuance of Drug Price Bulletins. From 2010 onwards, DPBs that include re-pricing seem to have been more frequent, but the opposite trend can be observed for DPB versions that include approvals for new active substances. **Since January 2011, there has been no pricing for new originator products**, which impedes timely patient access to innovative treatments. Moreover, the last re-pricing bulletin (the second for 2012) contains significant errors, as prices for several products are the lowest across the EU, thereby raising concerns about the adequate supply of these products in the Greek market. Obviously, there is an urgent need for a corrective DPB, expected in December 2012. It is also worth noting that this was the first Bulletin to be issued by EOF under Article 16 of Law 4052/12. The responsibility for the issuance of earlier DPBs lay with the General Secretariat for Commerce of the Ministry of Development, succeeded as from March 2011 by the Ministry of Health under Article 39 of Law 3918/2011.

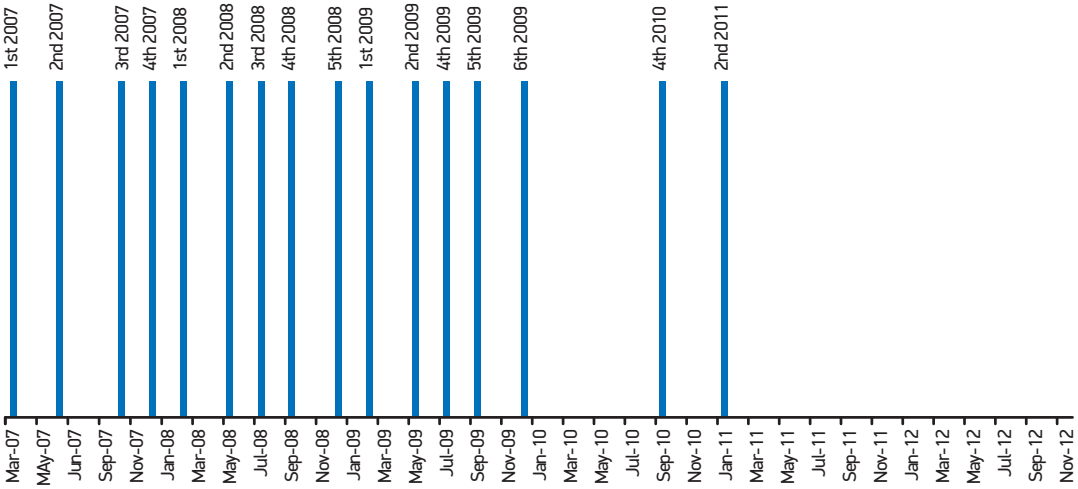
## Table 8: Dates of release of Drug Price Bulletins that included price changes, 2007-2012




**Source:** IOBE compilation of data from the General Secretariat for Commerce, the Ministry of Health and Social Solidarity and EOF

## Table 9: Dates of release of Drug Price Bulletins that included price approvals for new active substances, 2007-2012






**Source:** IOBE compilation of data from General Secretariat for Commerce, the Ministry of Health and Social Solidarity and EOF

**Price definitions**

**Maximum Wholesale price:** The maximum wholesale price of a medicinal product is the price at which it is sold to pharmacies. This does include the wholesale gross profit margin calculated as a percentage of the net ex-factory price. Until March 2012, the net profit margin for medicinal products reimbursed by Social Security Funds (SSFs) was set at 5.4% of the net ex-factory price, lowered to 4.9% thereafter. Wholesale profit margins are set at 7.8% of the ex factory price for non-prescription (OTC) drugs, 5.4% of the ex factory price for prescription drugs not reimbursed by SSFs, and 2% of the hospital price (defined in this case as "special wholesale price") for drugs of paragraph 2 of Article 12 of Law 3816/2010.

**Maximum Retail price:** The maximum retail price of a medicinal product is the price at which it is sold to the public by pharmacies and is determined by adding the legal retail mark-up to the wholesale price (35% for medicines that are not reimbursed by SSFs, 32.4% for medicines reimbursed by SSFs with a wholesale price of up to €200, 16% for drugs under Law 3816 having a special wholesale price of up to €200 and a fixed amount of €30 along with a regressive percentage of 8%, 7% and 6% for drugs with a wholesale or special wholesale price of €201-€ 500, €501-1000 and €1001+, respectively) plus VAT at a rate of 6.5%. Since October 2012, the profit margin of pharmacists for SSF-reimbursed medicines with a wholesale or special wholesale price of over €200 has been reduced to €30. The maximum retail prices are uniform throughout the country, except in areas where a reduced VAT rate is applicable.

**Ex-Factory price:** The net producer price or ex-factory price of a medicinal product is the price at which it is sold by importers, manufacturers or packagers to wholesalers. .The net price is determined based on the wholesale price reduced by: (i) 7.24% for non-prescription drugs; (ii) 5.12% for prescription drugs that are not reimbursed by the SSFs; and (iii) 4.67% for pharmaceuticals reimbursable by SSFs.

**Maximum Hospital price:** The maximum hospital price of a medicinal product is the price at which it is sold by importers, manufacturers or packagers to the State, public hospitals, Social Care Units and the public entities listed in paragraph 1 of Article 37 of Law 3918/2011, pharmacies of private hospitals with over 60 beds and, in the case of products in the list of paragraph 2 of Article 12 of Law 3816/2010, pharmacies and wholesalers. The maximum hospital price is based on the wholesale price reduced by 13%.



## PRICE STRUCTURE OF PHARMACEUTICAL PRODUCTS

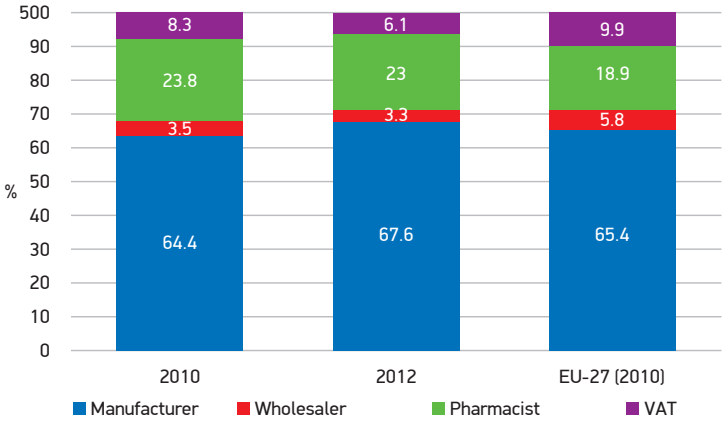
As from 2012, the prices of medicines reflect the lower profit margins (mark-ups) of wholesalers and pharmacists. Wholesale margins vary depending on the product's reimbursement status (negative or positive list, list of Law 3816/2011, OTC). Pharmacists' profit margins, on the other hand, vary depending on the wholesale price of each product. For medicines included in the positive list and having a wholesale price of less than €200, the profit margins and the price structure are as follows:

## Table 10: Mark-ups in the pharmaceutical supply chain, 2012

| | Positive reimbursed list | Products for serious diseases | OTC | Negative list |
|---|---|---|---|---|
| Wholesalers (on the net ex-factory price) | 4.9% | 2.0*% | 7.8% | 5.4% |
| Pharmacies (on the wholesale price) | 32.4% | 16.0**% | 35.0% | 32.4% |
| Pharmacies (on wholesale/ special wholesale price >€200) | €30 | €30 | 35.0% | 32.4% |

*On the hospital price
**On the special wholesale price
**Πηγή:** IOBE, 2012

## Figure 29: Price structure of reimbursed drugs with wholesale prices < €200 (retail price =100)




**Sources:** IOBE and EFPIA 2010 estimates

The current price structure of medicines, with the applicable VAT rate of 6.5% and the mark-ups along the supply chain introduced in 2012 is illustrated in the above figure. In addition, the figure shows the respective price structure for 2010 in Greece and the EU-27 average.

The price structure of prescription drugs with a wholesale price of more than €200 depends on the price level. Under the new provisions on retail mark-ups, the profit margin of a community pharmacy depends, on average, on the share, within its total sales, of pharmaceuticals with a wholesale price > €200; the margin varies between from 12% when the wholesale price is just over €200 to below 2% when the wholesale price exceeds €1,500. Based on the composition of consumption (products with a wholesale price of <€200 have a market share of 91%) and taking into account the pharmacy discounts and rebates, the average profit margin of pharmacies is estimated at about 19%.

In 2011, the total mark-up of the supply chain in Greece was one of the highest in the EU; however, following the recently enacted legislation, it is estimated to have declined by about 5.5 percentage points.

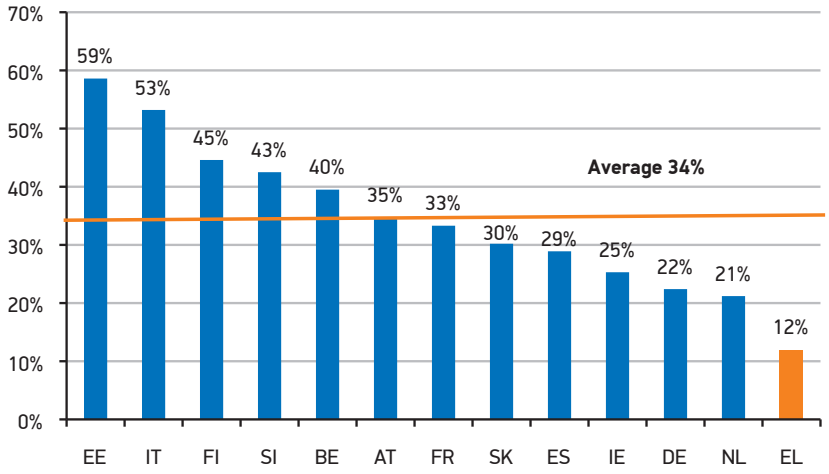
## Table 11: Mark-ups in the pharmaceutical supply chain in selected countries, 2011

| | % mark-up | Price/ packet (€) | Margin/ packet (€) | Packets per capita | Margin per capita (€) |
|---|---|---|---|---|---|
| Bulgaria | 27.49% | 4.46 | 1.14 | 17.55 | 20.06 |
| Hungary | 19.57% | 7.06 | 1.31 | 18.50 | 24.15 |
| Poland | 29.55% | 4.92 | 1.32 | 16.97 | 22.43 |
| Romania | 26.35% | 5.63 | 1.35 | 14.80 | 19.95 |
| Italy | 51.72% | 6.89 | 3.37 | 23.35 | 78.73 |
| Portugal | 38.89% | 10.48 | 3.67 | 18.39 | 67.49 |
| France | 34.89% | 11.77 | 3.81 | 23.36 | 88.98 |
| Greece | 42.19% | 9.88 | 3.90 | 30.93 | 120.59 |
| Spain | 46.76% | 9.00 | 3.91 | 22.98 | 89.92 |
| Netherlands | 41.84% | 11.20 | 4.57 | 15.18 | 69.38 |
| Austria | 42.12% | 13.61 | 5.22 | 17.02 | 88.83 |
| Belgium | 31.03% | 21.04 | 6.10 | 11.72 | 71.46 |
| Finland | 44.09% | 20.98 | 8.93 | 10.10 | 90.16 |
| Ireland | 54.55% | 20.13 | 9.33 | 14.68 | 137.00 |
| Norway | 52.04% | 25.79 | 10.35 | 8.67 | 89.70 |
| Switzerland | 40.98% | 33.20 | 12.89 | 9.31 | 120.05 |

**Source:** IMS Pricing database; based on combined regulated wholesaler and pharmacy margin, 2011 Rx only



## Figure 30: Average patient copayment for medicines in the positive list, in selected countries




**Source:** EFPIA, 2012

## Table 12: Reimbursement and copayment policies in selected countries

| | Policies for patient copayment |
|---|---|
| **Austria** | For reimbursable products patients pay a fixed prescription fee of €4.60 in 2006 |
| **Belgium** | Coinsurance from 25% up to 80% depending on the family's net income. For serious or chronic diseases 0% patient copayment |
| **Denmark** | Depending on the annual pharmaceutical expenditure, the copayment rate varies from 100% to 15% |
| **France** | Fixed fee of €0,53 and copayment equal to the difference of the retail price and the reimbursement rate |
| **Germany** | Patient copayment at a rate of 10% and minimum and maximum contributions are €5 and €10 respectively. Drugs whose price is 30% lower than the reference price are exempt from copayment, a rule which applies to more than 12,000 pharmaceutical products |
| **Greece** | All drugs that gain price approval are reimbursed at a fixed rate of 75%, 90% or 100%. The categorisation is based on the ATC4 classification. Negative list, OTC and 'lifestyle' products are not reimbursed. |
| **Italy** | Prescription fee of €1 or €2 which is applied in few areas |
| **Netherlands** | No specific policy to determine the copayment rate. Patients pay 100% of the difference between the reimbursable and retail price. |
| **Spain** | Depends on the drug's price, generally it is around 40% of the drug's price |
| **Sweden** | Depends on the private pharmaceutical expenditure, copayment rates vary from 100% to 10% and have a cap of €194 per year |
| **Switzerland** | A deductible and a coinsurance rate of 10% above that deductible (20% for off-patent prototypes for which there available generics in the market) |

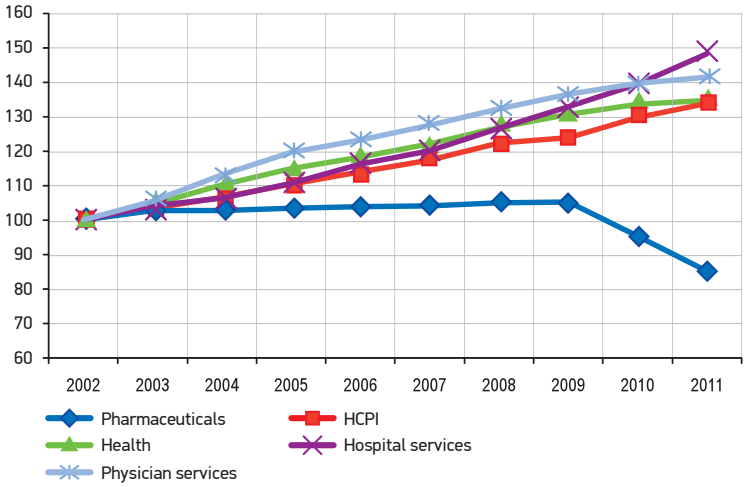
**Source:** Lambrelli and o'Donnell, "Why Does the Utilization of Pharmaceuticals Vary So Much Across Europe? Evidence from Micro Data on Older Europeans", HEDG Working Paper 09/06, 2009



### PHARMACEUTICAL PRICE INDICES

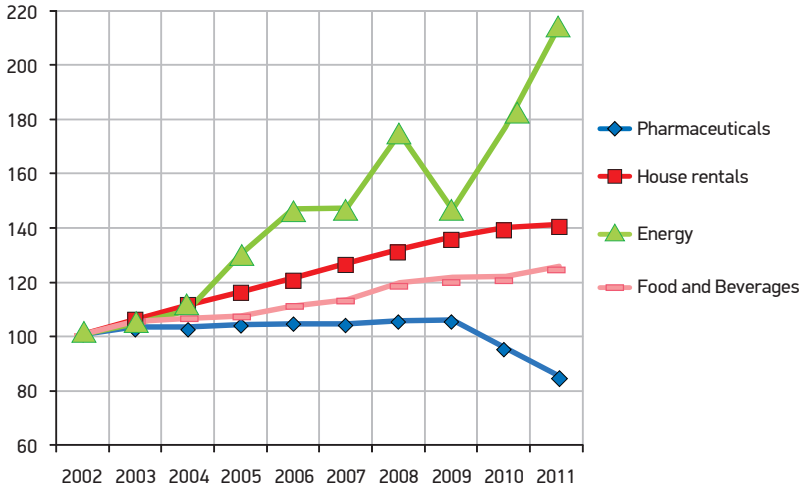
The prices of medicinal products in Greece followed a moderate, slightly upward course until 2009, significantly weaker than HICP inflation. The pricing reforms introduced from 2009 onwards are reflected in **a decline of 19.1% in the pharmaceutical price index during 2010-2011.**

## Figure 31: Pharmaceutical price index vs. HICP and health price indices (2002=100)




**Πηγή:** Eurostat, 2012

## Figure 32: Pharmaceutical price index vs. price indices of other basic goods (2002=100)




**Source:** Eurostat, 2012

## 7. Reimbursement

In 1998, a list setting out the medicinal products that could be reimbursed by social security funds (positive list) was introduced in the Greek health system, in accordance with Article 20 of Law.2458/1997. Against the background of significant delays in access to new medications, inconsistently with Community legislation (Directive 89/105/EEC), and the questionable gains from its introduction, the list was abolished in 2006. According to Law 3457/2006, all prescription medicines would be automatically reimbursed at a rate of 75%, 90% or 100% depending on their indication.

By recent Ministerial Decisions (Government Gazette 479 B/2012 and 2883 B/2012) copayment rates for chronic diseases were increased. The major changes are:

Higher copayment of 25%, up from 10%: rheumatoid arthritis, psoriasis, SLE, vasculitis, ankylosing spondylitis, scleroderma, COPD, pituitary adenomas, osteoporosis, Paget's disease, Crohn's disease, cirrhosis of the liver.

Higher copayment of 10%, up from 0%: Alzheimer's disease, dementia, epilepsy, Buerger's disease.

Also, zero copayment was introduced for patients under haemodialysis, but only for medications closely related to their condition.



In 2010, a new positive list of prescription drugs was introduced (Article 12 of Law 3816/2010), separating the pricing and reimbursement processes. The positive list, published in Government Gazette 2141/B/26.9.2011, classified medicinal products according to the system of Anatomical Therapeutic Chemical Classification (ATC) of the World Health Organization. A reference price system was also introduced according to the therapeutic category of pharmaceutical products.

With Ministerial Decision 104744, Government Gazette B 2912/30.10.2012, products in the positive list were classified at ATC4 level. For cases where an ATC4 class includes products authorised for more than one indication, sub-classification by active substance at the same ATC level is possible, while new classes can be developed where an active substance of an ATC4 class is not therapeutically interchangeable and automatically substitutable for the main indication with the rest of the class.

The Reference Price (RP) of each therapeutic class was defined as the lowest daily treatment cost (DTC) among all reference drugs (with or without patent protection) and the average of all the generic pharmaceuticals in the class, i.e.: RP = lowest DTC among 1. .. i patent protected products, 1... n non-patent protected, average DTC of 1 ...m generics.

Under the same Ministerial Decision, certain medicinal products can be classified at ATC5 level, if after 1 January 2010 they have been approved through an accelerated process by the FDA or the EMA, or have been classified in an ATC5 category in the corresponding positive list of Germany, or in ASMR 1 or 2 category in France, following positive HTA assessment that recognizes their therapeutic benefit.

A subcategory of the positive list are the medicines used for the treatment of the serious diseases listed in Article 12, paragraph 2 of Law 3816/2010. These medicines are fully reimbursed by SSFs and are available, under restrictions, from hospital pharmacies, EOPYY pharmacies and private pharmacies. Pharmaceutical companies are required to sell them at hospital prices only, while reduced profit margins apply throughout the supply chain (wholesalers, private pharmacies).

There is also a list of non-reimbursable prescription medicines (negative list, Government Gazette 559/B/8.4.2011), as well as a list of non-prescription medicines (OTC) that can be sold without a prescription.

Law 4052/2012, Article 21 paragraph 5b, introduced prescribing by active substance, whereby medicinal products are categorised at level ATC5 and are reimbursed at a "social security price", which corresponds to the value of the cheaper generic with the same active substance. The patient is required to pay any price difference above the social security price, in addition to the primary copayment. As from mid-April 2012, the measure is effective for NHS hospitals and on a pilot basis to physicians of social security funds (SSFs) and only for the first 10 most consumed active substances. The expansion of the scope of the measure to encompass all active substances was initially scheduled for June 2012, under Ministerial Decision 149 (Government Gazette 545 B/2012), but finally occurred on 1 October 2012, following an EOPYY circular (ref. no. 40890/28.09.2012) specifying that a physician can e-prescribe by active substance rather than by brand name.



By Ministerial Decision EMP4, Government Gazette B 3057/18.11.2012, prescribing by active substance became mandatory, without an option to prescribe by brand name. A number of exemptions to this measure were however specified, as follows:

- Medications for transplant and immunocompromised patients
- Medicines with narrow therapeutic range
- Blood derivatives
- Insulins
- Vaccines
- Organics / biosimilars
- Anti-convulsants
- Anti-psychotic and anti-schizophrenic medicines
- Anti-asthmatic medicines
- Medications for chronic, degenerative and autoimmune diseases
- Products administered with devices that require patient education
- Medications that cause allergies and reactions

The brand name may be specified alongside the active substance in cases of patients suffering from chronic diseases who are sufficiently and effectively adjusted to their current treatment regimen.

SFEE's position is that the cases listed above should not be included in the ceiling of 15% applying to the value of prescriptions by active substance, under paragraph 6 of the above-mentioned Ministerial Decision. This would help to preserve the high-quality and effectiveness of pharmaceutical provision to the public.

Furthermore, there is still a need for clarifications about the parallel implementation of the two reimbursement schemes, i.e. reimbursement based on the positive list and reimbursement at the social security price for medicines prescribed by active substance.

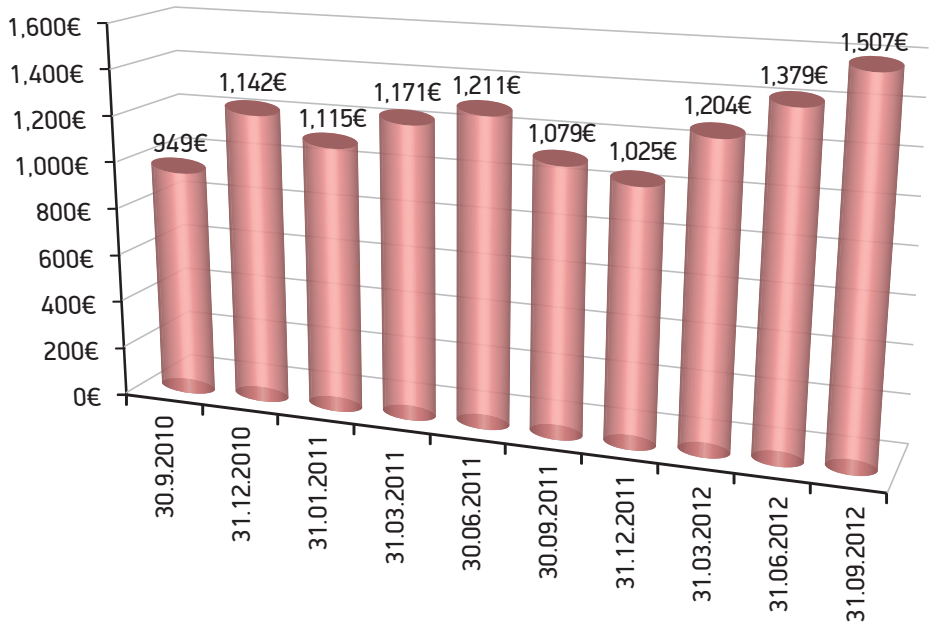
## 8. Hospital arrears to pharmaceutical companies

An analysis of data on total receipts, sales and unpaid receivables of SFEE member companies from public hospitals, for invoices issued between 01.01.2010 and 30.09.2012, indicates the following:

- **The total sales** by SFEE member companies to the State during the period from 01.01.2010 to 30.09.2012 amounted to **€3,265.2 million**

- As at 30.09.2012, **the total amount received** by SFEE member companies from the State for invoices issued between 01.01.2010 and 30.09.2012 was **€1,821.1 million**; in other words, 55.7% of the government's total debt to SFEE member companies had been settled by 30.09.2012.
- As at 30.09.2012, **the total amount of State debts** to SFEE member companies for invoices issued between 01.01.2010 and 30.09.2012 stood at **€1,506.5 million**. It should be noted that total debts include pre-2010 debts, i.e. €9.6 million owed by EOPYY (IKA), €50.9 million owed by military hospitals and €1.9 million owed by the Institute of Pharmaceutical Research and Technology (IFET).

**Figure 33: State debt towards pharmaceutical companies up until Q3 of 2012**




**Source:** SFEE, 2012

## 9. Problems facing the pharmaceutical market and SFEE's proposals

**A key priority for SFEE is the signing of a Stability Pact with the Government, aimed to address the following issues:**

1. Ensuring immediate access of all patients to necessary treatments and to new and innovative medicines
2. Ensuring adequate supply of pharmaceuticals in the market and establishment of sound pricing and reimbursement methods
3. Creating a stable business environment, increasing investment in research and development and safeguarding the thousands of jobs in the pharmaceutical sector
4. Urgently dealing with the explosive situation that has arisen as the arrears of IKA-EOPYY and public hospitals to pharmaceutical companies, compounded by losses as a result of the haircut on Greek government bonds given to pharmaceutical companies in settlement of old debts, pose serious challenges for the operation and viability of pharmaceutical companies in Greece.

The key issues facing the industry today are:



1. **Ensuring immediate access of patients to all medications, treatments and care they deserve.** Patients must have **unhindered access to essential medicines and especially to new and innovative treatments**. Otherwise, the consequences for individuals and society at large will be devastating, threatening social cohesion and solidarity; moreover, the economy will suffer a blow, as investment in research and innovation will shrink and tens of thousands of jobs in the sector will be jeopardised. **The scarce introduction of new pharmaceuticals in the market is not compatible or conducive to the achievement of the goal of enhanced patient access.**
2. **Arrears of public hospitals and EOPYY.** As at end-September 2012, the arrears of NHS hospitals, military hospitals and EOPYY amounted to an intolerable level of €1.5 billion. SFEE proposes:

- Immediate settlement of the financing issues of EOPYY and public hospitals to restore the normal flow of payments to pharmaceutical companies and other partners in the pharmaceutical sector
- Enabling pharmaceutical companies to set off their claims on the government against tall types of their debts to the government (e.g .rebate, claw-back, income tax, VAT, social security contributions, etc.)
- Implementation of legislation (Presidential Decree 113/2010) according to which the State must settle its debts within a period of 90 days, after the lapse of which it is liable to pay default interest

3. **Haircut on the so-called pharma bonds.** Pharmaceutical companies expected to recover 100% of the value of the pre-PSI bonds they held (which were given to them by the government in settlement of public hospital arrears for the years 2007, 2008 and 2009) upon maturity in 2012 and 2013. Following the PSI, 53.5% of the nominal value of the bonds was written down, and the remaining 31.5% will mature in the next 30 years. SFEE proposes:

- In the context of the expected recapitalisation of the banking system, care should be taken about the pre-PSI bonds pledged as collateral for bank loans to pharmaceutical companies
- EOPPY and public hospitals should immediately pay their arrears up to the equivalent of the haircut on the pre-PSI bonds held by pharmaceutical companies
- Pharmaceutical companies should be exempted from any rebates and claw-backs up to the amount of the haircut
- Unpaid monthly VAT should be set off against the amount of VAT included in the haircut, which, although already paid to the State via the regular monthly returns, was paid once again through the PSI: this is not only unfair, it is totally absurd
- Pharmaceutical companies should have the option to set off their income tax liabilities against public sector arrears to them
- The impact of the haircut should be excluded from the net position of companies under Law 2190/1920
- The loss due to the PSI and the associated bond impairment of 53.5% should be eligible for tax deferral, starting from 2011 and until the maturity of the new bonds given in exchange
- Any loss likely to arise from the sale of the new bonds should be set off against tax liabilities, until fully extinguished



4. **Rationalisation of public pharmaceutical expenditure.** The government tends to resort to horizontal measures (e.g. price reductions, rebates, etc.) which put an unfair burden on pharmaceutical companies, instead of pressing ahead with the necessary structural changes to achieve the targets of the Memorandum and reduce public pharmaceutical spending. SFEE fully supports the government's effort to rationalise public pharmaceutical expenditure, but believes that the piecemeal measures to increase public revenue are not the right way to achieve this rationalisation. SFEE proposes:

Rationalising public pharmaceutical expenditure by curbing overspending and mismanagement through the full computerisation of the system and the application of therapeutic and diagnostic protocols.

5. **Need for simplification and a uniform framework for clinical trials,** which should be seen as a strategic sector of the economy, as well as **incentives to attract investment in pharmaceutical manufacture**.

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